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RESEARCH ARTICLE

Competencies for the position of the Responsible Person in good distribution practice

Bettina von Brockdorff, Lilian M Azzopardi
Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Malta

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Correspondence
Bettina Von Brockdorff
Department of Pharmacy
Faculty of Medicine and Surgery
Malta
bettina.vonbrockdorff.12@um.edu.mt

Abstract

Defined competencies are not currently established for technical personnel working in the pharmaceutical wholesale distribution setting who must adhere to Good Distribution Practice (GDP). Educational development for the Responsible Person (RP) position is topic-driven and not competency based. This research aimed to establish a validated tool to identify competencies relevant for the role of the Responsible Person (COMP-RP tool). There were 62 criteria based on competencies, knowledge, and skills across six domains which were included in the draft COMP-RP tool developed. The tool was based on a Likert scale ranking. Two Delphi rounds by a panel of experts were applied for validation. Data were statistically analysed and passed through cut-off points to reach final version of the COMP-RP Tool. The selection of wholesale distribution, quality and leadership skills, knowledge and competencies were consistently rated both Delphi rounds. The final validated COMP-RP Tool consisted of 58 criteria across the six domains.

Introduction

Wholesale distribution forms an integral part of pharmaceutical distribution and bears a strong socio-economic impact on multi-faceted healthcare systems (Stoimenova *et al.,* 2019). In the European Union (EU), Good Distribution Practices (GDP), are described in the 'Guideline on Good Distribution Practice of Medicinal Products for Human use' (European Directive, 2001/83/EC). EU-GDP requires that a technical person, referred to as the Responsible Person (RP) oversees the implementation of GDP. The Directive requires that the RP must possess academic and practical background which supports the performance of the responsibilities required pertaining to this position. The RP must adhere to the legislation present in each respective member state of the European Union (EU). An earlier study by Von Brockdorff and Azzopardi in 2022 established the current status of the requirements of the RP position across different European countries. It was established that there was no homogenous alignment across the countries for both the number of years of expertise and the educational requirements for eligibility to the RP position. There is a lack of an existing uniform framework to define skills, competencies and practical, hands-on experience. Discrepancies also exist in the nomenclature of the RP role across EU countries and this creates challenges in having a common understanding of the proposal and the development of educational competencies in the field. Educational requirements are not defined for wholesale distribution in a competency-based manner as the competencies which the RP would require to be able to fulfil the role in line with the legally binding responsibilities are not established. Vetiutneva and team described the role of the RP as a diverse role and one which relates to different areas of expertise. These include leadership, planning, organisational, control, and information, and are described as 'a tree of functions'. (Vetiutneva *et al.,* 2018). RPs also have an organisational, managerial or leadership role within the structure of a wholesale dealer's company. Technical expertise in relation to the pharmaceutical industry, wholesale distribution, and patient safety contributes to the RP role. To gain awareness and knowledge of the obligations defined in legislation as well as skills to support technical decision-making that safeguards patient safety and access to quality, safe medicines are required. Pharmacy education

frameworks are required to support such knowledge, skills and competencies development.

Pharmaceutical educational systems aim to prepare professionals in different pharmaceutical areas with adequate levels of skills and competencies to allow graduates to enter the pharmaceutical workforce with relevant skills and competencies (Anderson *et al.,* 2008). A requisite of pharmacy education at the graduate level is to instil lifelong learning education and an aptitude for specialised education (Deshpande, 2013). Within pharmacy education, over the past years, re-focusing has occurred towards establishing competency-based curricula. In 2016, Bajis and team stated that *'competency-based education is an educational paradigm with a primary focus on the capability or ability of the learner and not solely on knowledge acquisition'*. Competence-driven pedagogy forms the basis of a competency-based educational framework (Bajis *et al.,* 2016) This research presents a novel manner in which relevant competencies, skills and knowledge in the pharmaceutical wholesale distribution field are investigated for the role of the RP position in the pharmaceutical sector.

The aims were to undergo an assessment of the competencies in pharmacy education required in wholesale distribution. The impact of this research is to establish educational concepts and competencies which could constitute a framework for the RP position. In addition, defined educational competencies could be beneficial and implemented on a European level. For this reason, accreditation and recognition of competencies and a harmonised framework would be imperative (Martin, 2016).

