Concepts in Pharmaceutical Entrepreneurship

A thesis submitted in partial fulfilment
of the requirements for the award of
Doctorate in Pharmacy

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2023

To my family

Acknowledgements

I would like to express my sincere gratitude to my supervisor, Professor Anthony Serracino-Inglott, for his guidance, support and constructive criticism throughout. Thank you for recognising my ability to undertake this Doctorate degree. I would like to thank my co-supervisor, Dr Maresca Attard Pizzuto, for her constant dedication, approachability, support and encouragement.

I would like to thank the Head of the Department of Pharmacy at the University of Malta, Professor Lilian M. Azzopardi, and to all those who have contributed to my educational development in some way or another. You have all been part of this challenging journey, and your able guidance has been crucial to its successful completion.

I would like to thank all the contributors who participated in this study. Your input was integral in the undertaking of this research.

I would like to thank my colleagues at the Malta Medicines Authority for their friendship and continuous encouragement.

On a personal note, heartfelt thanks go to my friends with whom I have shared both the good times and hardships.

Finally, I am deeply grateful to my family for their constant love and unwavering support. The one thing that has never changed in my journey, the one thing I can always count on, is my family. I am truly blessed to have you in my life.

The research work disclosed in this publication is funded by the

Tertiary Education Scholarships Scheme.

Abstract

Pharmaceutical entrepreneurship (PhE) is closely linked to innovation and collaboration. PhE improves healthcare and contributes to the evolvement of the pharmacy profession through the proactive identification, creation and pursual of novel pharmaceutical products and processes. The study aims to 1. Investigate the contribution that PhE has to innovation 2. Evaluate the role of education and training in the evolvement of PhE 3. Analyse PhE initiatives which are implemented at a medicines regulatory authority and 4. Identify tools used to measure accountability in PhE.

The methodology was divided into four phases: 1. Critical analysis of results obtained from a systematic literature review and structured interviews with pharmaceutical entrepreneurs to identify innovative practices and PhE characteristics, traits and skills 2. Development and validation of a training programme for the advancement of PhE through the identification of established education and training in PhE and responses to structured interviews to identify training aspects to be incorporated in the training programme 3. Retrospective analysis of entrepreneurial activities at the Malta Medicines Authority through a focus group and observational study within the Pharmaceutical Products Entrepreneurship Unit 4. Identification of tools used to measure the accountability of entrepreneurial initiatives through an assessment of the impact and effectiveness of the PhE activities.

Results identified five innovative practices related to PhE and thirteen PhE characteristics, traits and skills from twenty-three studies. Innovative practices identified were: Open innovation and collaboration, digital health technologies, precision medicine and genomics, artificial intelligence and patient-centred approaches. PhE characteristics, traits and skills identified were: Autonomy, competitiveness, goal-

orientation, innovativeness, an internal locus of control, leadership skills, motivation, people skills, proactiveness, problem-solving skills, risk-taking, social responsibility and strategic planning. A training programme consisting of thirteen modules was developed and validated. The modules were related to: Communication skills, conflict resolution, financial management, human resources, leadership, innovation, market research, marketing, negotiation techniques, project management, public relations, quality improvement and risk management. An innovative framework for PhE in regulatory sciences consisting of eight components was developed. The components in the framework are: Accountability, collaboration, ethics, financial management, innovation, leadership, the regulatory pillars and risk management. The interviews with pharmaceutical entrepreneurs and focus group with representatives from the Malta Medicines Authority confirmed the relevance of a patient-centred approach to PhE. Eight tools used to measure the accountability of pharmaceutical entrepreneurial initiatives were identified: Key performance indicators, financial projections, impact assessments, cost-benefit analysis, SWOT analysis, internal audits, balanced scorecard and business model canvas.

The study related to concepts in entrepreneurship in pharmaceutical processes enabled the identification of knowledge and competences needed to develop and advance new pharmaceutical endeavours. In the context of this research, PhE is considered beyond the traditional sense of business and financial planning, but rather as a product of creative thinking, the taking of calculated risk when conducting pharmaceutical entrepreneurial ventures and evidence-based decision making as related to a progressive innovative pharmaceutical scenario.

Keywords Pharmaceutical entrepreneurship – Innovation – Training – Regulatory Sciences – Accountability

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List of Abbreviations

AI	Artificial Intelligence
APIs	Active Pharmaceutical Ingredients
CEO	Chief Executive Officer
EMA	European Medicines Agency
EMRN	European Medicines Regulatory Network
EU	European Union
IT	Information Technology
KPIs	Key Performance Indicators
MMA	Malta Medicines Authority
MOQs	Minimum Order Quantities
MTM	Medication Therapy Management
NCA	National Competent Authority
PhE	Pharmaceutical Entrepreneurship
PO	Probability of Occurrence
R&D	Research and development
RMS	Reference Member State
SI	Severity of Impact
SMART	Specific, measurable, achievable, relevant, and timely
SVP-LTCF	St Vincent de Paul Long-Term Care Facility
WHO	World Health Organization

Chapter One

Introduction

1.1 What is Pharmaceutical Entrepreneurship?

This dissertation deals with the concept of pharmaceutical entrepreneurship (PhE). It is worth starting with understanding the term entrepreneurship with its implication to a pharmaceutical scenario, environment, and processes. During this exposition on PhE it is of essence to avoid the risk of applying entrepreneurship norms to pharmaceutical processes without considering that pharmaceutical processes are considered to be special, in that these processes involve the safeguarding of quality, safety and efficacy of medicines, and furthermore could also entail accessibility and environmental aspects.

An increase in interest in the area of entrepreneurship has been observed over recent years and may be associated with a link between entrepreneurial endeavours and economic growth. Research suggests that better economic performance may be related to entrepreneurial activities (Morris et al, 2001; Berkowitz and DeJong, 2005; Carree and Thurik, 2010; Harrison et al, 2016a; Chen et al, 2018; Solikahan and Mohammad, 2019; Alhosseini et al, 2021).

Entrepreneurship is linked to the pursuit of opportunities, innovation, proactiveness and the management of risk whilst affecting change with an attitude of dedication and perseverance (Holiday-Goodman, 2012; de Jong et al, 2015; Eesley, 2016; Harrison et al, 2016b; Barringer and Duane Ireland, 2019; Mattingly et al, 2019a). Perhaps in the case of PhE the order of these pursuits needs to be re-addressed to meet patient needs. In addition, some other pursuits may take precedence over the pursuits described by the authors referred to. An opportunity may be described as a particular set of conditions which collectively create a favourable lacuna for a new idea or concept (Shane and Venkataraman, 2000). In the case of PhE, an example of an opportunity would be when

a medical representative identifies a need for a particular treatment following the identification of medical conditions which are not responding to standard treatment protocols. The medical representative may convey such a finding to the mother company where the presence of a pharmaceutical entrepreneur may grasp this opportunity for innovation. Central themes related to entrepreneurship include the creation of business, the identification or creation of opportunities, innovation, and the creation of value in an environment of uncertainty (Prince et al, 2021). An in-depth understanding of the subject of PhE contributes to an effective evaluation of how advancements in the pharmacy profession may be achieved through the application of entrepreneurial concepts.

Despite the fact that the term entrepreneurship has been in use for more than 200 years, there appears to be no consensus on a definition for this phenomenon (Morris et al, 2001; Zimmerman, 2010; Barringer and Duane Ireland, 2019; Prince et al, 2021; Scahill and D'Souza, 2022). This is more so in the case of PhE. A commonly used definition for entrepreneurship is that put forward over 35 years ago by Stevenson and Jarillo-Mossi who state that entrepreneurship is: "The process of creating value by bringing together a unique package of resources to exploit an opportunity" (Stevenson and Jarillo-Mossi, 1986).

Further evaluation of this definition by Tice (2005) of interest to the pharmaceutical scenario, leads to the identification of four aspects related to the concept of entrepreneurship:

i. Creating value: as a necessary aspect for the success of an entrepreneurial venture. The application of this concept within the pharmaceutical scenario is further elaborated in Section 1.4.
ii. Bringing together a unique package of resources: within the pharmacy profession, this is represented by the distinct knowledge base that pharmacists possess and by their aptitude for using that knowledge for the efficient management of pharmaceutical processes and promotion of quality patient care.
iii. Exploiting an opportunity: depicts the pursuit of novel opportunities to add value within pharmaceutical processes and serve patient needs.
iv. Continuous process: as the process may be learned, modified, and repeated as necessary to promote the provision of service excellence for patients (Tice, 2005; Tice, 2012).

Further research related to the definition, and diversity thereof for entrepreneurship, has been carried out and is documented (Shane and Venkataraman, 2000; Shane, 2012; Audretsch et al, 2015; Alegre et al, 2017; Prince et al, 2021). Shane and Venkataraman (2000) describe entrepreneurship as a process whereby opportunities are "discovered, evaluated and exploited" for the development of services and products (Shane and Venkataraman, 2000; Laverty et al, 2015). Prince et al (2021) proposed the following definition for entrepreneurship: "The act of generating and developing an idea for validation". In this definition, entrepreneurship is presented as an activity consisting of diverse behaviours. The entrepreneur as the generator of the idea, recognising an

opportunity within the idea, is responsible for the quality and sustainability of that said idea, whilst bearing the uncertainty related to it. The entrepreneur may recognise an opportunity as it emerges already formed in the environment through the discovery approach, or formulate the opportunity and demonstrate its viability through a constructivist approach. Validation in the above definition refers to the realisation of an idea's added value, created through the development process by the entrepreneurial entity. A development process is considered successful when the idea is validated by the intended audience. The definition presented by Prince et al (2021) encourages a shift in thinking that sees entrepreneurship as a far larger phenomenon than the formation of organisations or the exploitation of opportunities. It encourages conceptualisation that is more focused on the nature of ideas and a growth process that is centred on getting ideas validated by having them be adopted by others (Prince et al, 2021). The intended audience within the pharmaceutical scenario includes suppliers, healthcare professionals, patients and caregivers.

Entrepreneurship has been described as a philosophy of life in a way that one's approach to life includes the identification of problems which are proactively translated into opportunities to improve the situation in an individual's life, a profession or society at large (Tice, 2005; Mattingly et al, 2019b). Since pharmacists meet with patients on a regular basis and assist in the management of health and medication issues, they are in an ideal position to apply PhE acumen for the identification of opportunities to meet patients' unmet needs (Panther et al, 2019; Scahill and D'Souza, 2022). Literature suggests that the pharmacists' potential to fulfil this need has not been reached to date (Smith and Jambulingam, 2017; Panther et al, 2019).

1.2 An Entrepreneurial Spirit in Pharmacy

Change is essential for the development of any individual, organisation or profession which typically adapts in response to stakeholder demands or to a competitive environment. Healthcare and patient care have undergone significant transformation in recent history (Holiday-Goodman, 2012; Huston, 2018; Shealy and McCaslan, 2018; Adulin and Pan, 2022). This includes the practice of pharmacy which has changed from being primarily defined by the dispensing of medication, to a practice that is increasingly defined by the cognitive delivery of pharmaceutical information and services and the expansion of the pharmacist's role as a healthcare provider through the provision of progressive services (Holiday-Goodman, 2012; Shealy and McCaslan, 2018; Holdford, 2021; Rebelo et al, 2022; Scahill and D'Souza, 2022). Research suggests that one of the main forces promoting innovation in pharmacy practice is entrepreneurship (Mattingly et al, 2019a). Examples of PhE initiatives include the development of chain pharmacies, pharmaceutical care which has developed into medication therapy management (MTM), entrepreneurial activities in disease management, pharmacist prescribing, services for minor ailments and immunisation delivery (Holiday-Goodman, 2012; Laverty et al, 2015; Huston, 2018; Scahill and D'Souza, 2022).

In a poster presentation presented at the 80th International Pharmaceutical Federation World Congress of Pharmacy and Pharmaceutical Sciences by Giudice et al (2022), it was noted that the current environment in healthcare is affected by a number of factors including issues related to rising costs and affordability, the challenges of chronic diseases, evolvement of the workforce, advanced healthcare outcomes, the benefits and challenges of regulatory sciences and situations such as crisis management in a pandemic

or conflict (McLaughlin et al, 2017; Shaikh et al, 2020).[1] The dynamic landscape of healthcare presents pharmacists with the challenge of undertaking innovative practices to transform the healthcare system and create novel opportunities and revenue streams (Huston, 2018; Shealy and McCaslan, 2018).[1] This extended landscape may include innovative practices to add, or improve, existing services, and to develop new services to meet patients' needs (Murray Gillin and Hazelton, 2021). The development and implementation of such services could benefit from entrepreneurial skills (Laverty et al, 2015; Huston 2018; Mogul et al, 2020). Entrepreneurship in pharmaceutical processes plays a fundamental role in improving healthcare (Mogul et al, 2020; Afeli and Adunlin, 2021). Pharmaceutical entrepreneurial outcomes, which include innovative venture development, start-ups, and the creation of new jobs, support economic growth and development (Mattingly et al, 2019a). Pharmacists already possess a number of technical skills and expertise which diminish health disparities and broaden knowledge through research. These skills and knowledge may be used to attain positions other than those traditionally sought by pharmacists. Technological inventions, telemedicine and artificial intelligence (AI) offer new avenues and opportunities for pharmacists (Park et al, 2021).

The cultivation of an entrepreneurial spirit, together with critical thinking, problem-solving and intellectual curiosity, are essential for advancements and the future of pharmacy practice. A spirit of entrepreneurship includes aspects such as adaptability, risk taking, creativity and a sense of uniqueness to develop potential ideas and projects (Brazeau, 2013; Shealy and McCaslan, 2018). The term 'entrepreneur' may be considered

[1] Giudice L, Attard Pizzuto M, Serracino-Inglott A. Entrepreneurship in Pharmaceutical Processes. Poster session presented at the 80th International Pharmaceutical Federation World Congress of Pharmacy and Pharmaceutical Sciences; Seville 2022.

to have several definitions with potential negative connotations, such as that business opportunities or initiatives may be undertaken for the entrepreneur's personal gain, with little or no regard for other individuals, or positive connotations whereby an entrepreneur may be considered to be a visionary and leader, creating innovative prospects for the benefit of society whilst balancing risks linked to the potential for failure in the quest for success (Barringer and Duane Ireland, 2019).

Intellectual curiosity and an entrepreneurial spirit play an instrumental role in the implementation of systems and technologies in the area of healthcare which is rapidly changing. History has shown time and again that successful individuals possess, and maintain, an entrepreneurial spirit and intellectual curiosity, whilst overcoming adversity and disappointment, along their journey to success. Pharmacists are to be encouraged to stimulate and strengthen an entrepreneurial spirit to maintain their key role in the development of innovative and dynamic models in healthcare (Brazeau, 2013; Laverty et al, 2015).

One individual cannot have expertise in every area required to start, expand, and manage an entrepreneurial initiative, therefore entrepreneurs tend to establish networks of experts who can assist in areas as required. Awareness of how to access information and individuals required, and the ability to ask for help, are key to an entrepreneur's success (Hayter, 2013; Saxton et al, 2016). Often, the road to success is not easy. When developing a new venture, entrepreneurs are typically required to perform some degree of experimentation, wherein failure is a possibility. Challenges may include financing and inadequate capital, human resources, leadership skills, stakeholder requirements, inadequate infrastructure and issues when bringing the product or service to market. The

perseverance required to soldier through these challenges is often fuelled by passion (Harrison et al, 2016a; Barringer and Duane Ireland, 2019). Tice (2012) has stated that the pharmacy profession requires passionate professionals who are motivated to improve the services and products offered to society.

Considering the lack of training for pharmacists in financial, entrepreneurial, intellectual property and marketing aspects, pharmacists may lack confidence in their capacity to create an idea and launch a pharmaceutical enterprise (Asieba and Nmadu, 2018). To date, pharmaceutical entrepreneurial initiatives have been conducted without formal training in the entrepreneurial field for pharmacists (Mogul et al 2020; Afeli and Adunlin, 2021). Some pharmaceutical entrepreneurs have arisen as they are born possessing the characteristics which entrepreneurs tend to possess. Others may have been offered support through their environment and life experience, whilst being motivated to pursue entrepreneurial opportunities (Tice 2012; Saxton et al, 2016; Barringer and Duane Ireland, 2019). Studies suggest that individuals having personal contact with entrepreneurs, including those whose parents are self-employed, or those having entrepreneurs as role models, are more inclined to becoming entrepreneurs (Powell and Eddleston, 2013; Blumberg and Pfann, 2016; Fashami et al, 2021).

1.3 The Process of Entrepreneurship in Pharmacy

The process of entrepreneurship provides a structured approach for the development of entrepreneurial initiatives which may be learned, analysed, improved upon, and repeated through creativity, imagination and motivation (Morris et al, 2001; Moroz and Hindle, 2012; Barringer and Duane Ireland, 2019). The process consists of six steps as represented in Figure 1.1. Although the beginning of the process, particularly the formulation of the concept, may be where creativity is most generally associated, in reality, it is the later stages that frequently call for the entrepreneur to demonstrate the most innovative and risk-taking practices (Morris et al, 2001).

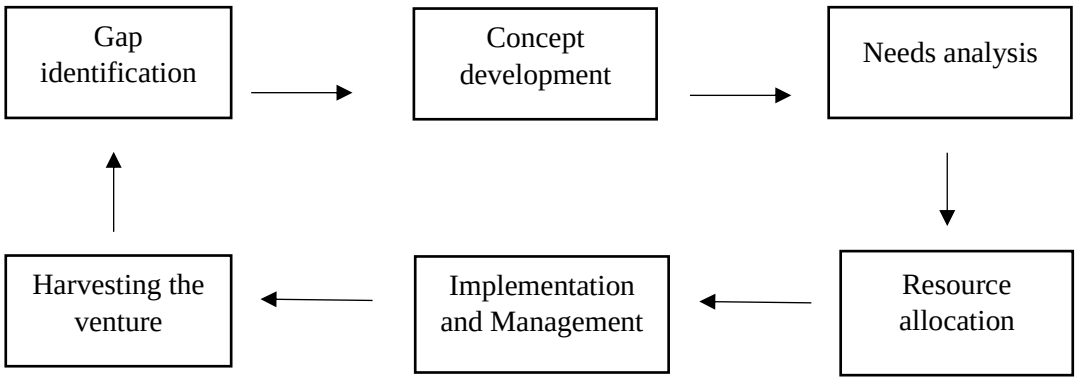


Figure 1.1: The Entrepreneurial Process

Adapted from: Tice BP. Entrepreneurship and Innovation. In: Desselle SP, Zgarrick DP, Alston GL, editors. Pharmacy Management: Essentials for All Practice Settings. 3rd edition. New York City: McGraw Hill. [Internet] 2012:1-12 [cited 2023 May 29]. Available from URL: https://accesspharmacy.mhmedical.com/content.aspx?sectionid=41096250&bookid=509

Step 1: Gap Identification

The initial step within the entrepreneurial process consists of identifying a gap in the market, or a novel opportunity, in an effort to create added value. Entrepreneurs tend to identify opportunities where others do not. McGrath and MacMillian (2000) describe how entrepreneurs typically have an 'opportunity register' consisting of a list of new ideas or opportunities for improving or reinventing existing business models, products or services. Areas in which opportunities may be identified in the pharmaceutical scenario include the emanation of new markets, changes to existing demographics, changes in pharmaceutical process, the development of novel technologies, changes to regulatory scenarios, and societal changes (Morris et al, 2001; Tice, 2005; Barringer and Duane Ireland, 2019). Within pharmacy, pharmaceutical entrepreneurs are faced with gaps and opportunities for improvement which arise from areas including the emergence of an aging population with more complex medication regimens to treat chronic diseases, the potential of polypharmacy arising from complex regimens, advanced healthcare outcomes, the development of new processes and technologies including biotechnology, gene therapy and precision therapy, and challenges related to the sustainability of evolving healthcare systems (Holiday-Goodman, 2012; Tice, 2012; Shaikh et al, 2020; Park et al, 2021).

Step 2: Concept Development

Following the identification of the gap which the pharmaceutical entrepreneur wishes to address, a concept must be developed to identify the way in which this gap will be filled. Often, there are several ways in which an idea may be implemented. This could take the form of novel or improved products, services, processes, systems or technologies, either alone or in combination with others. Within this step, pharmaceutical entrepreneurs

determine which option is best suited to address the gap identified and how best to go about filling the gap. This includes market research to identify the extent of the problem or gap identified, and how to organise tackling the issue at hand (Morris et al, 2001; Tice, 2005; Tice 2012). A feasibility analysis is also conducted at this stage. Pharmaceutical entrepreneurs must be disciplined in their approach when identifying which of the identified endeavours they are going to pursue (Barringer and Duane Ireland, 2019).

Step 3: Needs Analysis

Following the development of the idea and the concept of the endeavour being pursued, a pharmaceutical entrepreneur must formulate a structure and identify the resources required. Resources required include financial projections and funding, adequate personnel having the necessary skills and expertise, a clear vision for management and marketing, infrastructural needs, and logistical and legal considerations. This stage may be a limiting step for some as they may not have the necessary knowledge and skills to carry out such an extensive analysis and this may be perceived as an insurmountable challenge (Morris et al, 2001; Tice, 2005; Tice 2012). Studies have shown that there is a lack of business training in pharmacy education. Offering training in entrepreneurship in a pharmaceutical scenario may encourage and enable pharmaceutical entrepreneurs in their pursuit of new pharmaceutical endeavours, including the formulation of the structure for the endeavour, and the resources required to be able to implement it (Mogul et al 2020; Afeli and Adunlin, 2021).

Step 4: Resource Allocation

In this step, the resources identified are acquired. Aspects to consider include the formulation of a management team, the possibility of outsourcing activities, leasing premises, the contracting out of labour, capital, liability, equity and the possibility of joint ventures or partnerships. The pursuit of a pharmaceutical entrepreneurial initiative may require the use of personal capital or the potential creation of partnerships to obtain financial backing. Due to the financial aspects and liabilities, the pharmaceutical entrepreneur commits to the undertaking of the endeavour at this stage (Morris et al, 2001; Tice, 2005; Tice, 2012; Barringer and Duane Ireland; 2019).

Step 5: Implementation and Management

Subsequent to the necessary allocation of resources, the venture may be implemented and managed. Activities include an examination of performance, reimbursement for investments made, reinvestment, and development and advancement of the service or idea. This step consists of typical business activities and is usually the first opportunity the pharmaceutical entrepreneur has to observe the stakeholders' appetite for the product or service (Morris et al, 2001; Tice, 2005).

Step 6: Harvesting the Venture

Following the pharmaceutical entrepreneurial initiative's establishment, the cycle is concluded by handing over the initiative to someone else and may include selling the service, product or process off to a third party. Within this step, pharmaceutical entrepreneurs realise that their role in the process is not to stay in it but rather hand it over

to someone to manage (Morris et al, 2001; Tice, 2005; Diandra and Azmy, 2020). It is important to note that following the identification, development and implementation of an idea, product or service, activities related to its management and the running of a business cease to be entrepreneurial but rather become managerial (Prince et al, 2021). It is the pursuit of new opportunities and starting of an enterprise that is considered part of the entrepreneurial process. (Morris et al, 2001; Tice, 2005; Diandra and Azmy, 2020).

To be able to harvest the venture, entrepreneurs need to be able to articulate the benefits and value of their enterprise, product, or service to sell the opportunity to a third party. The elevator pitch is a common element within entrepreneurship and consists of the individual having the entrepreneurial idea, attempting to convince others to buy into a proposal between the time one enters an elevator and the time one exits it (Barringer and Duane Ireland, 2019). Entrepreneurs must be able to explain a concept in a clear and concise manner (Laverty and Little, 2020). Effective communication is considered an essential competence for pharmacists worldwide (Kerr et al, 2021) as pharmacists often provide advice to patients or suggest therapeutic changes to doctors in a limited timeframe, therefore pharmacists are well equipped to pitch the entrepreneurial idea to a third party to harvest the venture. Three key factors to be considered in an effective elevator pitch include the novelty of the product, service or business, the benefit and value being offered, and the reason to believe and invest in it (Tice, 2012).

1.4 Innovation and Pharmaceutical Entrepreneurship

Innovation and entrepreneurship have long been linked (Huston, 2018; Ballor and Claar, 2019; Prince et al, 2021). Innovation is considered a central component of entrepreneurship (Ballor and Claar, 2019; Prince et al, 2021) including PhE (Huston, 2018; Mattingly et al, 2019a). The rapidly increasing amount of biomedical data, technological improvements, and demands for cost-effective care are placing the health care system under pressure, making innovation and entrepreneurship paramount for the development of pharmaceutical services (Mogul et al, 2020; Afeli and Adunlin, 2021).

Innovation relates to the sustenance and evolution of novelty, creativity, market awareness and testing which may result in the creation of novel goods, services, or technological advancements or improvements of existing products, services or processes to create added value (Masa'deh et al, 2018; Diandra and Amzy, 2020; Rebelo et al, 2022). Innovation is thought to consist of a new way of combining existing resources. Innovation within PhE leads to increased value and market restructuring as a result of inventive change, with resources and market share being transferred to new innovative pharmaceutical enterprises. (Prince et al, 2021). Sustainability is brought about by means of innovation through the promotion of economic growth (Chen et al, 2018). Research suggests that innovation is best when it comes from within an organisation, whereby employees at all levels of the organisation and industrial ecosystem work coherently to produce the best innovations (Murray Gillin and Hazelton, 2021).

1.5 Entrepreneurial Orientation in Pharmaceutical Processes

Lumpkin and Dess (1996) first introduced their entrepreneurial orientation framework which related a company's entrepreneurial orientation to its performance in 1996 (Lumpkin and Dess, 1996; Smith and Jambulingam, 2017; Ciabuschi et al, 2020). Entrepreneurial orientation describes the planning, organisational efforts and decision-making necessary for the development of innovations that create value by encouraging entrepreneurial activity. Entrepreneurial orientation reflects managerial vision and has been acknowledged as a substantial factor in the preparation of strategies (Smith and Jambulingam, 2017; Solikahan and Mohammed, 2019).

It is becoming more widely acknowledged that the entrepreneurial and managerial fields overlap, however they are not mutually exclusive. Entrepreneurship is more motivated by opportunities, whereas management is more focused on resources and conservation (Stevenson and Jarillo-Mossi, 1990; Renko et al, 2015; Prince et al, 2021). An entrepreneur may or may not be the one who came up with the notion or idea for an entrepreneurial initiative, but rather, an entrepreneur is the individual who persists in adapting and implementing the idea or concept and experiencing some degree of success or failure thereafter (Morris et al, 2001).

The dimensions linked to entrepreneurial orientation by Lumpkin and Dess (1996) are innovativeness, proactiveness, risk-taking, autonomy and competitive aggressiveness (Lumpkin and Dess, 1996; Smith and Jambulingam, 2017; Solikahan and Mohammed, 2019; Mattingly et al, 2019a). Companies that support entrepreneurial orientation are well positioned to identify market demands, seize opportunities, and maintain their competitiveness in the market (Smith and Jambulingam, 2017). Within the

pharmaceutical scenario, entrepreneurial orientation is not static in nature, as it varies depending on the innovation in question and specific developmental activities being considered by pharmaceutical enterprises (Ciabuschi et al, 2020).

1.6 Entrepreneurial Leadership in Pharmacy

An emergent paradigm known as entrepreneurial leadership has developed from the fields of entrepreneurship and leadership (Fernald et al, 2005; Bagheri and Harrison, 2020; Ahmed and Harrison, 2022). In general, leadership requires motivating a team's efforts to reach a common objective (DeVolld et al, 2022). Despite the concept's rise in popularity, entrepreneurial leadership has gotten little focused attention and, as a result, has remained largely conceptual. Entrepreneurial leadership is a special type of leadership that can occur in organisations of any nature, size or age in which visionary scenarios are created, whereby teams of participants are gathered and mobilised with a commitment for a common vision and utilisation of strategically created value (Renko et al, 2015; Harrison et al, 2016a). Renko et al (2015) said that “Entrepreneurial leadership entails influencing and directing the performance of group members towards the achievement of organisational goals that involve recognising and exploiting entrepreneurial opportunities”. Achieving entrepreneurial leadership requires the development of skills including rhetoric, the ability to work with numbers, use of technology in an effective manner, ethics, social responsibility, a sense of understanding, respect for multicultural aspects, innovativeness, and the ability to lead a team. Essential qualities of entrepreneurial leadership include risk-taking, recognition and exploitation of viable opportunities, and the vision needed to overcome the difficulties encountered in an entrepreneurial environment (Harrison et al, 2016a).

The pharmacy profession has been described as a purpose-driven profession (Lutz, 2005). Pharmacists have been working on implementing pharmaceutical care to meet patients' needs and improve patient outcomes (Shealy and McCaslan, 2018). It is the professional role of pharmacists acting in the interest of patients which keeps them motivated to seek new opportunities and take risks. Significant change within the pharmacy profession may be achieved through the application of visionary leadership within pharmacy practice, organisational leadership offering pharmacists the autonomy to instigate change, and the provision of the resources and knowledge required to carry out and maintain the change (Holiday-Goodman, 2012).

1.7 Applying an Entrepreneurial Mindset to Pharmacy

An entrepreneurial mindset involves the pursuit of new opportunities in a passionate and disciplining manner by prioritising the opportunities being pursued and focusing on the execution and adaptation of the identified project, whilst involving the necessary individuals to assist in successfully bringing the project to fruition (Morris et al, 2001; Murray Gillin and Hazelton, 2021). Entrepreneurs are commonly understood to possess an internal locus of control and a tolerance for ambiguity, which are necessary to reach high levels of achievement (Morris et al, 2001; Renko et al, 2015; Barringer and Duane Ireland, 2019).

Within the pharmacy profession, the use of an entrepreneurial mindset has led to pharmaceutical care being integrated into practice and quality improvement, in an effort to advance the profession (Tice, 2005; Holiday-Goodman, 2012). A proactive entrepreneurial mindset enables healthcare professionals, including pharmacists, to use

their knowledge in conjunction with entrepreneurial behaviours to accomplish ongoing, notable innovation, whilst adapting to changing environments (Panther et al, 2019; Murray Gillin and Hazelton, 2021). Such a vision-driven culture produces behaviours that enable healthcare to continuously adapt by reshaping the range of its operations and practices, to identify opportunities for innovation and produce better outcomes. The dimensions related to an entrepreneurial mindset include leadership, decision-making capabilities and awareness regarding healthcare ecosystems. Murray Gillin and Hazelton (2021) suggest that entrepreneurial leadership fosters innovative thinking and entrepreneurial mindsets. Healthcare professionals who have an entrepreneurial attitude are better able to identify opportunities, and gather the information and resources needed to take advantage of them (Murray Gillin and Hazelton, 2021).

When applying an entrepreneurial mindset, one must keep accountability in mind (Taylor, 2003). Accountability refers to a responsibility towards parties or individuals with who one has a relationship, and an obligation to uphold and justify conduct. Accountability is linked to transparency, responsibility and liability, and is based on three factors: a clear delineation of goals or objectives, the capacity to measure and track goal achievement, and a list of repercussions should goals or objectives not be achieved satisfactorily (Denis, 2014; Burga and Rezania, 2015). Accountability is necessary for the management and governance of healthcare systems (Denis, 2014), as should be the case when conducting PhE initiatives.

1.8 Creative Thinking in Pharmaceutical Entrepreneurship

The studying of prospective opportunities to identify whether any of them could serve as the basis of a workable pharmaceutical entrepreneurial endeavour is related to intellectual curiosity, the ability to think creatively and critical thinking in an environment of uncertainty (Brazeau, 2013; Shealy and McCaslan, 2018; Barringer and Duane Ireland, 2019; Alhosseini et al, 2021). Opportunities that could assist an individual or organisation in achieving a desired result are identified during the naturally goal-directed process of opportunity identification (Barringer and Duane Ireland, 2019; Korpysa et al, 2020). Creative thinking includes the need to think critically and solve problems, to be able to bring an idea to fruition (Mattingly et al, 2019b), possibly using divergent or lateral thinking in the creative process (Mattingly et al, 2019a). The ability to think creatively leads to the identification of innovative solutions to healthcare problems and the advancement of pharmacy and is linked to PhE in the literature as outlined in the Center for the Advancement of Pharmacy Education 2013 Educational Outcomes (Medina et al, 2013; Mattingly et al, 2019b).

1.9 Risks Related to Pharmaceutical Entrepreneurship

Research demonstrates that risk-taking is an important attribute for entrepreneurs, as the taking of risks is inevitable when managing uncertainty in entrepreneurial endeavours. Risks related to PhE include taking measures including investing in, or borrowing, large sums of money for projects in unknown environments, which may potentially not be successful (Rauch et al, 2009; de Jong et al, 2015; Harrison et al, 2016a; Smith and Jambulingam, 2017). Entrepreneurs are commonly thought to be high-risk takers (Norton and Moore, 2006; Harrison et al, 2016a; Barringer and Duane Ireland, 2019).

Studies suggest that in actual fact, entrepreneurs tend to take minor to moderate risk when conducting entrepreneurial ventures, as is the case in the general population (Norton and Moore, 2006; Harrison et al, 2016b; Barringer and Duane Ireland, 2019). According to research, entrepreneurs often rate a five on a scale of one to ten, where one denotes risk aversion and ten represents the highest risk tolerance. This depicts that although entrepreneurs must be able to tolerate risk, the stereotype that entrepreneurs are high-risk gamblers is incorrect (Tice, 2005). Findings from the Hartford 2015 Small Business Success Study indicate that 79% of the participants in the study take a conservative approach as opposed to an approach associated with a high risk.[2] Entrepreneurs are understood to take calculated risk during their ventures by considering available information from credible sources, and knowledge obtained from previous experiences (Norton and Moore, 2006; Smith and Jambulingam, 2017; Melović et al, 2022). Further evaluation of risk-taking behaviours leading pharmaceutical entrepreneurs to take calculated risks to ensure the viability of pharmaceutical entrepreneurial initiatives is required.

1.10 Evidence-based Decision Making in Pharmaceutical Entrepreneurship

Decision making is a crucial component of pharmaceutical entrepreneurial behaviour and is characterised as a decision made by pharmaceutical entrepreneurs who want to take advantage of discovered opportunities for market success (Murray Gillin and Hazelton,

[2] The Hartford. Small Business Success and Optimism Rev Up, Focus on Growth Stalls, The Hartford's Study Finds [Internet] Hartford: The Hartford; 2015. [cited 2023 May 29] Available from URL: https://newsroom.thehartford.com/newsroom-home/news-releases/news-releases-details/2015/Small-Business-Success-And-Optimism-Rev-Up-Focus-On-Growth-Stalls-The-Hartfords-Study-Finds/default.aspx

2021; Melović et al, 2022). When making decisions, entrepreneurs tend to weigh all potential outcomes of the available options, and frequently seek information and advice from reliable sources. Though as discussed, risk is inherent to entrepreneurship, including PhE, risky decision-making may not always be justifiable, as it may not result in the best possible outcome (Melović et al, 2022). It is unclear how rational and intuitive decision-making interact, however, research suggests that these two qualities support efficient patient-centred decision-making (Murray Gillin and Hazelton, 2021).

