A Framework to Support Educational Courses for Pharmaceutical Workforce Development

submitted in partial fulfilment

of the requirements of the Degree of

Doctorate in Pharmacy

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Dedication

To my parents, brother, sister-in-law, niece, my favourite human, the best boy, Borra and Salcedo family.

Acknowledgement

ABSTRACT

Course accreditation is an activity initiated by institutions of higher education aimed to maintain standards of educational quality. The aim of the study is to develop a tool to support the design of accredited professional development courses addressed to the pharmaceutical workforce. The study is carried out at the Malta Laboratories Network - Institute for Scientific Development (MLN-ISD). MLN-ISD provides an academic platform of sharing of expertise, knowledge and skills through course development. A thematic analysis involving a 2-member focus group, consisting of a scientist with experience in regulatory and laboratory field, and the quality manager of the MLN-ISD was undertaken from the requirements for course accreditation as set by the Malta Further & Higher Education Authority (MFHEA) as reflected in the Malta Qualifications Framework (MQF). Themes identified were used to develop the "Course Accreditation Gap Analysis Tool (CAGAT)". CAGAT is a checklist intended to encompass the list of requirements necessary for course accreditation. The CAGAT was validated by a 5-member expert panel consisting of 2 academic pharmacists, a pharmacist with experience in quality and, 2 members of the focus group then was subjected to pilot testing by 3 fellows from MLN-ISD. The developed CAGAT consists of 6 headings namely: organisation information, course information, requirements and learning outcomes, lecturers and teaching method, delivery of the course and post course evaluation. All members of the expert panel, (N=5) agreed that the CAGAT is easy to use and assists the user to identify missing gaps of information required to provide an accredited continuous professional course. All fellows (n=3) agreed that each section in the CAGAT was met in accordance to the requirements listed for two courses for accreditation.

The developed CAGAT assists in the design and delivery of accredited courses intended for the pharmaceutical workforce allowing the sharing and enhancement of expertise in fields such as forensics, medical devices expertise and quality management systems. The CAGAT identifies gaps in the organization's current management system and the requirements for courses accreditation targeting professional pharmaceutical workforce development.

Keywords: Course accreditation, higher education, courses, pharmaceutical workforce, quality management system, gap analysis tool.

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Glossary*

TERM	DEFINITION
Accredited course	Refers to a course which has been assessed by an academic accreditation board such as the Malta Further & Higher Education Authority (MFHEA) and pegged to a qualifications framework such as the Malta Qualifications Framework (MQF).
Accredited provider	An entity which has obtained provider accreditation in accordance with regulations, set by an academic accreditation board such as MFHEA.
Contact Hours	Tuition hours whereby there the students and lecturers share expertise.
Credit	A quantified expression of the volume of learning based on the achievement of learning outcomes and their associated workloads. 25 hours is equivalent to 1 ECTS (European Credit Transfer and Accumulation System).
Assessment Hours	The number of hours spent working on an assignment as well as/or the hours the students spend during examinations.
Higher Education Institution	An institution that delivers programmes or modules which are self-awarded and that have been formally accredited at Level 5 or higher in line with the Malta Qualifications Framework MQF or a foreign qualification at a comparable level.
Further Education Institution	An institution that delivers programmes which are self-awarded and which lead to a qualification at Levels 1 to 4 in line with the Malta Qualifications Framework MQF or a foreign qualification at a comparable level.
Licensee	An academic institution provider licensed by the National Commission in accordance with regulations set by the MFEA.

Definitions put forward have been adapted by the researcher for the scope of the study based on the national academic accreditation body or Malta Further & Higher Education Authority (MFHEA).

List of Abbreviations

CAGAT	Course Accreditation Gap Analysis Tool
ECTS	European Credit Transfer and Accumulation System
EQF	European Qualifications Framework
FIP	International Pharmaceutical Federation
FREC	Faculty Research Ethics Committee
ISO	International Organization for Standardisation
MFHEA	Malta Further & Higher Education Authority
MLN-ISD	Malta Laboratories Network - Institute for Scientific Development
MQF	Malta Qualifications Framework
QA	Quality assurance
QMF	Quality management framework
QMS	Quality management system
SL	Subsidiary Legislation

CHAPTER 1
INTRODUCTION

1.1. Quality management systems: principles and standards

A quality management system (QMS) is a set of interrelated elements of an organization to establish a series of policies, objectives and processes, which benefits the organisation. A QMS provides a framework for organisations to consistently deliver services that meet the needs of the stakeholders whilst at the same time enhancing customer satisfaction through the effective application of the management systems (Mourougan et al, 2017). It continuously improves the structure and governs the organisation's capability to meet stakeholders and regulatory requirements relating to the services, products and organisation's needs (Duffy et al, 2019). A QMS can be beneficial in planning, organizing, monitoring and verifying various processes, steps or services with the aim of targeting feasibility by improving costs, increasing productivity and ensuring quality based on the dynamic and multifactorial needs of the stakeholders. Quality standards such as ISO standards support quality management systems ensuring that the highest quality of the service is provided (Sfreddo et al, 2018). ISO 9001:2015 is the international standard for a Quality Management System (QMS) centred on customers through leadership, teamwork, process and systems approach, continued improvement, and information based decision-making, for this reason, it is the most extensive standard for establishing and maintaining a QMS. ISO 9001:2015 can be applied to organizations of all types since it covers the basic processes within the organisation and provides certain actions for control over processes and management.[1] ISO 9001:2015 improves both internal and external issues within an organisation including choosing auditors who are competent and experienced is crucial in ensuring reliable and accountable certification process (Fonseca et al, 2019). ISO 9001:2015 is a useful tool for organisations to adapt

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[1] International Standards Organisation. [Internet]. ISO 9001:2015 Quality management systems [cited 2022 Oct 17]; Available from: https://www.iso.org/standard/62085.html

to the international standard (Fonseca et al, 2017). Organisations, which are ISO 9001:2015-certified aim to continuously improve its processes and procedures to achieve sustainable outcomes.

1.1.1 *Quality management systems and accreditation in pharmacy education*

QMS plays a role in educational planning and quality assurance of training courses in order to ascertain that the courses provided are effective in reaching the standards and learning objectives outlined in their description in relation to the needs of the students (Stensaker, 2018, (Sfreddo et al, 2021). Quality management systems and quality in relation to education planning and course delivery with particular reference to pharmacy workforce and practice has been the subject of various literature reviews (Guimaraes Morias et al, 2011; Zellmer et al, 2013; Atkinson et al, 2014; Mestrovic et al, 2015; Bajis et al, 2018; Anderson et al, 2020; Engle 2020; Nouri et al, 2020). In education, a quality management system embeds quality principles into the educational system to develop and deliver training courses or programmes that are based on the appropriate competencies as required by the candidates whilst employing non bias in the delivery method and scientific principles of the programme providers (Pratasavitskaya and Stensaker, 2010; Manatos et al, 2015).

The International Federation of Pharmacists through its FIP Development goals: transforming global pharmacy put forward in 2020[2] and the FIP Global Advanced

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[2] International Pharmaceutical Federation (FIP). The FIP Development Goals Transforming global pharmacy [Internet*].The Netherlands: FIP; 2019 [cited 2023 May 31] Available from:https://www.fip.org/file/4793

Development Framework (GADF) supporting the advancement of the profession[3] published in 2019 are two documents that support and highlight the relevance and impact of quality management systems in pharmacy education to support the need of the profession to keep up with the dynamic changing needs of society at large. Quality management systems are closely linked to two main concepts namely quality assurance and accreditation. Quality assurance (QA) entails a continuous assessment and improvement of academic indicators, which is accomplished through external assessment carried out by peer reviewers and internal self-assessments in reaching societal demands as put forward onto the pharmacy profession (Ewell, 2010; Paor, 2016). Students in addition to faculty members are considered a crucial stakeholder and this relevance is identified in a robust quality assurance related to course development (Ryan, 2015; Coates, 2006). Quality assurance reflect competence and drive learning outcomes in addition to course design which responds to the needs of the students (Zarembski et al, 2019). QA drives institutions to achieve and sustain high standards to increase trust and confidence of the public whilst boosting the institution's accountability (Ulker et al, 2019). Accreditation assures interested parties to place a certain level of trust on the institution and the course offered based on the accreditation received (Massaro, 2010; Hillman et al, 2019). Accreditation is a procedure undertaken by educational institutions including pharmacy related institutions, revolving around quality assurance and providing continuous quality improvement leading to accountability and higher levels of quality education services provided (Drumm et al, 2020).