Methods

Two stages were used for the research design after the research was registered with the Faculty of Medicine and Surgery Ethics Committee. The first stage consisted of the development of a competency tool consisting of an extensive list of knowledge, skills and competencies entitled; a tool to identify competencies relevant to the role of the Responsible Person – COMP-RP tool. The COMP-RP tool was used in the identification and assessment of competencies to address pharmacy education in the pharmaceutical wholesale distribution field. The COMP-RP Tool encompasses the knowledge, skills and competencies defined in line with GDP legislation guidelines. The second stage of this research consisted of performing validation of the COMP-RP Tool by adopting the Delphi technique with a panel of European experts encompassing different areas of expertise. Two Delphi rounds were planned.

The Delphi technique was chosen to validate the developed tool since it allows a panel of experts to appraise each criterion in the contexts directed by the researcher. Two Delphi rounds were planned to facilitate the engagement of the panel of experts to select the relevance of each criterion in the six areas of expertise for the RP role. To identify the relevance of each criterion, the panel were asked to rank criteria via the Likert scale categorising their selection as '1. Not important, 2. Quite Important, 3. Very Important, 4. Essential: Obligatory and 5. I do not know'.

Development of the tool

An extensive list of competencies for the areas of expertise related to wholesale distribution was listed and documented. This was carried out by a scoping review of the Good Distribution Practices (European Directive, 2001/83/EC). Information was collected and adapted from the EU *'Guidelines on Good Distribution Practice of Medicinal Products for Human Use'* (Directive 2001/83/EC), the Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications. A review of the competencies from PHARMINE and PHAR-QA was performed whereby relevant competencies such as leadership, good documentation skills and other professional skills were identified, extracted and adapted for this research competency from all sources. The competencies collected were compared to already implemented frameworks including the study of Atkinson and team, the Phar-QA project and European legislation (Atkinson *et al.,* 2014,).

A list of competencies was documented according to six areas of expertise and systems identified from the GDP European legislation and the literature assessed (Table I).

Table I: List of areas of expertise for the RP role

Number	List of areas of expertise for the RP role
1.	Quality management in relation to a quality system
2.	Management of 'outsourced activities'
3.	Reviewing and monitoring
4.	Leadership
5.	Wholesale distribution premises and activities related to medicinal products
6.	Documentation

Once the list of competencies was compiled, all the criteria in the areas of expertise were subdivided into three sub-groups: Knowledge, Skills and

Competencies. The categorisation was done to segregate the data collected into specific criteria based on whether the data was: knowledge in the area, a skill required to carry out a task or competence necessary for the RP position. A total of 63 lists of criteria were generated after the two Delphi rounds. The six areas of expertise which were identified were confirmed. Competencies were categorised according to the area of expertise to which each particular criterion pertained. All the listed criteria per area of expertise were further subdivided into three categories as shown in Table II. Out of these 63 criteria, n=17 pertain to knowledge, n=17 pertain to competencies and n=29 pertain to skills.

Table II: Categorisation of criteria

Area of expertise	Keyword/s	Subdivided categories
Quality management in relation to a quality system	Quality	Knowledge, skills, and competencies
Management of 'outsourced activities'	Outsourced activities	
Reviewing and monitoring	Reviewing	
Leadership	Leadership	
Wholesale distribution premises and activities related to medicinal products	Wholesale distribution	
Documentation	Documentation	

The panel of experts were invited to prioritise criteria selection in this COMP-RP Tool using a 4-point Likert ranking scale: 1. Not important: Can be ignored, 2. Quite important: Valuable, 3. Very important: Obligatory in the Wholesale Distribution field and 4. Essential: Obligatory

Validation of the COMP-RP Tool

Two Delphi rounds consisting of a panel of European experts were planned to ensure the robustness of the criteria included in the developed tool. Some of the reasons why the Delphi technique was selected included: the reduction of risks of any bias or influence which can arise from participants during decision-making, ascertaining agreement in an area that lacks evidence-based knowledge, providing validity through the expert panel, engaging participants who are geographically dispersed, enabling feedback of information collated, and reviewing data from previous Delphi rounds.