The use of evidence-based practices has increased traction over recent years and consists of the gathering of evidence and the putting of that evidence to use in practice, using critical thinking to make informed decisions. (Learmonth, 2008; Baba and HakemZadeh, 2012; Ray, 2022). The making of decisions based on evidence reduces reliance on sources of information that are dependent on intuition and personal experience, enabling the making of better decisions and the taking of informed actions in an effort to have a better impact on the organisation.

Evidence-based decision making offers an objective, logical, and empirical approach (Ray, 2022). The concept of evidence-based decision making evolved from healthcare and consists of the use of scientific data when making decisions. Evidence-based decision making is considered a beneficial strategy for the optimisation of costs, and prevention of waste. The making of decisions, without enough consideration for the evidence, may result in undesirable outcomes (Brownson et al, 2009; Majdzadeh et al, 2012; Shafaghat et al, 2022). Advantages associated with the use of evidence-based decision making include cost-effectiveness, improved customer satisfaction, appropriate use of limited resources, minimisation of harm and better outcomes (Shafaghat et al, 2022). Following

the lessons learned regarding the use of evidence-based decision making within the above-described scenarios, the use of evidence-based decision making within PhE may prove to be beneficial.

1.11 Pharmaceutical Entrepreneurship Training

As published in a poster presentation presented at the 80th International Pharmaceutical Federation World Congress of Pharmacy and Pharmaceutical Sciences by Giudice et al (2022), research suggests that individual characteristics and personality traits are key to motivating entrepreneurial intentions and behaviours, and training is another significant factor (Marvel, 2013; Shaikh et al, 2020).[3] Entrepreneurship training is crucial to develop innovative pharmaceutical processes (Afeli and Adunlin, 2021; DeVolld et al, 2022). Education is key for the identification of potential alternative or unconventional roles and successful achievement of these opportunities. The goal of professional development opportunities is to help individuals cultivate knowledge and confidence to see beyond perceived limits and envisage themselves in innovative aspirations (Alhosseini et al, 2021; Park et al, 2021). The Accreditation Council of Pharmacy Education (ACPE) Standards 2016 urges educators to provide students with the necessary training to demonstrate innovation and entrepreneurship skills, and suggests that graduates "engage in innovative activities by using creative thinking to envisage better ways of accomplishing professional goals" (Gatwood et al, 2018; DeVolld et al, 2022;

[3] Giudice L, Attard Pizzuto M, Serracino-Inglott A. Entrepreneurship in Pharmaceutical Processes. Poster session presented at the 80th International Pharmaceutical Federation World Congress of Pharmacy and Pharmaceutical Sciences; Seville 2022.

Holdford et al, 2022).[4] There is a growing interest in training within the field of PhE among pharmacy students, however there is a noticeable gap in entrepreneurship training in pharmacists' learning (Laverty et al, 2015; Scahill and D'Souza, 2022). Research shows that training in this area is required for the successful advancement of pharmaceutical careers, however no consensus exists for entrepreneurship in pharmacy practice and education (Mattingly et al, 2019a; Scahill and D'Souza, 2022).[5]

1.12 Entrepreneurship in Various Pharmaceutical Scenarios

As indicated in section 1.2, the application of PhE to pharmacy practice has led to the evolvement of community and hospital pharmacy through the establishment of chain pharmacies, the development of MTM services, pharmacist prescribing and the opportunity for immunisation services to be offered by pharmacists (Holiday-Goodman, 2012; Laverty et al, 2015; Scahill and D'Souza, 2022). Community pharmacies can successfully pursue their performance goals in the highly competitive climate of today by implementing entrepreneurial activities (Smith and Jambulingam, 2017).

With respect to the pharmaceutical industry, a decline in research and development (R&D) within the pharmaceutical industry has been linked to a lack of entrepreneurial behaviour which arises due to limitations brought about by the bureaucracy which ensues

[4] Accreditation Council for Pharmacy Education (ACPE). Accreditation standards and key elements for the professional program in pharmacy leading to the Doctor of Pharmacy degree [Internet]. Illinois; ACPE: 2015 [cited 2023 May 29]. Available from URL: https://www.acpe accredit.org/pdf/Standards2016FINAL.pdf

[5] Giudice L, Attard Pizzuto M, Serracino-Inglott A. Entrepreneurship in Pharmaceutical Processes. Poster session presented at the 80th International Pharmaceutical Federation World Congress of Pharmacy and Pharmaceutical Sciences; Seville 2022.

within large pharmaceutical companies. In an effort to increase productivity within the R&D sector, large pharmaceutical companies are reorganising their R&D structures to promote an entrepreneurial culture and behaviour which thrives within smaller biotechnology companies. Studies suggest that operations involving 20 to 40 persons are ideal, as this allows for efficient data sharing and effective allocation of resources (Douglas et al, 2010).

The European Medicines Agency (EMA) defines regulatory science as "a range of scientific disciplines that are applied to the quality, safety and efficacy assessment of medicinal products and that inform regulatory decision-making throughout the lifecycle of a medicine. It encompasses basic and applied medicinal science and social sciences and contributes to the development of regulatory standards and tools".[6]

The EMA developed the 'Regulatory Science to 2025' strategy to advance EMA's involvement with regulatory sciences and create a more flexible regulatory framework that will promote advancements in research and innovation in relation to human and veterinary medicine.[6] The application of PhE principles may aid in the implementation of this strategy. To the best of the researcher's knowledge, literature related to the application of PhE in regulatory sciences is scarce and warrants investigation.

[6] European Medicines Agency (EMA). EMA Regulatory Science to 2025 Strategic reflection. [Internet]. EMA; 2020. [cited 2023 May 29]. Available from URL: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ema-regulatory-science-2025-strategic-reflection_en.pdf

1.13 Aims, Objectives and Rationale

The study aims to answer the following questions with regards to entrepreneurship in the pharmaceutical scenario:

1. How does pharmaceutical entrepreneurship contribute to innovation?
2. What is the role of education and training in the evolvement of pharmaceutical entrepreneurship?
3. How can an innovative framework for pharmaceutical entrepreneurship in regulatory sciences be developed?
4. How can accountability in pharmaceutical entrepreneurship be measured?

The objectives of the study are:

a. To identify innovative practices and the pharmaceutical entrepreneurship characteristics, traits and skills that contribute to innovation.

b. To develop and validate a training programme for the advancement of pharmaceutical entrepreneurship.

c. To develop an innovative framework for pharmaceutical entrepreneurship by analysing entrepreneurship initiatives which are implemented at the Malta Medicines Authority (MMA).

d. To identify tools used to measure accountability in pharmaceutical entrepreneurship.

In the context of this research, PhE is considered beyond the traditional sense of business and financial planning, but rather as a product of creative thinking, the taking of calculated risk when conducting pharmaceutical entrepreneurial ventures and evidence-based decision making as related to a progressive innovative pharmaceutical scenario. In this vein, pharmaceutical entrepreneurship may be considered to be in its infancy, hence the rationale behind this study.

Chapter Two

Methodology

2.1 Research Design

The research study adopted a qualitative approach and consisted of four phases as summarised in Figure 2.1.

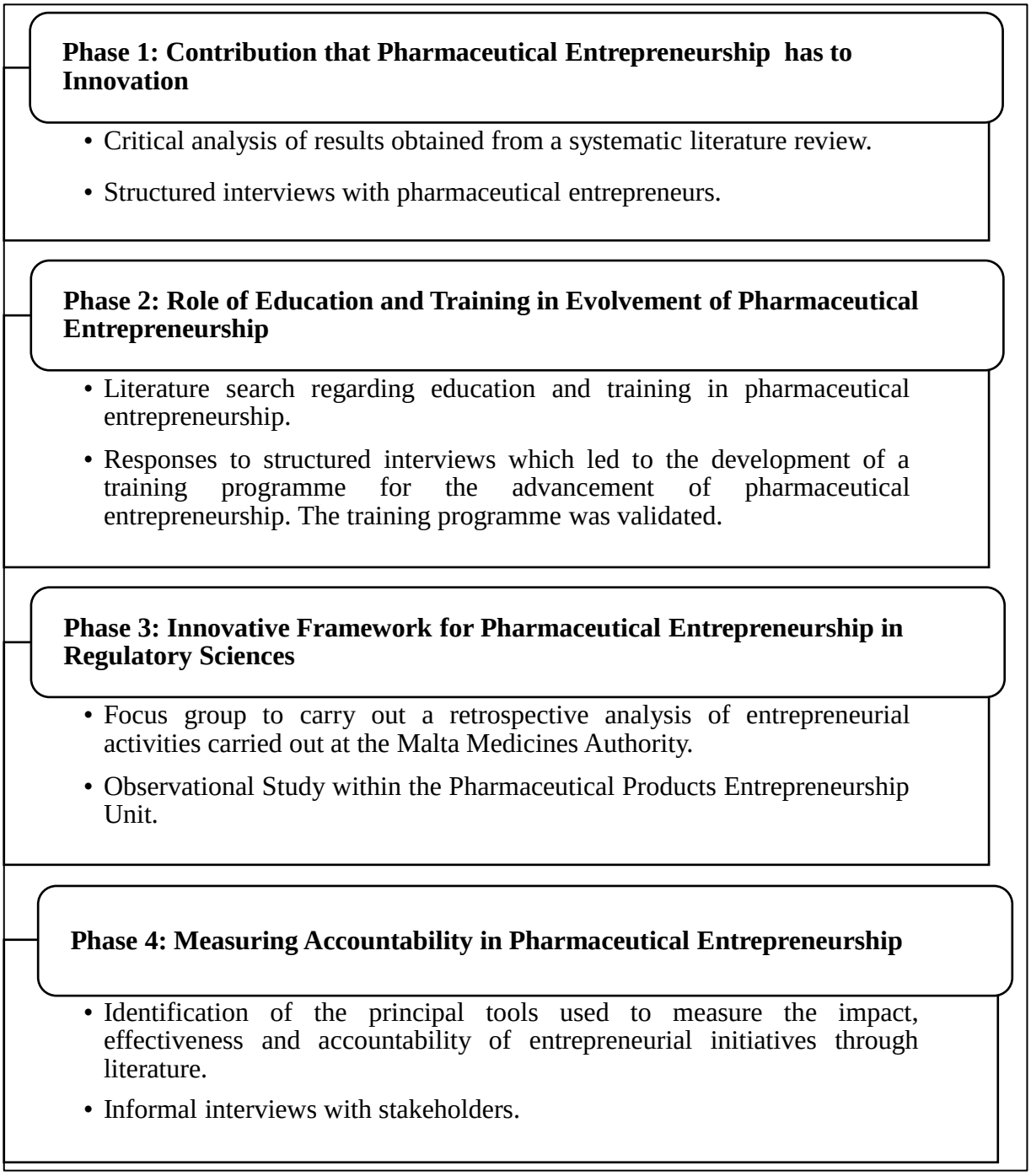


Figure 2.1 Overview of Research Methodology

2.2 Setting and Approvals

The research was carried out at the Department of Pharmacy at the University of Malta, and the Pharmaceutical Products Entrepreneurship Unit within the Malta Medicines Authority (MMA).

Prior to initiation of the study, ethics approval was sought through submission of a Research Ethics and Data Protection form, together with a dissertation proposal and detailed protocol, to the Faculty of Medicine and Surgery Research Ethics Committee (Appendix 1). Institutional approval to carry out research at the MMA was obtained from the Chief Executive Officer (CEO).

2.3 Phase 1: Contribution to Innovation

A systematic literature review was conducted to identify articles related to innovative aspects and how entrepreneurship skills improved innovation in a pharmaceutical scenario. The review was carried out using PubMed and HyDi (Hybrid Discovery), the library search gateway for the University of Malta. Peer-reviewed journal articles relevant to the research area were retrieved and reviewed. Keywords included those related to the aims and objectives found in Section 1.13, namely pharmaceutical entrepreneurship (PhE), innovation, characteristics, personality traits and skills. The snowball method was applied by searching reference lists of reviewed articles and obtaining any relevant articles for review.[7] Books and reports which were found to be relevant were also reviewed. Articles published between 2010 and December 2022 were considered for inclusion. Articles were excluded where full text articles were not available, or if

[7] Wohlin C. Guidelines for snowballing in systematic literature studies and a replication in software engineering. 18th International Conference on Evaluation and Assessment in Software Engineering - EASE '14. New York, USA. 2014:38:1–10. doi: 10.1145/2601248.2601268.

publications were not available in English. Protocols and conference abstracts were excluded.

Following completion of the search, duplicate entries were removed, and article titles and abstracts were reviewed to ensure eligibility against inclusion criteria. Inclusion criteria were peer-reviewed, full-text articles, published between 2010 and 2022, in the English language, describing innovative practices in relation to PhE and the characteristics, traits and skills linked to PhE behaviour. A full text review of articles which matched the inclusion criteria was conducted. Data was extracted from relevant articles. A critical analysis of the results of the review led to the identification of innovative practices in PhE and PhE characteristics, traits and skills that contribute to innovation.

2.4 Interviews with Pharmaceutical Entrepreneurs

Structured interviews were held with local pharmaceutical entrepreneurs to investigate areas including pharmaceutical entrepreneurial behaviour, the process of entrepreneurship in the pharmaceutical scenario, challenges related to PhE, PhE characteristics, traits and skills that contribute to innovation, education and training related to the advancement of PhE, and the potential benefits and risks associated with the introduction of an entrepreneurship appetite in pharmaceutical processes.

Participants were selected through convenience sampling and were offered a choice to conduct the interviews either face-to-face or virtually.

2.4.1 Design of Interview Questions

Questions were developed by the researcher using literature sources. The questions sought to gain understanding of PhE in the local scenario, to obtain information from individuals with hands-on experience, and compare responses to results gathered in the systematic literature review. A combination of open-ended and close-ended questions were used. Open-ended questions were chosen as they enabled respondents to provide answers to questions in their own words without being influenced by the researcher and allowed for the collection of detailed and nuanced responses, though it is understood that open-ended questions are more difficult to analyse (Fowler, 2014; Babbie, 2016). The use of open-ended questions enabled the researcher to comprehend respondents' attitudes, viewpoints, and behaviours more thoroughly. Additionally, unexpected viewpoints and insights were revealed that the researcher may not have foreseen.

Closed-ended questions were used to obtain higher response rates, more accurate results and facilitate statistical analysis due to a greater uniformity of responses when compared to open-ended questions, though it is documented that close-ended questions may introduce bias due to a limited number of suggested responses offered to participants (Reja et al, 2003; Fowler, 2014).

Close-ended questions were presented as follows:

i. Multiple-choice, checklist type and categorical questions, whereby respondents chose the most suitable answer/s from a list of pre-set categories.
ii. Using a 5-point Likert-scale as a psychometric scale, whereby respondents rated their choice on the most appropriate point of a given scale (Taylor-Powell, 1998).

Checklist type questions were used for questions where one or more response was required. An 'Other' option was included to allow for responses not included in the checklist. The use of a 5-point Likert scale provided a standardised method of measurement which allowed for comparisons of data to be made (Krosnick, 1999). A 5-point option series has been found to be the most appropriate for measuring attitudes. Likert-scales were used to measure level of agreement with a range from one to five, whereby five represented the highest level of agreement. Respondents were provided with a comments section to be able to provide further insight into the choices made and to offer examples.

2.4.2 Structure of Interview Questions

A total of 17 questions were compiled for the interviews with pharmaceutical entrepreneurs (Appendix 2); of which seven questions were open-ended and ten were close-ended. Five questions made use of a 5-point Likert-scale and five consisted of multiple-choice questions.

Interview questions were related to:

i. Demographic data: participants were asked regarding the number of years they have been practicing in the pharmaceutical scenario, and the area/s of pharmacy they have experience in.

ii. Pharmaceutical entrepreneurial behaviour: participants were asked to mention three points to define such behaviour.

iii. The process of entrepreneurship within the pharmaceutical scenario: participants were asked to identify the most challenging step in the entrepreneurial process within the pharmaceutical scenario.

iv. Challenges faced when carrying out PhE initiatives: participants were asked to rate the extent to which they face stipulated challenges in a real-world scenario when executing their pharmaceutical entrepreneurial endeavours.

v. Reaching a state of concordance in PhE: Participants were asked regarding their perception of the importance of moving from compliance to adherence to concordance when conducting pharmaceutical entrepreneurial endeavours, and the effect which moving towards a state of concordance could have on stipulated challenges.

vi. Reaching a state of wisdom in PhE: Participants were asked regarding their perception of the importance of moving from data to information to knowledge to wisdom when conducting pharmaceutical entrepreneurial endeavours, and the effect which moving towards a state of wisdom could have on stipulated challenges.

vii. PhE characteristics, traits and skills: participants were asked to rate the importance of the PhE characteristics, traits and skills which were identified in Phase 1 of this study (Section 2.3).

viii. Pharmaceutical entrepreneurs and managers: participants were provided with functions and asked to identify which of these functions are to be carried out by managers and/or pharmaceutical entrepreneurs. Additionally, participants were asked to identify attributes required for a pharmacist to be a manager and a pharmaceutical entrepreneur.

ix. Entrepreneurship attributes used to solve issues related to the pharmaceutical scenario: participants were asked to describe entrepreneurship attributes used in their experience when tackling the COVID-19 pandemic, including COVID-19 testing, and medicine shortages, as examples of issues arising within the pharmaceutical scenario.

x. Training for pharmaceutical entrepreneurs: participants were asked to rate their level of agreement with aspects to be included in a training programme for PhE, and to provide their recommendations for additional training aspects to be included in the training programme.

xi. Introducing an entrepreneurial appetite in pharmaceutical processes: participants were asked to rate their level of agreement with the perceived benefits and potential risks associated with the introduction of an entrepreneurial appetite in pharmaceutical processes.

xii. Risks in PhE: participants were asked about the level of risk they would consider taking when embarking on a pharmaceutical entrepreneurial venture.

2.4.3 Validation of Interview Questions

The questions used in the interviews with pharmaceutical entrepreneurs were validated using a two-round Delphi method. The Delphi technique was chosen as it is a widely used and respected systematic procedure used to gather feedback from respondents within their area of expertise (Linstone and Turoff, 2002; Grisham, 2009; Rowe and Wright, 2011; Sourani and Sohail, 2015; Quirke et al, 2021). The aim of using the Delphi technique was the achievement of a reliable consensus among a panel of experts in an iterative process; conducted through multiple stages or rounds using questionnaires (Sourani and Sohail, 2015; McMillian et al, 2016; Quirke et al, 2021). The method was designed to eliminate any bias that might exist when different expert groups come together (Linstone and Turoff, 2002; Grisham, 2009; Sourani and Sohail, 2015; Quirke et al, 2021).

Selection of Validation Panel Expert Members

The quality of the outcome of the study is dependent on the expertise of the chosen panel (Linstone and Turoff, 2002; Steurer, 2011), therefore care was taken when the selection of experts was made. A total of seven participants with different areas of expertise were invited to form part of a panel in the Delphi-based exercise for validation of the interview questions: one pharmacist working in academia and research, one pharmacist working in regulatory sciences, one community pharmacist, one pharmacist working in the pharmaceutical industry, one clinical pharmacist, one pharmaceutical entrepreneur and one lay person. Members were selected using convenience sampling to assess content, relevance and structure. Since participants were not selected randomly, representativeness could not be assured. Each participant was approached by the researcher and invited to participate. The experts were contacted by electronic mail or phone, and the aims of the validation study were clearly outlined. All identified

candidates, five females and two males, accepted to participate. Validators were kept anonymous throughout the process allowing for participants to express their views without being influenced by others within the group, as per usual practice (Steurer, 2011; Sourani and Sohail, 2015).

Delphi Method

Face and content validity were assessed by the panel using a 5-point Likert scale questionnaire, whereby five represented the highest agreement, and one represented the least agreement. Round I of the Delphi study presented participants with 18 questions in which participants were requested to give feedback on content, relevance, and structure. Participants were asked to recommend additional parameters within stipulated sections. Participants were requested to complete the Delphi exercise within one week.

Following an analysis of the results obtained from Round I of the validation exercise, revisions, additions and deletions were made to develop a questionnaire for Round II of the study. As a general rule of thumb, recommendations made by two or more validators were reviewed and taken on board. There were 14 remaining suggestions made by one validator, of which 10 suggestions were taken on board as they were deemed important by the researcher due to their potential impact on the results obtained in the interviews. In Round II of the Delphi study, the updated questionnaire was submitted to the same panel of experts as that used in Round I, thereby respecting norms for the Delphi technique whereby it is desired to have the same expert panel for the entire process (Day and Bobeva, 2005). A consensus threshold was established in the planning phase of the Delphi study to avoid post-hoc bias of results obtained. Research suggests that the median threshold used to define consensus is 75% (Diamond et al, 2014). Within this study, a

consensus for the inclusion of interview questions was reached if 80% or more of participants agreed, or strongly agreed, that the questions were relevant. As indicated in literature, the number of rounds within the Delphi technique usually ranges between two and four rounds, however the number may vary between two and ten. Studies indicate that the majority of changes in responses occur within the first two rounds, and little progress is made thereafter (Day and Bobeva, 2005; Sourani and Sohail, 2015). Similarly in this study, two rounds of Delphi were performed wherein consensus was reached, after which no further changes were made.

2.4.4 Conduction of Interviews with Pharmaceutical Entrepreneurs

Sixteen local pharmaceutical entrepreneurs, thirteen males and three females, were invited to participate in this study by means of an interview. Participants were selected by convenience sampling. Pharmaceutical entrepreneurs invited to participate in this study consisted of pharmacists having a reputation to think and act in an entrepreneurial manner. Each participant was approached by the researcher by phone or electronic mail, and the aims of the study and interview were clearly outlined. Participants were advised that the interview was planned to last approximately 60 minutes and offered a choice of having the interviews organised either in a face-to-face or remote manner. A total of 12 local pharmaceutical entrepreneurs accepted to participate in the study. Responses to the validated interview questions were recorded by the researcher and analysed.

2.5 Phase 2: Training Programme for Pharmaceutical Entrepreneurship

A training programme for the advancement of PhE was developed and validated. As stated in the poster presentation presented at the 80th International Pharmaceutical Federation World Congress of Pharmacy and Pharmaceutical Sciences by Giudice et al (2022), the training programme aims to offer the necessary knowledge and skills to identify, create and pursue new opportunities and implement new ideas in a successful and sustainable manner, whilst nurturing an entrepreneurship spirit within pharmaceutical processes[8] and creates a balance between financial sustainability and patient benefits.

2.5.1 Design and Structure of the Training Programme

PubMed and HyDi were used to conduct a literature search regarding education and training in the area of PhE. The literature search aimed to identify existing training programmes in this area, determine common topics included in such programmes and identify methodologies used in the conduction of training in the area of PhE. Journals used include the *American Journal of Pharmacy Education*, *Currents in Pharmacy Teaching and Learning* and *Industry and Higher Education*. Institutions which offer training programmes in PhE include the Mercer University College of Pharmacy, Presbyterian College School of Pharmacy, the University of Georgia College of Pharmacy, the University of North Carolina Eshelman School of Pharmacy, the University of the Pacific Thomas J Long School of Pharmacy, and the University of South Florida College of Pharmacy.

[8] Giudice L, Attard Pizzuto M, Serracino-Inglott A. Entrepreneurship in Pharmaceutical Processes. Poster session presented at the 80th International Pharmaceutical Federation World Congress of Pharmacy and Pharmaceutical Sciences; Seville 2022.

Information gathered from journal articles, websites of institutions offering training in PhE and responses to the expert team validated interview questions described in Section 2.4, formed a base for developing an educational training programme for PhE. Main areas to be included in the programme were identified. The researcher developed a description of the content, aims and learning outcomes for each of the main areas. Learning outcomes were divided into knowledge and understanding, and skills.

2.5.2 Validation of the Training Programme

The training programme for pharmaceutical entrepreneurs was validated using a two-round Delphi method in a process similar to that described in Section 2.4.3.

Selection of Experts for Validation of the Training Programme

A total of seven participants with different areas of expertise were invited to form part of a panel in the Delphi-based exercise for validation of the training programme for PhE, one pharmacist working in academia and research, two pharmaceutical entrepreneurs, two pharmacists working within the Academy for Patient Centred Excellence in Regulatory Sciences within the MMA, one community pharmacist, and one lay person. Members were selected using convenience sampling and asked to assess content, relevance, and structure. Since participants were not selected randomly, representativeness could not be assured. Each participant was approached by the researcher and invited to participate. The experts were contacted by electronic mail, and the aims of the validation study were clearly outlined. All identified candidates, five females and two males, accepted to participate. Validators were kept anonymous throughout the process.

Delphi method

Face and content validity were assessed by the panel using a 5-point Likert scale questionnaire, whereby one represented the least agreement, and five represented the highest agreement. Round I of the Delphi study presented participants with the description, aims and learning outcomes for each module within the training programme. Participants were asked to evaluate the content, relevance, and structure of each module and to provide comments within stipulated sections. Participants were requested to complete the Delphi exercise within one week.

Following an analysis of the results obtained in Round I of the validation exercise, revisions and deletions were made within the training programme. A consensus for the inclusion of the aims and learning outcomes was reached if 80% or more of participants agreed or strongly agreed that the aims and learning outcomes were relevant. In Round II of the Delphi study, updates to the training programme were submitted to the same panel of experts as that used in Round I, thereby respecting norms for the Delphi technique as described in Section 2.4.3. Consensus was reached after two rounds of Delphi were performed.

2.6 Phase 3: Pharmaceutical Entrepreneurship in Regulatory Sciences

The process undertaken to develop an innovative framework for PhE in regulatory sciences involved the setting up of a focus group to acquire knowledge and gather qualitative data. The focus group in this research was set up by using the MMA, the National Competent Authority (NCA) responsible for the regulation of medicines, pharmaceutical activities and medical devices in Malta, as the setting for regulatory sciences. A retrospective analysis of initiatives implemented at the MMA was carried out in consultation with the focus group and led to the identification of pharmaceutical initiatives conducted at the Authority which are entrepreneurial in nature. The strengths, weaknesses, opportunities, threats and risks of the identified initiatives were analysed.

2.6.1 Design of Focus Group Questions

A combination of open-ended and close-ended questions were developed by the researcher for use in the focus group discussion. Open-ended questions were used where respondents were asked to identify aspects, explain processes, and where further explanation related to the rationale for a response given was desired. Close-ended questions using a 5-point Likert-scale were used to gather data regarding participants' level of agreement to a statement. The scale ranged from one to five, where five represented the highest level of agreement. An 'Other' option was included to allow for the identification of aspects not included by the researcher.

A risk assessment tool was developed to assess risks related to PhE initiatives implemented within regulatory sciences. The tool consisted of a risk matrix which was used to investigate Severity of Impact (SI) and Probability of Occurrence (PO). The development of a 5 x 5 risk matrix was based on the World Health Organization (WHO) guidelines for quality risk management.[9] Risks were assigned SI and PO scores by considering inherent risks which were, or could be, encountered. Scores ranged between one and five whereby one indicated a low SI/PO score, and five indicated a high SI/PO score.

The Risk Rating Score was then obtained by calculating the product of SI and PO which could range between one and twenty-five. A Risk Rating Score of one indicates negligible risk which would require no attention, whilst a score of 25 indicates a high risk which requires immediate attention. A classification for the Risk Rating Score was developed and colour coded; green representing low-risk, amber, medium risk, and red, high risk.

[9] World Health Organization (WHO). WHO guidelines for quality risk management [Internet]. Geneva: WHO; 2013 [cited on 2023 May 29]. Available from URL: https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/production/trs981-annex2-who-quality-risk-management.pdf

Probability What is the probability that the risk will occur?		Impact How severe would the outcome be if the risk occurred?				
		Insignificant 1	**Minor 2**	**Significant 3**	**Major 4**	**Severe 5**
	Rare 1	1	2	3	4	5
	Unlikely 2	2	4	6	8	10
	Moderate 3	3	6	9	12	15
	Likely 4	4	8	12	16	20
	Almost certain 5	5	10	15	20	25

Figure 2.2 Risk Assessment Tool for Pharmaceutical Entrepreneurship Initiatives in Regulatory Sciences

Reproduced from: World Health Organization (WHO). WHO guidelines for quality risk management [Internet]. Geneva: WHO; 2013 [cited on 2023 May 29]. Available from URL: https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/production/trs981-annex2-who-quality-risk-management.pdf

Risk Rating Score between 1 and 4 – Low Risk

Risk Rating Score between 5 and 10 – Medium Risk

Risk Rating Score between 11 and 25 – High Risk

2.6.2 Structure of Focus Group Questions

A total of 10 questions were compiled for the focus group (Appendix 3); of which four questions were open-ended, five were close-ended and one made use of the risk assessment tool described in Section 2.6.1. For the close-ended questions, participants were asked to offer ratings on a 5-point Likert scale, or tick applicable scenarios.

Focus group questions were related to:

i. Attributes which constitute a PhE initiative and their applicability to different pharmaceutical scenarios.
ii. Areas and initiatives implemented within the MMA having an aspect of PhE.
iii. The strengths, weaknesses, opportunities and threats, or risks, of the aforementioned initiatives.
iv. Risks associated with PhE initiatives using a risk assessment tool, and the use of risk mitigation strategies.
v. Potential risks related to the introduction of pharmaceutical entrepreneurial functions within regulatory sciences in a medicines regulatory authority.
vi. Entrepreneurial characteristics, traits and skills used in the implementation of the identified PhE initiatives within the MMA.
vii. Actions which may be used to ensure accountability when carrying out PhE initiatives.

2.6.3 Validation of Focus Group Questions

The questions prepared for use in the focus group discussion were validated using a two-round Delphi method in a process similar to that described in Section 2.4.3.

Selection of Validation Panel Expert Members

A total of seven participants with different areas of expertise were invited to form part of a panel in the Delphi-based exercise for validation of the interview questions, one academic, four pharmacists working in regulatory sciences, one pharmaceutical entrepreneur and one lay person. Members were selected using convenience sampling. Since participants were not selected randomly, representativeness could not be assured. Each participant was approached by the researcher and invited to participate. The experts were contacted by electronic mail, and the aims of the validation study were clearly outlined. All identified candidates, six females and one male, accepted to participate.

Delphi Method

Face and content validity were assessed by the panel using a 5-point Likert scale, whereby five represented the highest level of agreement, and one represented the least level of agreement. Round I of the Delphi study presented participants with 10 questions related to content, relevance, and structure. Participants were asked to comment within stipulated sections and requested to complete the Delphi exercise within one week.

Following an analysis of the results obtained in Round I of the validation exercise, amendments were made to develop a questionnaire for Round II of the study. As described in Section 2.4.3, as a general rule of thumb, recommendations made by two or more validators were reviewed and taken on board. There were two remaining suggestions made by one validator, of which both suggestions were taken on board as they were deemed important by the researcher. In Round II of the Delphi study, the updated questionnaire was submitted to the same panel of experts as that used in Round I, thereby respecting norms for the Delphi technique as described in Section 2.4.3. Within this study, a consensus for the inclusion of questions was reached if 80% or more of participants agreed or strongly agreed that the questions were relevant. Two rounds of Delphi were performed within this study wherein consensus was reached.

2.6.4 Focus Group Protocol

The focus group consisted of eight senior members of the MMA including representatives from the Office of the CEO and each of the six Directorates within the Authority, namely the Licensing Directorate, the Post-Licensing Directorate, the Inspectorate and Enforcement Directorate, the Advanced Scientific Initiatives Directorate, the Regulatory Operations, Medicines Intelligence and Access Directorate and the Medical Devices and Pharmaceutical Collaboration Directorate.[10] Participants were selected by convenience sampling, whereby two representatives from the Office of the CEO and a representative from each Directorate within the MMA were recommended to the researcher. The

[10] Malta Medicines Authority. Directorates and Units [Internet]. Malta: Malta Medicines Authority; 2023 [cited 2023 May 29]. Available from URL: https://medicinesauthority.gov.mt/directoratesunits?l=1

recommended experts were approached by the researcher and sent an electronic invitation to confirm their availability to attend the focus group.

The researcher acted as a moderator by leading the focus group whilst encouraging discussion and equal participation from each member of the expert panel. Notes related to the discussion were recorded in writing. Krueger and Casey (2015) was consulted when devising the focus group protocol which consisted of the following main sections:

a. Introduction [Approximately 10 minutes]

   A brief introduction of the concept of PhE, the aims of the study, the aims of the focus group and a definition for a pharmaceutical entrepreneurial initiative were presented.

b. Discussion [Approximately 90 minutes]

   The participants were presented with the questions prepared for the focus group as described in Section 2.6.1, 2.6.2 and 2.6.3. An in-depth discussion consisting of an exchange of thoughts and views was encouraged by the moderator.

c. Closure [Approximately 10 minutes]

   A summary consisting of the main outcomes of the discussion was presented to the focus group participants.

2.6.5 Observational Study within the Pharmaceutical Products Entrepreneurship Unit

An investigation of the activities carried out at the Pharmaceutical Products Entrepreneurship Unit within the MMA was conducted. The observational study consisted of an assessment of the functions of the Unit, projects handled by personnel within the Unit, and the contribution offered to stakeholders.

An innovative framework for PhE in regulatory sciences was developed based on the responses gathered in the focus group held with representatives from the MMA, and the observational study held within the Pharmaceutical Products Entrepreneurship Unit. The framework may be used as a roadmap for the management of policy priorities.

2.7 Phase 4: Measuring Accountable Pharmaceutical Entrepreneurship

An assessment of tools used to measure accountability in PhE was conducted through a literature search. Principal tools used to measure the impact, effectiveness and accountability of entrepreneurial initiatives were identified. Interviews with pharmaceutical stakeholders were conducted to identify tools used in a real-world scenario.

Informal one-to-one interviews with 16 pharmaceutical stakeholders were performed. Stakeholders included pharmaceutical entrepreneurs and pharmacists having experience participating in PhE initiatives in regulatory sciences and were recruited using convenience sampling. Information gathered from these interviews, together with the results from the literature, led to the identification of tools which can be used to measure the impact, effectiveness and accountability of entrepreneurial initiatives. The use of such tools ensures that operations are being conducted in an accountable, responsible and sustainable manner whilst ensuring that desired outcomes are achieved.

Stakeholders were asked an open-ended question to prompt a discussion regarding the subject; 'Which tools do you use when carrying out pharmaceutical entrepreneurial initiatives, including ones used to measure impact, effectiveness and accountability?'

2.8 Data Analysis

Descriptive statistics of the quantitative data gathered from the validation studies conducted through the course of this research (Section 2.4.3, Section 2.5.2, Section 2.6.3), interviews with pharmaceutical entrepreneurs (Section 2.4.4), focus group discussion (Section 2.6.4) and interviews with stakeholders (Section 2.7) were undertaken using Microsoft® Excel® for Microsoft 365. Qualitative data was analysed.

Chapter Three

Results

The results chapter reports on the following:

1. The contribution that pharmaceutical entrepreneurship (PhE) has to innovation.
2. The development and validation of a training programme for the advancement of PhE.
3. The analysis of entrepreneurship initiatives which are implemented at a medicines regulatory authority and observational study within a unit responsible for PhE which led to the development of an innovative framework for PhE in regulatory sciences.
4. The manner in which accountability in PhE can be measured.