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[3] International Pharmaceutical Federation (FIP). Global Advanced Development Framework (GADF) Supporting the advancement of the profession [Internet*].The Netherlands: FIP; 2019 [cited 2023 May 31] Available from: https://www.fip.org/file/4331

1.1.2 Course accreditation

Course accreditation is an activity initiated by institutions of higher education in order to maintain standards of educational quality agreed upon by members of an accrediting body (Sysoiev, 2019). It requires rigorous self-evaluation and an independent, objective peer-appraisal of the overall educational quality (Salto, 2018). Courses provided are effective in reaching the standards and learning objectives outlined in their description whilst ensuring that educators and training can reflect upon and improve their practice in relation to the needs of the students (Stensaker, 2018; Bravi et al, 2019). The institution must seek to identify training needs within the dynamic scientific field according to the needs of the stakeholders. Processes and procedures are developed by accrediting agencies to guide institutions to conform to standards of accreditation. Review committees use these standards as the basis for their recommendations and decisions in achieving the goal of continuous improvement and reaching harmonisation of courses. The Bologna Process adopted across Europe is the basis of harmonisation of quality management system principles and academic accreditation ensuring a common standard for courses within Europe and therefore mutual recognition (Zahavi and Friedman 2019; Bendixen and Jacobsen, 2020). On an international level and more concisely in relation to pharmacy education globally, between 2016 and 2017, the International Federation of Pharmacists, FIP launched what has become known as the Nanjing statements[4] which capture the global benchmarks for pharmacy education worldwide consisting of 67 statements summarised into 8 clusters amongst which quality assurance and continuing professional development (Law et al, 2019).

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[4] International Pharmaceutical Federation (FIP). Nanjing Statements: Statements on Pharmacy and Pharmaceutical Sciences Education. 2017. Available from: https://www.fip.org/files/fip/PharmacyEducation/Global_Conference_docs/Nanjing_Statements.pdf

In Malta, courses are accredited through the Malta Further & Higher Education Authority[5] which operates against European accreditation standards. Accreditation of educational entities providing accredited or recognised further and/or higher courses is a legal requirement as per Subsidiary Legislation (SL) 607.03 also known as the "Further and Higher Education (Licensing, Accreditation and Quality Assurance) Regulations". The scope of the MFHEA is to promote and develop further and higher education in Malta by means of regulation and by the promotion of best practices[6]. As background to this study, a brief overview of the process of accreditation of a course program is summarised (Figure 1.1).

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[5] Malta Further & Higher Education Authority. [Internet]. Program Accreditation - Malta Further & Higher Education Authority [cited 2022 Oct 17]; Available from: https://mfhea.mt/programme-accreditation/
[6] Malta Further & Higher Education Authority. [Internet]. Timeline - Malta Further & Higher Education Authority [cited 2022 Oct 17]; Available from: https://mfhea.mt/timeline/
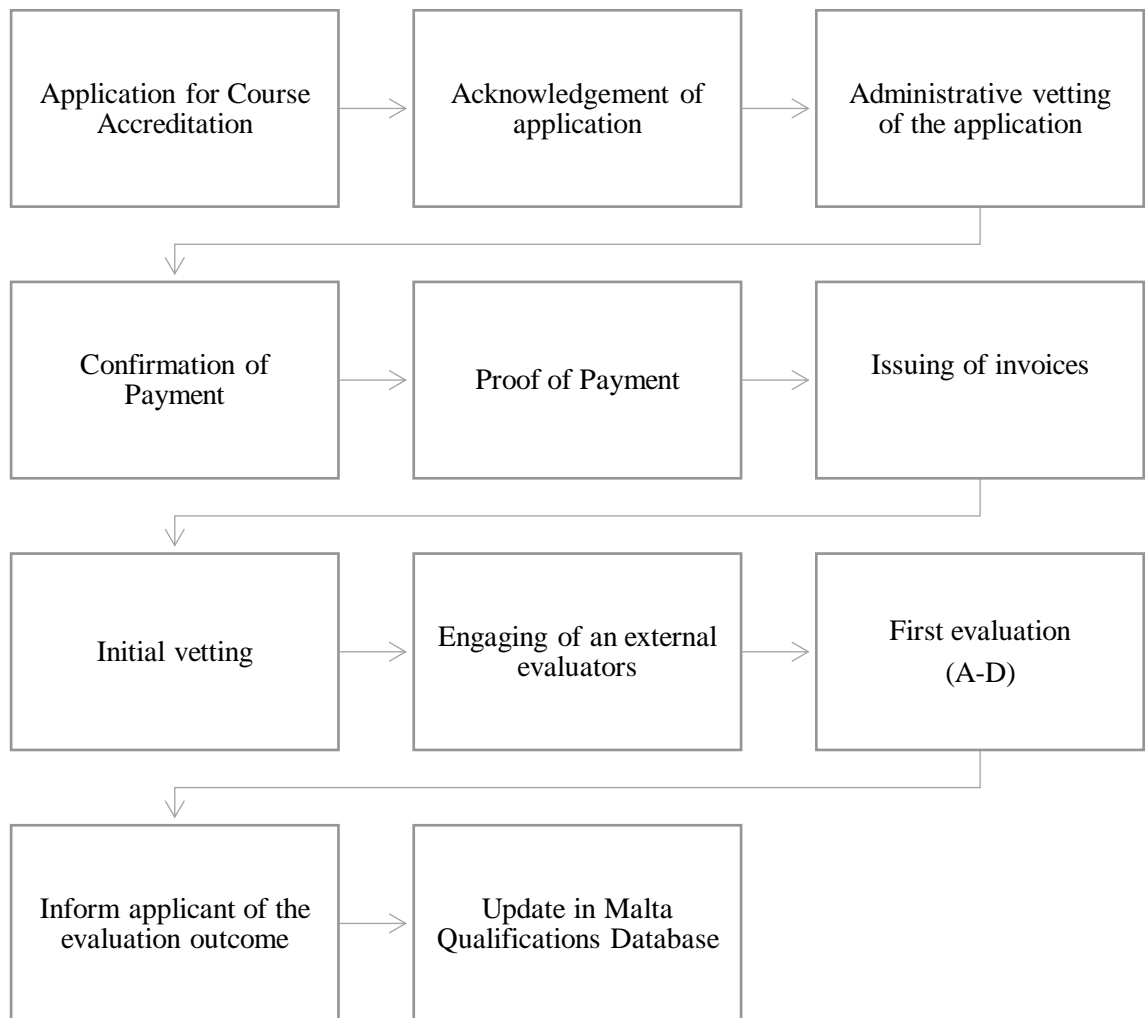
Figure 1.1. Flowchart of the process for Course Accreditation

Adapted from: Malta Further & Higher Education Authority available from: https://mfhea.mt/programme-accreditation/

The process of course accreditation as set by the MFHEA, starts with the application for course accreditation submitted to the MFHEA. Vetting of the application will determine whether the application provides information required for the payment to be requested and subsequently the accreditation process. On successful completion of course accreditation, the course provider details and details of the course are updated in an online database.