A total of 16 experts were identified to participate in the Delphi study. These 16 participants were identified from areas of experience in different Pharmaceutical fields of work including Academia, the Pharmaceutical Industry, Regulatory Affairs and Responsible Persons in the public and private sectors. The Delphi panel was chosen according to their diverse experience and level of expertise in the field. The panel's participation was voluntary and each participant was asked to provide their consent upon acceptance of participation. The participants were asked to enrol in both Delphi rounds actively.

The first round of the Delphi technique focused on the validation of the developed competencies, knowledge and skills based on the literature review in the COMP-RP Tool. In the first Delphi round, participants were given clear instructions on how to rank each criterion. Participants were asked to select the most appropriate option for each criterion (knowledge, skills and competencies) according to the consensus of the four-pointed Likert scale evaluating the importance of inclusion of the criterion. Participants were also given the option to select a fifth rank; that of 'Not selected: I do not know'. A second Delphi round, consisting of the same panel of experts, was planned to finalise the validation of the COMP-RP Tool by reflecting on updates arising from the first Delphi round. After the first Delphi round, the scoring results from the assessment of the COMP-RP Tool were tabulated into three tables as per the three investigated categories: 'Knowledge, Skills and Competencies'. The cut-off point for the exclusion of a criterion for the feedback of 'Not selected: I do not know' was established as the percentage majority; greater than half of the number of participants. Any criteria not making the cut-off point were eliminated in both Delphi rounds.

Statistical analysis of Delphi round results

Statistical analysis was carried out to determine trends, and establish the acceptance or elimination of assessment criteria from the COMP-RP Tool and the significance or non-significance of results obtained in the Delphi rounds.

Statistical analysis of the results obtained from the results of the RP investigated criteria generated from the COMP-RP Tool was carried out using IBM®SPSS® using two methods of data analysis. These two methods include: evaluating mean rating scores for each criterion assessed in the COMP-RP tool and; the weighted average for all those criteria ranked: 'Quite important: Valuable', 'Very important: Obligatory in the wholesale distribution field' and 'Essentialobligatory'. Cut-off points or exclusion criteria for both the mean rating score and the weighted averages for criteria were established as the minimum acceptance criteria for retaining competencies for the second Delphi round of the COMP-RP tool validation. The cut-off points or exclusion criteria were: > 3.0 (mean rating score) and > 90% (weighted average). These ensured that a particular criterion was retained on the basis that the majority of participants selected it as obligatory for the RP Role or wholesale distribution.

Criteria were assessed in the COMP-RP tool by running statistical analysis for the n=63 criteria. If one criterion passed both the mean rating score and weighted average cut-off then it was accepted and deemed to be validated. If a criterion failed both statistical tests it was eliminated. If a criterion failed one statistical test and then passed the other, this competence was passed on again to the panel of experts in a second round of assessment of the COMP-RP in the second Delphi round. This was performed to re-evaluate the ranking score with justified results.

After the second Delphi round, results were tabulated into three separate tables to segregate findings for knowledge, skills and competencies and statistical analysis was re-run. The criteria which failed to pass both cut-off points were eliminated from the COMP-RP tool. The remaining competencies were retained for the final validated COMP-RP Tool.

Results:

Demographic data from the panel of experts indicates that a total of 15 out of the 16 identified participants of the Delphi panel participated in the online focus group. In terms of demographic data, the panel of experts, n=9 of the participants were female while n=6 were male. The results captured from the Delphi focus group with a panel of experts whose years of work experience in the principal area of professional practice include: RPs in the private sector (n=5) and public sector (n=2), academics (n=2), regulatory affairs specialists (n=5) and an assistant of RPs at wholesale distributors (n=1). Almost half the participants (n=7) had 11-20 years of working experience and n=4 had over 20 years of experience.