3.1 The Contribution that Pharmaceutical Entrepreneurship has to Innovation

The results reported in the first phase are related to the contribution that PhE has to innovation, examined through a critical analysis of literature obtained from a systematic literature review, and structured interviews with local pharmaceutical entrepreneurs.

3.1.1 Systematic Literature Review

The literature search yielded 589 articles, 124 of which were duplicates. The remaining titles and abstracts were reviewed by the researcher. A full-text review of 58 articles was conducted by the researcher. An additional nine articles were obtained using the snowball method. Twenty-three articles were determined to be relevant to the study using the inclusion criteria described in Section 2.3. Results are presented in Figure 3.1.

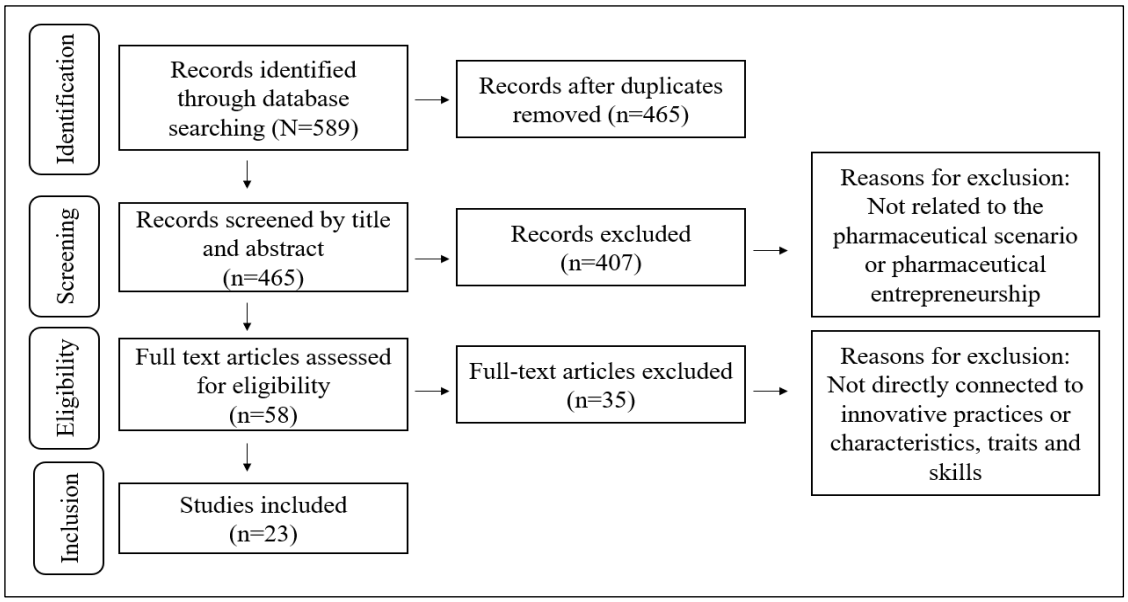


Figure 3.1. Process Flow of the Contribution found in the Literature that Pharmaceutical Entrepreneurship has to Innovation expressed as a PRISMA Diagram

The literature review indicated five points regarding innovative practices related to PhE, and 13 PhE characteristics, traits and skills. The innovative practices identified are open innovation and collaboration, digital health technologies, precision medicine and genomics, artificial intelligence (AI), and patient-centred approaches, which are further elaborated in Section 3.1.2. The identified PhE characteristics, traits and skills are autonomy, competitiveness, goal-orientation, innovativeness, an internal locus of control, leadership skills, motivation, people skills, proactiveness, problem-solving skills, risk-taking, social responsibility, and strategic planning, which are further elaborated in Section 3.1.3.

3.1.2 Innovative Practices related to Pharmaceutical Entrepreneurship

Innovative practices within PhE incorporate a range of strategies that aim to drive forward advancements within the pharmaceutical scenario. These practices often entail novel business models, technological solutions, and collaborative approaches:

a. Open innovation and collaboration: Pharmaceutical entrepreneurs are increasingly embracing open innovation practices by collaborating with external partners, such as academic institutions, research organisations, and start-ups. These collaborations foster the exchange of knowledge, resources, and expertise which enable the development of novel drugs and therapies (Jeon et al, 2016; Xia and Roper, 2016; Sahasranamam et al, 2019; Belousova et al, 2020; Hait and Stoffels, 2021).

b. Digital health technologies: The integration of digital health technologies, including the use of mobile health applications, wearable devices, and telemedicine, is revolutionising healthcare as these technologies enable remote patient monitoring, real-time data collection, and personalised medicine approaches, leading to improved patient outcomes. These technologies facilitate remote clinical trials and decentralised research methodologies (Belousova et al, 2020; Holdford, 2021; Park 2021; Saunders et al, 2022).

c. Precision medicine and genomics: The emergence of precision medicine offers several opportunities for PhE endeavours through the identification of variability in patient genes, environments and lifestyles. The use of genomic data, biomarkers and advanced diagnostics, enable pharmaceutical enterprises to develop targeted therapies which are tailored to the patient's genetic makeup. In so doing, the efficacy of treatments is enhanced, whilst minimising side effects and improving patient safety (Tarkkala, 2019; Belousova et al, 2020; Au and da Silva, 2021; Hall et al, 2022).

d. Technological innovation and AI: Technological innovation and AI are increasingly being used within pharmaceutical processes and lead to the acceleration of the discovery of drugs and development processes through the analysis of data, predictions related to drug-target interactions, and the identification of potential drug candidates in a more efficient manner. Technological advancements and AI enable improved efficiency and agility within pharmaceutical processes by reducing costs and timelines (Jeon et al, 2016; Rake, 2017; Belousova et al, 2020; Park et al, 2021; Saunders et al, 2022).
e. Patient-centred approaches: There is a growing focus on patient-centricity as pharmaceutical enterprises are actively involving patients, seeking their input to identify patient priorities, and ensure that therapies meet patient needs, whilst safeguarding safety, quality and efficacy, and improving accessibility and patient compliance (Sindakis and Kitsios, 2016; Belousova et al, 2020).

3.1.3 Pharmaceutical Entrepreneurship Characteristics, Traits and Skills

Research suggests that the possession of characteristics, personality traits and skills linked to entrepreneurship play a significant role in how well an entrepreneur takes advantage of novel opportunities (Shaver and Commarmond, 2019; Korpysa et al, 2020; Murray Gillin and Hazelton, 2021). The PhE characteristics, traits and skills identified in this study are autonomy, competitiveness, goal-orientation, innovativeness, an internal locus of control, leadership skills, motivation, people skills, proactiveness, problem-solving skills, risk-taking, social responsibility and strategic planning (Ramia et al, 2016; McLaughlin et al, 2017; Shahiwala, 2017; Huston, 2018; Mattingly et al, 2019a; Mattingly et al, 2019b; Ruas Ferreira dos Santos et al, 2019; Shaikh et al, 2020; Fashami et al, 2021; Nili et al, 2021), the definitions of which are presented in Appendix 4.

3.2 Interviews with Pharmaceutical Entrepreneurs

Structured interviews were held with local pharmaceutical entrepreneurs to investigate pharmaceutical entrepreneurial behaviour, the process of entrepreneurship in the pharmaceutical scenario, challenges related to PhE, PhE characteristics, traits and skills that contribute to innovation, education and training related to the advancement of PhE, and the potential benefits and risks associated with the introduction of an entrepreneurship appetite in pharmaceutical processes, as described in Section 2.4.2. The aims of the interviews were to gain understanding of PhE in the local scenario, obtain information from individuals with hands-on experience, and compare responses to information found in the literature, including results gathered in the systematic literature review.

Questions used in the interviews with pharmaceutical entrepreneurs were validated by an expert panel. All seven members recruited to participate in the validation expert panel accepted the invitation and participated in both rounds of the Delphi study, in which face and content validity were assessed. Five participants were female, and two participants were male. The major changes to the interview questions during the validation exercise were related to additions, changes in ranges, and changes to the nomenclature used to define numbers on Likert-scales.

Following the presentation of the modifications made in Round I of the Delphi study to the expert panel, consensus was reached in Round II. The interview questions prepared for use with local pharmaceutical entrepreneurs were considered validated.

The results of the interviewing process are conferred in the following sections: Section 3.2.1 presents demographic data, Section 3.2.2 presents results related to pharmaceutical entrepreneurial behaviour, Section 3.2.3 presents results related to the process of entrepreneurship in the pharmaceutical scenario, Section 3.2.4 presents results related to challenges in PhE, Section 3.2.5 presents results related to reaching a state of concordance in PhE, Section 3.2.6 presents results related to reaching a state of wisdom in PhE, Section 3.2.7 presents results related to PhE characteristics, traits and skills, Section 3.2.8 presents results related to pharmaceutical entrepreneurs and managers, Section 3.2.9 presents results regarding entrepreneurship attributes used to solve issues related to pharmaceutical scenarios, Section 3.2.10 presents results regarding the role of education and training in evolving PhE, Section 3.2.11 presents results related to the introduction of an entrepreneurship appetite in pharmaceutical processes, and Section 3.2.12 presents results related to risks in PhE.

3.2.1 Demographic Data for Interviews with Pharmaceutical Entrepreneurs

Twelve of the sixteen local pharmaceutical entrepreneurs who were invited to participate in the study accepted to contribute by means of an interview. Eleven participants opted to hold the interview face-to-face and one participant opted to conduct the interview over an online platform. The duration of the interviews ranged between 40 minutes and 82 minutes. The demographic data for the interview participants is presented in Table 3.1.

Table 3.1 Demographic Data for Interview Participants (N=12)

Demographic Characteristics		Frequency
Gender	Male	11
	Female	1
Number of years practicing in the pharmaceutical scenario	≤ 5 years	0
	6 – 10 years	2
	11 – 15 years	2
	16 – 20 years	1
	>20 years	7
Area/s of pharmacy participants had experience in	Community Pharmacy	10
	Hospital Pharmacy	3
	Importation and Distribution	11
	Industrial Pharmacy	2
	Medical Representation	10
	Pharmacy administration	3
	Regulatory Sciences	8

3.2.2 Pharmaceutical Entrepreneurial Behaviour

Participants were presented with the below description of PhE and asked to provide additional aspects associated with entrepreneurial behaviour in the pharmaceutical scenario:

> Pharmaceutical entrepreneurship entails the identification, creation, and pursuit of new opportunities to serve patient needs and plays a fundamental role in improving healthcare through innovation. Pharmaceutical entrepreneurship requires a combination of scientific knowledge, business acumen, and risk-taking ability to improve patient care.
>
> (Mattingly et al, 2019b)

The results of the three points participants were asked to mention to define entrepreneurial behaviour in the pharmaceutical scenario, together with the number of times they were mentioned by the participants, are presented in Table 3.2.

Table 3.2 Pharmaceutical Entrepreneurial Behaviours described by Participants (N=12)

Pharmaceutical Entrepreneurial Behaviour	Frequency
Agility	3
Ambition and drive	3
Determination	3
Market awareness to be able to identify needs by having a listening ear	3
Perseverance	3
Adaptability and flexibility	2
Identifying niches where patients are not being served properly, offering value added activity including access to innovative medicines	2
Informed decision-making	2
Innovation	2
Leadership	2
Ability to learn from mistakes and self-critical	1
Awareness of future technologies and innovations	1
Being a team-player	1
Being hard-working	1
Commitment and consistency	1
Ethical values related to the pharmaceutical scenario	1
Motivation	1
Proactiveness	1
Self-confidence	1
Sincerity	1
Trust and respect	1

An aspect that was discussed in the interviews was that the advantage of being a pharmacist when carrying out PhE is that pharmacists are known to act in an ethical manner and consider patient care as the priority in their endeavours. A pharmacist's perspective is required in the understanding of patient needs and the implications and repercussions of scenarios such as medicine shortages. Pharmacists understand that although the need for sustainability is significant, the financial aspect is not the most important aspect of PhE. It is the desire to attend to patient needs and offer services which establish continuous quality care to patients, that gives pharmacists the drive to participate in PhE initiatives.

Four pharmaceutical entrepreneurs commented on the fact that although business acumen is important, it is not necessarily something that pharmaceutical entrepreneurs have at the beginning of their career, and tends to be learned over time, as pharmacists do not usually receive training in areas related to entrepreneurship and business management. In addition, qualities related to entrepreneurship and business acumen could be inborne, especially in individuals who have family members, or role models, who are involved in entrepreneurship and business. In such cases, entrepreneurial skills, behavioural traits and qualities are developed throughout the individual's life, through the environment they are exposed to.

Three pharmaceutical entrepreneurs commented that although risk-taking ability is important, the risk being taken is calculated as pharmaceutical entrepreneurs would have a good awareness of the market. Three participants expressed the importance of agility, especially in the case of entrepreneurship related to pharmaceuticals and healthcare, due to rapid shifts in the environment which require one to observe progressing scenarios and respond as quickly as possible. It is the ability to identify upcoming trends and needs in

an agile manner that enables one to keep oneself at the forefront. The ability to make decisions quickly is a basic need when carrying out PhE endeavours and tends to come with experience.

Two pharmaceutical entrepreneurs said that at times, initial ideas and plans may need to be altered due to changes in conditions in the market or the environment in which one is operating. Examples of such changes include the emergence of new entrants in the market, changes in legislation, the emergence of a war or a pandemic, or a lack of active pharmaceutical ingredients (APIs), due to a lack of raw materials or issues in the manufacturing process. This may result in the need for changes to be made to plans for PhE initiatives, or the original need no longer existing by the time the project is ready to come to fruition. In such a case, a pharmaceutical entrepreneur must be able to adapt in real-time and focus on different aspects to those that were originally envisaged.

Two participants expressed the importance of pharmaceutical entrepreneurs investigating niche disease areas including orphan diseases, where energy must be focused on facing hurdles to garner better access to innovative medicines for patients who suffer from orphan diseases. In Malta, this poses a greater challenge due to the size of the local market and economies of scale, which may result in a lack of viability of the pursual of opportunities which address such niches, due to the size of the local market.

Two participants commented on the importance of having a strong information technology (IT) infrastructure and digitalisation, as a means of keeping up-to-date with current affairs in the evolving healthcare scenario. IT was described as a big boost for entrepreneurship. Participants shared that it is important that the pharmaceutical entrepreneur remain current with software systems, as such systems often get superseded.

Pharmaceutical entrepreneurial behaviours described by participants are agility, ambition, drive, determination, market awareness to be able to identify needs by having a listening ear, perseverance, adaptability, flexibility, identifying niches where patients are not being served properly, offering value added activity including access to innovative medicines, informed decision making, innovation, leadership, ability to learn from mistakes, being self-critical, awareness of future technologies and innovations, being a team-player, being hard-working, commitment, consistency, ethical values related to the pharmaceutical scenario, motivation, proactiveness, self-confidence, sincerity, trust and respect.

When asked whether the interview participants consider themselves to be pharmaceutical entrepreneurs, 11 participants responded in the affirmative as they have created pharmaceutical enterprises and undertaken pharmaceutical entrepreneurial initiatives throughout their career, are constantly seeking new opportunities to cater for patient needs, and look for new ways to improve patient services and expand their enterprises. One participant said that he did not consider himself to be a pharmaceutical entrepreneur, even though he acknowledges that he took an initial step by taking a risk to open a pharmaceutical enterprise, which can be considered an entrepreneurial move. Although this is the case, he does not consider himself to be a pharmaceutical entrepreneur at this stage. It is worth nothing that this participant falls within the category of having six to ten years of work experience.

3.2.3 The Process of Entrepreneurship in the Pharmaceutical Scenario

Participants were presented with the process of entrepreneurship as described in Section 1.3 and asked regarding their perception of the most challenging step within the entrepreneurial process as experienced within the pharmaceutical scenario. Responses are depicted in Figure 3.2.

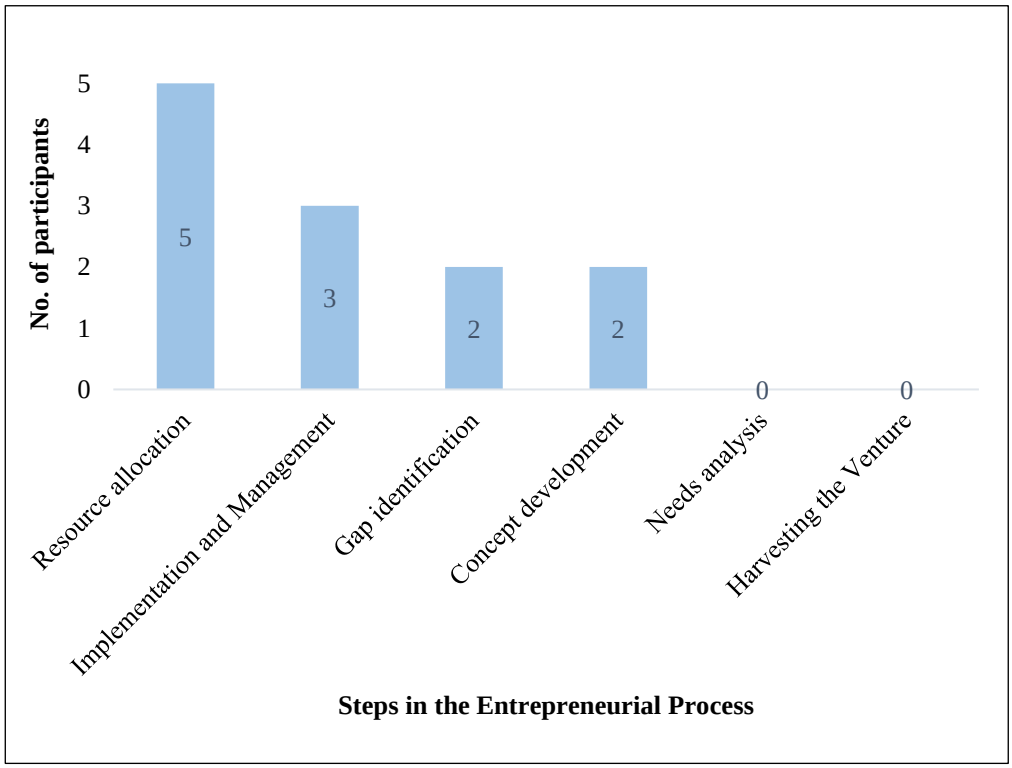


Figure 3.2 Challenges within the Entrepreneurial Process in the Pharmaceutical Scenario (N=12)

Five respondents believe that the most challenging step within the pharmaceutical scenario is resource allocation due to a lack of resources, both in terms of finances, with regards to the best way of spending available funds in developing the pharmaceutical entrepreneurial initiative, but even more so with regards to Human Resources (HR). Participants disclosed that is becoming very difficult to find professionals, especially pharmacists, with sufficient work experience. This is a substantial issue in the

pharmaceutical scenario as pharmacy is a service-based industry and requires trained personnel to succeed. Three participants declared that they have not embarked on certain pharmaceutical entrepreneurial endeavours due to a lack of HR which has occasionally stalled the growth of their enterprise. It was discussed that financial resources pose a challenge earlier on in a pharmaceutical entrepreneur's career but become less of a challenge as time goes by, and experience is gained.

Three participants reported that they consider implementation and management to be the most difficult step as it is challenging to face obstacles and hurdles when creating and managing an organisational structure to be able to implement pharmaceutical entrepreneurial ventures. It was discussed that on certain occasions, between the time it takes for the gap to be identified and the pharmaceutical entrepreneurial endeavour to be implemented and managed, the original gap may no longer exist, and the pharmaceutical entrepreneur would need to adapt to the change in conditions, as described in Section 3.2.2. One respondent claimed that they do not consider management to be difficult in the pharmaceutical scenario as one is dealing with professionals who can be managed efficiently with the use of robust Key Performance Indicators (KPIs).

Two participants responded that they consider gap identification to be the most challenging step. One of these participants said that it is not always clear what is required within the market, and it is difficult to identify niches which have the potential to be successful in a small market, such as that in Malta. The second participant said that since there are several issues which need to be resolved in the pharmaceutical scenario, he considers gap identification to be the most challenging step as a pharmaceutical entrepreneur must be able to identify one specific gap and focus on targeting the chosen

gap, whilst disregarding all other possible identified opportunities. Other interview participants commented by saying that gap identification is more challenging at the beginning of a pharmaceutical entrepreneur's career and is a skill which one gains with experience. As time progresses, pharmaceutical entrepreneurs become better at identifying patient needs and gaps within the market.

Two respondents believed that concept development is the most challenging step as a significant amount of time must be invested in developing a concept at a stage where the pharmaceutical entrepreneur is unsure regarding whether the entrepreneurial initiative will come to fruition or not. Pharmaceutical entrepreneurs typically have several ideas regarding how to address a gap, however, finding a solution which partners, employees and potential investors believe in requires persistence and grit.

Results show that challenging steps within the entrepreneurial process in the pharmaceutical scenario are resources allocation, implementation and management, gap identification and concept development.

3.2.4 Challenges related to Pharmaceutical Entrepreneurship

Participants were asked to rate the extent to which they face 10 challenges when carrying out pharmaceutical entrepreneurial initiatives, namely business acumen, competition, inadequate capacity, infrastructural facilities, leadership, meeting stakeholder needs, project management, regulation, resistance to change and time restraints, on a Likert-scale, where five represented the highest level of agreement, and one represented the lowest level of agreement. Results are presented in Figure 3.3.

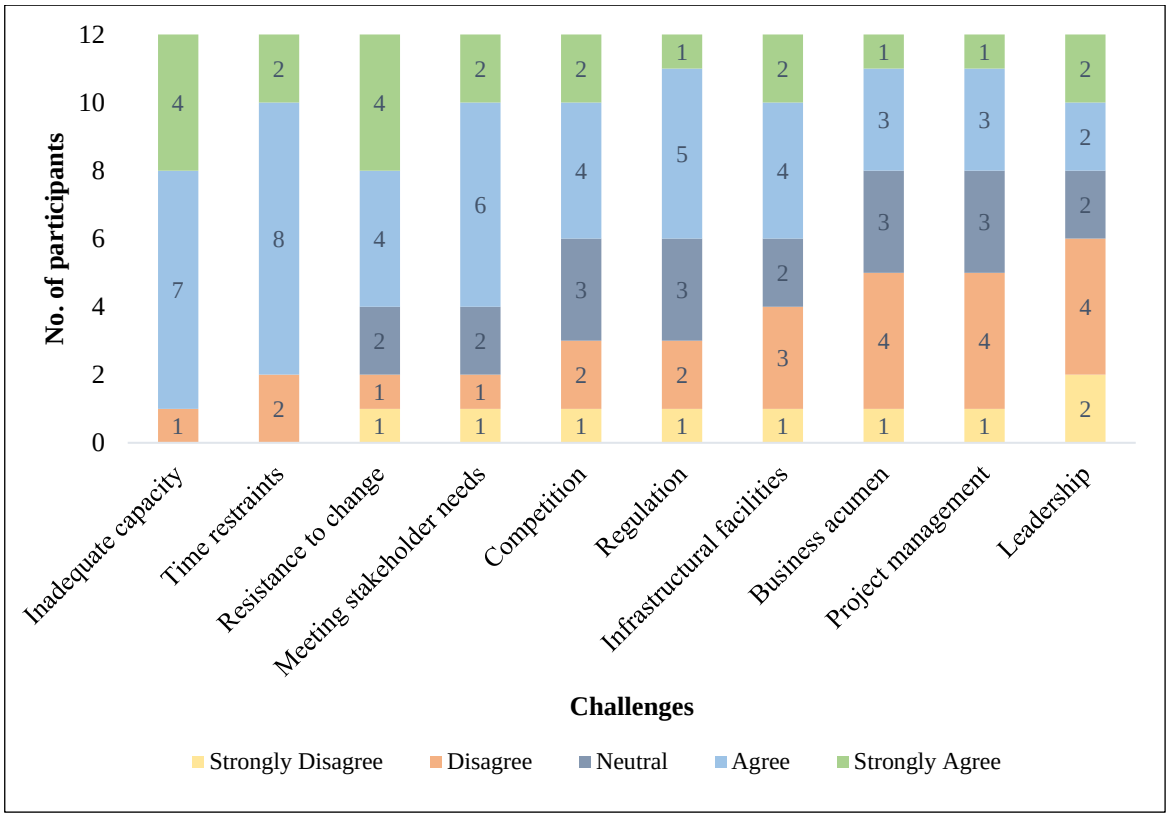


Figure 3.3: Challenges faced when carrying out Pharmaceutical Entrepreneurial Initiatives (N=12)

a. Business acumen

Four participants agreed or strongly agreed that business acumen is a challenge when carrying out pharmaceutical entrepreneurial initiatives, three participants neither agreed nor disagreed and five participants disagreed or strongly disagreed. Participants stated that since pharmacists do not receive training on aspects related to business and entrepreneurship, business acumen is a considerable challenge at the beginning of a pharmaceutical entrepreneur's career. Participants stated that business acumen is acquired through experience and developed over time. To this effect, six participants stated that although they found business acumen to be a challenge earlier in their career, they got bolder and built self-confidence as their careers progressed and do not consider business acumen to be a challenge any longer. One participant commented by stating that if

business acumen is not considered a challenge, one cannot give it its due importance. When one intends to embark on a pharmaceutical entrepreneurial venture, one must make sure to have the relevant knowledge and information to be able to make informed decisions.

Participants acknowledged that should one want to succeed in PhE, business acumen, together with organisational skills and people management, are necessary competences for a pharmaceutical entrepreneur. Another aspect that was discussed is that good business abilities must be embedded within the individual, and that certain individuals have a natural gift for entrepreneurship. However, a natural gift is not enough on its own merit, as one can only get so far with basic grit. Participants commented that one must keep in mind that as a pharmaceutical entrepreneur, one is constantly learning, and one never knows enough. Pharmaceutical entrepreneurs must constantly use different sources to gather information and be on the lookout for new innovations and trends within the market.

b. Competition

Six participants agreed or strongly agreed that they consider competition a challenge when carrying out pharmaceutical entrepreneurial initiatives, three participants neither agreed nor disagreed and three participants disagreed or strongly disagreed. Participants acknowledged that competition is evident within the pharmaceutical scenario, just as it exists in every other area of business. Five participants stated that they view competition as an opportunity for growth, rather than as a challenge, and that it does not detract them from conducting pharmaceutical entrepreneurial initiatives. The priority pharmaceutical entrepreneurs should have is to act in a professional manner and offer a good service, in

turn leading to a rise in standards within the pharmaceutical scenario. Competition keeps pharmaceutical entrepreneurs on their toes, spurring them on to be creative. Participants shared that on a level playing field, competition is a healthy challenge, but sometimes the playing field is not level due to unjust allowances. Two participants stated that such competition limits PhE as an environment is created where one is no longer able to compete. Additionally, competition constitutes a considerable challenge when barriers to entry to a market are so high that they preclude one from entering the market.

Examples of competition within PhE scenarios include, medicinal products targeting the same indication being manufactured by different companies, parallel importation, generic medicinal products and a limited number of licenses for community pharmacies within the Maltese islands.

c. Inadequate capacity

Eleven participants agreed or strongly agreed that they consider inadequate capacity to be a challenge when carrying out pharmaceutical entrepreneurial initiatives and one disagreed. Eleven participants stated that inadequate capacity is a considerable challenge within the pharmaceutical sector and is considered one of the most significant challenges. Inadequate capacity is a global issue as less students are taking up science subjects, as students are pursuing studies in other industries. Pharmaceutical entrepreneurial initiatives cannot be implemented without personnel. Finding skilled personnel is becoming more of a challenge as time progresses due to a limited pool of pharmaceutical professionals. The recruitment of proficient personnel tends to come at a considerable financial cost. In addition, companies are keeping operations lean, therefore increasing difficulty in allocating resources to explore new opportunities due to busy schedules.

Three participants reported that they have had to hold back on pharmaceutical entrepreneurial initiatives due to a lack of HR.

d. Infrastructural facilities

Participants had varying views regarding whether warehousing and company infrastructure present a challenge. Six participants agreed or strongly agreed that infrastructural facilities constitute a challenge when carrying out pharmaceutical entrepreneurial initiatives, two participants neither agreed nor disagreed and four participants disagreed or strongly disagreed. Participants who disagreed with infrastructural facilities posing a challenge said that should one require additional space to conduct a pharmaceutical entrepreneurial initiative, one could rent space. One participant stated that on an island such as Malta, with limited space and costs related to property and rent increasing drastically over time, unless one owns property, prohibitive costs may harm the viability of undertaking pharmaceutical entrepreneurial initiatives. One participant believed that there is a lack of government support when it comes to support for warehousing and pharmaceutical stores. The participant believed that due to the high standards required within the pharmaceutical scenario, incentives should be introduced to help pharmaceutical enterprises in this regard. Other participants stated that there are no barriers with regards to infrastructure. Two participants stated that digitalisation is currently the largest infrastructural challenge.

e. Leadership

Four participants agreed or strongly agreed that they consider leadership to be a challenge when carrying out pharmaceutical entrepreneurial initiatives, two participants neither agreed nor disagreed and six participants disagreed or strongly disagreed. Participants acknowledged that leadership is required in PhE, however, they no longer consider it a challenge as they have established leadership over time, whilst developing mutual respect, and understand the capabilities and motivations of team members. One participant stated that pharmaceutical entrepreneurs must be good leaders to be remotely connected to PhE. The team must be on board for the direction in which a pharmaceutical entrepreneur wants to take the organisation. To achieve this, one must be a strong leader. Participants who agreed or strongly agreed with leadership constituting a challenge, stated that there are different ways of leading and that the challenging aspect is finding the right way of conducting leadership within the particular organisation. Additionally, members within the organisation must also be encouraged to take leadership roles for the success of the enterprise, which may prove to be challenging.

f. Meeting stakeholder needs

Eight participants agreed or strongly agreed that they consider meeting stakeholder needs a challenge when carrying out pharmaceutical entrepreneurial initiatives, two participants neither agreed nor disagreed and two participants disagreed or strongly disagreed. Participants stated that pharmaceutical entrepreneurs must create a balance between the needs of patients, staff members, suppliers, customers, and regulatory authorities, whilst offering the best service to patients. Relationships with stakeholders are built on trust and respect. Patients must be the priority and kept as the central focus in PhE. Although

sustainability is of utmost importance for a pharmaceutical enterprise to survive, sustainability cannot come at the cost of patient safety by giving a disservice to patients.

Three participants discussed challenges they face with suppliers due to the size of the local market. Suppliers set Minimum Order Quantities (MOQs), often averaging 10,000 units for medicinal products. Such quantities are difficult for pharmaceutical entrepreneurs to require locally, due to the small market in Malta. This is more so an issue when considering medicinal products targeting niche areas, where quantities required locally are even smaller. One participant stated that supplier needs are the most difficult needs pharmaceutical entrepreneurs must meet, due to the minimum quantities required to successfully place an order.

Two respondents did not consider meeting stakeholder needs a challenge, as they stated that pharmaceutical entrepreneurs know their stakeholders well and are adequately equipped to meet their needs, however they acknowledged that at times there may be issues that arise. One example of an issue which may pose a challenge to be able to meet stakeholder needs is the occurrence of problems related to deliveries of medicinal products. Such issues with deliveries cause delays in the arrival of the medicinal products which inherently affects patients. Though such occurrences are a possibility, the participants stated that such happenings do not arise frequently.

g. Project Management

Four participants agreed or strongly agreed that they consider project management to be a challenge when carrying out pharmaceutical entrepreneurial initiatives, three participants neither agreed nor disagreed and five participants disagreed or strongly disagreed. Participants stated that should one have a robust structure within an organisation, project management should not pose a significant challenge. However, project management could be considered a challenge should one not have adequate personnel. It was stressed that a pharmaceutical entrepreneur should be able to delegate tasks to members within the team as this would allow the pharmaceutical entrepreneur to focus on pursuing opportunities for PhE. Participants stated that a pharmaceutical entrepreneur should have strong organisational skills and planning abilities to be able to manage projects successfully.

h. Regulation

Six participants agreed or strongly agreed that they consider regulation to be a challenge when carrying out pharmaceutical entrepreneurial initiatives, three participants neither agreed nor disagreed and three participants disagreed or strongly disagreed. Participants agreeing with regulation presenting a challenge in PhE stated that should regulations not exist, there would be more opportunities for PhE. Additionally, legislation and regulation have become stricter over time, affecting accessibility to medicinal products and medical devices. Examples include the implications of Brexit and the Medical Device Regulation. Brexit has affected companies which local enterprises procure medicinal products from, thereby affecting accessibility and pricing of medicinal products. One participant stated that an example of regulation posing a challenge in PhE is the maintenance of highly regulated premises, which increase costs.

Participants who disagreed with regulation posing a challenge stated that regulation is a stable aspect which exists for all players, thereby offering a level playing field. Three participants shared that they do not consider regulation to be a challenge, especially in areas in which they have experience. Participants did acknowledge that regulation could pose a challenge in newer areas where regulations, or changes in pre-existing regulation, are not as clear. Such changes affect a pharmaceutical entrepreneur's ability to make decisions.

i. Resistance to change

Eight participants agreed or strongly agreed that they consider resistance to change to be a challenge when carrying out pharmaceutical entrepreneurial initiatives, two participants neither agreed nor disagreed and two participants disagreed or strongly disagreed. Participants agreed or strongly agreed that resistance to change poses a substantial challenge as people are comfortable with the status quo, and inherently resistant to change. Locally, the cultural mindset is mainly conservative, offering opposition to those who try to do things differently. Pharmaceutical entrepreneurs make a considerable effort in convincing stakeholders, including employees, that the proposed change will be beneficial. The presence of a sound change management approach, and leadership, are required to address this challenge.

j. Time restraints

Ten participants agreed or strongly agreed that they consider time restraints to be a challenge when carrying out pharmaceutical entrepreneurial initiatives and two participants disagreed. Participants stated that pharmaceutical entrepreneurs must balance their time between existing operations which ensure a healthy growth of the business and exploring new opportunities which require a significant amount of time and do not generate revenue at the initial stages. Therefore, one cannot neglect existing business as this would be what is keeping the enterprise viable. Pharmaceutical entrepreneurs must be able to make decisions quickly and delegate tasks to be able to focus on aspects which require their attention. Scenarios within the pharmaceutical sector are constantly evolving, therefore the longer one takes to implement a pharmaceutical entrepreneurial initiative, the higher the chance that an environmental change will occur which may result in the original request, or gap, no longer existing.

k. Additional challenges:

Further to the above, additional challenges pharmaceutical entrepreneurs face when carrying out pharmaceutical entrepreneurial initiatives include the setting up of organisational structures and processes in a way that does not become excessively bureaucratic, the size of the local market, economies of scales, and bureaucracy in complicated procedures associated with tendering procedures.

Results show that the most challenging aspects local pharmaceutical entrepreneurs face when carrying out pharmaceutical entrepreneurial initiatives are inadequate capacity, meeting stakeholder needs, resistance to change, and time restraints.