1.2 Collaborative initiatives as a means to support professional accredited development

One of the factors that contributes to the developing and maintain of a pharmacy workforce that is competent to respond to the dynamic needs of an advancing society is the need to propose academic platforms supporting the pharmacy workforce (Hawthorne and Anderson, 2009; Al-Haqna et al, 2021). On an international level, the Federation of International Pharmacists (FIP), the American Society of Health System Pharmacists (ASHP), the Royal Pharmaceutical Society are examples of platforms that provide such courses. In Malta, the need to design and develop professional accredited courses targeting pharmacy workforce, pharmacy practice and related scientific fields was a highlight in a doctoral study carried out by Rogelio Rivera in 2021 whilst undertaking a doctoral traineeship at the Malta Laboratories Network.

The Malta Laboratories Network is committed to sustain the continuous needs of stakeholders and professionals working in the pharmaceutical and scientific field where the ground-breaking aspects such as within forensic science, regulatory science, big data, and artificial intelligence are amongst the drivers of innovation in pharmaceutical and scientific field. The Malta Laboratories Network Institute for Scientific Development (MLN-ISD) is the academic arm which raison d'être is that of providing an academic platform in Malta through an innovative process of fostering a model of sharing of knowledge, expertise and empowerment of the stakeholders to continuously address the dynamic needs of the network's stakeholders. The MLN-ISD is also dedicated to enhance knowledge sharing by organising interactive and advanced educational training and development courses in the field of science and technology and breaking down silos. The researcher was following a traineeship at the Malta Laboratories Network at a time when the MLN-ISD was being established as an accredited institute by the Malta Further &

Higher Education Authority (MFHEA) in response to a need by stakeholders to be provided with continuous accredited courses in areas such as quality management systems, risk management, environmental systems, and forensic sciences. This personal experience led to the rationale of this research.

1.3. Rationale of the research

The research aims at developing a quality management framework to support educational accredited courses for the pharmaceutical workforce in order to assist the workforce in keeping abreast with latest scientific and pharmaceutical technological advancements in the field.

The objectives of the study are to:

i)   Identify quality management system documentation procedures required for course accreditation.

ii)   Develop and validate a gap analysis tool to be used in the design of courses being developed in order to conform to the requirements for accreditation against a quality management framework.

CHAPTER 2
METHODOLOGY

2.1 Research Design

The methodology of the research was divided into two phases (Figure 2.1). Phase I, focused on thematic analysis carried out through a focus group targeting the identification of i)gaps in processes and procedures, such as missing or not clear documentation, which need to be reviewed and amended to conform to accreditation requirement; ii) priority courses, which need to be designed and accredited in line with the Malta Further & Higher Education Authority (MFHEA) as the national academic accreditation body in Malta iii) themes that are to be included in a gap analysis tool to assist course accreditation. Preliminary findings from Phase 1 lead to Phase II. Phase II of the research focused on the development and validation of a gap analysis tool, which can be utilised for the implementation of the validation process of the courses and subsequently assist in the accreditation process of the courses intended to address the dynamic evolving needs of the pharmaceutical workforce.
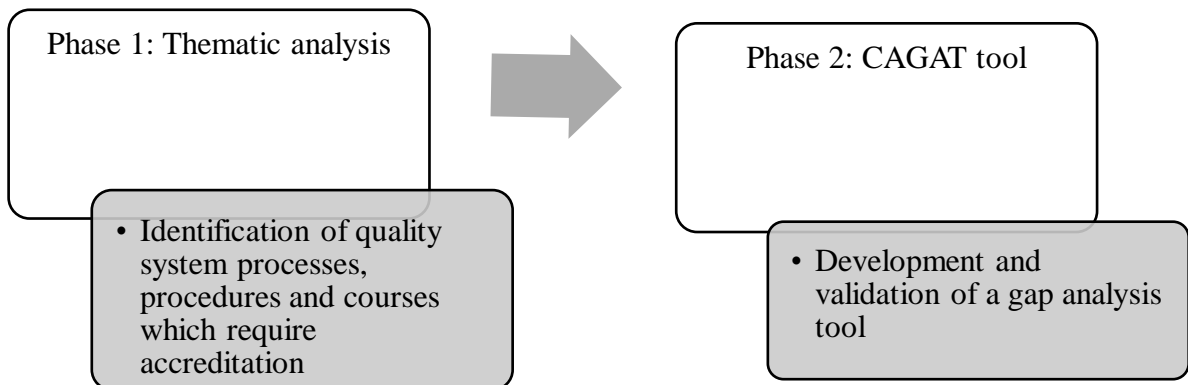

Figure 2.1   Research design to support framework development for course accreditation

2.2   Research Setting

The research was carried out at the Malta Laboratories Network - Institute for Scientific Development (MLN-ISD). The MLN-ISD is accredited in line with the Malta Further & Higher Education Authority (MFHEA) and provides an academic platform of sharing of expertise, knowledge and skills through course developments targeting the continuous needs of the scientific and pharmaceutical workforce reflecting the advancements in the field. The MLN-ISD supports a postgraduate fellowship programme whereby students reading for a degree at Level 7 or Level 8 in the pharmacy courses are offered to undertake a 20-hour/week traineeship allowing the fellows to be proactively involved in a professional working environment whilst furthering their postgraduate degrees. Prior to the initiation of the research, the study was registered with the Faculty of Medicine and Surgery Research Ethics Committee (FREC) at the University of Malta for the proposed protocol. Application was acknowledged by the FREC (Appendix 1).

2.3.   Phase 1 - Thematic analysis

Phase 1 consisted of a thematic analysis based on the use of a focus group consisting of 2 professionals working within the MLN-ISD namely, a scientist with experience in regulatory and laboratory field who was leading the MLN-ISD and a pharmacist with a doctoral degree working as the quality manager of the MLN-ISD. The focus group meeting was held online to accommodate the focus group needs with the researcher introducing the scope of the research and the focus group. The meeting took approximately 1 hour. The deliverables of the meeting were the identification of:

i)   gaps in quality management processes and procedures related to course accreditation

ii)   priority courses for course accreditation

iii)   themes that need to be included in a gap analysis tool with the scope of assisting course accreditation.