Validation results – First Delphi round

Following the first Delphi round, all respondents (n=15) completed all the fields in the COMP-RP Tool. Out of 17 criteria for knowledge in the six RP areas of expertise, two criteria did not pass the required weighted average and the mean rating score criteria, which were less than 90% and less than 3.0 respectively. These two criteria were both about leadership: 'possess leadership qualities and effective leadership style' and 'people management'. An additional five criteria did not meet the weighted average criteria with consistent results of 80%. These results ranged from three of the six areas of expertise as shown in Table III. The remaining 11 passed both the mean score and weighted average criteria. The highest criteria with the highest rating ranked were 3.93 for the mean rating score and weighted average of 100%; this pertained to the 'implementation and upholding of a quality system'.

Table III: Knowledge criteria with a weighted average score less than 90%

RP area of expertise	Knowledge criteria	Weighted average score (%)
Quality management for a quality system	Validation of processes	80
Leadership	Possess leadership qualities and effective leadership style	80
	People management	80
Wholesale distribution premises and activities related to medicinal products	Verification and validation of any online systems that are in place; via SOPs or documented procedures/guidelines	80
	Parallel importation: its implications and requirements	80
	Ensuring the calibration of the equipment used to transport these products is validated	80

The skills criteria contained n=29 evaluation criteria in the six areas of expertise. From these criteria, there was one criterion that did not pass the required weighted average and the mean rating score criteria. This was the criterion of 'identification and proposition of enhancements of systems and tasks' (under the management of outsourced activities) and its results were 80% and 2.87 for the weighted average and the mean score respectively. There were an additional two which had a mean rating score of less than 3.0, which were 'robust communication skills' under Leadership and 'maintenance of documentation which is not directly GDP related; such as financial statements, invoices, are also retained' under documentation. These two criteria scored 100% weighted average and only passed one score (weighted average) but not the other (mean rating score). Table IV indicates all the skills criteria which did not pass the weighted average from four of the six areas of expertise.

Out of the skills category, the criterion which ranked the highest weighted average and the mean rating score was '*control of environment/area and temperature: recording all conditions including humidity and light*' pertaining to the wholesale distribution premises and activities related to medicinal products area of expertise. This criterion had a score of 100% and 3.80 (weighted average and mean score respectively).

Table IV: Skill criteria with a weighted average score less than 90%

RP area of expertise	Skill criteria	Weighted average score (%)
Management of outsourced activities	Identification and proposition of enhancements of systems and tasks	80
Reviewing and monitoring	Monitoring and review of one's own responsibilities	80
Wholesale distribution premises and activities related to medicinal products	Archiving of data and structured backup systems for maintenance of data integrity	80
Documentation	Documentation is easily available and comprehensive	80

In relation to the educational competencies identified, only one (out of n=17) criterion did not pass both mean rating and weighted average scores with scores of 2.73 and 80% respectively. This criterion was '*being an active stakeholder in supply chain communication'* in the leadership area of expertise. There were additional three competencies which did not pass the weighted average criteria (less than 90%) but these three competencies passed the mean score rating (more than 3.0) – which is displayed in Table V.

Table V: Competence criteria with a weighted average score less than 90%

RP area of expertise	Competence criteria	Weighted average score (%)
Management of outsourced activities	Assessment of the value of outsourced vendors; ensuring that all marketing authorisations and other authorisations are in place	80
	Assessment of procedures in place and approval (ability to define responsibilities)	80
Leadership	Being an active stakeholder in supply chain communication	80
Wholesale distribution premises and activities related to medicinal products	Management of issues with medicinal products to ensure patient safety	80

The competency having the highest score both in terms of weighted average and mean rating score was '*conducting all recall activities and complaints'* classified under the reviewing and monitoring area of expertise. The second highest score both in terms of weighted average and mean rating score was *'risk assessment, management and mitigation'* in the wholesale distribution premises and activities related to medicinal products area of expertise.

Validation - Second Delphi round

In the second Delphi round, a total of 12 participants from the expert panel provided their responses (n=16). Out of the n=59 criteria under assessment, n=58 (98%) were deemed to be validated as both the weighted average and the mean rating score passed the elimination criteria. One of the 59 criteria did not pass the elimination criteria as its mean rating score failed – the score was 2.83 (<3.0) while it had a weighted average score of 92% (>90% - passed this elimination criteria). This criterion was related to the documentation area of expertise entitled *'maintenance of documentation which is not directly GDP related; such as finance statement, invoices, are also retained'* which was removed from the final COMP-RP tool. It also failed the mean rating score in the first Delphi round. The final validated COMP-RP tool (Appendix A) possesses a total of n=58 criteria (consisting of knowledge, skills and competencies).