3.2.5 Reaching a state of Concordance in Pharmaceutical Entrepreneurship

Participants were presented with the concept of compliance, adherence and concordance in a pharmaceutical entrepreneurial scenario. Similar to the way compliance is used in the clinical scenario to explain the extent to which a patient follows recommendations made by the prescriber, compliance within PhE was described to participants as a means of adhering to legislation and regulation in a manner which follows demands and direction, implying passivity. Adherence in the clinical scenario is characterised as the degree to which a person corresponds with agreed recommendations from a healthcare professional. In PhE, adherence was described as the taking of a more active role in processes related to PhE. Concordance in the clinical scenario is described as an agreement made, after consultation between a patient and a healthcare professional, in which the patient's values and preferences are taken into consideration when deciding whether, when, and how the patient will take medication. In the scenario of PhE, concordance was described as a state wherein parties are in agreement within a particular scenario through active participation of the pharmaceutical entrepreneur who takes an assertive stance within PhE processes.

Interview participants were presented with the below chain and asked whether they thought it was important for a pharmaceutical entrepreneur to move from compliance to adherence to concordance in PhE.

Compliance → Adherence → Concordance

A state of concordance within the PhE scenario was described by participants as a state of building relationships with stakeholders, including regulatory authorities, who actively contribute to pharmaceutical entrepreneurial endeavours, and engage to discuss struggles and how difficulties being experienced can be improved. Additionally, a good pharmaceutical entrepreneur is aware that to be successful, one cannot act alone. One needs to lead a team by empowering team members to achieve more, collectively. This is achieved through the establishment of an organisational culture, sharing a common vision and avoiding the creation of silos. Teamwork forms part of the trajectory to reaching concordance. The team must escalate and gather inputs from experts in different fields when formulating a pharmaceutical entrepreneurial venture. An inside-out approach within an enterprise was discussed with one participant, where employees within the organisation were described as the enterprise's first customer. Internal and external needs are identified and genuine care for employees within the organisation is applied. In this case, concordance is considered the highest level of engagement, whereby employees are empowered to give their inputs, opinions and ideas.

Results show that reaching a state of concordance is a target one should aim to achieve, as reaching a state of concordance enables pharmaceutical entrepreneurs to achieve their goals.

From the challenges which pharmaceutical entrepreneurs experience as discussed in Section 3.2.4, participants identified the following as areas in which reaching a state of concordance could benefit the organisation:

i. Leadership: by encouraging staff to take assertive roles.
ii. Meeting stakeholder needs: whereby one does not wait for needs to be identified but searches for niches and opportunities.
iii. Project management: whereby the pharmaceutical entrepreneur must be the driver, but the team must collaborate to achieve common goals.
iv. Regulation: for the identification of opportunities for pharmaceutical entrepreneurial ventures which may arise due to changes in legislation, through a collaborative approach.
v. Resistance to change: as stakeholders are brought on board to believe in a common vision.
vi. Time restraints: through delegation of tasks to team members to allow for the identification and development of opportunities for PhE.

3.2.6 Reaching a state of Wisdom in Pharmaceutical Entrepreneurship

Participants were presented with the below chain and asked regarding the importance of moving along this chain within the scenario of PhE.

Data → Information → Knowledge → Wisdom

Data was described as a vital aspect in PhE, and the foundation upon which a pharmaceutical entrepreneur builds a vision and purpose for the enterprise. Examples of

data include sales figures and competitive information. Participants stated that PhE starts with data, however its value is not always appreciated as alone data does not bear significant meaning. Data must be collected to gather information which enables a better understanding of the market, and the identification of trends, for the development of knowledge and wisdom. A state of wisdom allows for business development as pharmaceutical entrepreneurs make informed decision regarding how to proceed in their endeavours and act accordingly. Wisdom is essential in the establishment of the vision, mission, purpose and business strategy of a pharmaceutical enterprise.

A pharmaceutical entrepreneur must have reliable, comprehensive sources of data, and an intelligence system to translate the data into information, knowledge and wisdom to give one a competitive edge and gain the confidence of customers. Pharmaceutical entrepreneurs should address the gatekeepers of certain scenarios, to gather data and information from grassroots, as the knowledge and wisdom garnered is what drives PhE. Results show that the process of moving from data to information and translating that into knowledge and wisdom is a central component of PhE.

From the challenges which pharmaceutical entrepreneurs experience as discussed in Section 3.2.4, participants identified the following as areas in which reaching a state of wisdom could benefit the pharmaceutical enterprise:

i. Business acumen: to be able to make informed decisions.
ii. Meeting stakeholder needs: through wisdom gathered from data analysis for the identification of trends and stakeholder needs.
iii. Project management: for the governing of PhE endeavours to be based on knowledge and wisdom.

3.2.7 Pharmaceutical Entrepreneurship Characteristics, Traits and Skills

Participants were asked to rate their perception regarding the importance of the 13 PhE characteristics, traits and skills described in Section 3.1.3 on a Likert-scale, where five represented the highest level of agreement, and one represented the lowest level of agreement. Responses gathered are presented in Figure 3.4.

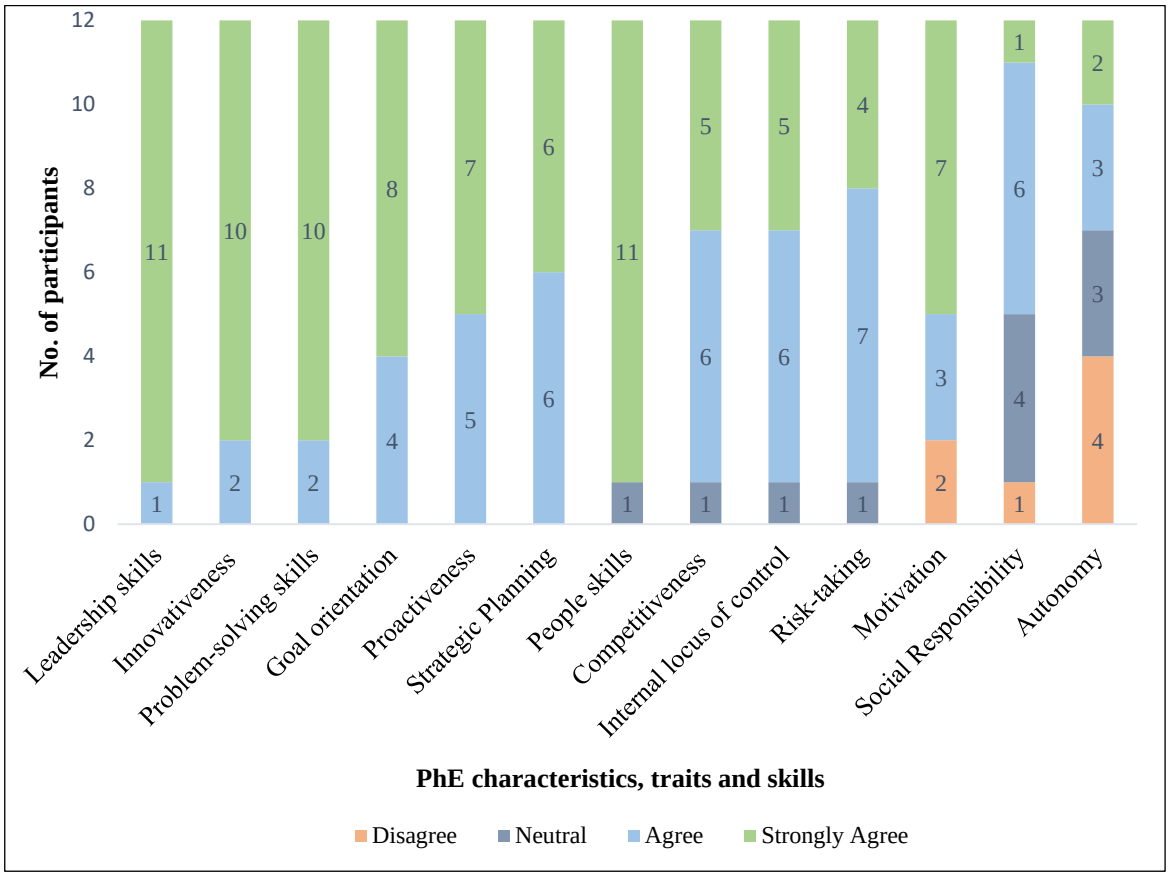


Figure 3.4 Pharmaceutical Entrepreneurship Characteristics, Traits and Skills (N=12)

Participants made the following comments regarding the identified PhE characteristics, traits and skills. Leadership was identified as one of the most important skills within PhE, for the achievement of a common goal and vision. With regards to goal orientation, pharmaceutical entrepreneurs should set goals and be able to measure the goals and ensure the achievement of the set goals. Additionally, pharmaceutical entrepreneurs should

consider long-term goals when carrying out PhE initiatives. Competitiveness was described as human instinct and a driver of PhE. With regards to risk-taking, although PhE is often related to the taking of risks, success may occur due to chance, not the taking of calculated risk. Two participants stated that motivation is not a necessity when carrying out PhE initiative. The participants stated that determination, dedication and perseverance are required to carry on through periods when one lacks motivation. Participants shared that it would be ideal for all individuals to be socially responsible, however this does not necessarily translate to success in business. With regards to autonomy, participants shared that although one may have a venture brain which does not require input from other individuals, this is not essential. Four participants disagreed that a pharmaceutical entrepreneur requires autonomy as though one should be independent, one is never knowledgeable enough and needs to consider input from different individuals, especially when consider areas which are new to the pharmaceutical entrepreneur. One must be able to make decisions alone, however this could be based on information gathered from individuals who could influence the decision being made. One participant shared that they believe that team members should be enrolled in decision-making processes.

Results show that participants agreed or strongly agreed that leadership skills, innovativeness, problem-solving skills, goal-orientation, proactiveness, strategic planning, people skills, competitiveness, an internal locus of control, risk-taking, motivation and social responsibility constitute PhE characteristics, traits and skills. Autonomy was not considered a necessary trait for PhE. Additionally, perseverance was considered an additional PhE trait.

3.2.8 Pharmaceutical Entrepreneurs and Managers

Participants were presented with eight functions and asked whether they consider these functions to form part of the role of a manager, a pharmaceutical entrepreneur or both. Results are presented in Table 3.3.

Functions mainly considered to be the responsibility of the pharmaceutical entrepreneur are: taking risks by investing time and money in novel opportunities, for example digitalisation of health data, growing a business by finding new customers, expanding into new markets, improving operations taking into consideration the ethical codes to be observed in a pharmaceutical scenario, identifying opportunities to meet patients' unmet needs, creating and developing a business plan, securing funding, and establishing a business whilst keeping the patient as a central component of the business. Functions mainly considered to be the responsibility of the manager are: allocating resources including finances, personnel and time in line with legal requisites, for example having the necessary qualified personnel (Qualified Person/ Responsible Person/ Managing pharmacist), developing strategies and plans for the enterprise in such a way that they are in accordance with pharmaceutical regulatory sciences including Good Manufacturing Practice and Good Distribution Practice, and monitoring and adjusting performance ensuring that the goals of quality, safety, efficacy and accessibility to medicines are met. The function considered to be a shared responsibility between the pharmaceutical entrepreneur and the manager is motivating and leading personnel to achieve common objectives, namely that the patient comes first.

Table 3.3: Roles of Pharmaceutical Entrepreneurs and Managers (N=12)

Function	Manager	Pharmaceutical Entrepreneur	Both
Allocating resources including finances, personnel and time in line with legal requisites	9	1	2
Creating and developing a business plan, securing funding, and establishing a business, whilst keeping the patient as a central component of the business	2	7	3
Developing strategies and plans for the company in such a way that they are in accordance with pharmaceutical regulatory sciences	9	0	3
Growing a business by finding new customers, expanding into new markets, and improving operations, taking into consideration the ethical codes to be observed in a pharmaceutical scenario	0	10	2
Identifying opportunities to meet patients' unmet needs	0	9	3
Monitoring and adjusting performance ensuring that the goals of quality, safety, efficacy and accessibility to medicines are met	8	0	4
Motivating and leading personnel to achieve common objectives, namely that the patient comes first	1	1	10
Taking risks by investing time and money in novel opportunities	0	12	0

A pharmacist may carry out the roles of a manager and pharmaceutical entrepreneur simultaneously. Alternatively, the roles of a manager may be delegated to an individual other than the pharmaceutical entrepreneur. There were varying opinions regarding whether these roles should be conducted by the same individual or by separate individuals. Three participants stated that one should conduct the roles of a manager and pharmaceutical entrepreneur simultaneously, to have access to sources of information through daily contact with stakeholders and team members. Such interactions would add to entrepreneurial knowledge and assist in the carrying out of PhE. Nine participants reported that although the roles may be carried out by one individual, this should not be the case as a pharmaceutical entrepreneur should use one's time to focus on the identification and pursuit of PhE initiatives, while the manager focuses on the day-to-day running of the operation, ensuring operations are running smoothly and in an organised manner. Should the pharmaceutical entrepreneur be conducting managerial duties, this would limit the growth of the pharmaceutical enterprise. Participants shared that although the roles may be kept separate, the manager and pharmaceutical entrepreneur must work hand in hand. It was discussed that towards the beginning of a pharmaceutical entrepreneur's career, one should carry out both roles simultaneously to gain hands-on and logistical experience which would give a better understanding of the feasibility of initiatives and enable the making of informed decisions following experience gained. As the enterprise grows, one can start to delegate work as activities related to PhE take up most of the pharmaceutical entrepreneur's time.

Entrepreneurship attributes required for a pharmacist to be both a manager and a pharmaceutical entrepreneur are a clear-headed vision, the gathering of data and information, leadership, communication, collaboration, analytical skills, dedication, determination, and perseverance.

3.2.9 Pharmaceutical Entrepreneurship Attributes used to Solve Issues related to Pharmaceutical Scenarios

Participants were presented with the COVID-19 pandemic, including COVID-19 testing, and medicine shortages, as examples of issues within pharmaceutical scenarios, and asked to describe personal experience regarding the PhE attributes used to solve these issues.

a. COVID-19

PhE attributes used to solve issues related to the COVID-19 pandemic, and COVID-19 testing, together with the number of participants with who the attributes were discussed, are outlined in Table 3.4.

Table 3.4 Pharmaceutical Entrepreneurship Attributes used to Solve Issues related to the COVID-19 Pandemic and COVID-19 Testing (N=12)

Pharmaceutical Entrepreneurship Attributes	Frequency
Adaptability and flexibility	7
Agility and speed	5
Communication and collaboration	4
Perseverance	4
Leadership	4
Digitalisation	3
Innovation	3
Problem-solving	3
Resilience	2
Empathy	1

Pharmaceutical entrepreneurs described ways in which they applied adaptability, flexibility and leadership during the COVID-19 pandemic through the use of mitigation measures, including the shifting of operations and strategies to address developing needs and market conditions. Mitigation measures used included the adjusting of work schedules, separating the workforce into segregated groups, and adapting layouts in community pharmacies to protect patients and staff members, while ensuring that service to patients was maintained to the best of one's ability. Pharmaceutical entrepreneurs adopted new technologies and used digitalisation to manage operations and explore alternative revenue streams. Online platforms were used to communicate with stakeholders, for example medical representatives kept in contact with medical practitioners through virtual meetings.

Agility and speed were implemented as pharmaceutical entrepreneurs made swift decisions and took expeditious actions in response to the evolving situation during the COVID-19 pandemic through an adjustment of strategies, the identification of alternative supply chains, and maintenance of operations to promptly meet changing customer preferences, at a time when market dynamics were changing daily. Innovation was employed in the creation of innovative solutions to address emerging needs and demands, and in the identification of niches. Examples of innovative practices implemented include the preparation of hand sanitizer at a time of worldwide shortage, and the establishment of COVID-19 testing clinics for the provision of a holistic COVID-19 related service.

Pharmaceutical entrepreneurs were resilient and applied problem-solving skills through critical thinking, in an environment where significant disruptions and setbacks were experienced. Pharmaceutical entrepreneurs used communication and collaboration to source supplies of medicines and medical devices and identify alternative suppliers to ensure sustainability of supply to be able to address patient needs. One strategy in which this was applied was by increasing stockholding of medical products, especially those which were envisaged to be considered a priority, for example medicinal products used for respiratory conditions. Empathy was applied through the development of special concessions for members of staff who were vulnerable or shared a household with vulnerable individuals. Empathy was also applied with patients at a time of fear and uncertainty.

Results show that PhE attributes used to solve issues related to the COVID-19 pandemic, and COVID-19 testing, are adaptability, flexibility, agility, speed, communication, collaboration, perseverance, leadership, digitalisation, innovation, problem-solving, resilience and empathy.

b. Medicine shortages

PhE attributes used to solve issues related to medicine shortages, together with the number of participants with who the attributes were discussed, are outlined in Table 3.5.

Table 3.5 Pharmaceutical Entrepreneurship Attributes used to Solve Issues related to Medicine Shortages (N=12)

Pharmaceutical Entrepreneurship Attributes	Frequency
Proactiveness	8
Communication and collaboration	6
Agility and speed	5
Adaptability and flexibility	4
Perseverance	4
Innovation and creativity	3
Leadership	3
Problem-solving skills	2

Participants stated that similar to ways in which the COVID-19 pandemic was addressed, medicine shortages are tackled through the application of PhE attributes as pharmaceutical entrepreneurs strive to increase accessibility to medicines for patients. Medicine shortages have arisen due to occurrences including the COVID-19 pandemic, Brexit and the war in Ukraine. Additionally, interview participants have assisted in the restoration of the supply of vaccines, antibiotics and medicinal products impacted by nitrosamines and scarcity of APIs.

Agility, communication, collaboration and proactiveness were identified as PhE attributes of significant importance when addressing medicine shortages. Communication with stakeholders allows for the gathering of information related to consumptions of medicinal products, and the identification of trends to be able to predict shortages prior to their occurrence. Pharmaceutical entrepreneurs are agile and quick to step in to find supplies of medicines following the identification of a shortage through communication and collaboration. Pharmaceutical entrepreneurs described how they acted proactively in anticipation for Brexit, as plans for the sourcing of medicinal products which were typically sourced from the United Kingdom were made ahead of time. Additionally, several pharmaceutical manufacturers were proactive as they moved their operations to Member States, other than the United Kingdom ahead of Brexit, allowing for supplies to be maintained within the EU.

Participants described how Malta constitutes a microenvironment which results in the arising of several logistical issues, including difficulties in sourcing medicinal products due to MOQs set by manufacturers, as described in Section 3.2.4. Therefore, pharmaceutical entrepreneurs must be creative to find solutions in this regard. Medicine shortages are tackled through aspects such as the identification of alternative sources of supply including parallel trade, the use of registration routes for medicinal products, including 126A applications, Article 20, named patient basis requests and batch specific requests, and the over labelling of product packs whose packaging bears a language other than English or Maltese.

Participants discussed the concept that one should not only consider that a medicinal product is present in the market, but that it is also accessible to patients through fair pricing, as high costs may be prohibitive for patients. The importance of transparency at a time of medicine shortages was stressed by interview participants. Transparency allows pharmaceutical entrepreneurs to use available information to assess potential risks and make informed decisions, ultimately benefiting patients due to improved accessibility to medicines at fair prices.

Results show that PhE attributes used to solve issues related to medicine shortages are proactiveness, communication, collaboration, agility, speed, adaptability, flexibility, perseverance, innovation, creativity, leadership and problem solving skills.

3.2.10 Role of Education and Training in Evolving Pharmaceutical Entrepreneurship

Participants were advised that a training programme for the advancement of PhE will be developed in this study. Participants were presented with 14 training aspects which could potentially be included in the training programme and asked to rate their level of agreement regarding whether the training aspects should be included in the training programme on a Likert-scale, where five represented the highest level of agreement, and one represented the lowest level of agreement. The training aspects presented to participants were accounting, communication skills, conflict resolution, financial management, human resources, leadership, innovation, market research, marketing, negotiation techniques, project management, public relations, quality improvement and risk management. Additionally, participants were asked to make further recommendations for training aspects to be included within the training programme. Responses are presented in Figure 3.5.

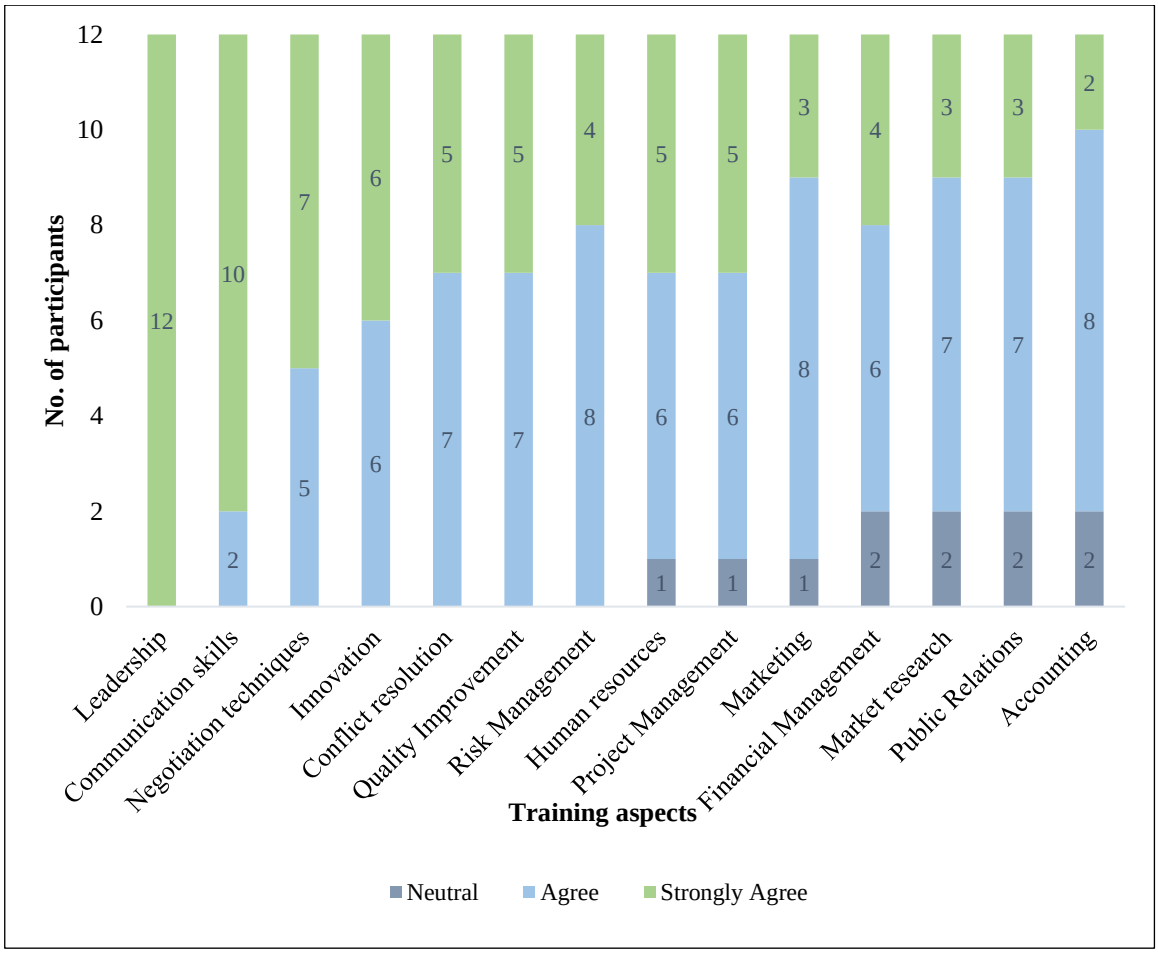


Figure 3.5 Training Aspects for a Training Programme for Pharmaceutical Entrepreneurship (N=12)

Participants unanimously strongly agreed that leadership should be included in a training programme for PhE. All participants agreed or strongly agreed that communication skills, conflict resolution, innovation, negotiation techniques, quality improvement and risk management should be included in a training programme for PhE. Eleven participants agreed or strongly agreed that human resources, marketing, and project management should be included in a training programme for PhE, whilst one participant neither agreed nor disagreed. Ten participants agreed or strongly agreed that accounting, financial management, market research, and public relations should be included in a training programme for PhE, whilst two participants neither agreed nor disagreed that the aforementioned training aspects should be included.

Results show that all 14 training aspects presented should be included in a training programme for PhE. It was suggested that accounting should be included in the module concerning financial management. Participants suggested that team management and data analysis be added as training aspects within the training programme for PhE. Additionally, participants shared that although didactic training is important, in addition to the didactic component, individuals who show an interest in PhE should be offered an opportunity for practical experience, to gain hands-on experience.

3.2.11 An Entrepreneurship Appetite in Pharmaceutical Processes

Participants were asked regarding the impact of the introduction of an entrepreneurial appetite in pharmaceutical processes, particularly how the introduction of an entrepreneurship appetite could improve, or harm, these processes.

a. Potential benefits of introducing an entrepreneurship appetite in pharmaceutical processes

Participants were asked to rate their level agreement with the potential for the introduction of an entrepreneurship appetite within pharmaceutical processes to improve aspects related to the pharmaceutical scenario on a Likert-scale, where five represented the highest level of agreement, and one represented the lowest level of agreement. Aspects participants were presented with are accountability, collaboration, financial rigorousness, efficiency, innovation, market responsiveness, patient outcomes and sustainability. Results are presented in Figure 3.6.

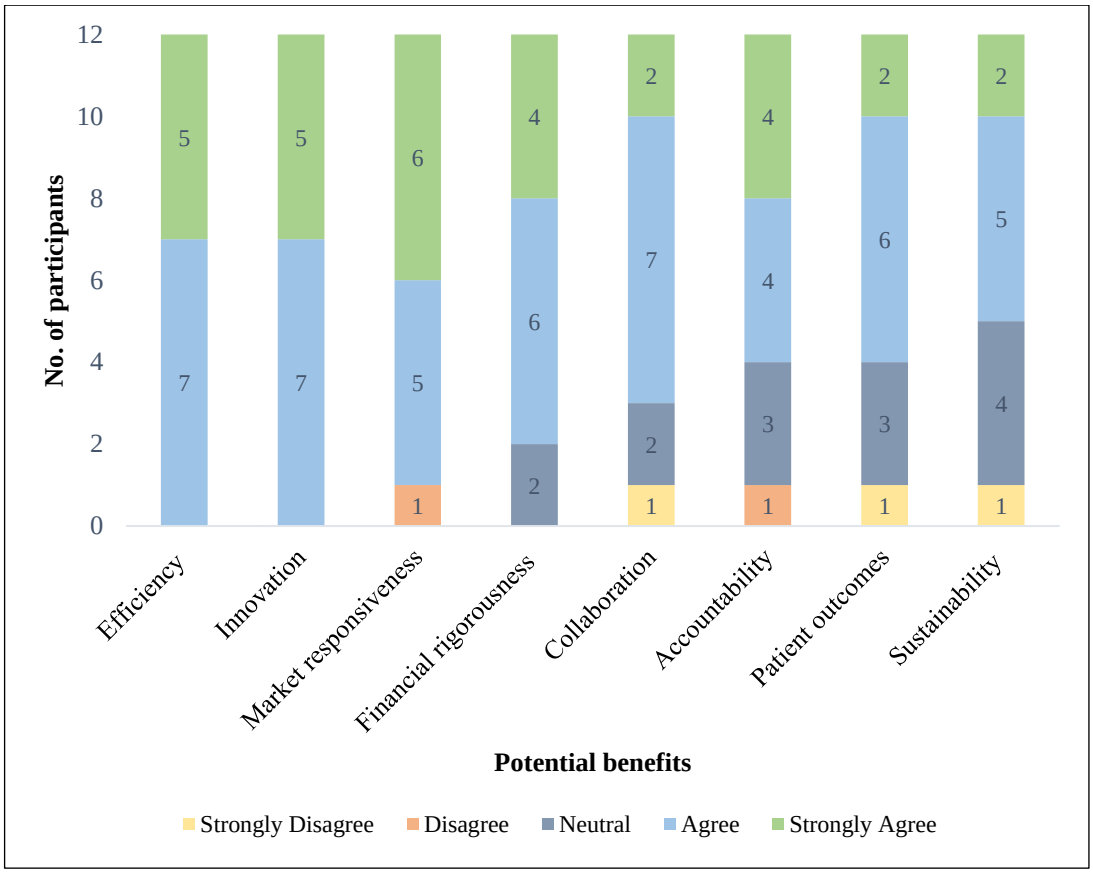


Figure 3.6 Potential Benefits related to the Introduction of an Entrepreneurship Appetite to Pharmaceutical Processes (N=12)

All participants agreed or strongly agreed that the introduction of an entrepreneurship appetite to pharmaceutical processes could improve efficiency and innovation through the streamlining of processes, reduction in costs and the creation of new ideas, services and products. Seven or more participants agreed or strongly agreed that accountability, collaboration, financial rigorousness, market responsiveness, patient outcomes and sustainability could be improved through the introduction of an entrepreneurship appetite in pharmaceutical processes.

With regards to financial rigorousness, two participants neither agreed nor disagreed that financial rigorousness could be improved due to risks associated with the introduction of an entrepreneurship appetite. Participants who neither agreed nor disagreed (two) and strongly disagreed (one) that collaboration could be improved with an entrepreneurship appetite commented that on the contrary, collaboration could be harmed, as pharmaceutical entrepreneurs may choose not to collaborate with others so as to gain competitive advantage. Three participants neither agreed nor disagreed, and one participant disagreed that accountability could be improved through the introduction of an entrepreneurship appetite, as they believed that accountability comes from within and is related to the pharmaceutical entrepreneur's integrity. Three participants neither agreed nor disagreed, and one participant strongly disagreed that patient outcomes could be improved through the introduction of an entrepreneurship appetite as at times, one could forget the patient and lose sight of the goal to keep the patient as the priority when conducting PhE endeavours. One participant shared that within their enterprise, they occasionally invite patients to share their experiences to remind themselves of who they are striving to serve. With regards to sustainability, four participants neither agreed nor disagreed, and one participant strongly disagreed that PhE could improve sustainability as although sustainability is important for any pharmaceutical enterprise, PhE initiatives are not always successful and may affect the sustainability of the enterprise.

Results show that accountability, collaboration, financial rigorousness, efficiency, innovation, market responsiveness, patient outcomes and sustainability could be improved through the introduction of an entrepreneurship appetite within pharmaceutical processes.

b. Potential risks associated with the introduction of an entrepreneurship appetite in pharmaceutical processes

Participants were asked to rate their level agreement with the potential for the introduction of an entrepreneurship appetite within pharmaceutical processes to harm aspects related to the pharmaceutical scenario on a Likert-scale, where five represented the highest level of agreement, and one represented the lowest level of agreement. Aspects participants were presented with are altruistic performance, collegiality, integrity, patient safety, quality control, regulatory compliance, scientific approach and social responsibility. Responses are presented in Figure 3.7.

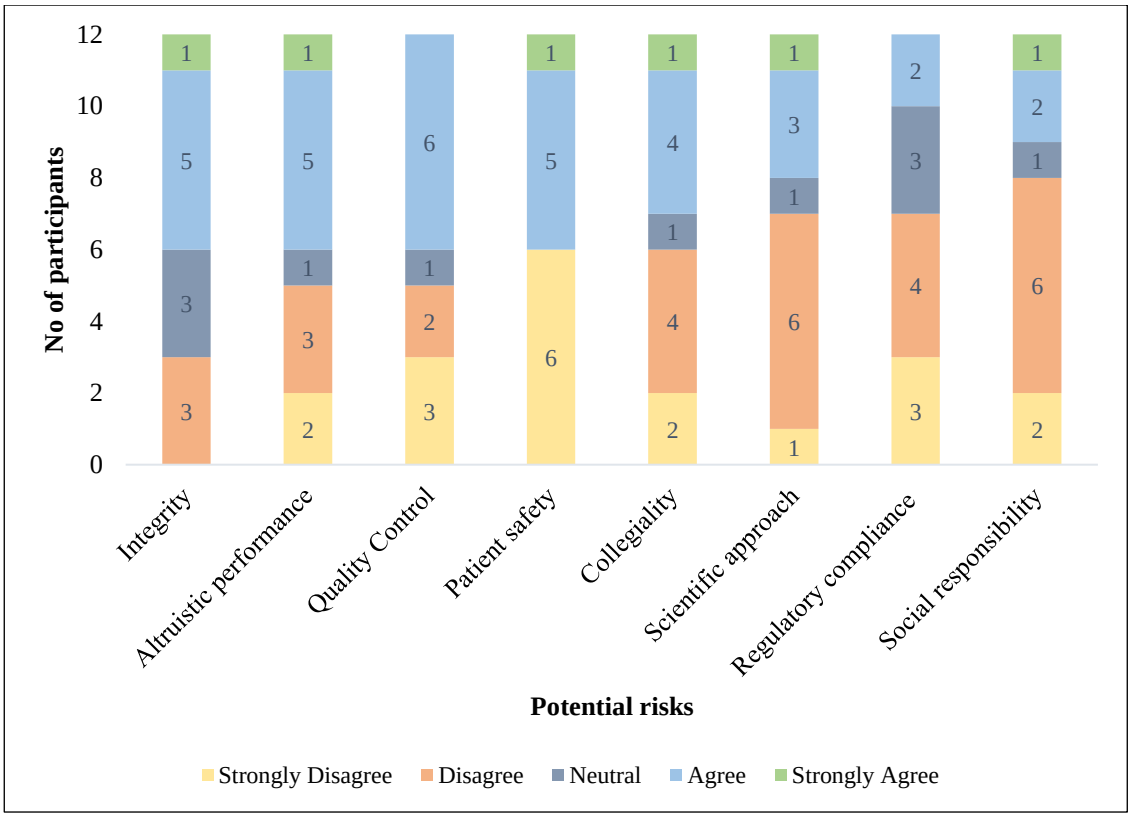


Figure 3.7 Potential Risks related to the Introduction an Entrepreneurship Appetite to Pharmaceutical Processes (N=12)

Participants' ratings for level of agreement with the possibility of the occurrence of potential harm on aspects presented, following the introduction of an entrepreneurship appetite to pharmaceutical processes, varied significantly (Figure 3.7). A common discussion shared between each participant and the researcher when discussing these potential risks was that although none of the aspects discussed should be harmed through the introduction of an entrepreneurship appetite to pharmaceutical processes, the participants acknowledged that harm could be instilled in each of the eight aspects discussed. Participants stated that as pharmacists, one must keep in mind that the patient must be kept as a central component in the making of decisions, and patient safety should be protected at all times. Notwithstanding, when decisions are related to significant financial risk, pharmaceutical entrepreneurs may make decisions which may potentially harm the eight aspects described. This is significantly related to the integrity of the pharmaceutical entrepreneur.

Six participants agreed or strongly agreed that integrity may be suspect in PhE as pharmaceutical entrepreneurs may make decisions which may harm integrity if they find themselves in a position where they have a lot to lose, especially in terms of financial risk. Three participants neither agreed nor disagreed, and three participants disagreed that integrity would be harmed through PhE, as pharmacists are trained to act in an ethical manner and base their evaluations on ethical criteria and implications, namely, to serve patient interests and protect patient safety.