The focus group discussion was facilitated through the use of a questionnaire consisting of 6 questions (Appendix 2). Prior to implementation within the focus group, the focus group discussion questionnaire was validated for clarity and relevance of statement by 2 external doctoral pharmacists who had carried out doctoral work in the area of course development and quality (Appendix 2). Figure 2.2 summarises the facilitation of the focus group discussion to support Phase 1 and its deliverables.
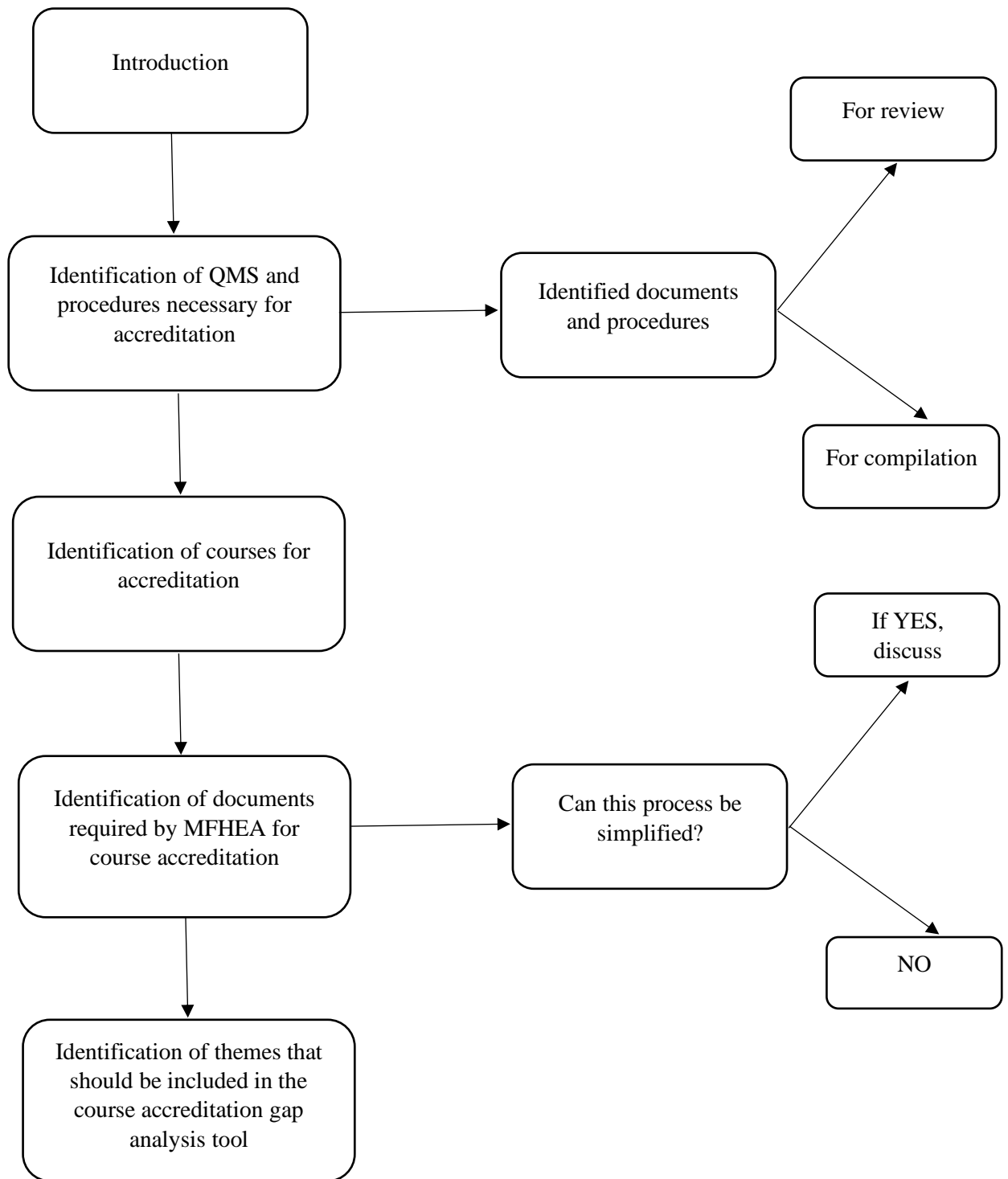
Figure 2.2   Facilitation of focus group discussion for thematic analysis Phase 1

The figure provides a schematic flow of the discussion facilitated during Phase 1 through the focus group approach. The focus group were invited to reflect on gaps in the current quality management system in place at the MLN-ISD leading to the identification of Standard Operating Procedures and Quality Management System documents that required compilation on review in order to support course accreditation. The focus group was asked to indicate top priority courses with the prioritisation put forward based on the demands of the stakeholders. The requirements and procedures necessary for course accreditation were discussed and themes to be included in the gap analysis tool were identified.

2.4. Phase 2 - Development and validation of the Gap Analysis tool

Phase 2 focused on the development and validation of a gap analysis tool intended to facilitate and enhance an effective and timely preparation for course accreditation. Thematic findings identified in Phase 1 were used to compile the Course Accreditation Gap Analysis Tool (CAGAT) (Appendix 3). The CAGAT is a checklist summarising the requirements for course accreditation as set by the framework adopted by the Malta Further & Higher Education Authority (MFHEA). It is intended to encompass the list of requirements necessary for course accreditation allowing educational institutions seeking to offer courses which need to be accredited in accordance to national standards.

2.4.1 Structure and design of Gap Analysis Tool

The developed CAGAT consisted of questions that are answerable by "yes" or "no" to determine whether the specified requirement has been identified, compiled or met. The CAGAT was divided into 6 sections.

Section 1 targeted organisation information with questions pertaining to general information about the organisation seeking accreditation and providing the course. Section 2 focused on course information consisting of questions aimed at identifying the course description of the course seeking accreditation, the number of European Credit Transfer and Accumulation System (ECTS) to be awarded, mode of delivery and target audience of the course. Section 3 on requirements and learning outcomes consisted of questions capturing eligibility requirements for students to be able to join the specific course in addition to identification of the learning outcomes in terms of knowledge and skills. The assessment methods and grading system were also checked in this section.

Section 4 focused on the lecturers and teaching method with questions seeking to highlighting the resource materials, teaching method, tutors and tutors' qualifications to be able to provide the course meeting the learning outcomes identified. Section 5 focused on the delivery of the course with questions designed at determining whether details such as dissemination of course posters and agenda, venue, participants, course fee and relevant necessary online resources have been established or compiled. The final section, section 6, is the post-course delivery section, which was dedicated to activities to be accomplished upon completion of the course such as student assessment, certification and evaluation of the course.

2.4.2. *Gap Analysis Tool Validation*

The CAGAT was subjected for validation by an expert panel consisting of 2 academic pharmacists, a pharmacist with experience in quality and, 2 members within the MLN-ISD who were also part of the focus group used in Phase 1. A 5-point validation questionnaire was used for the validation of CAGAT (Appendix 4). Each expert panel member assessed the questions in the CAGAT based on the relevance and the level of agreement to the questions presented. The relevance of the questions was ranked on a scale of 1 to 5 with 1 being "not relevant at all" and 5 being "extremely relevant". The expert panel (n=5) marked clarity based on their level of agreement to the questions provided on a scale of 1 to 5, with 1 being "strongly disagree" and 5 being "strongly agree". Each member of the panel were contacted via email and an electronic copy of a validation questionnaire was provided. The members were asked to give comments and suggestions to improve the structure of the questions, clarity and relevance accordingly.

2.4.3   *CAGAT pilot testing*

Pilot testing of the CAGAT was undertaken by 3 fellows[7] of MLN-ISD and the CAGAT was used to check or otherwise identify gaps in the requirements necessary for accreditation application process of 2 courses namely '*Award in ISO/IEC 17025 Awareness   course*' and '*Award in Environment Management Systems course*' as required for submission to the MFHEA. The fellows (n=3) were asked to use CAGAT independently of each other to eliminate any bias.

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[7] Fellow – a person undergoing a traineeship program and forms a part of a multi-disciplinary team that support different regulatory and administrative duties as required by the MLS-ISD.

CHAPTER 3
RESULTS

This chapter presents the study findings pertaining to Phase 1, which focused on the thematic analysis in relation to quality management processes and procedures related to course accreditation, identification of priority courses for accreditation and themes to be included in the development of a gap analysis tool. Study findings in relation to Phase 2, which focused on the development and validation of the CAGAT are presented in the second part of this chapter.

3.1. Phase 1 Thematic analysis: Identification of Quality Management Systems gaps

The focus group questionnaire (Appendix 2) was validated by 2 external doctoral pharmacists with experience in course development. Both experts rated the questionnaire to be clear and relevant to its scope. The questionnaire which was used during the focus group meeting with MLN-ISD members (n=2), led to the identification of 6 Standard Operating Procedures utilised by the MLN-ISD (Table 3.1). One of the members also highlighted that a quality manual to support accreditation processes was implemented at the MLN-ISD. The quality manual was designed to provide references to procedures and activities reflecting the QMS adopted and needs to be regularly reviewed, updated and maintained.