Discussion

This research defined and validated the educational competencies required for the RP role. There was a need to establish the common requirements of the RP role and define the prerequisites for the RP role – in a harmonised, clear and validated manner (Wadelin, 2017; Vetiutneva *et al.,* 2018). As a building block of the prerequisites for the RP role, this study focused on the development of the following criteria: the knowledge that needs to be acquired, the skills that need to be developed and the competencies to achieve deliverables within the RP role. Henman in 2020 claims that the importance of establishing a competency-based educational framework can be defined as a '*dominant approach in the education of healthcare professionals around the world today'.* The importance of the proposed competency-based educational framework ensures that such competencies which define the role of the RP are reflected in education programs and that learning outcomes are achieved; thereby, satisfying learning objectives (Henman, 2020). After an extensive literature investigation, there was found to be no previous competency framework for the RP position which has been established in pharmacy education

frameworks. However, Atkinson and colleagues in 2016 defined a set of validated harmonised competencies required for '*PHAR-QA'*; the 'Quality Assurance in European Pharmacy Education and Training framework' for the undergraduate pharmacy degree (Jarrett 2018). A similar strategy to what Atkinson and team adopted in this study as a building block during the development of the validated COMP-RP tool resulted in validated competencies and led to the development of a proposed educational competency framework for good distribution practices (Atkinson *et al.,* 2016).

Croft and team claimed that recently healthcare professional-related competencies are driven by *'competency-based education models'* and that there should be '*integration of professional competency standards into education programs'*. This research highlights the relevance and importance of developing knowledge, skills and competencies designed for the specialisation of the RP role. This mindset is in accordance with Croft and colleagues' stance whereby a 'one-size fits all' approach is not practical for all pharmacy roles. (Croft *et al.*2019) Henman (2020) also claimed that there was a lack of development of specialisation and competency-based education frameworks. The competencies proposed in the COMP-RP tool are uniquely designed for the RP role and in line with the argument of Croft and team; that it is not feasible to implement the same competency tool for all pharmaceutical sectors (Croft *et al.,* 2019).

The initial collection, adoption and documentation consisted of 63 criteria put forward including knowledge, skills and competencies which targeted the specific requirements in six areas of RP expertise. The approach to developing the criteria in the six areas of expertise for the RP role in this research was thoroughly defined based on the legal obligations, literature findings and outcomes that the role requires. This formed the structure for the development of the COMP-RP tool. The legal implications and obligations in the RP role are uniform across the board, both on a European Union and a local level, and was required to be addressed in this study when establishing the six areas of expertise. The six areas of expertise reflect the GDP's legally binding obligations which must be maintained in all GDP activities (Joeng and Ji, 2018).

The findings during validation of the COMP-RP tool indicate that both wholesale distribution activities and leadership skills contribute to the largest total number of competencies and skills. These two areas of expertise are essential to the RP role which correlates to the largest number of criteria defined in the COMP-RP tool. Wholesale distribution activities are the responsibility of concern all staff involved and employed at wholesale dealers though it is the RP who has the ultimate responsibility to ensure all legally obliged activities comply with GDP. By acquiring the professional skills and competencies required for wholesale distribution activities, requirements, and standards of the movement of medicinal products throughout the supply chain can be met (Bhaskaran and Venkatesh, 2019). These requirements and standards ensure that medicinal products reach patients in a timely manner in line with the GMP-defined specifications of the Marketing authorisation holder. During validation of the COMP-RP tool, the majority of the expert panel who participated in the first Delphi round ranked knowledge about the supply chain of medicinal products as *'very important: obligatory in the wholesale distribution'*. This indicates that this obligatory requirement is essential in the RP role while the second Delphi round, gave the same ranking to this criterion which infers consistency in the decision process of the panel of experts and portrays the accuracy of the validation of these criteria related to wholesale distribution obligations. Two Delphi rounds were necessary to ensure accurate validation of the criteria in question. The two Delphi round approach in this research was adopted in concordance with Croft and team (2019) claim that to generate robust and valid results, it is essential to ensure that one undergoes the validity of the method of assessment selected in the study. The final validated criteria of knowledge, skills and competencies assessed in the two Delphi rounds demonstrated a robust collection of criteria in the final COMP-RP tool which are relevant and accurate.