With regards to altruistic performance, although this should be increased through empathy and attention to others, there may be an element of harm to altruistic performance due to competition or the avoidance of waste, for example, patients may be

offered one medicinal product over another due to a short expiry date. With regards to quality control, seven participants agreed that this could be harmed through PhE as the success of the business may be put first when there is a risk of significant financial loss. One example of this is related to deciding whether to discard stock should medicinal products be exposed to temperature fluctuations, to the extent that they fall outside the limits of specification. Although the majority of pharmaceutical entrepreneurs would report such fluctuations and proceed appropriately, there may be entrepreneurs who lack integrity who do not act appropriately.

With regards to patient safety, six participants agreed or strongly agreed that although every effort should be made to protect patient safety, it is possible that this could be put at risk. Should a product offer minimal risk-benefit ratio, pharmaceutical entrepreneurs may be tempted to attempt to sell the product by magnifying benefits which constitutes an issue of integrity. Six participants strongly disagreed that patient safety could be harmed through the introduction of an entrepreneurship appetite in pharmaceutical processes, as pharmacists are trained to do no harm to patients. A common theme through the discussions with participants was that a price should not be put on a patient's life.

With regards to collegiality, although competition is considered healthy by several participants, competition may cause pharmaceutical entrepreneurs to lack collegiality with stakeholders who they may be competing with. When discussing regulatory compliance, seven participants disagreed or strongly disagreed, and three participants neither agreed nor disagreed, that regulatory compliance may have detrimental effects on the enterprise, therefore one would not risk a lack of compliance.

Results show that that altruistic performance, collegiality, integrity, patient safety, quality control, regulatory compliance, scientific approach, and social responsibility should not be harmed through the introduction of an entrepreneurship appetite to pharmaceutical processes as within PhE, patients must be kept as a central component in decision-making processes. However, participants stated that these aspects may be harmed should the pharmaceutical entrepreneur lack integrity.

3.2.12 Risk in Pharmaceutical Entrepreneurship

Participants were asked to identify the level of risk (low, medium or high) they would consider taking when embarking on a new pharmaceutical entrepreneurial venture. Results are presented in Figure 3.8.

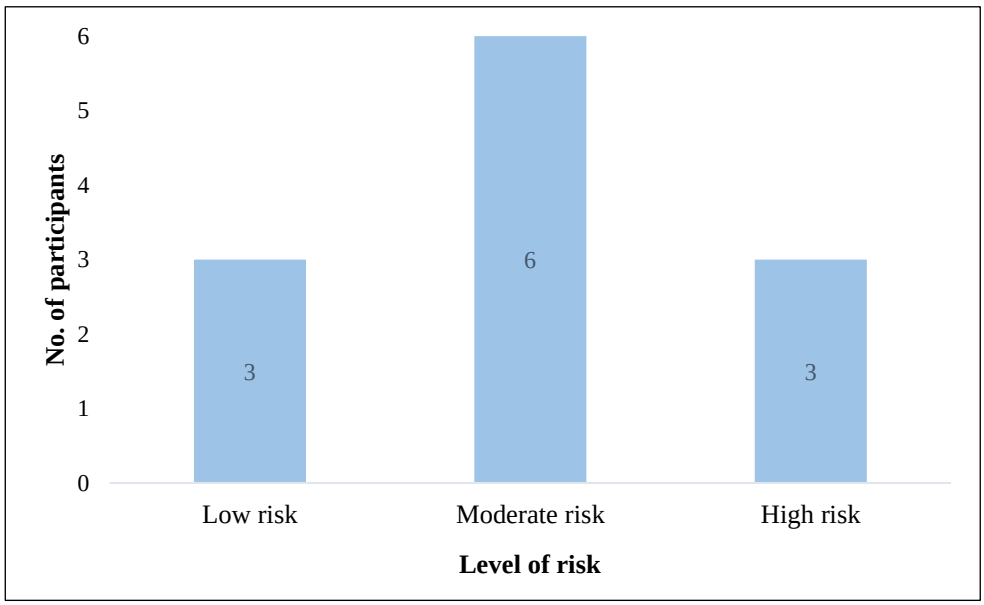


Figure 3.8 Level of Risk Pharmaceutical Entrepreneurs would consider taking when Embarking on a New Pharmaceutical Entrepreneurial Venture (N=12)

Three participants reported that they would consider, or have experience, undertaking pharmaceutical entrepreneurial ventures which have a high financial risk. Participants stated that when considering whether to participate in a pharmaceutical entrepreneurial initiative associated with high risk, they would need to feel confident in the success of the venture by performing significant research prior to embarking on the venture. These participants shared that they have an appetite for risk and would consider taking a high risk if the reward is high enough, considering all risk factors and mitigations measures which could be applied to reduce that risk. One scenario offered as an example of a high-risk initiative was an entrepreneurial initiative associated with a niche market for an orphan drug. A significant investment must be put into undertaking such an initiative, however this may not reap large financial rewards due to the size of the market, and because access to the particular orphan drug may not be a priority within the public sector.

Six participants stated that they would consider pharmaceutical entrepreneurial initiatives associated with moderate risk, especially when the risk is associated with the financial aspect of the entrepreneurial initiative. In such cases, participants shared that they would need to feel confident on aspects such as the quality of the product and the integrity of the manufacturer, therefore they consider that the risk is a calculated risk since decisions are based on market research and feasibility studies.

Three participants shared that they undertake pharmaceutical entrepreneurial initiatives associated with low risk as they run a stable, established operation and prefer not to jeopardize the stability of the enterprise.

Results show that pharmaceutical entrepreneurs take mild to moderate risk when embarking on pharmaceutical entrepreneurial ventures. A central theme which arose from the discussions with participants was that pharmaceuticals are a necessity, not a luxury, and although they would take varying degrees of risk when considering financial and logistical aspects, participants would only consider embarking on pharmaceutical entrepreneurial ventures if they present low or zero risk with respect to patient safety. Another central theme among discussions was that participants were more likely to consider a higher level of risk at an early stage in their career. Participants shared that at the current stage in their careers, they take a more conservative approach. In addition, it was discussed that an affinity for risk is related to one's personality and depends on aspects such as character, previous experience and previous successes.

3.3 Training Programme for Pharmaceutical Entrepreneurship

The second phase of the study pertains to the development and validation of a training programme intended for individuals working within the pharmaceutical scenario having an interest in PhE. The development of the training programme was based on a literature search concerning education and training in the area of PhE, and responses to structured interviews with local pharmaceutical entrepreneurs.

3.3.1 Interviews with Pharmaceutical Entrepreneurs

As described in Section 3.2, interviews were held with 12 local pharmaceutical entrepreneurs. Participants were presented with 14 training aspects, identified from literature, and asked to rate their level of agreement regarding whether these aspects should be included in a training programme for PhE. Results obtained during the interviews are presented in Section 3.2.10.

Following suggestions made by interview participants, accounting was included in the module concerning financial management. In addition to the training aspects presented by the researcher, participants suggested that team management should be included in the training programme for PhE. During the development of the training programme, team management was incorporated in the module concerning leadership. Data analysis was also suggested as a possible additional training aspect by interview participants and this was incorporated in the module concerning market research.

Interview participants stated that although the didactic component of a training programme for PhE is essential, it was recommended that training for PhE also include a practical aspect, as this would offer prospective candidates hands-on experience in the field. This study delves into the development of the didactic component of training for PhE. It is recommended to investigate the practical aspect of training in future research.

3.3.2 Development of the Training Programme for Pharmaceutical Entrepreneurship

A training programme for the advancement of PhE was developed by the researcher. The training programme aims to offer the necessary knowledge and skills to identify, create and pursue new opportunities and implement new ideas in a successful and sustainable manner, whilst nurturing an entrepreneurship spirit within pharmaceutical processes,[11] and creates a balance between financial sustainability and patient benefits. Thirteen training aspects were included within the training programme for pharmaceutical entrepreneurs namely: Communication Skills, Conflict Resolution, Financial Management, Human Resources, Innovation, Leadership, Market Research, Marketing, Negotiation Techniques, Project Management, Public Relations, Quality Improvement and Risk Management. As described in Section 2.5.1, the training programme consists of a description of the contents of the module, aims and learning outcomes for each training aspect, with learning outcomes being further subdivided into knowledge and understanding, and skills.

[11] Giudice L, Attard Pizzuto M, Serracino-Inglott A. Entrepreneurship in Pharmaceutical Processes. Poster session presented at the 80th International Pharmaceutical Federation World Congress of Pharmacy and Pharmaceutical Sciences; Seville 2022.

3.3.3 Validation of the Training Programme for Pharmaceutical Entrepreneurship

Each of the seven individuals invited to participate in the Delphi study for the validation of the training programme accepted to participate. Five participants were female, and two were male.

The panel of experts provided positive feedback regarding the training programme. Recommended changes included omissions, re-wording and re-structuring. Five aims and learning outcomes (3%) failed to reach consensus in Round I of the Delphi study: one learning outcome from the module regarding Communication Skills, one aim from the module regarding Financial Management, one learning outcome from the module regarding Human Resources, one learning outcome from the module regarding Leadership and one aim from the module regarding Marketing. The aim which failed to reach consensus within the module concerning Marketing was maintained within the training programme as it was deemed important by the researcher, due to the special considerations and regulatory environment surrounding marketing in the pharmaceutical scenario.

The modified aims and learning outcomes all reached consensus following Round II of the Delphi study. Therefore, the training programme for the advancement of PhE was considered to be validated. The validated training programme consists of 13 modules, with a total of 50 aims and 102 learning outcomes. The training programme is presented in Appendix 5.

3.4 Pharmaceutical Entrepreneurship in Regulatory Sciences

This section reports on the third phase of the study which involved the setting up of a focus group to carry out a strategic investigation of pharmaceutical entrepreneurial activities carried out at the Malta Medicines Authority (MMA), as a setting for PhE in regulatory sciences (Section 3.4.1), and an observational study within the Pharmaceutical Products Entrepreneurship Unit (Section 3.4.2) which led to the development of an innovative framework for PhE in regulatory sciences (Section 3.4.3).

3.4.1 Analysis of Entrepreneurial Activities at the Malta Medicines Authority

A focus group consisting of representatives from the MMA was set up to analyse pharmaceutical entrepreneurial activities at the MMA. Questions used in the focus group were validated by an expert panel who assessed face and content validity. All seven participants invited to form part of a panel in the Delphi-based exercise for validation accepted to participate, six females and one male. The major changes to the interview questions following the validation exercise were related to additions of aspects for which focus group participants would rate their level of agreement. Following the presentation of the modifications made in Round I of the Delphi study to the expert panel, consensus was reached in Round II. The focus group questions prepared for use with representatives from the MMA were considered to be validated.

The focus group consisted of eight senior members of the MMA, including representatives from the Office of the Chief Executive Officer (CEO) and each of the six Directorates within the Authority, namely the Licensing Directorate, the Post-Licensing Directorate, the Inspectorate and Enforcement Directorate, the Advanced Scientific Initiatives Directorate, the Regulatory Operations, Medicines Intelligence and Access Directorate and the Medical Devices and Pharmaceutical Collaboration Directorate.[12] All the participants invited to partake in the focus group accepted the invitation. The duration of the focus group was 113 minutes.

The focus group investigated attributes which constitute a PhE initiative and their applicability to different pharmaceutical scenarios (Section 3.4.1.2), a retrospective analysis of initiatives implemented within the MMA having an aspect of PhE, together with the strengths, weaknesses, opportunities, threats, and risks, of the aforementioned initiatives (Section 3.4.1.3), risks related to PhE initiatives in regulatory sciences (Section 3.4.1.4), PhE characteristics, traits and skills used in the implementation of the identified PhE initiatives within the MMA (Section 3.4.1.5), and actions used to ensure accountability when carrying out PhE initiatives (Section 3.4.1.6).

[12] Malta Medicines Authority. Directorates and Units [Internet]. Malta: Malta Medicines Authority; 2023 [cited 2023 May 29]. Available from URL: https://medicinesauthority.gov.mt/directoratesunits?l=1

3.4.1.1 Attributes related to a Pharmaceutical Entrepreneurship Initiative

Focus group participants were presented with an explanation for the term PhE initiative:

> A pharmaceutical entrepreneurship initiative consists of a proactive and innovative effort to create a new venture, or to improve an existing one, to meet patients' needs in a robust and efficient manner. It involves identifying a problem or opportunity, and taking action to develop a product, service, or business model to address the identified need. Successful entrepreneurial initiatives typically involve careful planning, research, and execution, as well as the ability to adapt and pivot as necessary to changing demands. The goal is to create added value for stakeholders, including patients.
>
> (Mattingly et al, 2019a; Murray Gillin and Hazelton, 2021)

Participants were asked to rate their level of agreement regarding attributes required for a PhE initiative on a Likert-scale, where five represented the highest level of agreement, and one represented the lowest level of agreement. Attributes presented to the focus group were calculated risk taking, creative thinking, evidence-based decision making, flexibility and adaptability, innovation, leadership, meeting stakeholder needs, robustness and willingness to challenge conventional thinking. Results are presented in Figure 3.9. Participants were asked to provide additional attributes for PhE initiatives.

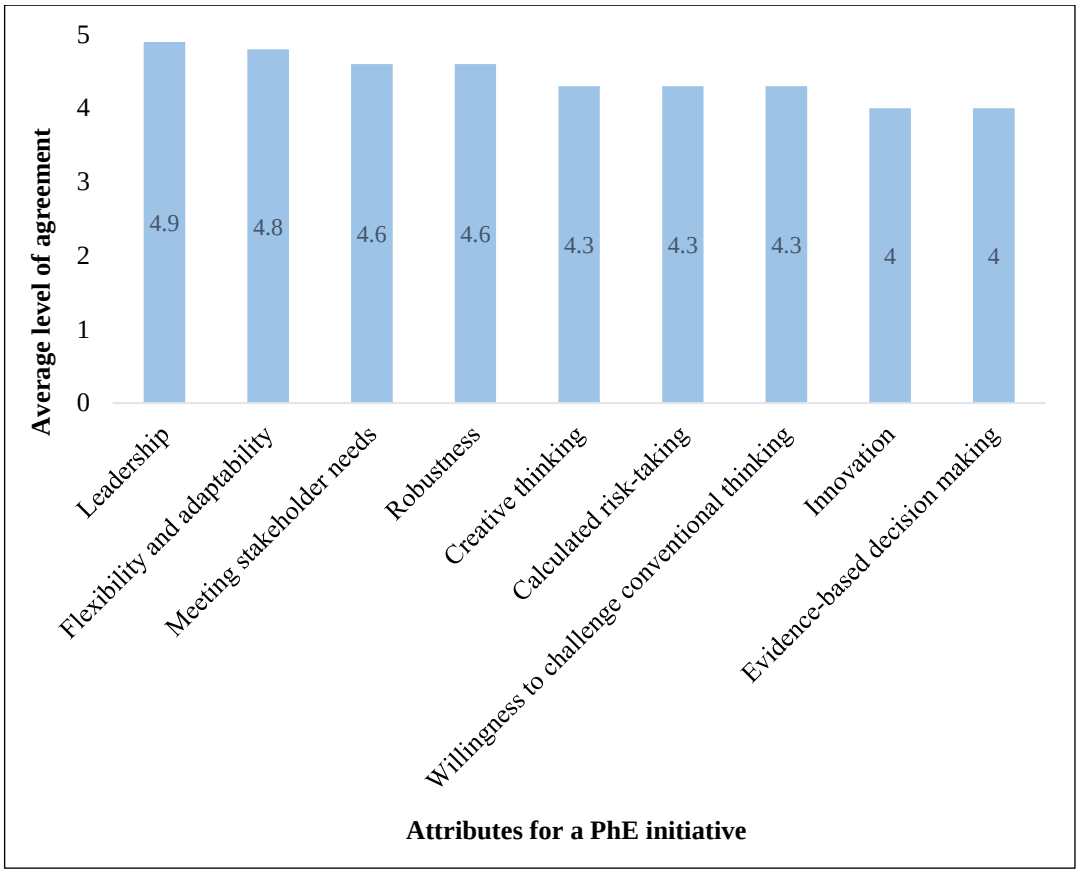


Figure 3.9 Attributes Required for a Pharmaceutical Entrepreneurship Initiative (N=8)

Participants strongly agreed that creative thinking is an attribute related to PhE initiatives, however within the regulatory scenario, parameters established by law and mandates which exist within an agency, may limit PhE. Participants agreed that the taking of calculated risk is attributed to PhE initiatives and includes an assessment of the impact of potential risks on aspects including the reputation and operations of an establishment. Participants shared that experience plays a significant role in the taking of risks. Participants agreed that evidence-based decision making is to be attributed to PhE initiatives. Participants shared that in cases where evidence is available, evidence is crucial when making decisions, however the presence of evidence is not a necessity and should not be considered a limiting factor. Should there not be evidence related to an

entrepreneurial idea, a PhE initiative may still be initiated, with evidence being accumulated as time progresses. In such cases, one can make informed decisions through information gathered by means of research, whilst keeping ethical values related to the pharmaceutical scenario in mind. Participants strongly agree that a PhE initiative should be robust and have a strong infrastructure through aspects including Rules of Procedure and Terms of Reference, which govern the framework for the PhE initiative.

Participants believe that in addition to the attributes provided, collaboration, practicality and pragmatism are also required for PhE initiatives to be successful. A lack of collaboration, and the creation of silos, are considered deterrents to PhE. Collaboration with areas such as academia is essential within PhE as this allows for the sharing of ideas and expertise, the pooling of resources, the avoidance of duplication of work and the creation of added value for the development of innovative solutions for the provision of holistic patient-centred care.

Participants strongly agreed that leadership, flexibility and adaptability, meeting stakeholder needs and robustness are attributes required for a PhE initiative. Participants agreed that creative thinking, calculated risk-taking, evidence-based or informed decision making, innovation and willingness to challenge conventional thinking are required for PhE initiatives. Collaboration, practicality and pragmatism are considered additional attributes required for PhE initiatives.

Focus group participants were asked whether the PhE attributes discussed could vary across different pharmaceutical scenarios. Results related to the pharmaceutical scenarios presented, together with the attributes which could vary depending on the pharmaceutical scenarios, are presented in Table 3.6.

Table 3.6 Pharmaceutical Entrepreneurship Attributes affecting different Pharmaceutical Scenarios (N=8)

Pharmaceutical Scenario	Attributes related to Pharmaceutical Entrepreneurship Initiatives
National Competent Authorities (NCAs)	Creative thinking, Calculated risk-taking, Evidence-based decision making, Flexibility and adaptability, Innovation, Leadership, Meeting stakeholder needs, Robustness, Willingness to challenge conventional thinking
Manufacturing Industry	Creative thinking, Calculated risk-taking, Evidence-based decision making, Flexibility and adaptability, Innovation, Leadership, Meeting stakeholder needs, Robustness
Batch release sites	Calculated risk-taking, Evidence-based decision making, Flexibility and adaptability, Leadership, Robustness
Importation and Wholesale Dealing	Calculated risk-taking, Evidence-based decision making, Flexibility and adaptability, Leadership, Meeting stakeholder needs, Robustness
Hospital Pharmacy	Creative thinking, Calculated risk-taking, Evidence-based decision making, Flexibility and adaptability, Innovation, Leadership, Meeting stakeholder needs, Robustness, Willingness to challenge conventional thinking
Community Pharmacy	Creative thinking, Calculated risk-taking, Evidence-based decision making, Flexibility and adaptability, Innovation, Leadership, Meeting stakeholder needs, Robustness, Willingness to challenge conventional thinking

3.4.1.2 Retrospective Analysis of Pharmaceutical Entrepreneurship Initiatives

A retrospective analysis of areas and initiatives implemented within the MMA which are entrepreneurial in nature, led to the identification of the below initiatives:

- Assessments of centralised procedures.
- Assessments related to procedures where Malta acts as a Reference Member State (RMS).
- Auditing of community pharmacies through self-assessment.
- Horizon scanning to extend the regulatory portfolio, for example the introduction of competence for medical devices regulated through a patient-centred approach.
- ISO 9001 certification and prospects to on-board ISO 27001.
- Optimising stakeholder management and communication in the planning, development and implementation of new regulatory initiatives and legal proposals, including collaboration with stakeholders not necessarily directly related to the pharmaceutical industry with innovative aspects of assisting the industry, such as a project pertaining to an Official Medicines Control Laboratory, and forensics.
- The conducting of third country inspections.
- The establishment of an Academy for Patient Centred Excellence and Innovation in Regulatory Sciences.
- The establishment of the Medicines Intelligence and Access Unit, including activities related to medicines intelligence.
- The establishment of the Pharmaceutical Products Entrepreneurship Unit.
- The introduction of competence in regulating cannabis for medicinal and research purposes.
- The provision of a joint direct healthcare professional communication service.
- The provision of scientific advice.

- A vision for cooperation and networking though a collaborative framework with national and international bodies.

The strengths, weaknesses, opportunities, threats and risks discussed in the focus group are presented in Table 3.7a and b.

Table 3.7a SWOT Analysis related to Pharmaceutical Entrepreneurship Initiatives at Malta Medicines Authority (N=8)

Strengths	Weaknesses
• Esteemed reputation and prestigious image through services and training offered • Communication and collaboration • Patient-centred approach • Integrity • Increasing expertise through training opportunities • Meeting patient needs through innovative solutions and maximising collaborations in various areas by sharing expertise • Sustainability • Offering services which sustain growth of the local pharmaceutical industry • Predictable, reliable and accountable operations • Increasing accessibility to medicinal products – social responsibility • Presence of an intelligence system allowing one to be proactive rather than reactive • Increasing visibility for the country	• Inadequate capacity due to a lack of HR • Infrastructural resources, namely IT infrastructure • Limited expertise in areas such as advanced therapies, leading to a lack of competitive edge in such areas • Reliance on external experts for areas in which there is a paucity of competence • Need to engage or have available a very wide array of experts to be able to deliver training through the Academy on a multitude of subjects • Limited opportunity to participate in clinical trials due to the limited size of the country • A restricted amount of third country inspections can be carried out due to the limited number of trained inspectors, and the need for inspector availability for activities related to license renewals

Table 3.7b SWOT Analysis related to Pharmaceutical Entrepreneurship Initiatives at Malta Medicines Authority (N=8)

Opportunities	Threats and Risks
• Growth in scientific areas allowing for additional revenue, more competence and learnings, for example gaining competence in the area of advanced therapies allowing for the opportunity of carrying out third country inspections of facilities manufacturing such products • Offering training in additional areas through the accredited Academy for Patient Centred Excellence and Innovation in Regulatory Sciences, enabling the acquisition of additional revenue • People engagement and increasing job satisfaction and awareness of what a regulatory authority can achieve to maintain and increase staff compliment • Extending services in the interest of patient safety and accessibility, for example the identification of new sources of supply of medication through the in-house intelligence system, following which sources of supplies can be further explored by local suppliers	• Loss of highly specialised and trained staff leading to an inability to meet obligations, for example an inability to meet deadlines for EU procedures • Possibility of giving an incorrect scientific output following an assessment which would have been done inaccurately • Activities not being sufficiently sustainable possibly causing financial liability • Changes in legislation leading to potential changes in operations and new regulatory requirements • Potential infrastructural risk affecting IT hardware and software, affecting staff's ability to carry out duties • Competition related to bidding for EU assessment procedures • Reputational risk if the outcome of activities is not correct or desirable • Recommendations for the provision of Article 20 approvals for the use of unlicensed medicinal products with limited information related to quality, safety and efficacy

3.4.1.3 Risks related to Pharmaceutical Entrepreneurship Initiatives in Regulatory Sciences

This section reports on results associated with a risk assessment tool developed to investigate risks associated with PhE initiatives, risk mitigation strategies, and potential risks related to the introduction of pharmaceutical entrepreneurial functions within regulatory sciences.

a. Risk assessment tool

A risk assessment tool for the assessment of risks associated with PhE initiatives was developed for this study. The assessment tool consists of a risk matrix assessing the probability of the occurrence (PO) of an identified risk within a PhE initiative and the severity of impact (SI) should the identified risk occur, as presented in Section 2.6.1. The identification of risk critical numbers to classify risks within low, medium and high-risk categories assists in the making of decisions when carrying out PhE initiatives.

Focus group participants were asked whether they were in agreement with the developed risk assessment tool and risk classification outlined. Participants agreed with the risk framework, as it is akin to those used by official bodies, and institutions, in areas other than PhE. The assessment tool was pilot tested by assessing pertinent risks encountered in the PhE initiatives discussed in the retrospective analysis of PhE initiatives (Section 3.4.1.2). Participants were asked to indicate the PO and SI of these risks. Impact refers to the severity of the impact on the institution should the identified risk associated with the PhE initiative occur. Probability refers to the likelihood of the identified risk associated with the PhE initiative occurring. As discussed in the focus group, the probability of a risk occurring varies depending on the timeframe being considered. It was suggested that

a five-year period be considered when classifying risks associated with PhE initiatives in regulatory sciences.

The three risks discussed in the focus group, using the risk assessment tool were:

Lack of HR due to the possibility of a strike: a risk rating score of 25 was assigned as it is almost certain that a strike would occur over a five-year period, especially at a time when collective agreements are being negotiated. The assigned impact should the risk occur was classified as severe, as this could result in the potential for obligations to not be met. Difficulty in meeting obligations within stipulated deadlines for assessment reports related to EU procedures and rapporteurships, comprises an example of repercussions associated with the unavailability of staff. This may result in procedures being re-assigned to other Member States, affecting the reputability of the MMA. Risk mitigation measures in place to reduce the probability of the risk occurring are the engaging of non-unionised personnel who could be assigned tasks related to assessment reports and rapporteurships as a back-up, should a strike occur. Additionally, the Authority contracts external experts who are assigned work depending on the exigencies of the Authority, through Contracts for Service. Such contracts are active for a definite period and not covered by a Collective Agreement. Another risk mitigation measure is the development of a good rapport between management and staff, and the taking of a proactive approach in the management of issues, including negotiations for collective agreements to safeguard job satisfaction for employees and curtail the risk of a strike. The presence of these risk mitigation measures reduces the probability of the risk occurring from almost certain to moderate, therefore reducing the risk rating score to 15.

Issues related to IT infrastructure: a risk rating score of 20 was assigned as it is likely that issues related to IT occur over a five-year period. The assigned impact should the risk occur is severe, as this would result in the possibility of obligations not being met. An example of such a risk is the occurrence of technical issues or issues with payments related to software licenses. This would lead to the unavailability of software used when carrying out RMS procedures. Unavailability of such software would cause disruptions in assessment work for EU procedures, as staff would be unable to read and validate dossiers. Risk mitigation measures set to reduce the probability of the risk occurring are the utilisation of the strong governmental IT infrastructure for support in technical matters, together with the setting of procedures for yearly payments for software licenses. This includes improved procedures for the attainment of financial approvals, and the setting of adequate reminders for license payments to be processed in time. In this way, management oversight and leadership are used to reduce the probability of the risk occurring from likely to unlikely, reducing the risk rating score to 10.

Possibility of output being scientifically wrong: a risk rating score of 10 was assigned as it is unlikely that outputs over a five-year period are scientifically wrong. The assigned impact should the risk occur is severe, as this would result in the possibility of assessment procedures being incorrect, affecting patient safety. Risk mitigation measures include effective management prior to bidding for rapporteurships, with considerable attention to ensuring that sufficient competence exists with the Authority, that staff is available to conduct rapporteurship work, and that tasks are assigned to qualified personnel. Additionally, checks and balances exist at the European Medicines Agency (EMA) through the presence of co-rapporteurs and peer reviews. Training is offered to ensure

competence in areas of interest. In this way, the probability of the risk occurring is reduced from unlikely to rare, reducing the risk rating score to five.

The risk assessment tool is considered validated since it was piloted within the focus group and consensus was reached.

b. Potential risks associated with the introduction of pharmaceutical entrepreneurial functions within regulatory sciences

Participants were asked regarding their level of agreement with regards to the occurrence of potential risks related to the introduction of pharmaceutical entrepreneurial functions within regulatory sciences occurring on a Likert-scale, where five represented the highest level of agreement, and one represented the lowest level of agreement. Potential risks presented to the focus group were conflict of interest, introduction of bias, questioning of integrity, reduction in objectivity and uncertainty. Results are presented in Figure 3.10.

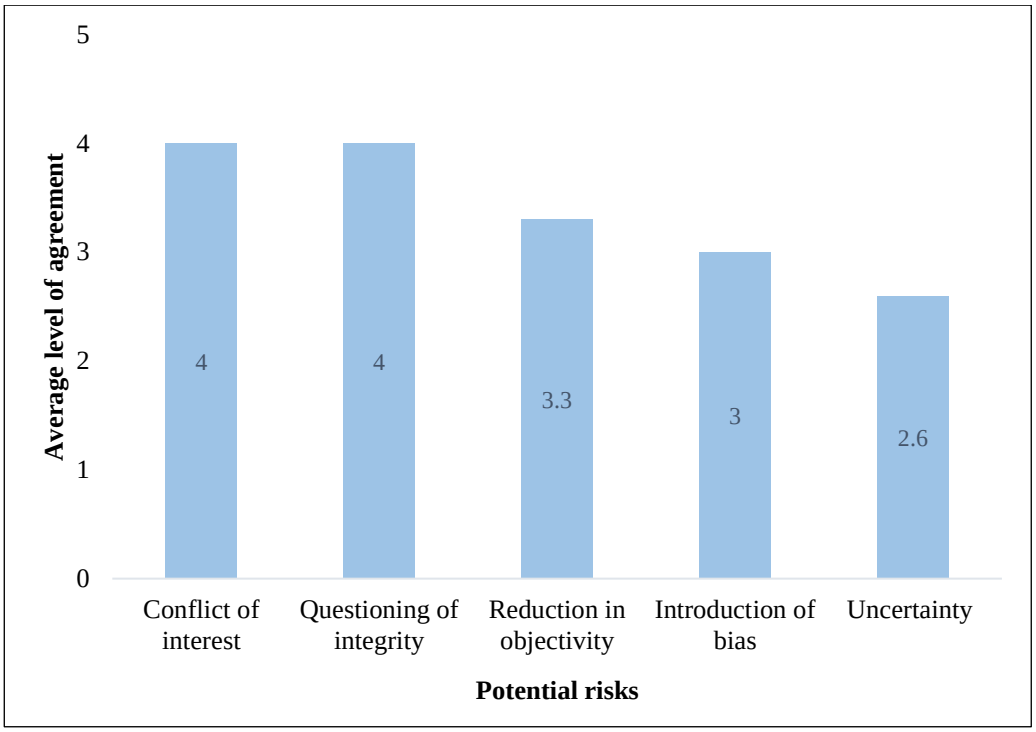


Figure 3.10 Potential Risks associated with the Introduction of Pharmaceutical Entrepreneurial Functions within Regulatory Sciences (N=8)

Conflict of interest is a potential risk associated with the introduction of pharmaceutical entrepreneurial functions within a NCA, as it may be perceived that the institution is undertaking activities associated with a conflict of interest, potentially risking the reputation of the institution. Similarly, questioning of integrity may be a potential risk, as the institution's reputation may be questioned due to its involvement in pharmaceutical entrepreneurial activities. With regards to uncertainty, although sustainability may be at risk if pharmaceutical entrepreneurial functions are not successful, personnel may be redeployed to other areas and assigned revenue generating duties to safeguard financial stability.

Participants agreed that conflict of interest and questioning of integrity are potential risks related to the introduction of pharmaceutical entrepreneurial functions within regulatory sciences. Participants neither agreed nor disagreed that potential risks associated with an introduction of bias and reduction in objectivity occur following the introduction of pharmaceutical entrepreneurial functions in the regulatory scenario. Participants disagreed that uncertainty may occur following the introduction of pharmaceutical entrepreneurial functions in the regulatory scenario.

3.4.1.4 Pharmaceutical Entrepreneurship Characteristics, Traits and Skills in the Regulatory Scenario

Participants were asked regarding their level of agreement with regards to whether the PhE characteristics, traits and skills identified in Section 3.1.3 were used in the implementation of the PhE initiatives discussed in the retrospective analysis of PhE initiatives within the MMA (Section 3.4.1.3). Level of agreement was indicated on a Likert-scale, where five represented the highest level of agreement, and one represented the lowest level of agreement. Results are presented in Figure 3.11.

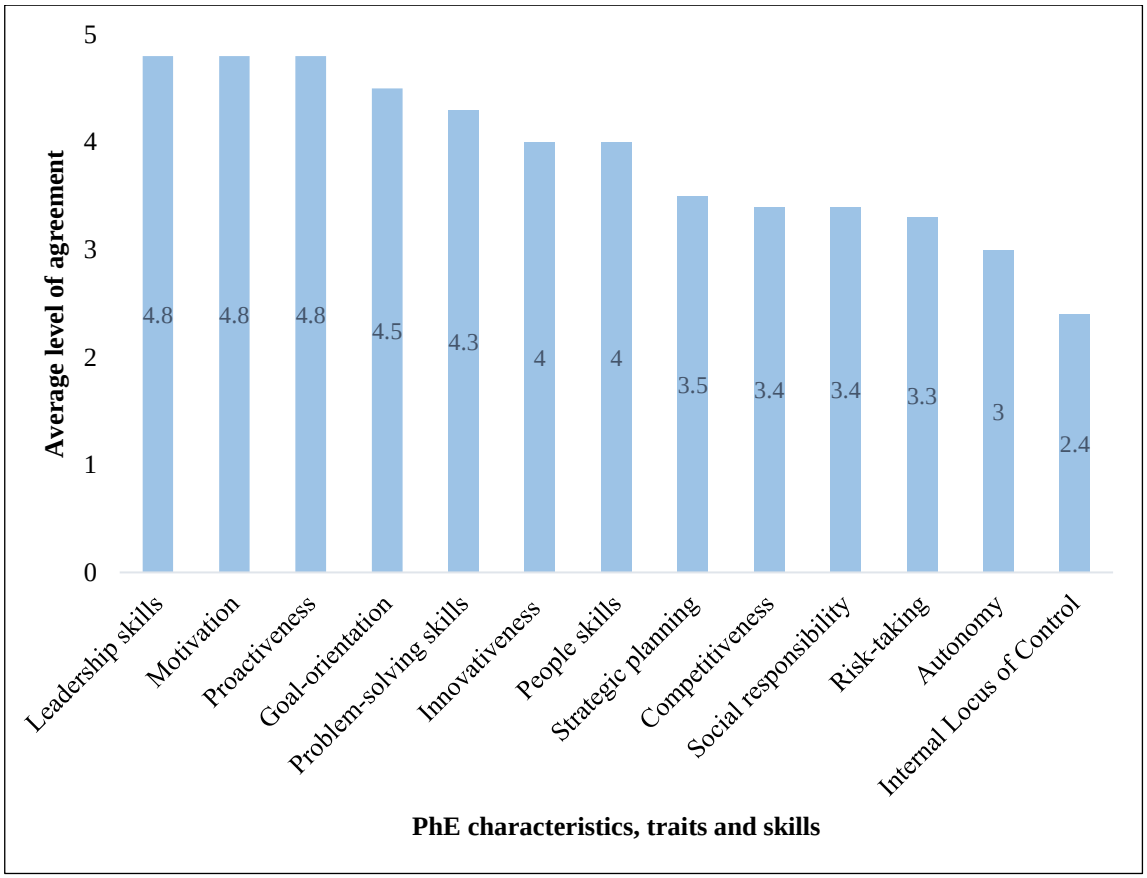


Figure 3.11 Pharmaceutical Entrepreneurship Characteristics, Traits and Skills in Regulatory Sciences (N=8)

With regards to autonomy and an internal locus of control, participants shared that due to the structure of the entity, personnel within the MMA could not be autonomous and did not have an internal locus of control as approvals were required for the implementation of PhE initiatives. Regarding competitiveness, participants stated that although competitiveness applies to initiatives where the MMA bids for EU procedures, the Authority is not competitive in the majority of the PhE initiatives mentioned, due to the nature of the activities carried out and the role of the Authority as a NCA.