Table 3.1.   List of Standard Operating Procedures utilised by MLN-ISD

SOP Number	SOP name
S-Q01	Internal Audit Process
S-Q02	Management Review
S-Q03	Production and Control of documents within the Quality Management System
S-Q04	Quality Improvement and Corrective Actions
S-Q05	Deviation from policies and procedures
S-Q06	Staff Training Procedure

The members of the focus group (n=2) indicated that a total of 3 out of the 6 SOPs needed to be reviewed and one SOP specifically focusing the process of preparation and implementation process of an accredited course required to be compiled in order to support an educational framework (Table 3.2).

Table 3.2.   Updating of current Standard Operating Procedures

SOP	Action required	Reviews and changes undertaken
Preparation and implementation of an accredited course	Compilation	Not applicable
Internal Audit Process	Review	Inclusion of MLN audit plan, scope and objectives
Quality Improvement and Corrective Actions	Review	Inclusion of process for quality improvement, identification and evaluation of audit findings and corrective action plan
Production and Control of documents within the Quality Management System	Review	Inclusion of preparation, process of approval, distribution, revision or withdrawal and the control of documents of MLN

The researcher reviewed the 3 highlighted SOPs and compiled the SOP entitled 'Preparation and implementation of an accredited course' which was then subjected to internal MLN-ISD QMS procedures and subsequently adopted as SOP.

3.1.1 Phase 1 Thematic analysis: Identification of course accreditation prioritisation

The focus group (n=2) highlighted 4 priority courses namely '*Award in Auditing Processes*', '*Award in Good Distribution Practices in Medical Devices*', '*Award in Risk Management Processes*' and '*Award in ISO 14001: Environmental Management*

Systems'. These courses were identified by the members of the focus group (n=2) as top priority for accreditation processes and ranked secondary to repeated demand from the stakeholders of the MLN-ISD (Table 3.3).

Table 3.3.   Order of Prioritisation of Courses for Accreditation

Order of prioritisation for accreditation	Course name
1	Award in Risk Management Processes
2	Award in Good Distribution Practices in Medical Devices
3	Award in Auditing Processes
4	Award in ISO 14001: Environmental Management Systems

Both members of the focus group (n=2) agreed on the ranking, which reflects the repeated demand for courses by the stakeholders of the MLN-ISD.

3.1.2   Phase 1: Thematic analysis for compilation of a gap analysis tool

The themes identified by the focus group (n=2) recommended for inclusion in the course accreditation gap analysis tool are summarised in Figure 3.1.
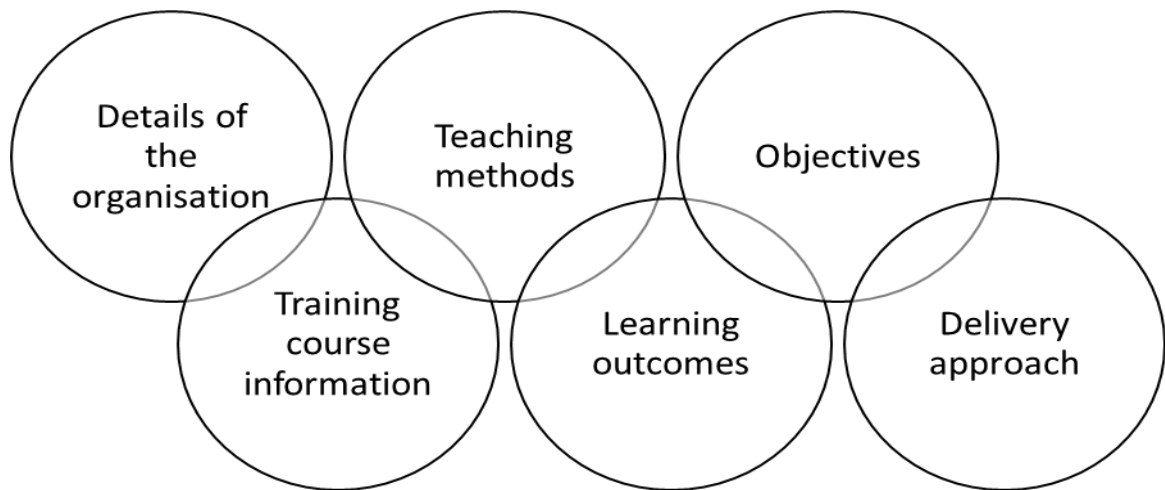
Figure 3.1. Themes to be included in the Course Accreditation Gap Analysis Tool

Figure 3.1 presents the themes indicated by focus group (n=2) that need to be included in the gap analysis tool intended to assist in course accreditation namely, details of the organisation providing the course, training course information, teaching methods, learning outcomes and objectives and delivery approach of the course.

3.2. Phase 2: Development and validation of a gap analysis tool for course accreditation

The *"Course accreditation gap analysis tool"* (Appendix 3) was developed based on the thematic analysis identified through the focus group and consists of questions referring to the i. provider of the educational course, ii. type of course, iii. title of the qualification or award, iv. mode of delivery, v. attendance of the courses, vi. teaching methods, vii. total learning hours, viii. learning objectives, ix. learning outcomes, and x. assessment methods was developed in order to aid in the identification of any lacking requirement for the accreditation processes of courses. All members of the expert panel (n=5) agreed that the CAGAT is relevant, clear and easy to use, not time-consuming, comprehensive and would assists the user in identifying missing gaps of information required to provide an accredited professional course.

3.2.1 Pilot testing of the CAGAT

The CAGAT was disseminated to the fellows (n=3) of MLN-ISD for pilot testing of the developed tool. The fellows used the CAGAT to check that the requirements for course accreditation by the MFHEA for the MLN-ISD proposed '*Award in ISO/IEC 17025 Awareness course*' and '*Award in Environment Management Systems course*' were met. The results of the pilot testing from the 3 fellows were reviewed and documented to be the same. All 3 fellows agreed that each section was in accordance to the requirements listed in the CAGAT for both courses (Table 3.4 and Table 3.5).

Table 3.4.   Pilot Testing for 'Award in ISO/IEC 17025 Awareness course'

Section	Requirements checklist as per Fellow 1	Requirements checklist as per Fellow 2	Requirements checklist as per Fellow 3
1. Organisation information	Conform	Conform	Conform
2. Course information	Conform	Conform	Conform
3. Requirements/Learning Outcomes	Conform	Conform	Conform
4. Lecturers/Teaching Method	Conform	Conform	Conform
5. Delivery of the course	Conform	Conform	Conform
6. Post-course delivery	Conform	Conform	Conform

All fellows (n=3) agreed that requirement for accreditation of '*Award in ISO/IEC 17025 Awareness course*' were met.

Table 3.5.   Pilot Testing for 'Award in Environment Management Systems course'

Section	Requirements checklist as per Fellow 1	Requirements checklist as per Fellow 2	Requirements checklist as per Fellow 3
1. Organisation information	Conform	Conform	Conform
2. Course information	Conform	Conform	Conform
3. Requirements/Learning Outcomes	Conform	Conform	Conform
4. Lecturers/Teaching Method	Conform	Conform	Conform
5. Delivery of the course	Conform	Conform	Conform
6. Post-course delivery	Conform	Conform	Conform

All fellows (n=3) agreed that requirement for accreditation of *'Award in Environment Management Systems course'* were met.