A limitation of this study was that the panel of experts was not randomly selected. Influential selection bias may have been present in the findings of the Delphi rounds. The proposed and selected experts were chosen due to their area of expertise in a non-random manner. Another limitation is that responses could have potentially been biased since only closed-ended selections were possible under the Likert Scale – whereby participants could only select the five options from the Likert scale to view their opinions about the criteria under assessment for validation of the COMP-RP tool. Due to the large number of criteria assessed in the Delphi rounds, it was not possible to have a focus group discuss every criterion in question. The Delphi methodology is justified as it provided the opportunity for participants to follow a structured, systematic review of the criteria.

The proposed, validated COMP-RP tool has the potential to address future changes and preparation for novel responsibilities in the RP role. These competencies could be acquired by the competency-

based Pharmacy Education received at the tertiary education level and/or by means of specialisation. Certain competencies defined in the COMP-RP Tool are applicable to other pharmaceutical fields and should be adopted in the curricula of pharmacy education.

Competence goes beyond knowledge of GDP but rather the capability to instil the practices by all workers in pharmaceutical areas of expertise. Leadership is competence and quality which RPs should possess to deliver an effective leadership style and should reflect the management and organisation of actions and tasks in the RP team or wholesale distribution organisation. Attaining a suitable leadership style encourages achievements and the realisation of objectives of the tasks required for the role of the RP (Akparobore and Omosekejimi, 2020). Leadership-related competencies are faced in the day-to-day tasks of an RP which aid to transmit culture-sustaining GDP practices to all staff. Leadership competencies are relevant not only for the wholesale distribution field. Leadership and other competencies established in this study are beneficial, applicable and advantageous to other pharmaceutical sectors including the pharmaceutical industry. The consideration of the implementation of a competency-based approach in this research is also supported by other studies (Croft *et al.,* 2019, Henman, 2020, Volmer *et al.,* 2021) which highlight the importance of having a competency-based pharmacy education-centric approach. In contrast, this study goes a step further in developing a framework with pharmaceutical considerations by specifically focusing on the educational requirements for the RP role. Acquired skills and educational requirements should link the theoretical versus the practical skills and competencies on the job to support the defined learning outcomes (Volmer *et al.,* 2021). The learning outcomes must be associated with the competencies they reflect considering the objectives which are put forward (Henman, 2020).

Further work

Based on the results of the developed tool, this tool can be applied to potentially identify gaps in the current curricula and current workforce or it may be applied within a focus group of graduates and employers to identify gaps in the current educational or workforce setting. Another potential use for this tool is the proposal of a robust and relevant competency-based framework that will address the realistic needs of the workforce both from a theoretical point of view (as addressed in this study via the COMP-RP tool) and also from a practical point of view. The skills, knowledge and competencies identified in this tool can also be adapted for other pharmaceutical areas for areas of expertise that are common to other pharmaceutical sectors.

Conclusion

The establishment of the COMP-RP Tool identified the acquired knowledge, skills and competencies required for the RP role. The most highly ranked competencies identified in this study for the RP role included competencies relating to; Wholesale distribution premises and activities related to Medicinal Products (such as management of patient safety issues); Leadership (such as being an active stakeholder in the supply chain) and; Managing outsourced activities (such as assessment of outsourced vendors and ensuring all authorizations are in place). The implementation of this tool in pharmacy educational institutes may have positive impacts on both the business aspect of wholesale dealers and contribute to minimizing potential risks to patients as pharmacy graduates aiming to work in the wholesale distribution sector would be more prepared for the skill-set required in the role. Both the theoretical and practical competencies have been established in the COMP-RP Tool.