Participants agreed that goal-orientation, leadership skills, motivation, proactiveness, innovativeness, problem-solving skills and people skills were used in the implementation of the aforementioned PhE initiatives. Participants neither agreed nor disagreed that autonomy, competitiveness, risk-taking, social responsibility and strategic planning were used in the implementation of the PhE initiatives discussed and disagreed that an internal locus of control was applied in these initiatives.

3.4.1.5 Accountability in Pharmaceutical Entrepreneurship in the Regulatory Scenario

Participants were asked regarding their level of agreement in relation to actions which may be used to ensure accountability when carrying out PhE initiatives namely defining clear roles and responsibilities, setting specific, measurable, achievable, relevant, and timely (SMART) goals, establishing performance metrics, for example KPIs, reviewing progress, fostering a culture of transparency and open communication, gathering feedback and carrying out evaluations, and conducting internal audits. Level of agreement was indicated on a Likert-scale, where five represented the highest level of agreement, and one represented the lowest level of agreement. Results are presented in Figure 3.12.

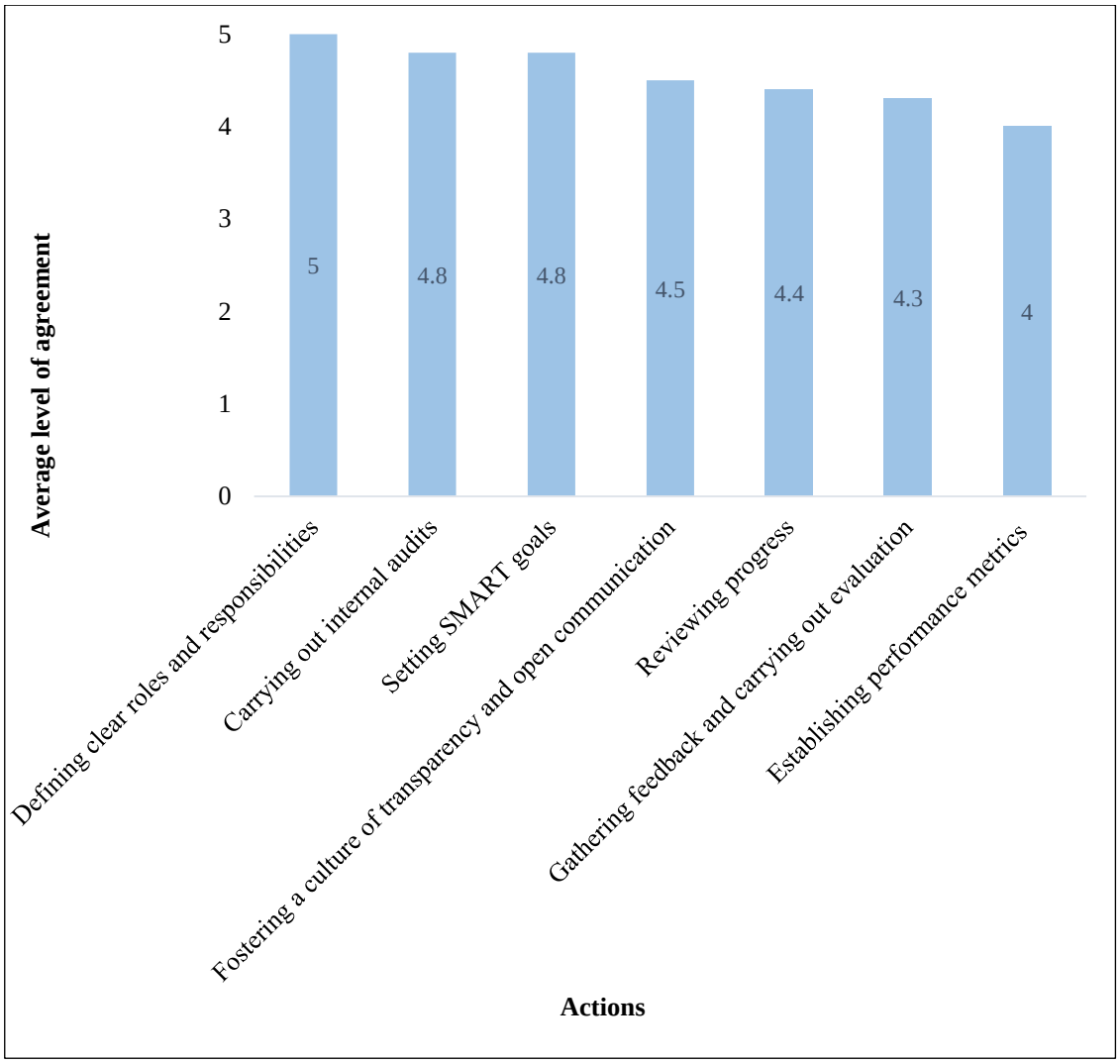


Figure 3.12 Actions to ensure Accountability when carrying out Pharmaceutical Entrepreneurship Initiatives (N=8)

Participants agreed that defining clear roles and responsibilities, carrying out internal audits, setting SMART goals, fostering a culture of transparency and open communication, reviewing progress, gathering feedback and carrying out evaluations, and establishing performance metrics may be used to ensure accountability when conducting PhE initiatives.

3.4.2 Observational Study within the Pharmaceutical Products Entrepreneurship Unit

The major step taken towards stimulating PhE initiatives at the MMA was the establishment of the Pharmaceutical Products Entrepreneurship Unit in January 2022. The Unit coordinates synergy in PhE processes, spearheads projects of relevance to regulatory sciences, ensures the effective and efficient management of entrepreneurship processes related to pharmaceutical products, addresses pharmaceutical queries in an entrepreneurship manner and supports financial planning and management within the Authority, including the identification of opportunities for EU funding. The Unit collaborates with private enterprises, entities and public figures including, the Superintendent of Public Health, the Central Procurement and Supplies Unit, the Ministry for Health, the Malta Enterprise, the Ministry for Education, the Malta Laboratories Network, the Malta Competition and Consumer Affairs Authority and the University of Malta, on relevant projects. The collaboration with 22 stakeholders (29 meetings in 2022) to discuss PhE initiatives on key projects pointed to real world scenario models to incorporate an entrepreneurship appetite in regulatory sciences.

PhE initiatives undertaken by the Pharmaceutical Products Entrepreneurship Unit include the organisation of an academic initiative in the form of a conference, the development of a state-of-the art innovative clinical pharmacy service, and participation in a Joint Action within the EU4Health Programme related to increasing capacity building.

3.4.2.1 Academic Initiative

The Pharmaceutical Products Entrepreneurship Unit within the MMA, in collaboration with the Faculty of Medicine and Surgery within the University of Malta, together with a private enterprise, organised a two-day conference in November 2022. The conference consisted of plenary sessions presented by 22 local and foreign speakers, with a focus on Innovative Techniques in Medicine, Enabling Technologies, Smart Factory and Future Trends in Pharmacy. Short communication sessions and poster presentations were also held. The audience consisted of 150 academics, professionals and students, and offered the opportunity for networking and discussions on policy-making and regulation, health inquiry, medical innovation and personalised, patient-focused technology. The Unit was responsible for communicating with speakers, developing the conference programme and organising logistics for the conference. An entrepreneurship spirit was maintained throughout the conference which allowed for the facilitation of an exchange of views between the conference participants.

3.4.2.2 State-of-the Art Innovative Clinical Pharmacy Service

The Pharmaceutical Products Entrepreneurship Unit, and the Advanced Scientific Initiatives Directorate, are collaborating with the Department of Pharmacy, within the University of Malta, to develop a state-of-the art innovative clinical pharmacy service at St Vincent de Paul Long-Term Care Facility (SVP-LTCF). The aim of the introduction of the clinical pharmacy service is to optimise pharmaceutical care for elderly patients residing at SVP-LTCF. The development of the clinical pharmacy service will commence by means of a pilot project occurring in two wards which were identified by clinicians practising at SVP-LTCF. The pilot project is planned to include a situation analysis

through an observation phase, followed by the making of recommendations, and implementation of the service. A multidisciplinary approach is to be adopted throughout the project, through the establishment, and maintenance, of effective communication and collaboration between the healthcare providers involved in patient care, including physicians, pharmacists, nurses, and other specialists.

The clinical pharmacy service will address the following key areas: assessments of patient needs, medication optimisation, patient education, monitoring and follow-up, and documentation and reporting. An assessment of patient needs includes conducting a thorough medication review and assessment of the patient's health status, functional abilities, and social support systems. Medication optimisation involves reviewing the patient's existing medication regimen and making recommendations to optimise drug therapy, considering each patient's unique needs and medical conditions. Patient education involves providing patients and caregivers with education and resources related to their medications, including advice regarding proper use of medical products, potential side effects, and ways to manage adverse events. Monitoring and follow-up involve the regular monitoring of the patient’s medication regimen and health status, to ensure safe and effective care, and making necessary adjustments to treatment plans. Documentation and reporting involve maintaining accurate and comprehensive documentation of the patient's care, including medication and health records, and the reporting of adverse events or other concerns to the appropriate parties.

3.4.2.3 Joint Action related to Capacity Building

The Pharmaceutical Products Entrepreneurship Unit is actively participating in an EU joint action within the EU4Health Programme which is working towards increasing the capacity building of the EU Medicines Regulatory Network (EMRN).[13] The overall objectives of the joint action are: to improve the accessibility, availability and affordability of medicinal products, medical devices and products required in a crisis within the EU, to encourage innovation concerning medical products by increasing the necessary regulatory expertise and competences within the EMRN, and to establish further capacities to enable the facing of challenges related to upcoming scientific advancements. The main challenges that the joint action aims to address are building capacity, building competence, promoting co-working and increasing network collaborations. The establishment and exchange of knowledge and capacity to facilitate improved collaboration among members of the EMRN, including the sharing of best practices and training opportunities, constitute the activities to be delivered by the joint action. Activities include exchange programmes among EMRN partners, in collaboration with EMA, through on-the-job-coaching and training.

A particular emphasis will be placed on supporting NCAs in addressing innovation and scientific developments, by identifying areas of expertise where active collaboration between NCAs and academia is considered beneficial, and by preparing recommendations to facilitate the interaction of NCAs with academia and small and

[13] European Commission. ANNEX II to the Commission Implementing Decision amending Commission Implementing Decision C(2021) 4793 final of 24 June 2021 and Commission Implementing Decision C(2022) 317 final of 14 January 2022 on the financing of the Programme for the Union's action in the field of health ('EU4Health Programme') and the adoption of the work programmes for 2021 and 2022 respectively [Online]. Brussels: European Commission;2022 [cited 2023 May 29]. Available from URL: https://health.ec.europa.eu/system/files/2022-04/amended_wp2022_en.pdf?cv=1

medium-sized enterprises. The joint action will encourage efficient use of resources through work-sharing, avoiding duplication of work and optimisation of regulatory processes, thereby creating a long-lasting opportunity for cooperation.

3.4.3 Framework for Pharmaceutical Entrepreneurship in Regulatory Sciences

An innovative framework for PhE in regulatory sciences was developed based on data collected from the analysis of entrepreneurial activities carried out at the MMA (Section 3.4.1) and the observational study within the Pharmaceutical Products Entrepreneurship Unit (Section 3.4.2). The framework is presented in Figure 3.13.

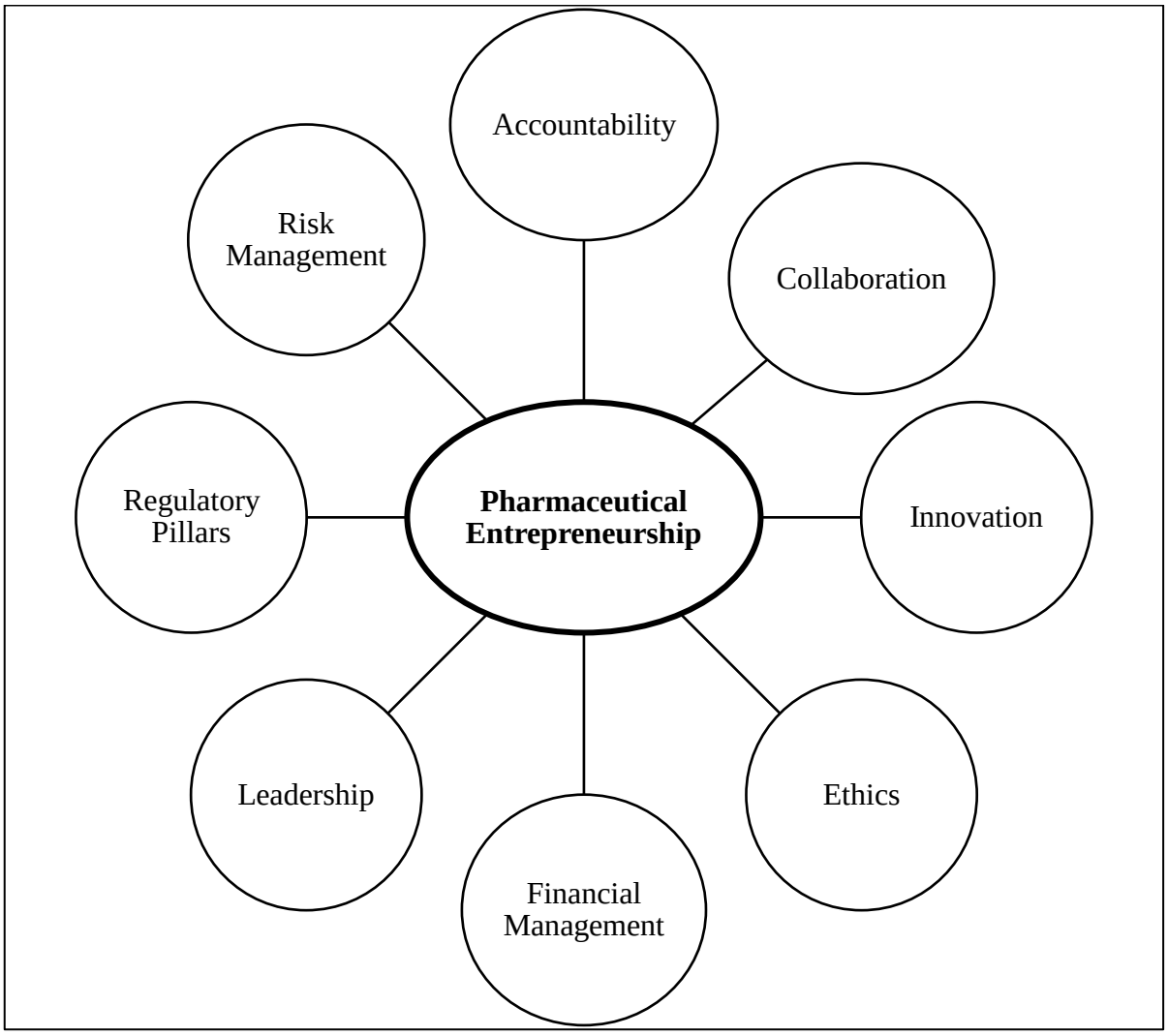


Figure 3.13 Framework for Pharmaceutical Entrepreneurship in Regulatory Sciences

The framework for PhE in regulatory sciences consists of eight components namely: accountability, collaboration, ethics, financial management, innovation, leadership, the regulatory pillars and risk management. The regulatory pillars of quality, safety, and efficacy are to be maintained as a central component of PhE in regulatory sciences for the protection of public health. The application of innovative solutions to meet stakeholder needs in a patient-centred approach plays a significant role in PhE in regulatory sciences, creating value within pharmaceutical processes for the advancement of patient care. Accountability and transparency are to be maintained in PhE in regulatory sciences to promote trust and inspire confidence, whilst ensuring patient safety and continuous quality care. Collaboration and networking allow for the sharing of ideas and expertise, the pooling of resources, the avoidance of duplication of work and the creation of added value, through effective communication to facilitate positive interpersonal relationships, and promote robust patient-centred care. The conservation of pharmaceutical ethical codes for PhE processes in regulatory sciences safeguards the establishment's integrity and reputation, allowing for the promotion of objectivity and impartiality through the setting of measures and controls to avoid conflict of interest and bias. Financial management safeguards the sustainability and viability of the establishment carrying out PhE in regulatory sciences. Leadership allows for the efficient management of processes within PhE initiatives through strategic direction. Risk management, including use of the risk assessment tool developed in this study (Section 2.6.1), risk registers, risk mitigation measures and risk control techniques safeguard patient safety, regulatory compliance, maintain quality and support continuous improvement. The framework may be used for the management of policy priorities within the area of regulatory sciences.

3.5 Measuring Accountable Pharmaceutical Entrepreneurship

Tools used to measure the impact, effectiveness and accountability of pharmaceutical entrepreneurial initiatives were identified through a literature search and interviews with 16 pharmaceutical stakeholders. The tools identified are presented in Table 3.8.

Table 3.8: Tools used to Measure Impact, Effectiveness and Accountability of Pharmaceutical Entrepreneurial Initiatives (N=16)

Tools	Frequency
Key Performance Indicators	10
Financial Projections	8
Impact assessments	8
Cost-benefit analysis	6
SWOT Analysis	5
Internal audits	4
Balanced Scorecard	2
Business Model Canvas	2

Ten interviewees stated that KPIs, including return on investment, time to market, and customer satisfaction, can be used to assess the effectiveness and accountability of pharmaceutical entrepreneurial ventures. KPIs provide an objective way of assessing performance and determining whether targets are being met through data and metrics which are measured and tracked over time, to assess areas including financial performance, operational efficiency and employee productivity, thereby establishing accountability in PhE, and allow pharmaceutical entrepreneurs to make informed, data-driven decisions to optimise outcomes and achieve set objectives (Setiawan and Hardi Purba, 2020).

Eight interviewees stated that they use financial projections to estimated financial performance based on past performance, current trends, and future expectations. Financial projections using metrics inclusive of revenue growth, profitability and cash flow are used to assess the financial viability and potential return on investment of pharmaceutical entrepreneurial ventures, and assess accountability, as financial projections stipulate a benchmark for the monitoring of actual financial performance of the initiative (Cassar, 2009). Additionally, financial projections enable pharmaceutical entrepreneurs to make informed decisions regarding aspects including the allocation of resources, financial outcomes and marketing strategies for the pharmaceutical entrepreneurial initiative, whilst adapting and making adjustments based on changes in circumstances.

Eight participants stated that they perform impact assessments, including stakeholder feedback, to evaluate whether a pharmaceutical entrepreneurial initiative is achieving its intended impact on healthcare outcomes. Such assessments incorporate an investigation regarding whether the initiative is effectively addressing the target health issues, improving patient outcomes, or advancing healthcare access and quality. Additionally, impact assessments are used to assess the social, environmental, and economic impact of the pharmaceutical entrepreneurial initiative. Impact assessments provide a mechanism for continuous improvement, corrective actions, and transparent reporting, ultimately enhancing the accountability of initiatives (Trautwein, 2021).

Six participants stated that they use a cost-benefit analysis as a systematic approach to evaluate the costs and benefits of a particular pharmaceutical entrepreneurial initiative, thereby assessing the financial and non-financial impact of pharmaceutical entrepreneurial ventures and determining their overall viability and accountability. Costs considered include capital expenditure, operational expenses and costs related to personnel (Ali, 2022). Benefits include a potential increase in revenue, improved patient outcomes or customer satisfaction, and reduced costs due to increased efficiency in pharmaceutical processes. A cost-benefit analysis enables pharmaceutical entrepreneurs to assess the long-term impact and sustainability of pharmaceutical entrepreneurial initiatives.

Five participants shared that they use a SWOT analysis to identify the strengths, weaknesses, opportunities, and threats of a particular pharmaceutical entrepreneurial initiatives. A SWOT analysis is used to evaluate the risks and challenges associated with the pharmaceutical entrepreneurial ventures, and to develop strategies to mitigate these risks (Gürel and Tat, 2017).

Four participants stated that they use internal audits to evaluate regulatory compliance, identify risks, monitor performance and improve pharmaceutical processes. By assessing compliance, internal audits ensure that the pharmaceutical entrepreneurial initiative operates within legal and ethical boundaries, whilst assessing industry standards, and internal policies, holding the enterprise accountable for meeting these obligations (Tsvetanova, 2014). The insight gained from internal audits contributes to strengthening the pharmaceutical entrepreneurial initiative's overall accountability and governance practices.

Two participants stated that they use the Balanced Scorecard, a performance tool which offers a thorough assessment of an enterprise's performance from several perspectives. The framework provides a comprehensive and balanced view of performance, ensuring that the initiative is accountable to stakeholders, including financial outcomes, customer satisfaction, internal processes, organisational learning, and engagement with stakeholders, and can be used to measure the impact, and success, of pharmaceutical entrepreneurial ventures, and to ensure accountability (Masa'deh et al, 2018).

Two participants stated that they use the Business Model Canvas, a visual tool used to enable enterprises to understand and analyse their business model and strategy. The Business Model Canvas enables the understanding of crucial elements of an initiative, and the evaluation of the feasibility and sustainability of pharmaceutical entrepreneurial ventures. The tool provides a framework for strategic planning and decision-making by aligning the various components of the business model and focusing on stakeholder needs, value delivery, and responsible practices. The Business Model Canvas can be used to enhance the pharmaceutical entrepreneurial initiative's overall accountability to stakeholders and demonstrate its commitment to reaching its set objectives (Holdford et al, 2022).

Eight tools which may be used to measure the impact, effectiveness and accountability of pharmaceutical entrepreneurial initiatives were identified in this study, namely KPIs, financial projections, impact assessments, the cost-benefit analysis, the SWOT analysis, internal audits, the Balanced Scorecard, and the Business Model Canvas.

3.6 Dissemination of results

An abstract submission entitled ‘Entrepreneurship in pharmaceutical processes’ was accepted as a poster presentation and presented at the 80th International Pharmaceutical Federation World Congress of Pharmacy and Pharmaceutical Sciences in Seville in September 2022 (Appendix 6). An abstract submission entitled ‘Applying pharmaceutical entrepreneurship as a pharmacoeconomic paradigm shift in clinical pharmacy’ was accepted as a poster presentation and presented at the European Society of Clinical Pharmacy Symposium in Prague in October 2022 (Appendix 6).

Chapter Four

Discussion

In this research, an investigation of the evolvement of concepts in entrepreneurship in pharmaceutical processes enabled the identification of knowledge and competences present within the pharmacy profession associated with the identification, pursual and advancement of pharmaceutical entrepreneurial endeavours. The need for a pharmacist's perspective in the understanding of patient needs, the safeguarding of quality, safety, efficacy and accessibility of medicines, and the implications of issues in the pharmaceutical scenario presented areas for reflection as related to pharmaceutical entrepreneurship (PhE). This discussion deals with the findings that concur with the literature and those that originated from this research.

There could be a perception that the financial aspect is the most significant facet of PhE. This study has pointed towards the notion that although sustainability could be improved through the introduction of an entrepreneurship appetite within pharmaceutical processes (Section 3.2.11), financial success should not come at the cost of patient safety (Section 3.2.2). Participation in pharmaceutical entrepreneurial initiatives ought to create a strong appetite for pharmacists to meet patient needs and offer services to establish continuous quality care for patients. The results in this research suggest that it is this appetite to serve patient needs that gives pharmacists the drive to participate in PhE initiatives which go beyond the traditional roles associated with pharmacy, including endeavours related to social entrepreneurship which, as described by Mattingly et al (2019b), incorporate activities that are not profit generating. There is perhaps a need for the profession, and society at large, to link pharmacy with such a finding.

Similar to the way in which Prince et al (2021) describe central themes related to entrepreneurship to include the creation of business, the identification or creation of opportunities, innovation, and the creation of value in an environment of uncertainty, this study (Section 3.2.2, Section 3.4.1.1) points to central themes related to PhE which include the serving of patient needs, scientific knowledge, business acumen, the taking of calculated risk, creative thinking, innovation, evidence-based decision making, problem-solving and critical thinking to improve patient care. Results in this study suggest that accountability, collaboration, financial rigorousness, efficiency, innovation, market responsiveness, patient outcomes and sustainability could be improved through the introduction of an entrepreneurship appetite within pharmaceutical processes (Section 3.2.11) and confers with findings by Tice (2005), Holiday-Goodman (2012) and Mattingly et al (2019a), that the integration of PhE contributes to the enriching of the profession as it moves towards innovation in the future.

4.1 Contribution of Pharmaceutical Entrepreneurship to Innovation

Mogul et al (2020) and Afeli and Adunlin (2021) stated that innovation forms an integral component of PhE, enabling the evolvement of pharmaceutical processes to meet patient needs in a robust and efficient manner, which agrees with the findings in this study (Section 3.1.2). Innovative practices identified in this research are open innovation and collaboration, digital health technologies, precision medicine and genomics, artificial intelligence (AI), and patient-centred approaches. Collaboration allows for the sharing of a common vision and the avoidance of the creation of silos (Section 3.1.2a). D'Souza and Scahill (2020) exposed further than the findings in this study, by suggesting that an *interdisciplinary* approach carried out through enterprising skills has a higher potential to

produce valuable outcomes. It is proposed to consider the embracing of innovative aspects including big data, AI and the internet of things in an enterprising manner, under such title as ‘Pharmaceutical Entrepreneurship 5.0’ as paralleled to Industry 5.0. This corresponds to the reference to today’s enterprising features in the industry as Industry 5.0. This idea of introducing the concept of Pharmaceutical Entrepreneurship 5.0 results from the study of the work of Belousova et al (2020), Park et al (2021) and Hall et al (2022). Collaboration and the collection of insights from different stakeholders, including patients and patient communities, medical practitioners and industry representatives, and the sharing and exchange of data through communal biorepositories, may be used to improve pharmaceutical processes and healthcare (Belousova, 2020). The innovative application of technology to pharmacy in this era of digital transformation enables pharmacists to be more approachable to patients beyond the typical hospital, community, or clinic environment. The use of technological innovations including 3D printing, AI, biotechnology, gene therapy, pharmacogenomics, precision medicine, telemedicine, social media and digital health, such as the creation of application software, offer pharmacists new opportunities which may determine innovative solutions to healthcare challenges and improve job satisfaction (Belousova et al, 2020; Park et al, 2021; Hall et al, 2022).

In addition to innovative practices and novel products, services or technologies, findings in this study also relate to improvements to pharmaceutical processes which enhance efficiency and create added value. It is worth considering in this discussion, the question of citing these improvements to pharmaceutical processes under the term renovation, rather than innovation. This is in line with Belousova et al’s (2020) statement that the application of PhE principles to develop sustainable innovation to surmount global

challenges in an effort to improve transparency, open dialogue and legitimacy, and is worthy of consideration. Current challenges in healthcare which may benefit from the application of innovation, renovation and PhE which were not discussed in this study include orphan drug development and antibiotic resistance. Alternative drug development pathways including drug discovery, rediscovery or redirection of treatments developed for more prevalent and widespread diseases, may lead to possible innovative reuse of existing treatments as a potential method of addressing these challenges (Bruyaka et al, 2013; Belousova et al, 2020; Ciabuschi et al, 2020).

4.2 Pharmaceutical Entrepreneurship Behaviours, Traits, Skills and Challenges

Results from this research indicated parameters significant in embarking on PhE endeavours. As presented in Section 3.2.7, pharmaceutical entrepreneurs who participated in this study agreed with the PhE characteristics, traits and skills identified from the literature (Section 3.1.3), namely leadership skills, innovativeness, problem-solving skills, goal-orientation, proactiveness, strategic planning, people skills, competitiveness, an internal locus of control, risk-taking, motivation and social responsibility (Ramia et al, 2016; McLaughlin et al, 2017; Shahiwala, 2017; Huston, 2018; Mattingly et al, 2019a; Mattingly et al, 2019b; Ruas Ferreira dos Santos et al, 2019; Shaikh et al, 2020; Fashami et al, 2021; Nili et al, 2021). It is interesting to note that although autonomy was identified as a PhE trait in the literature (McLaughlin et al, 2017; Mattingly et al, 2019a; Mattingly et al, 2019b; Shaikh et al, 2020; Fashami et al, 2021; Nili et al, 2021), participants in this research did not consider autonomy to be a necessary trait for PhE as although one should be able to make decisions alone, these decisions would be based on information and input given by others. Perseverance was considered an additional PhE trait by participants in this study. To the best of the researcher's

knowledge, perseverance is not documented as a PhE trait in the literature. This study went further in investigating PhE characteristics, traits and skills in regulatory sciences, which is unique to the best of the researcher's knowledge. It is interesting to note that goal-orientation, leadership skills, motivation, proactiveness, innovativeness, problem-solving skills and people skills were identified as characteristics, traits and skills used in the implementation of PhE initiatives within the regulatory scenario. However, participants neither agreed nor disagreed that autonomy, competitiveness, risk-taking, social responsibility and strategic planning were used in PhE initiatives discussed in the retrospective analysis of initiatives implemented within the Malta Medicines Authority (MMA), and disagreed that an internal locus of control was applied in a regulatory scenario (Section 3.4.1.4). This variation in PhE characteristics, traits and skills in the regulatory scenario relates to the functions and structure of the MMA as a Competent Authority for medicines and medical devices. Such a finding infers that PhE characteristics, traits and skills could vary depending on the pharmaceutical scenario and warrants further investigation.

Through the course of this study, leadership was identified as an important aspect in PhE, including in the context of solving issues related to pharmaceutical scenarios, such as addressing a number of challenges presented during the COVID-19 pandemic, medicine shortages, and in the management of pharmaceutical entrepreneurial initiatives in regulatory scenarios. The prominence of entrepreneurial leadership as a fundamental aspect of PhE incorporating adaptability, self-evaluation, the management of failure and effective communication confers with the literature (Tice, 2005; Harrison et al, 2016a; Mattingly et al, 2019a; Mattingly et al, 2019b; Murray Gillin and Hazelton, 2021; Scahill and D'Souza, 2022). Entrepreneurial leadership can be applied to the pharmacy

profession as a collective purpose for pharmacists to create value in an effort to improve the lives of patients through the optimal use of medicines and medical devices with a willingness to face struggles which arise within the process (Tice, 2005). This study (Section 3.2.4, Section 3.2.7, Section 3.4.1.1) reinforces the concept that entrepreneurial leadership involves the recognition of the significance of personnel within PhE and the ability to foster creativity by empowering individuals within an organisation, whilst establishing an environment of mutual respect (Renko et al, 2015; Murray Gillin and Hazelton, 2021). This concept on entrepreneurial leadership requires further evaluation.

In addition to the identification of PhE characteristics, traits and skills, an examination of behaviours and attributes associated with PhE was performed in this study. It is worth investigating the weighting given to such parameters. It is interesting to note for example, that agility, ambition, drive and market awareness have a threefold weighting compared to trust and respect, and being a team player, when evaluating the weighted contribution of parameters involved in PhE behaviours and attributes (Table 3.2). Parameters mentioned by participants in this study (Section 3.2.2, Section 3.2.9) match those stated in the literature, for example collaboration (McLaughlin et al, 2017; Shahiwala, 2017; Mattingly et al, 2019a; Mattingly et al, 2019b), creativity (Ramia et al, 2016; McLaughlin et al, 2017; Shahiwala, 2017; Mattingly et al, 2019a; Mattingly et al, 2019b; Ruas Ferreira dos Santos et al, 2019; Fashami et al, 2021), determination (Mattingly et al, 2019b), empathy (Mattingly et al, 2019b), flexibility (Mattingly et al, 2019b) and self-confidence (McLaughlin et al, 2017). To the best of the researcher's knowledge, the identification of agility, ambition and drive as PhE behaviours is unique to this study. Results of this research (Section 3.4.1.1) indicating the attributes related to a pharmaceutical entrepreneurial initiative (flexibility and adaptability, leadership, meeting stakeholder

needs, robustness, creative thinking, calculated risk-taking, evidence-based decision making, innovation, willingness to challenge conventional thinking, collaboration, practicality and pragmatism) where identified in the focus group and could vary in different pharmaceutical scenarios (for example a regulatory setting versus a clinical pharmacy setting).

An aspect of note from the interviews with pharmaceutical entrepreneurs was that participants commented that entrepreneurial behavioural traits and qualities may be inborne or developed throughout an individual's life, through the environment they are exposed to (Section 3.2.2). This is consistent with literature which suggests that an individual's motivation to pursue entrepreneurial opportunities may be associated with inherent characteristics or personality traits, the individual's environment, and life experience, including experience gained when exposed to families with a background in business, or role models who are entrepreneurs. Such individuals are more inclined to become entrepreneurs (Powell and Eddleston, 2013; Blumberg and Pfann, 2016; Saxton et al, 2016; Barringer and Duane Ireland, 2019; Fashami et al, 2021; Scahill and D'Souza, 2022). The significance of the contribution of genetics, environment and education remain an eternal debatable consideration in specific scenarios, more so when the scenario is less tangible, such as in PhE.

An aspect of note was a lack of female pharmaceutical entrepreneurs among interview participants in this study. This is consistent with literature which suggests that in general, the female gender is associated with lower entrepreneurial intention (Huston, 2018). As presented in the policy research working paper by the World Bank Group in 2017, less than one-third of entrepreneurs practising in different fields from the majority of the

economies evaluated in the study were female.[14] This finding is consistent with the number of female entrepreneurs encountered in this study, as only three out of the sixteen identified pharmaceutical entrepreneurs (19%) were female. This trend is consistent with findings reported 10 and 20 years ago. Ten years ago, Powell and Eddleston (2013) suggested that compared to male entrepreneurs, females typically have less access to financial, social and human resources, and females place more of an emphasis on work-family synergies. On the other hand, the male gender position promotes autonomy and independence, which is associated with entrepreneurial behaviour (Powell and Eddleston, 2013). Morris et al (2001), stated that females seem to encounter challenges that are distinct from those experienced by male entrepreneurs.