CHAPTER 4
DISCUSSION

4.1 Supporting educational courses for pharmaceutical workforce development

Pharmacy has transformed and moved away from its traditional product centred approach to a patient centred approach adapting concepts of pharmaentrepreneurs, and digitalisation along the course of years with graduates expected to keep adapting to the changes of the profession (Wheeler and Chrisholm-Burns, 2018; DiPiro, 2011). The area of pharmacy practice intermingled with big data, artificial intelligence, individualised telemedicine, advanced assisted tracking medical devices, pharmacogenetics, forensic science and robotics is a rapidly evolving practice thus the pharmaceutical workforce is in need of constant update on the latest advancements in the field (Murdoch and Detsky 2013, Miller and Brown, 2018, Baines et al, 2020; Del Rio-Bermudez, 2020, Wang et al, 2020). Continuing professional and personal development accredited courses tailor-made to the needs of the workforce offered by accredited providers are crucial to keep the workforce abreast with new emerging pharmaceutical developments (Hawthorne and Anderson, 2009; Prisco et al, 2023). A report by the World Health Organisation published in 2016 titled: 'Working for health and growth: investing in the health workforce'[8] documents that investing in the continuous professional development of the pharmacy workforce is critical in ensuring a safe and effective universal health system worldwide. In 2016, the International Federation of Pharmacists identified 13 workforce development goals that incorporate amongst others the need to focus on professional development for the advancement of the profession.[9] The continuous professional development fosters a much needed quality improvement in the service and deliverables of the pharmaceutical profession at the areas such as the industry, regulatory, clinical,

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[8] World Health Organisation. Working for health and growth: investing in the health workforce. 2016. Available at: https://apps.who.int/iris/bitstream/handle/10665/250047/97892415?sequence=1

[9] International Federation of Pharmacists (FIP). Pharmaceutical Workforce Development Goals. The Hague. 2016. Available at:https://www.fip.org/files/content/priority-areas/workforce/wdgs-online-version.pdf

hospital and community (Micallef and Kayyali, 2019). The sharing of expertise through educational platforms results in the expansion of knowledge, mindsets, skills and the breaking down of barriers to embrace innovation and leadership in the profession (Ramani et al, 2019, Batista et al, 2022).

Focusing on the national scenario where Malta is a small member state within the European Union but with a good turnout of scientists and pharmacists, one cannot not comment on the importance on intercollaborative practices within the nation and across international fora in order to support the developing educational needs of our profession and workforce. The MLN-ISD was born out of the concept to be the fulcrum for providing a platform where courses bringing together experts in the area of pharmacy and related sciences with candidates willing to learn. The next step for the MLN-ISD was to attempt to extend its intercollaborative practices and courses through the use of foreign networking groups in the area of pharmacy and related fields. The accreditation process of the MLN-ISD as an educational institute and subsequently of the courses offered was a challenge as indicated during the focus group discussion mainly because of the lengthy time to get accreditation with respect to setting up a quality management system, maintaining the QMS and in relation to the documents required to be submitted for accreditation purposes. This has also been witnessed by the researcher during the fellowship program and has led the researcher to attempt to scientifically provide an educational framework that facilitates the accreditation process and thereby balancing the need to provide optimum accredited courses with the fast demand of the stakeholders to actually have courses being delivered in a timely manner. The CAGAT was developed to be concise, easy to understand and use and with a potential to identify gaps which need to be addressed prior to the course accreditation application being submitted to the national accreditation body which in Malta is the MFHEA. The CAGAT assists the user

to resolve any pending issues thereby allowing a more fast tracked and timely response by the MFHEA. Following completion of this research, the 2 courses namely '*Award in ISO/IEC 17025 Awareness course*' and *'the Award in Environment Management Systems course'* whereby the CAGAT tool was pilot tested by the 3 fellows as indicated in section 3.2.1 were submitted for accreditation by the MFHEA and accredited without the need for major clarifications or missing details. This could indicate that the CAGAT tool may be a useful tool to decrease clarifications required by MFHEA although further studies need to be undertaken in this area. The CAGAT is a tool that can contribute to design continuous professional development courses reflecting the dynamic needs of the pharmaceutical workforce in a timely and efficient manner keeping up with the rapidly evolving changes brought about by innovation in science such as Artificial Intelligence, Big Data, IT incorporated in the daily practice of pharmaceutical workforce.

4.2   Limitations

This study was conducted within the MLN-ISD and results are limited to the network's stakeholders and might miss the needs of other stakeholders. The small size of the MLN-ISD is a limitation in itself. The focus group consisted of 2 members who make up the permanent staff at the MLN-ISD. The CAGAT was tested by 3 fellows available at the time to support the MLN-ISD. Another limitation is that CAGAT was structured based on the local accreditation requirements in Malta, and additional themes identified by the focus group are those that are relevant to the current practice of the MLN-ISD. However, this limitation could be used as a recommendation for further studies. Prioritisation of the courses was solely based on the feedback of the 2 members of the MLN-ISD, who were forming the focus group.

4.3 Recommendations for further studies

The concept of the developed CAGAT is to assist institutions in getting accreditation in a more timely manner and perhaps more efficiently. Thereby the CAGAT can be adapted by other institutions to match international accreditation requirements and assist international course accreditation that would offer educational support to the pharmacy workforce. On a national level, the CAGAT could be adopted by other educational institutions and used in the process for accreditation of courses thereby allowing for external testing of the tool. In an attempt to further address the need of the stakeholders, a study could be conducted to identify professional development activities including courses and webinars as required by the pharmacy workforce and the development and validation of a communication material such as for example in the form of a biannual newsletter that contributes to the sharing of information and research initiatives on latest developing and emerging scientific technologies.

4.4 Conclusion

The study led to the development and validation of the 'Course Accreditation Gap Analysis Tool', (CAGAT) which as indicated in the comments of the expert panel of the validation is comprehensive and moves along the requirements of the accreditation board in Malta. The CAGAT will facilitate the design, development and subsequent accreditation of courses developed by the MLN-ISD which courses could be potentially offered and shared at an international level, perhaps targeting the developing countries and assisting the pharmacy workforce in these countries to acquire the same expertise and skills of their colleagues worldwide. The CAGAT is a basic user-friendly tool that can be further adopted by other institutions on a national level to assist in the timely development

of accredited courses for the pharmaceutical workforce. The CAGAT can be adapted to international accreditation requirements put forward by international accreditation bodies and applied on a wider scope for professional development courses intended in the area of the pharmaceutical workforce.

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Appendix 1

Ethics approval

The status of your REDP form (MED-2022-00069) has been updated to Acknowledged 🖨 ⧉

form.urec@um.edu.mt   Tue, 3 May, 11:31 ☆ ↩ ⋮
to me ▾

Dear Jimenrose Borra,

Please note that the status of your REDP form (MED-2022-00069) 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.

↩ Reply   → Forward

Appendix 2

Questionnaire for Focus Group Discussion

i) What are the quality management systems procedures and documents required in order to seek course accreditation?

ii) Can you indicate if currently there are any documents or procedures that require review or compilation?

iii) Ranking from 1 upwards, from your experience at MLN-ISD which courses require prioritisation? What is the basis of the prioritisation?

iv) Briefly describe what documentation is required to be completed and submitted to the Malta Further & Higher education Authority for course accreditation?

v) Do you think that this process can be simplified? If yes can you discuss?

vi) What are the themes that should be included if a course accreditation gap analysis tool is to be developed to assist the compilation of documents required for submission?

Questionnaire for Focus Group Discussion

Validation Questionnaire

i.   What are the quality management systems procedures and documents required in order to seek course accreditation?

	Strongly Disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly Agree 5
Relevance					
Clarity					

ii.   Can you indicate if currently there are any documents or procedures that require review or compilation?

	Strongly Disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly Agree 5
Relevance					
Clarity					

iii. Ranking from 1 upwards, from your experience at MLN-ISD which courses require prioritisation? What is the basis of the prioritisation?

	Strongly Disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly Agree 5
Relevance					
Clarity					

iv. Briefly describe what documentation is required to be completed and submitted
to the Malta Further & Higher education Authority for course accreditation?

	Strongly Disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly Agree 5
Relevance					
Clarity					

v. Do you think that this process can be simplified? If yes can you discuss?