The COMP-RP Tool has the potential to form the basis for proposing a competency-based education framework, currently being investigated by the author. Through this research, the COMP-RP Tool has not only highlighted RP competencies but has also identified generic competencies which have the potential to be common and relevant to all pharmacy education specialisation programs.

Conflict of interest

The authors declare no conflict of interest.

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Appendix A: Validated COMP-RP Tool

KNOWLEDGE
Quality management for a quality system
Implementation and upholding of a quality system
Validation of processes
Management of outsourced activities
Procurement of medicinal products
Reviewing and monitoring
Quality risk management to minimise patient risks
Wholesale distribution premises and activities related to medicinal products
Supply chain of medicinal products – ensuring drugs reach patients in a timely manner
Storage conditions of medicinal products (including temperature, areas of segregation (received vs released), handling of medicinal products etc.
Regulatory requirements and regulatory implications on the wholesale distribution and release of medicinal products onto the market
Calibration of all equipment used within the GDP practices and ensure adequate alarms are in place
Verification and validation of any online systems that are in place; via SOPs or documented procedures/guidelines
Parallel importation; its implications and requirements
Special storage or transportation conditions (have extra secure procedures in place for these products and deliveries)

Ensuring the calibration of the equipment used to transport these products is validated
Documentation
Good Documentation Practice
Documentation of information related medicinal products such as batch numbers, expiry dates, FMD reports, quantities, supplier data, customer information
Legislation, licencing, marketing authorisation.

SKILLS
Quality management for a quality system
Risk management skills in tandem with tasks
Documentation and definition of organogram and standard operating procedures
Management of outsourced activities
Monitoring and reviewing 'outsourced activities
Reviewing and monitoring
Monitoring and review of one's own responsibilities
Recording – with accuracy
Training monitoring: upheld and
continuously adhered to
Leadership
Approval decisions
Definitions of responsibilities
Delegation and recording of delegation activities
Decisions for tampered products; whether falsified or recalled
Leadership skills for the team involved in good distribution practice (including provision of training etc.)
Robust communication skills
Wholesale distribution premises and activities related to medicinal products
Reporting of defects to marketing authorisation holder and manufacturers, and handle the compliant with assessment; with necessary CAPA.
Control of environment/area and temperature: recording all conditions including humidity and light
Archiving of data and structured back-up systems for maintenance of data integrity
Handling of stock rotation; via most recent to most dated shelf life
Stock inventory organisation and recording
Investigation of stock discrepancies should they arise
Destruction handling of medicinal products; in line with the disposal requirements of medicinal products on a national level (including the documentation)
Compliance with GDP guidelines upon accepting returned stock
Documentation
Possession of good documentation and organisational skills; and efficient recording of communications and documentation required
Expedient documentation recording
Maintenance of integrity of data and archiving in with accordance with national legislation (at least 5 years; according to GDP guidelines)
Documentation easily available and comprehensive to others
Responsibility for updating and revising the procedures and documents in place and communicating these updates to the team
Maintenance of documentation systems to ensure smooth supply of medicinal products and ensure record of transport and storage conditions as well as supplier details.

COMPETENCIES
Quality management for a quality system
Management of a change control system
Management of deviations from defined procedures (from
which corrective and preventative actions; 'CAPAs', should be taken).
Management of outsourced activities
Assessment of the value of outsourced vendors; ensuring that all marketing authorisations and other authorisations are in place
Assessment of procedures in place and approval (ability to define responsibilities)
Reviewing and monitoring
Conducting all recall activities and complaints
Participation in self-inspection activities
Leadership
Ability to actively solve issues and problems which arise
Ability to communicate in a clear and effective manner
Contribution of continual professional development and training of team members
Wholesale distribution premises and activities related to medicinal products
Quality mind-set to ensure the integrity of the medicinal product
Conduction of self-inspections for all GDP practices and engage in audits. These should be recorded and any CAPAs implemented within stipulated timeframes
Management of issues with medicinal products to ensure patient safety
Risk assessment, management and mitigation
Documentation
Maintaining accuracy
Evaluation of scientific data
Organisation management.