An analysis of the results pertinent to challenges faced during pharmaceutical entrepreneurial endeavours which were obtained in this study identified the main barriers that pharmaceutical entrepreneurs face in a real-world scenario. These are inadequate capacity, meeting stakeholder needs, resistance to change and time restraints. The challenge presented by inadequate capacity, both in terms of finances, but especially in terms of human resources, and challenges related to stakeholder requirements, are consistent with the literature (Harrison et al, 2016a; Barringer and Duane Ireland, 2019). Throughout this study, it was maintained that PhE is enhanced through a pharmacist's perspective. Inadequate capacity in pharmaceutical sciences is a global issue as less students are taking up science subjects leading to a shortage in human resources competent in scientific fields (Potvin and Hansi, 2014; Palmer et al, 2017; Evans et al, 2020). Findings from this dissertation demonstrate that inadequate capacity is a

[14] Meunier F, Krylova Y, Ramalho R. Women's Entrepreneurship: How to Measure the Gap between New Female and Male Entrepreneurs? World Bank Group, Washington; 2017.

significant factor which is limiting PhE due to a lack of skilled personnel who can participate in pharmaceutical entrepreneurial endeavours (Section 3.2.4). Inadequate infrastructure has been identified as a challenge related to PhE in the literature (Harrison et al, 2016a), and is in concordance with the views of six out of twelve interview participants in this study. An example of these infrastructural challenges identified in this study points to Malta constituting a microenvironment resulting in logistical issues, including difficulties in sourcing medicinal products due to minimum order quantities set by manufacturers.

With regards to the entrepreneurial process, findings from this study identify resource allocation, and implementation and management, as the most challenging steps within the pharmaceutical scenario (Section 3.2.3). This is consistent with literature which suggests that implementation and management of an entrepreneurial venture is the most difficult step, as pharmaceutical entrepreneurs make critical and strategic decisions whilst managing the process to grow the business, service, or product (Tice, 2005; Tice, 2012). Although the literature points to the step related to a needs analysis as a possible limiting step in the entrepreneurial process (Morris et al, 2001; Tice, 2005; Tice 2012), needs analysis was not identified as a challenge within this study (Section 3.2.3).

4.3 Risk in Pharmaceutical Entrepreneurship

In this research, the association between PhE and risk was investigated (Section 2.4.2, Section 2.6.2). Interviews with participants (Section 3.2.12) indicate that pharmaceutical entrepreneurs tend to take mild to moderate risks when conducting pharmaceutical entrepreneurial endeavours, which is consistent with findings in the literature (Norton and Moore, 2006; Harrison et al, 2016b; Barringer and Duane Ireland, 2019). Within this

study, nine out of twelve (75%) participants expressed that they would consider taking mild to moderate risk when carrying out pharmaceutical entrepreneurial initiatives compared to 79% of participants in the Hartford 2015 Small Business Success Study who indicated that they would take a conservative approach when conducting entrepreneurship initiatives, as opposed to an approach associated with high risk.[15] Participants in this research (Section 3.2.12) indicated that although they would take varying degrees of risk when considering financial and logistical aspects, participants would embark on pharmaceutical entrepreneurial ventures associated with low or zero risk with respect to patient safety, which finding is particular to *pharmaceutical* entrepreneurship.

The study points to the taking of calculated risk in PhE through the gathering of information to make informed decisions and includes an assessment of the impact of potential risks on the enterprise or institution (Section 3.2.2, Section 3.2.12, Section 3.4.1.1). Use of the risk assessment tool developed in this study (Figure 2.2) may assist in the management of risk when conducting pharmaceutical entrepreneurial initiatives. Participants suggested that considerations to be made when assessing risk are learnt over time, as indicated in previous studies related to entrepreneurship (Norton and Moore, 2006; Melović et al, 2022).

[15] The Hartford. Small Business Success and Optimism Rev Up, Focus on Growth Stalls, The Hartford's Study Finds [Internet] Hartford: The Hartford; 2015. [cited 2023 May 29] Available from URL:
https://newsroom.thehartford.com/newsroom-home/news-releases/news-releases-details/2015/Small-Business-Success-And-Optimism-Rev-Up-Focus-On-Growth-Stalls-The-Hartfords-Study-Finds/default.aspx

Findings in this study postulate that although altruistic performance, collegiality, integrity, patient safety, quality control, regulatory compliance, scientific approach and social responsibility may be considered to potentially be at risk following the introduction of an entrepreneurship appetite in pharmaceutical processes, these should under no circumstances be harmed, as otherwise the process would lack the keeping of patients as a central component in the making of decisions. A lack of integrity is associated with potential risk to the aforementioned aspects (Section 3.2.11). With regards to regulatory sciences, potential risks identified in this study related to the introduction of pharmaceutical entrepreneurial functions within regulatory sciences, are conflict of interest and questioning of integrity. These aspects could be considered as potential risks due to a possible perception that the regulatory body is participating in activities which may be considered to constitute a conflict of interest, possibly presenting a perception which harms the establishment's reputation and integrity (Section 3.4.1.3).

4.4 Education and Training

This study postulates that there is a lack of entrepreneurship training for pharmacists and that PhE initiatives are undertaken without formal training, making business acumen a considerable challenge at the beginning of a pharmaceutical entrepreneur's career, potentially limiting the undertaking of PhE initiatives (Section 3.2.2), and is concordant with findings by Mattingly et al (2019a), Mogul et al (2020), Afeli and Adunlin (2021) and Scahill and D'Souza (2022), who highlight include the need for further training in the field of PhE. Studies indicate that pharmacy curricula need to be updated to prepare students to be able to provide continuous improvements to patient care and respond to contemporary challenges in healthcare (McLaughlin et al, 2017; Mattingly et al, 2019b; Panther et al, 2019; DeVolld et al, 2022). Studies by Laverty et al (2015), Huston (2018)

and Scahill and D'Souza (2022) indicate that there is a growing interest for pharmacy students to develop knowledge and skills related to PhE.

The second phase of this study led to the development and validation of a training programme for PhE consisting of 13 training aspects, namely Communication Skills, Conflict Resolution, Financial Management, Human Resources, Innovation, Leadership, Market Research, Marketing, Negotiation Techniques, Project Management, Public Relations, Quality Improvement and Risk Management (Appendix 5). It is significant that the curriculum of the training programme evolving around these topics is related to the special considerations surrounding a pharmaceutical scenario. The particular case of health, especially as related to medicines use and accessibility, presents the need of a unique pharmaceutical knowledge related to these priorities in a healthcare scenario, including vulnerabilities of patients and sustainability where the fundamental principles of these 13 specialities need to be taken into consideration. It is these special considerations that compose a training programme for PhE. Interviews with pharmaceutical entrepreneurs inferred that one should have a basic knowledge in the training aspects identified in this study to be able to conduct pharmaceutical entrepreneurial initiatives successfully. It would be interesting to investigate the appetite of local pharmaceutical stakeholders for such developments in education and practice.

Participants in this study pointed to the need for training in the field of PhE to be a combination of a classroom and real-world experience. This confers with literature which suggests that a training programme for PhE should incorporate co-curricular activities and experiential education (Gee et al 2019; Mogul et al, 2020; Afeli and Adunlin, 2021; DeVolld et al, 2022; Holdford et al, 2022; Scahill and D'Souza, 2022). Examples of

practical experience include, the use of team based learning activities such as workshops (Laverty et al, 2015; Shealy and McCaslan, 2018; Mattingly et al, 2019b), mentorship programmes (Mattingly et al, 2019b; DeVolld et al, 2022), site visits (Afeli and Adunlin, 2021) and educational activities, including project based activities (Gatwood et al, 2018; Panther et al, 2019; Mogul et al, 2020; DeVolld et al, 2022; Nguyen et al, 2022). This study dealt with the development of the didactic component of training in the area of PhE (Appendix 5). Further research may lead to the development of a practical aspect to training in the area of PhE.

4.5 Pharmaceutical Entrepreneurship in Regulatory Sciences

The study related to PhE in regulatory sciences (Section 2.6) points towards the introduction of PhE as a new interest of a regulatory body. The concept of introducing PhE within regulatory sciences is entrepreneurial in itself as one is moving beyond the traditional functions of a regulatory agency to ensure that legalistic requirements are met by stakeholders. The introduction of PhE in regulatory sciences puts emphasis on patient outcomes and the establishment of innovative ways to meet patient needs, whilst keeping the pillars of regulatory science, namely quality, safety and efficacy, and accessibility, at the centre of all processes for the benefit of patients. A balance between the scientific and technological needs, and the knowledge and skills required to undergo PhE in a regulatory sciences environment, including a medicines regulatory authority, but not exclusive to a regulatory authority, must be created. Examples of how PhE in regulatory sciences may be implemented through the carrying out of non-statutory activities are described in the retrospective analysis of pharmaceutical entrepreneurial initiatives in Section 3.1.4.2.

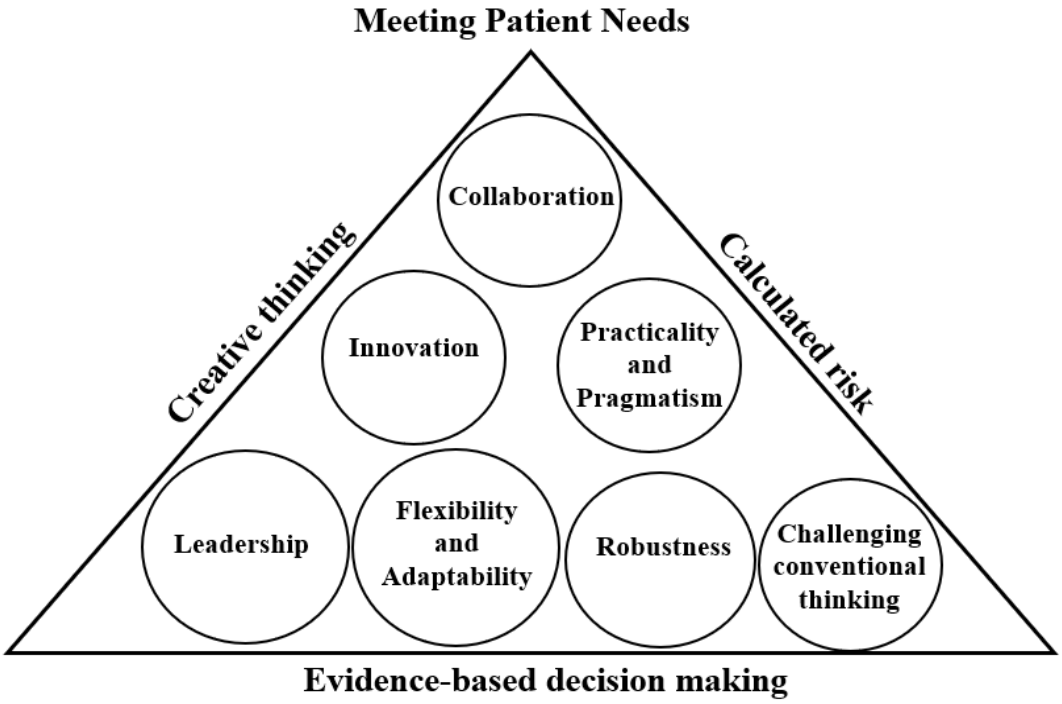
This study incorporated an analysis of entrepreneurial activities at the MMA as a setting for regulatory sciences (Section 3.4.1), and an observational study within the Pharmaceutical Products Entrepreneurship Unit (Section 3.4.2) which led to the development of an original framework for PhE in regulatory sciences (Figure 3.13). The framework consists of eight components, namely accountability, collaboration, ethics, financial management, innovation, leadership, the regulatory pillars and risk management, and may be used for the management of policy priorities in regulatory sciences. The framework incorporates a patient-oriented approach when conducting pharmaceutical entrepreneurial initiatives, whilst keeping in line with legal requirements and policies related to regulatory sciences. The next step would be to validate the setting up of a Pharmaceutical Entrepreneurship Unit within a regulatory agency, which matter is outside the scope of this dissertation.

4.6 Accountability and Pharmaceutical Entrepreneurship

This study points towards the notion that accountability should be considered an essential aspect for the code of practice in PhE. Classical points which contribute to outcomes, such as the defining of clear roles and responsibilities and the use of specific, measurable, achievable, relevant, and timely (SMART) goals, where amongst the actions identified in this study which may be used to ensure accountability when conducting PhE initiatives (Section 3.4.1.5). Results from literature and informal one-to-one interviews with pharmaceutical stakeholders led to the identification of tools used to measure the impact, effectiveness and accountability of pharmaceutical entrepreneurial initiatives (Section 3.5). These tools may be used to ensure PhE endeavours are being conducted in an accountable and responsible manner, thereby ensuring transparency, responsibility and liability (Denis, 2014; Burga and Rezania, 2015). Such an exercise in accountability

contributes to entrenching the sustainability of an innovative approach, including one related to regulatory sciences.

Through the results obtained in this research, PhE may be considered to be a combination of three dimensions, namely creative thinking, the taking of calculated risk and evidence-based decision making, as presented in Figure 4.1, with the ultimate goal being the meeting of patient needs. Leadership, flexibility and adaptability, robustness, innovation, willingness to challenge conventional thinking, collaboration, practicality and pragmatism were considered additional attributes related to PhE initiatives by members of the focus group (Section 3.4.1.1).



Apex: Meeting patient needs as a fundamental principle for PhE

Sides of triangle: PhE = Creative thinking x Calculated risk x Evidence-based decision making as stated in the rationale for this study (Section 1.13)

Circles inside triangle: Represent results from this study of attributes related to a pharmaceutical entrepreneurship initiative (Section 3.4.1.1)

Figure 4.1 The Dimensions of Pharmaceutical Entrepreneurship

The dimension of creative thinking within PhE leads to innovation or renovation, as stated in the discussion concerning the contribution of PhE to innovation, and the identification and development of new opportunities to find solutions to issues in healthcare, the meeting of patient needs and promotion of service excellence to patients, whilst supporting the sustainability of the pharmaceutical professions.

Risk in the fair of PhE was a significant dimension in the raison d'être of this dissertation. The dimension related to calculated risk taking involves the use of data and information to generate knowledge and wisdom which may be used to assess risks and the potential impact which risks may have on the establishment or enterprise. A finding from this research (Section 3.2.12) is that although pharmaceutical entrepreneurs would take varying degrees of risk when considering financial and logistical aspects, participants would embark on pharmaceutical entrepreneurial ventures associated with low or zero risk with respect to patient safety.

The significance of the making of informed decisions within PhE based on wisdom gained through evidence gathered from research and experience, whilst keeping ethical values related to the pharmaceutical scenario in mind, has been discussed in this dissertation. Research, forecasting, critical thinking and strategic analysis should be utilised in decision making processes.

4.7 Limitations of the Study

1. A limitation of the study was the use of convenience sampling for validation exercises (Section 2.4.3, Section 2.5.2, Section 2.6.3), interviews with pharmaceutical entrepreneurs (Section 2.4.4), the focus group (Section 2.6.4) and the interviews with pharmaceutical stakeholders (Section 2.7). Since participants were not selected randomly, selection bias may have occurred, and representativeness could not be assured. Data gathered may not be complete due to the number of pharmaceutical entrepreneurs interviewed. A larger number of participants could have reinforced results obtained and provided better representativeness.

2. The framework developed for PhE in regulatory sciences, based on data gathered from the analysis of entrepreneurial activities carried out at the MMA, and results from the observational study within the Pharmaceutical Products Entrepreneurship Unit at the MMA, needs to be validated and piloted.

3. The study could have benefited from a longitudinal perspective since it was cross-sectional in nature.

4.8 Recommendations for future work and research

1. The training programme for PhE needs to undergo an accreditation process.

2. The training programme for PhE should incorporate an experiential component, as discussed in Section 4.4. Future research may investigate, and develop, this practical aspect for training related to PhE.

3. The framework for PhE in regulatory sciences should be validated and pilot tested.

4. Research may be carried out to investigate PhE in other pharmaceutical processes in addition to regulatory sciences, such as in the community, clinical and industrial pharmacy settings.

5. The tools used for accountability in this research were extrapolated from general entrepreneurship situations. Tools specific to a pharmaceutical scenario may be extended.

6. Further research may investigate ways of how the subject of PhE could be used to enhance students to join science, technology, engineering, and mathematics fields, especially pharmaceutical sciences.

4.9 Conclusion

1. The analysis of the literature concludes that i. The concept of PhE may be considered to be in its infancy, ii. The application of PhE principles enables pharmaceutical stakeholders and policy makers to manage the rapidly changing environment in healthcare, as technology advances and societal needs shift, iii. PhE is closely linked to innovation and collaboration, and iv. PhE improves healthcare and contributes to the evolvement of the pharmacy profession through the proactive identification, creation and pursual of novel pharmaceutical products and processes.

2. The interviews with pharmaceutical entrepreneurs and focus group consisting of a representative group from the MMA concluded that i. Central themes related to PhE are the serving of patient needs, scientific knowledge, business acumen, the taking of calculated risk, creative thinking, innovation, evidence-based decision making, problem-solving and critical thinking, ii. Accountability, collaboration, financial rigorousness, efficiency, innovation, market responsiveness, patient outcomes and sustainability could be improved through the introduction of an entrepreneurship appetite within pharmaceutical processes, and iii. Inadequate capacity was identified as a significant factor which is limiting PhE due to a lack of skilled personnel who can participate in pharmaceutical entrepreneurial endeavours.

3. The interviews with pharmaceutical entrepreneurs confirmed the literature findings concluding that training in the area of PhE is required to prepare the pharmacy workforce for the application of PhE principles in the tackling of contemporary challenges in healthcare.

4. Research concludes that accountability should be considered an essential aspect for the code of practice in PhE.

5. The study concludes that a patient-centred approach is an essential element when carrying out PhE endeavours.

6. An innovative aspect of this dissertation is the conclusion that PhE is a product of creative thinking, the taking of calculated risk and evidence-based decision making as related to a progressive innovative pharmaceutical scenario, in contrast to the classical concept that entrepreneurship incorporates in its entirety a sense of business and financial planning.

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Appendix 1

Faculty Research and Ethics Committee Approval

Faculty Research and Ethics Committee Approval

The status of your REDP form (MED-2022-00093) has been updated to Acknowledged Inbox ×

form.urec@um.edu.mt Tue, 3 May 2022, 11:26

to me

Dear Lara Marie Giudice,

Please note that the status of your REDP form (MED-2022-00093) has been set to *Acknowledged*.

You can keep track of your applications by visiting: https://www.um.edu.mt/research/ethics/redp-form/frontEnd/.

This email has been automatically generated by URECA. Please do not reply. If you wish to communicate with your F/REC please use the respective email address.

Appendix 2

Questions for Interviews with

Pharmaceutical Entrepreneurs

Questions for Interviews with Pharmaceutical Entrepreneurs

The below questions apply to the pharmaceutical environment

Demographics

1. For how many years have you been practicing in the pharmaceutical scenario?
   - ❑ ≤ 5 years
   - ❑ 6 – 10 years
   - ❑ 11 – 15 years
   - ❑ 16 – 20 years
   - ❑ >20 years

2. What area/s of pharmacy have you worked in?
   - ❑ Community Pharmacy
   - ❑ Hospital Pharmacy
   - ❑ Importation and Distribution
   - ❑ Industrial Pharmacy
   - ❑ Medical Representation
   - ❑ Pharmacy administration
   - ❑ Regulatory Sciences
   - ❑ Other (please specify)

   _____

Pharmaceutical entrepreneurship entails the identification, creation, and pursuit of new opportunities to serve patient needs and plays a fundamental role in improving healthcare through innovation. Pharmaceutical entrepreneurship requires a combination of scientific knowledge, business acumen, and risk-taking ability to improve patient care.

3. Mention three points, other than those stated above, which define entrepreneurial behaviour in the pharmaceutical scenario.
   a.
   b.
   c.

   Comments

   _____

   _____

4. Do you consider yourself to be a pharmaceutical entrepreneur? Why?
    - ❑ Yes
    - ❑ No

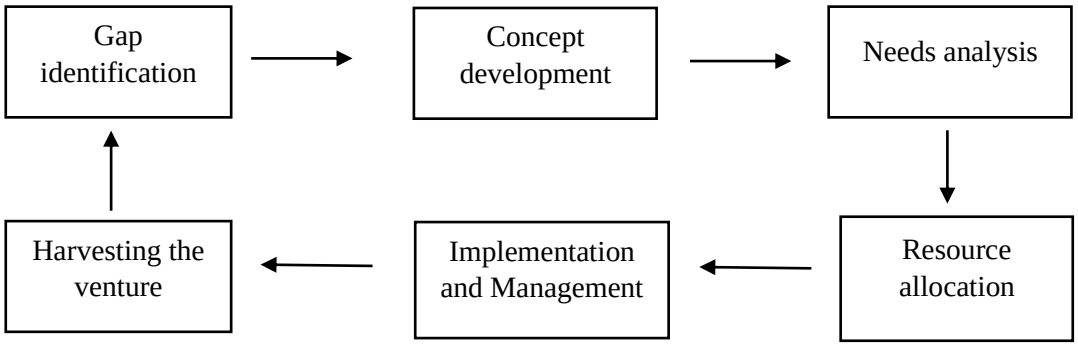
    Comments

    _____

    _____

    _____

The process of entrepreneurship consists of the following steps:



5. What is the most challenging step in this process in the pharmaceutical scenario and why?

    _____

    _____

    _____

    _____

6. On a scale from 1 to 5, to what extent do you face the following challenges when carrying out pharmaceutical entrepreneurship initiatives?
(1=Strongly disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree)

Business acumen

1 2 3 4 5

Comments

_____

_____

Competition

1 2 3 4 5

Comments

_____

_____

Inadequate capacity

1 2 3 4 5

Comments

_____

_____

Infrastructural facilities

1 2 3 4 5

Comments

_____

_____

Leadership

1 2 3 4 5

Comments

_____

_____

Meeting stakeholder needs

1 2 3 4 5

Comments

_____

_____

Project management

1 2 3 4 5

Comments

_____

_____

Regulation

1 2 3 4 5

Comments

_____

_____

Resistance to change

1 2 3 4 5

Comments

_____

_____

Time restraints

1 2 3 4 5

Comments

_____

_____

Other (please specify)

_____

_____

_____

7. To what extent do you think that a pharmaceutical entrepreneur should move from compliance to adherence to concordance?

   Compliance → Adherence → Concordance

   With respect to the challenges mentioned above (i.e. business acumen, competition, inadequate capacity, infrastructural facilities, leadership, meeting stakeholder needs, project management, regulation, resistance to change and time restraints), for which of these challenges do you believe that a pharmaceutical entrepreneur should move from compliance to adherence to concordance?

   _____

   _____

   _____

   _____

8. How important is it to move along the below chain in pharmaceutical entrepreneurship?

   Data → Information → Knowledge → Wisdom

   With respect to the challenges mentioned above (i.e. business acumen, competition, inadequate capacity, infrastructural facilities, leadership, meeting stakeholder needs, project management, regulation, resistance to change and time restraints), for which of these challenges do you believe that a pharmaceutical entrepreneur should move from data to information to knowledge to wisdom?

   _____

   _____

   _____

   _____

9. On a scale from 1 to 5, how important do you believe that the below characteristics, traits and skills are for a pharmaceutical entrepreneur to possess?
(1=Not at all important, 2=Not important, 3=Neutral, 4=Important, 5=Very important)

Autonomy

1 2 3 4 5

Competitiveness

1 2 3 4 5

Goal orientation

1 2 3 4 5

Innovativeness

1 2 3 4 5

Internal Locus of Control

1 2 3 4 5

Leadership skills

1 2 3 4 5

Motivation

1 2 3 4 5

Proactiveness

1 2 3 4 5

Problem-solving skills

1 2 3 4 5

People skills

1 2 3 4 5

Risk-taking

1 2 3 4 5

Social Responsibility

1	2	3	4	5

Strategic planning

1	2	3	4	5

Comments

_____

_____

_____

10. Which of the following functions are those of a manager, an entrepreneur or both?

Function	Manager	Entrepreneur
Allocating resources including finances, personnel and time in line with legal requisites e.g. having the necessary qualified personnel (QP/ RP/ Managing pharmacist)		
Creating and developing a business plan, securing funding, and establishing a business whilst keeping the patient as a central component of the business		
Developing strategies and plans for the company in such a way that they are in accordance with pharmaceutical regulatory sciences e.g. GMP and GDP		
Growing a business by finding new customers, expanding into new markets, and improving operations, taking into consideration the ethical codes to be observed in a pharmaceutical scenario		
Identifying opportunities to meet patients' unmet needs		
Monitoring and adjusting performance ensuring that the goals of quality, safety, efficacy and accessibility to medicines are met		
Motivating and leading personnel to achieve common objectives, namely that the patient comes first		
Taking risks by investing time and money in novel opportunities e.g. digitalisation of health data		

Comments

_____

_____

11. What are the attributes required for a pharmacist to be a manager and a pharmaceutical entrepreneur?

_____

_____

_____

_____

12. What entrepreneurship attributes were used to solve issues related to the COVID-19 pandemic and COVID-19 testing?

_____

_____

_____

_____

13. What entrepreneurship attributes are used to tackle medicine shortages?

_____

_____

_____

_____

14. On a scale from 1 to 5, which of the following aspects would you recommend to be included in training for pharmaceutical entrepreneurs?
(1=Strongly disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree)

Accounting

1 2 3 4 5

Communication skills

1 2 3 4 5

Conflict resolution

1 2 3 4 5

Financial Management

1 2 3 4 5

Human resources

1 2 3 4 5

Innovation

1 2 3 4 5

Leadership

1 2 3 4 5

Market research

1 2 3 4 5

Marketing

1 2 3 4 5

Negotiation techniques

1 2 3 4 5

Project Management

1 2 3 4 5

Public Relations

1	2	3	4	5

Quality improvement

1	2	3	4	5

Risk Management

1	2	3	4	5

Other (please specify)

_____

_____

_____

Comments

_____

_____

_____

15. To what extent do you agree that introducing an entrepreneurial appetite in pharmaceutical processes improves the following aspects?

(1=Strongly disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree)

Accountability

1	2	3	4	5

Collaboration

1	2	3	4	5

Efficiency

1	2	3	4	5

Financial rigorousness

1	2	3	4	5

Innovation

1	2	3	4	5

Market Responsiveness

1	2	3	4	5

Patient outcomes

1	2	3	4	5

Sustainability

1	2	3	4	5

Comments

_____

_____

_____

16. To what extent do you agree that potential risks related to having an entrepreneurial appetite in pharmaceutical processes may harm the following aspects?

(1=Strongly disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree)

Altruistic performance

1 2 3 4 5

Collegiality

1 2 3 4 5

Integrity

1 2 3 4 5

Patient safety

1 2 3 4 5

Quality control

1 2 3 4 5

Regulatory compliance

1 2 3 4 5

Scientific approach

1 2 3 4 5

Social responsibility

1 2 3 4 5

Comments

_____

_____

_____

17. What level of risk would you consider taking when embarking on a new pharmaceutical entrepreneurial venture?
    - ❑ Low risk
    - ❑ Moderate risk
    - ❑ High risk

Comments and Examples

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_____

Appendix 3

Questions for Focus Group with Representatives

from the Malta Medicines Authority

Questions for Focus Group

1. On a scale of 1 to 5, to what extent do you agree that the below attributes are required for a pharmaceutical entrepreneurship initiative?
   (1=Strongly disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree)

Creative thinking

1 2 3 4 5

Calculated risk-taking

1 2 3 4 5

Evidence-based decision making

1 2 3 4 5

Flexibility and adaptability

1 2 3 4 5

Innovation

1 2 3 4 5

Leadership

1 2 3 4 5

Meeting stakeholder needs

1 2 3 4 5

Robustness

1 2 3 4 5

Willingness to challenge conventional thinking

1 2 3 4 5

Other (please specify)

_____

_____

2. Can the application of the below pharmaceutical entrepreneurship attributes affect pharmaceutical scenarios differently? Kindly tick the pharmaceutical scenario/s in which the application of the mentioned attribute may have an effect.

	National Competent Authorities	**Manufacturing Industry**	**Batch release sites**	**Importation and Wholesale Dealing**	**Hospital Pharmacy**	**Community Pharmacy**
Creative thinking						
Calculated risk-taking						
Evidence-based decision making						
Flexibility and adaptability						
Innovation						
Leadership						
Meeting stakeholder needs						
Robustness						
Willingness to challenge conventional thinking						

3. Can you identify areas and initiatives implemented within the Malta Medicines Authority (MMA) which have an aspect of pharmaceutical entrepreneurship?

4. What are the strengths, weaknesses, opportunities and threats, or risks, of these initiatives?

Strengths:_____

_____

_____

_____

Weaknesses:_____

_____

_____

_____

Opportunities:_____

_____

_____

_____

Threats/Risks:_____

_____

_____

_____

Risks associated with pharmaceutical entrepreneurship initiatives will be investigated using a risk assessment tool developed in this study which consists of a risk matrix assessing the probability of the occurrence of an identified risk within a pharmaceutical entrepreneurship initiative, and the severity of impact should the identified risk occur.

		Impact **How severe would the outcome be if the risk occurred?** →				
Probability **What is the probability that the risk will occur?** ↓		**Insignificant 1**	**Minor 2**	**Significant 3**	**Major 4**	**Severe 5**
	Rare 1	1	2	3	4	5
	Unlikely 2	2	4	6	8	10
	Moderate 3	3	6	9	12	15
	Likely 4	4	8	12	16	20
	Almost certain 5	5	10	15	20	25

Risk Critical Numbers

Risk Rating Score between 1 and 4 – Low Risk

Risk Rating Score between 5 and 10 – Medium Risk

Risk Rating Score between 11 and 25 – High Risk

5. Do you agree with the risk assessment tool developed and risk classification as outlined above?

_____

_____

_____

6. Can you identify the three most pertinent risks encountered in the pharmaceutical entrepreneurship initiatives mentioned in Question 3? For each of these risks, indicate the probability of risk occurrence, and severity of impact, on the risk matrices provided.

Risk 1:

_____

		Impact **How severe would the outcome be if the risk occurred?** →				
Probability **What is the probability that the risk will occur?** ↓		**Insignificant** **1**	**Minor** **2**	**Significant** **3**	**Major** **4**	**Severe** **5**
	Rare **1**					
	Unlikely **2**					
	Moderate **3**					
	Likely **4**					
	Almost certain **5**					

Risk 2:

_____

Probability What is the probability that the risk will occur?		Impact How severe would the outcome be if the risk occurred? →				
		Insignificant 1	**Minor 2**	**Significant 3**	**Major 4**	**Severe 5**
	Rare 1					
	Unlikely 2					
	Moderate 3					
	Likely 4					
	Almost certain 5					

Risk 3:

_____

Probability What is the probability that the risk will occur?		Impact How severe would the outcome be if the risk occurred? →				
		Insignificant 1	**Minor 2**	**Significant 3**	**Major 4**	**Severe 5**
	Rare 1					
	Unlikely 2					
	Moderate 3					
	Likely 4					
	Almost certain 5					

7. For the three risks mentioned in question 6, what risk mitigation strategies were considered, or are you considering, to manage these risks? By how much can the Risk Rating Score for these risks be lowered through these risk mitigation strategies?

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

8. On a scale of 1 to 5, to what extent do you agree that potential risks related to the introduction of pharmaceutical entrepreneurial functions within regulatory sciences, in a National Competent Authority, may lead to the following aspects?

   (1=Strongly disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree)

Conflict of interest

1	2	3	4	5

Introduction of bias – knowingly or unknowingly

1	2	3	4	5

Questioning of integrity

1	2	3	4	5

Reduction in objectivity due to meeting with stakeholders in an entrepreneurship atmosphere

1	2	3	4	5

Uncertainty

1	2	3	4	5

Other (please specify)

_____

_____

_____

9. On a scale of 1 to 5, to what extent do you agree that the below pharmaceutical entrepreneurship characteristics, traits and skills, identified in this study, were used in the implementation of the above-mentioned initiatives?
(1=Strongly disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree)

Autonomy

1 2 3 4 5

Competitiveness

1 2 3 4 5

Goal-orientation

1 2 3 4 5

Innovativeness

1 2 3 4 5

Internal Locus of Control

1 2 3 4 5

Leadership skills

1 2 3 4 5

Motivation

1 2 3 4 5

Proactiveness

1 2 3 4 5

Problem-solving skills

1 2 3 4 5

People skills

1 2 3 4 5

Risk-taking

1 2 3 4 5

Social Responsibility

1	2	3	4	5

Strategic planning

1	2	3	4	5

Comments

_____

_____

_____

10. On a scale of 1 to 5, to what extent do you agree that the below actions may be used to ensure accountability when carrying out pharmaceutical entrepreneurship initiatives? (1=Strongly disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree)

Defining clear roles and responsibilities

1 2 3 4 5

Setting specific and measurable goals: SMART goals

1 2 3 4 5

Establishing performance metrics (key performance indicators)

1 2 3 4 5

Reviewing progress: including identification of opportunities for improvement

1 2 3 4 5

Fostering a culture of transparency and open communication

1 2 3 4 5

Gathering feedback and carrying out evaluation

1 2 3 4 5

Carrying out internal audits

1 2 3 4 5

Other (please specify)

_____

_____

_____

_____

_____

Appendix 4

Definitions for Pharmaceutical Entrepreneurship

Characteristics, Traits and Skills

Definitions for Pharmaceutical Entrepreneurship Characteristics, Traits and Skills

Pharmaceutical Entrepreneurship characteristic, trait or skill	Definition	Reference
Autonomy	Autonomy refers to when individuals make their own choice independent of others and the independent actions of an individual or team in bringing forth an idea or vision and carrying it through to completion.	Albert and Couture, 2013
Competitiveness	Competitiveness refers to a drive to succeed, a commitment to personal development and an enjoyment of competition.	Urbig et al, 2020
Goal-orientation	Goal orientation refers to the adoption of goals in situations that lead to achievement, motivation to succeed or the mental framework that shapes how people interpret and react to achievement scenarios.	Culbertson et al, 2011
Innovativeness	Innovativeness refers to a diligent pursuit of original concepts, novel prospects, and other possibilities that may ultimately result in improved value-based solutions (such as goods, services and processes) for the market.	Smith and Jambulingam, 2017
Internal locus of control	An internal locus of control refers to the ability to take initiative, be effective, take control over one's own life and accept responsibility for one's own actions. Individuals having a high internal locus of control consider that their interactions with their surroundings will result in predictable outcomes.	Dawwas and AL-Haddad, 2018

Leadership skills	Leadership refers to the capacity to lead, motivate, and inspire others in an effort to achieve a common goal.	DeVolld et al, 2022
Motivation	Motivation refers to the factors that originate both within and beyond individuals which determine their behaviour and actions to occur in a certain manner.	Murnieks et al, 2020
Proactiveness	Proactiveness refers to the tendency of individuals to act in spite of external restrictions, to intervene in, or control, predicted occurrences and in so doing have an impact on, and possibly transform, the environment in which they operate.	Zhao and Smallbone, 2019
Problem-solving skills	Problem-solving skills refer to the process of the identification of a problem, the development of potential solutions to address the problem, and the taking of appropriate actions to counteract the problem.	Baggen et al, 2017
People skills	People skills refer to the capacity to interact with people in a positive, effective and successful manner to achieve good results and promote a favourable environment.	Rosado-Cubero et al, 2022
Risk-taking	Risk-taking refers to the ability to deal with ambiguity, operate in an environment of uncertainty, and the disposition to take calculated risks.	Mattingly et al, 2019
Social responsibility	Social responsibility refers to an individual's responsibility to behave in the best interest of society and the environment and participate in activities that advance social development.	Blundel et al, 2010

Strategic planning	Strategic planning refers to the ability to devise plans and implement strategies for the facilitation of processes and success of an organisation. Strategic planning skills also involve the evaluation of results obtained through the execution of a strategic plan and their relation to overall aims, goals and objectives.	Ben Messaoud, 2022

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Appendix 5

Training Programme for Pharmaceutical Entrepreneurship

Training Programme for Pharmaceutical Entrepreneurship

A training programme for the advancement of pharmaceutical entrepreneurship was developed. The training programme is intended for individuals working within the pharmaceutical scenario, aims to offer the necessary knowledge and skills to identify, create and pursue new opportunities and implement new ideas in a successful and sustainable manner, whilst nurturing an entrepreneurship spirit within pharmaceutical processes and creates a balance between financial sustainability and patient benefits. The training programme consists of 13 training aspects identified through this study: Communication Skills, Conflict Resolution, Financial Management, Human Resources, Innovation, Leadership, Market Research, Marketing, Negotiation Techniques, Project Management, Public Relations, Quality Improvement and Risk Management. It is significant that the curriculum evolving around these topics is related to the special considerations surrounding a pharmaceutical scenario. The particular case of health, especially as related to medicines use and accessibility, presents the need of a unique pharmaceutical knowledge related to these priorities in a healthcare scenario, including vulnerabilities of patients and sustainability where the fundamental principles of these 13 specialities have to be taken into consideration. It is these special considerations that compose a training programme for pharmaceutical entrepreneurship.