	Strongly Disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly Agree 5
Relevance					
Clarity					

vi. What are the themes that should be included if a course accreditation gap
analysis tool is to be developed to assist the compilation of documents required
for submission?

	Strongly Disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly Agree 5
Relevance					
Clarity					

Appendix 3

Course Accreditation Gap Analysis Tool

Course Accreditation Gap Analysis Tool

Course Accreditation Gap Analysis Tool (CAGAT) is a checklist, which summarises the requirements for course accreditation as set by the Malta Further & Higher Education Authority (MFHEA) and Malta Qualifications Framework (MQF). It is intended to encompass the list of requirements necessary for course accreditation. Educational institutions interested in offering courses which need to be accredited must submit their prospective courses to the MFHEA for accreditation.

The goal of CAGAT is to identify the gaps in the organization's current management system and the requirements for course accreditation, with highlights to the following:

a. Existing company processes and procedures required for accreditation.
b. Existing procedures and processes, which need to be modified to meet accreditation requirements.
c. Additional procedures and processes to be created to meet accreditation requirements.

The CAGAT consists of questions that are answerable by yes or no to determine whether the specified requirement has already been identified, indicated, available or compiled. The questions in the questionnaire are grouped into 6 headings namely: **Organisation information, Course information, Requirements/Learning Outcomes, Lecturers/Teaching Method, Delivery of the course and Post course delivery.**

Course Accreditation Gap Analysis Tool

1.Organisation information
This section consists of questions pertaining to general information about the organisation.

1.1. Has your institution identified a contact person?
(Is the name, email address, telephone/mobile number provided?)
- o YES
- o NO

1.2. Is your institution already licensed or are you requesting a new, or revised license from Malta Further & Higher Education Authority (MFHEA)?
- o YES
- o NO

1.3. If NO, is your institution requesting accreditation for providers through a separate application?
- o YES
- o NO

2.Course information
This section consists of questions, that aim to identify the overall course description of the specific course that will be submitted for accreditation, also highlighting a description of the course, number of ECTS to be awarded, mode of delivery and target audience.

2.1. Is the course to be submitted for accreditation identified?
- o YES
- o NO

2.2. Does the course lead to a formal outcome of an assessment and validation process or a "Qualification"?
- o YES
- o NO

2.3. Does the course lead to a certification of learning achieved through courses or an "Award" of accreditation?
- o YES
- o NO

2.4. What is the mode of delivery for the course?
- o Completely Face-to-Face Learning
- o Blended Learning
- o Completely Online Learning
- o Work-Based Learning

2.5. Has the mode of attendance for the course been identified?
(Full-Time or Part-Time)
- o YES
- o NO

2.6. **Please indicate the number of hours to complete the course**
1 ECTS is equivalent to 25 total hours of learning, inclusive of contact hours, supervised placement and practice hours, self-study hours and assessment hours.

2.7. **Has the target audience for the course been identified?**
     o   YES
     o   NO

2.8. **Has the main contents of the programme been compiled?**
     o   YES
     o   NO

3.   **Requirements/Learning Outcomes** **This section is aimed to identify requirements compulsory from students before joining this programme, learning outcomes in terms of knowledge and skills, assessment methods and grading system.**

3.1. Are the entry requirements that students should have before joining any programme listed?
     o   YES
     o   NO

3.2. Are the Learning Outcomes for Knowledge which need to be obtained at the end of the programme listed?
     o   YES
     o   NO

3.3. Are the Learning Outcomes for Skills which need to be obtained at the end of the programme listed?
     o   YES
     o   NO

3.4. Are the assessment methods for a particular module/unit to be evaluated listed? Assessment weightings for this particular module. (Example: Presentation 40% and Assignment 60%)
     o   YES
     o   NO

3.5 Is the grading system to be used identified?
(Digital learning tools being used for the assessment chosen and pass mark indicated.)
     o   YES
     o   NO

4.Lecturers/Teaching Method **This section seeks to assess whether the resource materials, teaching method, tutor/s and qualification/s that will make the tutor eligible to provide the programme have been identified.**

4.1. **Is the teaching method chosen listed?**
Example: If the programme includes an online learning component,
entirely face-to-face or work based learning.
    ○ YES
    ○ NO

4.2. **Are the lecturers chosen?**
The selection criteria shall include the minimum qualifications in terms of level of
qualification and area.
    ○ YES
    ○ NO

4.3. **Is the documentation required in relation to the lecturers (such as CV)**
    gathered?
    ○ YES
    ○ NO

4.4. **Are the resources and reading material for the course identified and listed?**
    ○ YES
    ○ NO

5.   **Delivery of the course*** **This section is designed to determine whether course details have been established** **including dissemination of course posters and agenda, venue, participants, course fee** **and availability of course paraphernalia and other necessary online resources.**

5.1. **Has the course poster been disseminated?**
    ○ YES
 	
    ○ NO

5.2. **Has the course agenda been disseminated?**
    ○ YES
 	
    ○ NO

5.3. **Has the course venue been identified?**
    ○ YES
 	
    ○ NO

5.4. **Are the participants identified?**
    ○ YES
 	
    ○ NO

5.5. **Is the course fee set?**
    ○ YES
 	
    ○ NO

5.6. Is the participants list for the course for accreditation been compiled?
o   YES
o   NO
5.7. Have the students' packs for the course for accreditation been prepared?
o   YES
o   NO
5.8. Have the online resources been made available to the students?
o   YES
o   NO
6.   **Post-course delivery****   **This section is dedicated to activities to be accomplished upon completion of the course, involving student assessment, certificates and evaluation.**

6.1. **Have the students' assessments been processed?**
      o   YES
      o   NO

6.2. Have the students' assessments been filed?
      o   YES
      o   NO

6.3. Have the certificates been issued?
      o   YES
      o   NO

6.4. Is the evaluation process completed?
      o   YES
      o   NO

* This section is to be completed during course preparation.

** This section is to be completed once course is completed.

Appendix 4

Content Validation for Course Accreditation Gap Analysis Tool

Course Accreditation Gap Analysis Tool

Course Accreditation Gap Analysis Tool (CAGAT) is a checklist, which summarises the requirements for course accreditation as set by the Malta Further & Higher Education Authority (MFHEA) and Malta Qualifications Framework (MQF). It is intended to encompass the list of requirements necessary for course accreditation. Educational institutions interested in offering courses which needs to be accredited must submit their prospective courses to the MFHEA for accreditation.

The goal of CAGAT is to identify the gaps in the organization's current management system and the requirements for course accreditation, with highlights to the following:

d. Existing company processes and procedures required for accreditation.

e. Existing procedures and processes, which need to be modified to meet accreditation requirements.

f. Additional procedures and processes to be created to meet accreditation requirements.

The CAGAT consists of questions that are answerable by yes or no to determine whether the specified requirement has already been identified, indicated, available or compiled. The questions in the questionnaire are grouped into 6 headings namely: **Organisation information, Course information, Requirements/Learning Outcomes, Lecturers/Teaching Method, Delivery of the course and Post course delivery**

You are requested to validate the attached Gap Analysis Tool.

To each question you are to assess them according to:

A – relevance, rate them from 1 to 5 where 1 is not relevant at all and 5 is extremely relevant;

B - clarity, rate them from 1 to 5 where 1 is strong disagreement and 5 is strong agreement.

You are also kindly asked to give your comments or recommendations after each question as applicable.