1. Communication Skills

Communication skills are required when communicating with a person, group or organisation using verbal or non-verbal cues in the form of oral, written or interpersonal communication and lead to positive outcomes (Gee et al, 2019). Communication is considered an essential competence for pharmacists worldwide (Kerr et al, 2021). Effective communication skills are essential for the success of any entrepreneur (Soeryanto Soegoto, 2018), including entrepreneurs involved in pharmaceutical processes. Communication skills are critical for pharmaceutical entrepreneurs to succeed in building and maintaining relationships with stakeholders, including investors, regulators, patients and healthcare professionals, when pitching ideas to investors to secure funding for entrepreneurial ventures, to be able to collaborate with team members to ensure that everyone is working towards the same goals, and to educate patients and healthcare professionals about products or services. Pharmaceutical entrepreneurs are required to communicate effectively and clearly to help build trust and confidence in the pharmaceutical entrepreneur, the company and the product or service being offered. In the pharmaceutical scenario one often needs to finely balance between the advantages and disadvantages of using a medicinal product. This requires communication in presenting the advantages of, for example, the efficacy of a medicinal product versus the disadvantages of taking the medicinal product, including the possibility of adverse effects. Such a balancing act requires a combination of communication skills (Ilardo and Speciale, 2020).

Aims

This module aims to:

- Develop an understanding of the importance of effective communication for the efficient management of pharmaceutical processes and promotion of quality care.

- Develop effective verbal and nonverbal communication skills to convey ideas and information clearly and confidently, and facilitate positive interactions with stakeholders, including suppliers, employees, healthcare professionals, patients and the public in a way that inspires confidence whilst ensuring patient safety and continuous quality care.

- Enable participants to be able to adapt communication styles to different situations and audiences pertaining to their role in health with relevance to enabling the pharmaceutical entrepreneur to move from a process of compliance to adherence to concordance in decision-making, where concordance is considered to be the pinnacle of successful pharmaceutical communication.

- Expose participants to the importance of active listening and be able to use active listening techniques to enhance communication and build relationships with stakeholders, including patients.

- Expose participants to cultural awareness and sensitivity, enabling the communication of ideas across diverse cultures.

Learning Outcomes

Knowledge and Understanding

By the end of the module participants will be:

- Knowledgeable on the principles of effective communication and its importance in the pharmaceutical scenario and the promotion of quality care.
- Familiar with the various communication channels available and able to identify the most appropriate channels for different communication scenarios related to pharmaceutical endeavours.
- Knowledgeable on the importance of ethical communication practices and their impact on stakeholder trust and loyalty, keeping pharmaceutical ethical codes in mind.
- Knowledgeable of the significance of nonverbal communication and its impact on communication effectiveness within the pharmaceutical scenario.
- Able to understand the importance of feedback and reflection for continuous improvement of communication skills with stakeholders including patients.
- Familiar with the role of communication in building a strong reputation.

Skills

By the end of the module participants will be able to:

- Demonstrate active listening skills and apply questioning techniques to gain clarity in communication, to be able to provide quality patient care.
- Develop assertive communication skills to influence stakeholders.
- Develop empathy and emotional intelligence to facilitate positive interpersonal relationships and respond to patient concerns.

2. Conflict Resolution

Conflict may be considered to be an interacting process which arises due to discord, disagreement or incompatibility inside or between individuals, groups, or organisations (Afzalur, 2002). Conflicts tend to arise in various scenarios, including pharmaceutical processes, due to differing opinions on how to approach problems and serve patients' interests in the best possible way. The effective management of conflict leads to the fostering of positive relationships and creates a productive work environment for the effective management of pharmaceutical processes and the provision of optimal patient care. Conflict resolution skills promote teamwork and collaboration in an environment of mutual respect, thereby improving productivity and efficiency to meet patient care needs, improve decision-making and problem solving, minimise risks, including those related to delays in product development or regulatory approval, enhance communication, improve morale and increase productivity (Haumschild et al, 2015).

Aims

This module aims to:

- Identify the common causes and types of conflict that can arise and develop strategies to manage conflicts effectively, to be able to provide quality patient care collectively.
- Introduce the principles and models of conflict resolution within the pharmaceutical scenario.
- Outline the need for active listening, empathy, and assertiveness, to promote open and respectful communication during conflict resolution, and facilitate an

environment in which everyone is working towards the same goals, namely, to serve the interests of patients and public health.

- Expose participants to the role of cultural and diversity issues in conflict resolution and be able to incorporate inclusive practices into conflict resolution processes.

Learning Outcomes

Knowledge and Understanding

By the end of the module participants will be:

- Able to understand the role of conflict resolution in fostering positive relationships and creating a productive work environment.

- Able to understand the common causes and types of conflict in the workplace, as well as the potential consequences of unresolved conflict within the pharmaceutical scenario.

- Familiar with the principles and models of conflict resolution, such as negotiation, mediation, and arbitration whilst keeping pharmaceutical ethical codes in mind.

- Knowledgeable of the emotional and psychological aspects of conflict, including the role of emotions in decision-making and the impact of stress and anxiety on conflict resolution.

Skills

By the end of the module participants will be able to:

- Identify and analyse conflicts that arise in the workplace and navigate difficult conversations using the appropriate conflict resolution strategy.
- Effectively communicate with individuals involved in a conflict.
- Mediate conflicts, using techniques such as reframing, questioning, and creative problem-solving.

3. Financial Management

Financial management plays a crucial role in the success of pharmaceutical entrepreneurial endeavours as it enables pharmaceutical entrepreneurs to make informed decisions about pharmaceutical operations, prioritise initiatives and ensure sustainability and long-term viability to be able to continue to meet patient needs. A strong financial foundation is required for pharmaceutical entrepreneurs to manage resources, mitigate risks, and make informed decisions through budgeting and planning including forecasting revenue and expenses, determining the amount of funding needed, allocating resources and establishing financial goals. Financial management is essential in the fast-evolving healthcare environment for providers and institutions to establish new revenue streams, create cost-cutting strategies and implement long-term investment management. Good financial management enables pharmaceutical entrepreneurs to make informed investment decisions that support the growth and sustainability of healthcare systems (Adulin and Pan, 2022).

Informed financial decisions in the carrying out of a pharmaceutical entrepreneurial endeavour requires special skills that go beyond the basic knowledge and understanding of accounting principles, keeping in mind that accounting has a significant role in the development of any enterprise (Shkromyda et al, 2021). An introduction to accounting concepts and principles are presented to provide participants with a basic knowledge, understanding and skills required to make informed financial decisions when carrying out pharmaceutical entrepreneurial endeavours.

Aims

This module aims to:

- Introduce financial management principles and concepts as they apply to the pharmaceutical scenario, whilst keeping the patient as a central component of the business.

- Build a working knowledge of the creation and management of a financial plan for a pharmaceutical entrepreneurial endeavour, including the identification and evaluation of potential sources of funding, and budgeting within the pharmaceutical scenario such as disruption impacts in healthcare, for example budgeting needs for changes in treatment protocols.

- Discuss financial decision-making, including an understanding of the impact of financial decisions, weighing different options available to address pharmaceutical needs and choosing the best course of action to be able to serve patient needs.

- Introduce financial statements to enable participants to analyse financial performance, including the identification of strengths and weaknesses within financial performance in a pharmaceutical scenario, which entails the incorporation of financial assets attested to health achievements, for example a balance sheet must incorporate the standard aspects of a balance sheet but also a balance in pharmaceutical successes, such as the inclusion of a more effective analgesic within the portfolio which produces a better health outcome.

- Discuss cost management including how to measure and manage costs effectively to help pharmaceutical entrepreneurs make decisions that enable sustainability and facilitate enterprises to continue to meet patient needs.

Learning Outcomes

Knowledge and Understanding

By the end of the module participants will be:

- Familiar with the principles of capital budgeting and how to evaluate investment opportunities in the pharmaceutical scenario for new or existing ventures.

- Able to describe the different types of financial risks and ways in which they can be managed.

- Knowledgeable on how to apply the basic principles of accounting to the pharmaceutical scenario and the special concerns of business strategy and decision-making in the context of pharmaceutical entrepreneurship.

- Familiar with the key financial statements used in accounting and their interpretation in the pharmaceutical scenario through the relevant data and

information presented within them, including notes correlating to the intangible achievements which are remarkable in a pharmaceutical scenario.

- Familiar with financial plans and budgets, including sales forecasts, cost estimations and project cash flows as they relate to pharmaceutical entrepreneurship.

- Knowledgeable of the ethical considerations involved in financial management, financial reporting and decision-making, including the importance of accurate financial reporting and the consequences of fraudulent or inaccurate financial statements which could lead to serious consequences in the case of pharmaceutical entrepreneurship endeavours.

Skills

By the end of the module participants will be able to:

- Create and manage a financial plan for a pharmaceutical entrepreneurial initiative.

- Identify and evaluate potential sources of funding.

- Manage working capital and cash flow for a pharmaceutical entrepreneurial initiative.

- Use financial models and tools to support decision-making in a pharmaceutical enterprise, in the interest of patients and public health.

- Record pharmaceutical financial transactions accurately and efficiently.

- Use financial data to analyse business performance and identify areas for improvement, whilst keeping patients as a central component of the business.

4. Human Resources

Human Resources (HR) management facilitates the success of pharmaceutical companies and provides a competitive advantage (Venkateswara Reddy and Sekhara Rao, 2019). Effective HR practices are crucial for attracting, training and retaining skilled employees within the pharmaceutical scenario. Attracting and retaining personnel remains one of the biggest challenges in pharmacy (Babapour et al, 2018; Triantafillidou and Koutroukis, 2022). HR management can help pharmaceutical entrepreneurs to address this challenge by providing opportunities for employee development and growth, competitive compensation packages, and promoting a positive workplace culture through aspects including open communication and work-life balance initiatives, thereby retaining talent (Jindal and Shaikh, 2020).

Aims

This module aims to:

- Introduce HR management principles and concepts for the efficient management of personnel whilst promoting a positive environment that promotes professionalism, quality patient care, and professional development.
- Give an overview on how to create and manage a HR plan.
- Give an overview of performance management systems to promote the provision of service excellence for patients.
- Discuss the role of employee engagement and development in creating a strong organisational culture in different pharmaceutical scenarios.

Learning Outcomes

Knowledge and Understanding

By the end of the module participants will be:

- Knowledgeable about legislation as related to the management of human resources.
- Familiar with the principles of performance management and how to design and implement effective performance management systems within different pharmaceutical scenarios.
- Familiar with the ethical considerations in human resources management and the implications of HR decisions for stakeholders including patients.
- Able to understand the role of technology and innovation in transforming HR practices in the pharmaceutical scenario.

Skills

By the end of the module participants will be able to:

- Prepare a human resources plan for a pharmaceutical enterprise.
- Design and implement effective talent acquisition strategies and processes to manage employee relations.
- Manage employee engagement and development programs for a pharmaceutical enterprise.
- Motivate and engage staff so as to maintain optimal patient care, ensure patient safety, and inspire confidence.

5. Innovation

Critical thinking, creativity, and problem-solving skills are becoming increasingly important for professionals in all industries, including pharmacy, as they are important aspects which foster innovation (Cain, 2016). The health care system is under pressure from the exponentially growing volume of biomedical data, technological advancements, and demands for cost-effective care, making innovation and entrepreneurship paramount for the development of pharmaceutical services (Mogul et al, 2020; Afeli and Adunlin, 2021). Research suggests that pharmaceutical entrepreneurship is one of the main forces promoting innovation in pharmacy practice (Mattingly et al, 2019).

Aims

This module aims to:

- Introduce the principles and processes of innovation within the pharmaceutical scenario.
- Discuss innovation strategies for pharmaceutical enterprises to develop alternative and novel approaches to solving health care issues.
- Outline the role of innovation in creating a competitive advantage in the pharmaceutical scenario.
- Give an overview of the identification and evaluation of opportunities for pharmaceutical innovation.
- Introduce principles of intellectual property protection and how to manage intellectual property assets for pharmaceutical entrepreneurial ventures.

Learning Outcomes

Knowledge and Understanding

By the end of the module participants will be:

- Familiar with the principles of open innovation and how to collaborate effectively with external partners to drive innovation within the pharmaceutical scenario.
- Knowledgeable of the regulatory environment for pharmaceutical innovation and the role of regulatory agencies in approving and monitoring new medical products.
- Able to describe the role of data analytics, digital technologies and advancements in the driving of innovation in the pharmaceutical scenario.
- Able to recognise the importance of risk management and the ethical considerations related to pharmaceutical innovation.
- Able to understand the importance of stakeholder engagement and communication for driving innovation of medicinal and medical products.
- Familiar with the role of corporate culture and leadership in fostering a culture of innovation in the pharmaceutical industry.

Skills

By the end of the module participants will be able to:

- Examine issues in healthcare from a variety of perspectives and develop innovative approaches to address these issues.

- Identify and evaluate opportunities for innovation and effectively communicate innovative ideas to improve pharmaceutical processes.
- Create and implement an innovation strategy for a pharmaceutical enterprise.
- Collaborate effectively with external partners to drive innovation for the benefit of patients.
- Engage in innovative activities through creative thinking to develop improved solutions to reach professional goals.

6. Leadership

Leadership refers to the capacity to lead, motivate, and inspire others in an effort to achieve a common goal (DeVolld et al, 2022). Effective leaders provide their team members with a vision, and aid organisations in attaining the objectives set so as to realise that vision. A lack of leadership skills has been presented as one of the reasons why the pharmacy profession has not fully recognised its potential to meet unmet healthcare needs (Panther et al, 2019). Within healthcare, leadership entails the organising of patient health outcomes through the offering of guidance, motivation, support, coordination and advocacy for patients, by healthcare professionals being proactive in their roles and assuming leadership responsibilities, regardless of their position. It is crucial for pharmaceutical entrepreneurs to enhance their leadership abilities during difficult economic times, when making the most of healthcare professionals' talents and resources becomes a top priority. Leadership skills support the change required with the current shift in the pharmacy profession, where emphasis is being given to patient-centred care (Ali et al, 2022).

Aims

This module aims to:

- Give an overview of the principles and practices related to effective, ethical leadership in the context of patient care.
- Build the necessary knowledge and skills required to lead a pharmaceutical enterprise, whilst ensuring that patient needs are the primary focus in decision making processes.
- Discuss the role of leadership in creating a culture of innovation and collaboration within the pharmaceutical scenario to optimise patient healthcare outcomes.

Learning Outcomes

Knowledge and Understanding

By the end of the module participants will be:

- Knowledgeable of responsibilities and ethical considerations related to leadership whilst delivering compassionate, robust patient-centred care.
- Knowledgeable about human behaviour and the needs of individuals to enhance team performance and improve patient service.
- Able to understand the importance of stakeholder management and communication to improve collaboration and address health disparities.
- Familiar with the role of leadership in driving business strategy and growth within a pharmaceutical enterprise strategy.

- Able to understand the role of leadership in promoting public health and patient welfare.
- Develop resilience and personal self-awareness by considering who the participants are as inclusive leaders and identifying areas of strength and needs for further development.

Skills

By the end of the module participants will be able to:

- Demonstrate initiative in setting and accomplishing shared goals.
- Build and manage effective teams having a common goal of delivering patient-centred care.
- Manage risks when carrying out pharmaceutical entrepreneurial ventures.

7. Market Research

Market research consists of the gathering and analysing of information regarding a target market that an entrepreneur is considering for an entrepreneurial initiative and is considered an essential part of planning. Market research may include an analysis of competition in the market, an analysis of demographic information related to potential clients, including patients, and the monitoring of market trends. The primary goal of market research is to garner an understanding of patient needs to identify possible pharmaceutical entrepreneurial prospects (Laverty and Little, 2020).

Aims

This module aims to:

- Build the necessary knowledge and skills to conduct effective market research to lead to the successful identification of opportunities to meet patient needs.
- Discuss the different types of market research methods used for pharmaceutical entrepreneurial initiatives whilst describing the role of market research in strategic planning and decision-making.
- Discuss how to use market research and data analytics to identify new pharmaceutical entrepreneurial opportunities to solve health care issues and create a competitive advantage.
- Discuss how to effectively communicate market research findings to internal and external stakeholders.

Learning Outcomes

Knowledge and Understanding

By the end of the module participants will be:

- Able to understand the importance of using market research to identify patient unmet needs and create new opportunities which address health disparities.
- Able to describe the advantages and disadvantages of the various quantitative and qualitative market research methods and techniques within the pharmaceutical scenario.

- Knowledgeable of the importance of data quality and its impact on market research findings.
- Able to understand the importance of data privacy and security when conducting market research for pharmaceutical entrepreneurial initiatives.
- Knowledgeable of the impact of external factors such as the regulatory environment and competition on market research within the pharmaceutical scenario.

Skills

By the end of the module participants will be able to:

- Design and implement effective market research strategies to analyse the scenario being considered for a potential pharmaceutical entrepreneurial venture.
- Analyse and interpret market data and draw insights from market research findings to make informed decisions and provide quality patient care.
- Manage market research projects effectively and efficiently.

8. Marketing

Marketing is a critical aspect to consider to successfully launch and nurture a new enterprise or venture and enable the building and maintaining of relationships with key stakeholders. Marketing creates awareness about a new product, service or initiative and plays a critical role in shaping the public's perception thereof (Lam and Harker, 2015). Research suggests that marketing has a positive effect on an enterprise's performance (Alqahtani et al, 2022). Marketing is considered one of the pillars of pharmaceutical companies and includes the promotion of pharmaceutical enterprises and health-related products, brands and services to the general public and individuals working in the medical industry, for example through visits to healthcare professionals by medical representatives (Al Thabbah et al, 2022; Kejariwal et al, 2022). Pharmaceutical entrepreneurs must establish strategic marketing plans that do not compromise the ethical code of conduct to be observed in a pharmaceutical scenario (Al Thabbah et al, 2022).

Aims

This module aims to:

- Introduce marketing strategies and tactics used in the pharmaceutical scenario.
- Discuss the role of innovation in developing a market strategy, and how marketing can guide the development of novel medical products and services.
- Discuss the regulatory environment surrounding marketing in the pharmaceutical scenario and its impact on marketing strategies.
- Expose participants to the importance of measuring the effectiveness of marketing campaigns.

Learning Outcomes

Knowledge and Understanding

By the end of the module participants will be:

- Knowledgeable of the role of marketing in product life cycle management in the pharmaceutical scenario.
- Able to understand the impact of external factors on pharmaceutical marketing.
- Able to understand the role of marketing in creating value for patients and stakeholders in the pharmaceutical scenario and the role of innovation and creativity in developing successful marketing campaigns.
- Knowledgeable of the importance of branding and positioning in marketing for medical products.
- Able to explain the importance of relationship marketing and social networks.

Skills

By the end of the module participants will be able to:

- Design and implement marketing campaigns for medical products or services.
- Measure the effectiveness of marketing campaigns using metrics such as return on investment and sales growth.
- Create and deliver marketing messages to various stakeholders, including healthcare professionals, patients and the public.

9. Negotiation Techniques

Negotiation is required when dealing with multiple parties and requires preceding planning, preparation and patience to be successful. The goal of any negotiation is to create value and determine conditions on which parties with different and frequently conflicting goals will cooperate. One should gather information, be aware of priorities and principles, find areas of agreement, choose a walk-away position, and attempt to identify the next best option when preparing for a negotiation. The capacity to use relationships, expertise, power, money, time, and personality in negotiations is a set of abilities that may be learned and honed through experience. All parties win in successful negotiations (Hake and Shah, 2011). Negotiation is a central component of entrepreneurship. When running and growing a pharmaceutical entrepreneurial venture, entrepreneurs must come to agreements with diverse parties in order to obtain human and financial resources. Negotiation skills are essential for entrepreneurial success since the way in which entrepreneurs engage and communicate influences their outcomes (Artinger et al, 2015).

Aims

This module aims to:

- Introduce a systematic framework to understand negotiation and the main principles of effective negotiation to achieve successful outcomes for the benefit of patients in a sustainable way.
- Discuss how to effectively prepare for and conduct negotiations in the pharmaceutical scenario.

- Establish skills in building and maintaining sustainable and respectful relationships with key stakeholders in the pharmaceutical scenario, including suppliers, healthcare professionals, patients and caregivers, to achieve objectives in the long term.

Learning Outcomes

Knowledge and Understanding

By the end of the module participants will be:

- Able to describe different negotiation techniques and strategies as they apply to the pharmaceutical scenario.
- Knowledgeable of the impact of negotiation outcomes on the overall success of pharmaceutical enterprises and the role of negotiation in strategic decision-making in the context of pharmaceutical entrepreneurship.
- Knowledgeable of the importance of ongoing relationship management, and the importance of building trust and rapport with stakeholders, through active listening and effective communication.
- Able to understand the impact of cultural and interpersonal factors on negotiation outcomes.

Skills

By the end of the module participants will be able to:

- Prepare and plan effective negotiation strategies, including the identification and prioritisation of negotiation objectives whilst ensuring patient safety and continuous quality care.

- Develop creative solutions using problem-solving techniques for distributing value and strengthening relationships with the aim of reaching win-win outcomes in negotiations.
- Prepare and present effective arguments in negotiations.
- Manage emotions, demonstrate objectivity and maintain a professional demeanour during negotiations.

10. Project Management

Entrepreneurship and project management have long been linked in the literature (Belfort et al, 2016). Entrepreneurs act as project leaders during the entrepreneurial process as they explore and exploit opportunities, and implement initiatives, whilst adapting to emerging trends and challenges. Within entrepreneurship, innovative projects are managed in complex and uncertain environments (Tamberg et al, 2021). The three main dimensions of project management are time, resources including human, infrastructural and financial resources, and specifications which define the quality and quantity of the project at hand (Grudzinskas, 2006). Project management is essential to meet the particular regulatory, compliance, and quality-related needs which are particular to the pharmaceutical sector.

Aims

This module aims to:

- Introduce the fundamentals of project management in the context of pharmaceutical entrepreneurship and its role in driving innovation.
- Discuss the tools and techniques required for successful project planning, execution, and monitoring for pharmaceutical entrepreneurial initiatives.
- Develop the skills necessary to manage project stakeholders and communicate effectively with team members and external partners.

Learning Outcomes

Knowledge and Understanding

By the end of the module participants will be:

- Knowledgeable of the basic principles of project management, including project initiation, planning, execution, monitoring, and closing for the efficient management of pharmaceutical processes and promotion of quality care.
- Familiar with project management and evaluation tools and techniques, such as Gantt charts, critical path analysis, and risk management strategies.
- Knowledgeable of the challenges of project management in the pharmaceutical setting, including regulatory compliance, intellectual property issues, and the ethical codes to be observed in a pharmaceutical scenario.

Skills

By the end of the module participants will be able to:

- Create project plans, schedules, and budgets including effective strategies to engage team members during times of change.
- Identify and manage project risks and develop contingency plans.
- Evaluate project outcomes and identify opportunities for continuous improvement whilst delivering compassionate, robust patient-centred care.

11. Public Relations

Public relations play a pivotal role in the building of relationships between stakeholders and may be advantageous to both enterprises and society, if it is used strategically with the right tools and ethical concerns. Public relations are crucial, particularly in industries such as healthcare, where communication is essential for improving patient outcomes and patient engagement. Public relations support communication strategies so that the public may receive the required health and wellbeing information. A key attribute for public relations in healthcare is the need to listen to the patients, rather than just transmitting a message by a pharmaceutical enterprise (Hasenmeyer and Topic, 2017).

Aims

This module aims to:

- Discuss the importance of public relations as a process of communication for pharmaceutical enterprises to build a mutually beneficial relationship with the public.
- Discuss how to effectively communicate with stakeholders, such as healthcare professionals, patients and the general public.
- Expose participants to skills required to create and execute public relations campaigns.
- To understand the ethical considerations involved in public relations for pharmaceutical enterprises.

Learning Outcomes

Knowledge and Understanding

By the end of the module participants will be:

- Familiar with the importance of public relations in the pharmaceutical scenario and the role it plays in building and maintaining a positive reputation.
- Able to understand the needs and preferences of different stakeholder groups, and tailor communication strategies accordingly to create awareness about pharmaceutical brands, products and services.
- Able to understand the ethical considerations involved in pharmaceutical public relations, such as the need for transparency and accuracy.

Skills

By the end of the module participants will be able to:

- Plan and execute a public relations campaign, including defining goals, identifying target audiences, and evaluating results whilst keeping pharmaceutical ethical codes in mind.
- Develop effective messaging and communication materials, including press releases, social media content and marketing collateral.

12. Quality Improvement

Training in quality improvement has the potential to positively impact the attitudes, knowledge, and behaviours of participants undergoing training.[16] Both quality improvement and pharmaceutical entrepreneurship activities aim to improve healthcare, whether through more effective and efficient use of current processes, or the introduction of novel ideas, with the potential to alter the trajectory of improvements in entrepreneurial activities. Innovation skills are a natural complement to quality improvement activities (Beninger et al, 2019). Within the pharmaceutical scenario, quality improvement refers to the application of methodical techniques and technologies to raise the standard of patient care to promote safety, effectiveness and a positive patient experience (Latif et al, 2021).

[16] The Health Foundation. Quality improvement training for healthcare professionals. London: The Health Foundation; 2012 [cited 2023 May 29]. Available from URL: https://www.health.org.uk/sites/default/files/QualityImprovementTrainingForHealthcareProfessionals.pdf

Aims

This module aims to:

- Give an overview of the principles of quality improvement in the context of pharmaceutical entrepreneurship.
- Discuss tools and techniques required for successful quality improvement within pharmaceutical entrepreneurship initiatives, identify system errors and implement solutions where possible.
- Discuss quality metrics and how to measure and improve quality in the pharmaceutical scenario.

Learning Outcomes

Knowledge and Understanding

By the end of the module participants will be:

- Able to recognise the importance of quality improvement in the pharmaceutical scenario, and its role in ensuring patient safety and improving business performance.
- Familiar with the basic principles of quality improvement, including the Plan-Do-Study-Act cycle and Total Quality Management.
- Knowledgeable of regulatory requirements and guidelines for quality assurance in the pharmaceutical scenario.

Skills

By the end of the module participants will be able to:

- Identify and analyse quality issues, and develop and implement solutions, using quality improvement tools and techniques to complete a quality improvement cycle.
- Collect, analyse, and interpret data to measure and improve quality in the pharmaceutical scenario.

13. Risk Management

The link between risk and entrepreneurship is well established as risk is inevitable when managing uncertainty in entrepreneurial endeavours. Entrepreneurs are understood to take calculated risks during their ventures, by considering available information from credible sources and knowledge obtained from previous experiences (Norton and Moore, 2006; Smith and Jambulingam, 2017; Melović et al, 2022). An essential and crucial component of the company's overall operations is Risk Management (RM), which includes activities related to how risk is handled namely planning, identifying, analysing, compiling proactive and reactive tactics, monitoring, and controlling risks. The phases of RM are context definition, risk identification, risk analysis and evaluation, risk treatment, risk monitoring and reviewing (Hisrich and Ramadani, 2017).

Aims

This module aims to:

- Introduce the fundamentals of RM as they relate to the pharmaceutical scenario.
- Discuss the identification and assessment of potential risks associated with pharmaceutical entrepreneurial initiatives.
- Outline the functional structures, roles and responsibilities required to ensure the effective implementation of RM in pharmaceutical endeavours.

Learning Outcomes

Knowledge and Understanding

By the end of the module participants will be:

- Knowledgeable of the principles related to RM to maximise opportunities and minimise threats when conducting pharmaceutical entrepreneurial initiatives, including the potential consequences of not managing risks effectively.
- Familiar with the tools and techniques used for Risk Assessment, such as risk registers, risk bow-ties and risk matrices.
- Familiar with the relevant risk framework including roles & responsibilities, policies and appropriate guidance to ensure patient safety and continuous quality care.

Skills

By the end of the module participants will be able to:

- Conduct a risk-benefit analysis for the implementation of an innovative idea or simulated pharmaceutical entrepreneurial activity.
- Develop and implement risk management plans, including risk mitigation strategies and contingency plans.
- Monitor, review and evaluate the effectiveness of risk management plans over time.

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Appendix 6

Dissemination of results in international fora

Poster presentation, 80th International Pharmaceutical Federation World Congress of Pharmacy and Pharmaceutical Sciences, Seville, September 2022

L-Università ta' Malta | Faculty of Medicine & Surgery | Department of Pharmacy

ENTREPRENEURSHIP IN PHARMACEUTICAL PROCESSES

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INTRODUCTION

- The current environment in healthcare is affected by several factors including issues related to rising costs and affordability, challenges of chronic diseases, evolvement of the workforce, benefits and challenges of regulatory sciences and situations such as crisis management in a pandemic or conflict.
- Pharmacists are presented with the challenge of undertaking innovative practices to transform the healthcare system and create novel opportunities and revenue streams. Innovation and entrepreneurship are critical aspects which support economic growth and development.
- The application of entrepreneurship to pharmaceutical processes may enable the achievement of improvements in healthcare.

AIMS

i) To examine the contribution entrepreneurship has to pharmaceutical innovation

ii) To study the concept and role of education in the evolvement of pharmaceutical entrepreneurship

METHOD

Systematic literature review

Examination of innovative aspects and how entrepreneurship skills improved innovation conducted

Critical analysis of the literature undertaken

Semi-structured interviews

Held with entrepreneurs

Gain perspective, understand concepts and identify issues

Areas included proactiveness and competitive aggressiveness and pedagogical efficacy vs real-world approach

Educational programme

Developed for pharmaceutical entrepreneurs

Based on responses to interview questions

RESULTS

- The application of entrepreneurial skills enables the evolvement of pharmaceutical processes to meet patients' needs in a robust and efficient manner.
- Literature suggests that:
  - i. Individual characteristics and personality traits are key to motivating entrepreneurial intentions and behaviours
  - ii. Training is another significant factor
- Entrepreneurial traits identified through literature include:

Autonomy	Proactiveness	Motivation
Risk-taking	Problem-solving	Leadership
Internal locus of control	People liking	Innovativeness

- Research shows that no consensus exists for entrepreneurship in pharmacy practice and education.
- Semi structured interviews addressed:
  - i. How entrepreneurship contributes to a pharmacoeconomically sound innovation
  - ii. The concept and role of education and training in the evolvement of entrepreneurship
- Interviews showed how an interdisciplinary approach carried out through enterprising skills has a higher potential to produce valuable outcomes.
- The educational programme aims to offer the necessary knowledge and skills to identify, create and pursue new opportunities and implement new ideas in a successful and sustainable manner.

CONCLUSION

In the context of this research entrepreneurship is considered:

i. Beyond the traditional sense of business and financial planning

ii. As a product of creative thinking, the taking of calculated risk and evidence-based decision making as related to a progressive pharmaceutical scenario

The evolvement of concepts in entrepreneurship in pharmaceutical processes enables the identification of knowledge and competences needed to develop and advance new endeavours.

Funding: This research has been funded by the Tertiary Education Scholarships Scheme.

Poster presentation, European Society of Clinical Pharmacy Symposium, Prague, October 2022

L-Università ta' Malta | Faculty of Medicine & Surgery | Department of Pharmacy

APPLYING PHARMACEUTICAL ENTREPRENEURSHIP AS A PHARMACOECONOMIC PARADIGM SHIFT IN CLINICAL PHARMACY

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INTRODUCTION

Healthcare systems are constantly faced with challenges which require the undertaking of innovative practices for their transformation. Innovative healthcare systems support the notion of clinical pharmacy. Pharmaceutical entrepreneurship is a critical aspect to support the growth and development of clinical pharmacy in innovative healthcare systems.

AIMS

i. To examine the use of entrepreneurship skills in reducing polypharmacy as a means of promoting active aging including pharmacoeconomic implications.
ii. To exploit the concepts of pharmaceutical entrepreneurship to drive forward the introduction of clinical pharmacy in active aging institutions.

METHOD

- Phase 1: a systematic literature review of entrepreneurship skills related to reducing polypharmacy in critical areas and their application and adaptation to clinical pharmacy settings, with special emphasis to traits and skills that contribute to innovation.
- Phase 2: semi-structured interviews held with the participants listed in Figure 2.
- Phase 3: an examination of the needs required for a training programme developed for the application of entrepreneurship skills in pharmaceutical entrepreneurship in a clinical scenario.

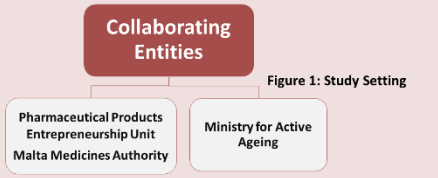

Figure 1: Study Setting

Figure 2: Study Participants

RESULTS

- Literature showed that no consensus exists on the pharmacoeconomic impact of entrepreneurship in pharmacy practice and training.
- The semi structured interviews addressed:
  i. How entrepreneurship contributes to a pharmacoeconomically sound clinical innovation
  ii. The concept and role of education and training in the evolvement of entrepreneurship
  iii. The ethics, accountability and good governance of the use of entrepreneurship skills
- A training program in the application of entrepreneurship skills in a clinical scenario should include emphasis on:
  i. Creative pharmacy concepts
  ii. Divergent-thinking in patient-care
  iii. Risk taking in saving lives
  iv. Versatility and critical thinking
  v. Cultural, economic and social public dealing competences
  vi. Persistence in disruptive pharmaceutical development
- Entrepreneurship is shown to be considered a product of creative thinking, the taking of calculated risk when embarking on new ventures and evidence-based decision-making.

CONCLUSION

Entrepreneurship with pharmacoeconomic implications leads to the progression of innovative advancement in the clinical pharmaceutical field. In the vein of the study entrepreneurship has been shown to be still in its infancy, more so when entrepreneurship is considered in a clinical pharmacy setting.

Funding: This research has been funded by the Tertiary Education Scholarships Scheme.