Course Accreditation Gap Analysis Tool					
1.Organisation information **This section consists of questions pertaining to the general information about the organisation.**					

1.1. Has your institution identified a contact person?
(Is the name and last name, email address, telephone/mobile number provided?)
    ○ YES
    ○ NO					

Comment/s:					
Validation	**1**	**2**	**3**	**4**	**5**
A. Relevance of the question					
B. Clarity					

1.2. Is your institution already licensed or requesting a new, or revised license from Malta Further & Higher Education Authority (MFHEA)?
    ○ YES
    ○ NO					

Comment/s:					
Validation	**1**	**2**	**3**	**4**	**5**
A. Relevance of the question					
B. Clarity					

1.3. If NO, is your institution requesting accreditation for providers through a separate application?
    ○ YES
    ○ NO					

Comment/s:					
Validation	**1**	**2**	**3**	**4**	**5**
A. Relevance of the question					
B. Clarity					
2.Course information **This section consists of questions, that aim to identify the overall course description of the specific course that will be submitted for accreditation also highlighting the description of the course, the number of ECTS to be awarded, mode of delivery and target audience.**					

		1	2	3	4	5

2.1. Is the course to be submitted for accreditation identified?
- o YES
- o NO

Comment/s:

Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					

2.2. Does the course lead to a formal outcome of an assessment and validation process or a "Qualification"?
- o YES
- o NO

Comment/s:

Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					

2.3. Does the course lead to a certification of learning achieved through courses or an "Award" of accreditation?
- o YES
- o NO

Comment/s:

Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					

2.4. What is the mode of delivery for the course?
- o Fully Face-to-Face Learning
- o Blended Learning
- o Fully Online Learning
- o Work Based Learning

Comment/s:

Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					

2.5. Has the mode of attendance for the course been identified?
(Either Full-Time or Part-Time)
- o YES
- o NO

Comment/s:

Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					

2.6. Please indicate the number of hours to complete the course

1 ECTS is equivalent to 25 total hours of learning, inclusive of contact hours, supervised placement and practice hours, self-study hours and assessment hours.

Comment/s:

Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					

2.7. Has the target audience for the course been identified?
- o YES
- o NO

Comment/s:

Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					

2.8. In this section, provide the main contents of the course submitted for accreditation.

Comment/s:					

Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					

3.   Requirements/Learning Outcomes
This section is aimed to identify requirements compulsory from students before joining this programme, learning outcomes in terms of knowledge and skills, the assessment methods and grading system.

3.1. Are the entry requirements that students should have before joining any programme listed?
o   YES
o   NO

Comment/s:					

Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					

3.2. Are the Learning Outcomes for Knowledge which needs to be obtained at the end of the programme listed?
o   YES
o   NO

Comment/s:					

Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					

3.3. Are there the Learning Outcomes for Skills which need to be obtained at the end of the programme listed?
- o YES
- o NO

Comment/s:

Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					

3.4. Are the assessment methods for a particular module/unit to be evaluated listed?
Assessment weightings for this particular module. (Example: Presentation: 40% and Assignment: 60%)
- o YES
- o NO

Comment/s:

Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					

3.5 Is the grading system to be used identified?
(Digital learning tools being used for the assessment chosen and the pass mark indicated.)
- o YES
- o NO

Comment/s:

Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					

4. Lecturers/Teaching Method
This section seeks to assess whether the resource materials, teaching method, tutor/s and qualification/s that will make the tutor eligible to provide the programme has been identified.

4.1. Is the teaching method chosen listed?   **Example: If the programme includes an online learning component, purely face-to-face or work based learning** o YES o NO

Comment/s:

Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					

4.2. Are the lecturers chosen? **The selection criteria shall include the minimum qualifications in terms of level of qualification and area.** o   YES o   NO

Comment/s:

Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					

4.3. Is the documentation required in relation to the lecturers (such as CV) gathered? o   YES o   NO

Comment/s:					
Validation	**1**	**2**	**3**	**4**	**5**
A. Relevance of the question					
B. Clarity					

4.4. Are the resources and reading material for the course identified and listed?
- o YES
- o NO

Comment/s:					
Validation	**1**	**2**	**3**	**4**	**5**
A. Relevance of the question					
B. Clarity					

5. Delivery of the course*

This section is designed to determine whether course details has been established including dissemination of course posters and agenda, venue, participants, course fee and availability of course paraphernalia and other necessary online resources.

5.1. Has the course poster been disseminated?
- o YES

- o NO

Comment/s:					
Validation	**1**	**2**	**3**	**4**	**5**
A. Relevance of the question					
B. Clarity					

5.2. Has the course agenda been disseminated?
    o   YES
 	
    o NO					

Comment/s:					
Validation	**1**	**2**	**3**	**4**	**5**
A. Relevance of the question					
B. Clarity					

5.3. Has the course venue been identified?
    o   YES
 	
    o NO					

Comment/s:					
Validation	**1**	**2**	**3**	**4**	**5**
A. Relevance of the question					
B. Clarity					

5.4. Are the participants identified?
    o   YES
 	
    o NO					

Comment/s:					
Validation	**1**	**2**	**3**	**4**	**5**
A. Relevance of the question					
B. Clarity					

5.5. Is the course fee set?
- o   YES

- o   NO

Comment/s:

Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					

5.6. Is the participant's list for the course for accreditation been compiled?
- o   YES

- o   NO

Comment/s:

Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					

5.7. Have the students' packs for the course for accreditation been prepared?
- o   YES

- o   NO

Comment/s:

Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					

5.8. Have the online resources been made available to the students?
- o   YES

- o   NO

Comment/s:

Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					

6. Post course delivery**
This section is dedicated to activities to be accomplished upon completion of the course, involving student's assessment, certificates and evaluation.

6.1. Have the students' assessments been processed?
- o YES
- o NO

Comment/s:

Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					

6.2. Have the students' assessments been filed?
- o YES
- o NO

Comment/s:

Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					

6.3. Have the certificates been issued?
- o YES
- o NO

Comment/s:

Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					
6.4. Is the evaluation process completed? o YES o NO					
Comment/s:					
Validation	1	2	3	4	5
A. Relevance of the question					
B. Clarity					

* This section is to be completed during course preparation.

** This section is to be completed once course is completed.

Appendix 5

Dissemination

Development of a course accreditation gap analysis tool to support professional development courses for the pharmaceutical workforce

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Introduction: Technology, Artificial intelligence and Big data are amongst the evolvements that lead to transformation in pharmacy which highlight the contribution of lifelong learning and professional development courses. At the same time, ensuring robust professional courses adds value to the relevance of the development courses to empowerment of the pharmaceutical workforce to embrace transformation.

Aims: To develop a tool to support the design of accredited professional development courses addressing pharmaceutical workforce and which target scientific and pharmaceutical advancements.

Materials and Methods: The study is carried out at the Malta Laboratories Network - Institute for Scientific Development (MLN-ISD). MLN-ISD is accredited in line with the (MFHEA) and provides an academic platform of sharing of expertise, knowledge and skills through course development. A thematic analysis was undertaken from the requirements for course accreditation as set by the Malta Further & Higher Education Authority (MFHEA) as reflected in the Malta Qualifications Framework. Themes identified were used to develop the "Course Accreditation Gap Analysis Tool (CAGAT)" which is a checklist, intended to encompass the list of requirements necessary for course accreditation. The CAGAT was validated by an expert panel consisting of two academic pharmacists, a pharmacist with experience in quality and, two members within the Malta Laboratories Network- Institute for Scientific Development.

Results: The developed "Course Accreditation Gap Analysis Tool (CAGAT)" consists of 6 headings namely: Organisation information, Course information, Requirements and

Learning Outcomes, Lecturers and Teaching Method, Delivery of the course and Post course delivery. The checklist can be completed within a maximum of 10 minutes. All members of the expert panel, (N=5) agreed that the CAGAT is easy to use and assists the user to identify missing gaps of information required to provide an accredited continuous professional course.

Discussion: The developed CAGAT assists in the design and delivery of accredited courses intended for the pharmaceutical workforce allowing the sharing and enhancement of expertise in fields such as forensics, medical devices expertise and quality management systems. The CAGAT identifies gaps in the organization's current management system and the requirements for courses accreditation targeting professional pharmaceutical workforce development.