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Requirements to balance risk and multi-user experience: the case of pharmaceutical packaging design

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ABSTRACT: This paper presents two studies with packaging design engineers and quality and risk professionals in the pharmaceutical packaging industry, addressing the critical need for design support. The studies contribute to the development of a framework aimed at balancing risk management and multi-user experience in the context of product support. A review of prior work highlights the gap in tailored support for designers in this field. Using structured interviews and thematic analysis, seven key requirements were identified to guide the framework's creation. A user persona was also developed, capturing the core responsibilities, challenges, and motivations of quality and risk professionals. These findings provide actionable insights to aid designers address complex regulatory and user-centric challenges, paving the way for innovation and improved outcomes in pharmaceutical packaging design.

KEYWORDS: user centred design, risk management, product support, design methodology, pharmaceutical packaging

1. Introduction

The packaging industry is one of the most versatile and extensive industries presently active, with the European packaging industry being expected to grow with a compound annual growth rate (CAGR) of 4.07%, from 153 billion euros in 2024 to 186 billion euros by 2029 (FACHPACK, 2024). Packages are made to satisfy four main functions: (1) product containment, (2) product protection, (3) user convenience and (4) communication of the package with the user (Robertson, 2012).

Taking into consideration the pharmaceutical packaging industry, the main challenges faced include, but are not limited to, the integrity and stability of medication which can be adversely affected by environmental conditions, including humidity levels, light exposure and temperature excursions. Tampering of medication and counterfeit products are additional issues which could be detrimental to consumer safety, and consequently, brand image (Raman et al., 2023). It is therefore critical for pharmaceutical packaging to be both compliant with regulations (for user safety) and easily usable by their target market. It is therefore necessary to ensure that human-centred design and user experience are integrated within a pharmaceutical packaging product.

1.1. Human-centred design in pharmaceutical packaging

According to ISO 9241-220:2019 by the International Organisation for Standardisation (2019), human-centred design (HCD) refers to the *"approach to system design and development that aims to make interactive systems more usable by focussing on the use of the system; applying human factors, ergonomics and usability knowledge and techniques"*. The implementation of HCD in the pharmaceutical packaging industry can aid in bringing forward the voice of the customer, user perspective, and boost innovation in the industry by eliciting empathy for target users during the design process. This results in the understanding of how distinct user groups experience a product or system,

recognising any challenges and limitations they may face, and working to mitigate them in a holistic manner (Adam et al., 2020). The implementation of HCD in the pharmaceutical packaging industry thus implies the application of multi-user experience and risk management to understand the user's experience when using a product and work towards eliciting a more positive user experience whilst minimising any potential risk that may arise when using the product. Such risks may include, for instance, the presence of impurities within a medication, an increase in medication weight and size which can have adverse effects on the consumer, and potential degradation within the package (Charoo & Ali, 2013; Ismael & Ahmed, 2020). Thus, pharmaceutical packaging designers must consider a wide range of factors which would collectively affect the subsequent life phases. Within this context, the overall objective of this research is to develop a framework to support packaging design engineers to balance risks and multi-user experience when designing pharmaceutical packaging products.

The following section describes the materials and methods used, inclusive of a review of related work and the methodology employed to conduct the studies defined throughout this paper. The results of the studies conducted are provided in Section 3, followed by a brief discussion in Section 4. A conclusion is ultimately drawn in Section 5.

2. Materials and methods

This section consists of a systematic literature review conducted to find related work on design support currently available for design engineers in the pharmaceutical packaging industry. This is followed by the methodology employed for the studies considered within this paper.

2.1. Review of related work

A systematic literature review was conducted to identify and analyse existing approaches and tools aimed at providing design support to packaging design engineers within a pharmaceutical context. To do so, the following question was inquired aimed at generating a focus for the systematic search:

> *"To what extent are design engineers supported when designing a pharmaceutical package?"*

Consequently, the following search string was formulated:

> *"design support" AND "pharmaceutical" AND "packaging" AND "product design"*

Of the studies returned, those that did not discuss a consumer product were removed. Such studies included, for instance, discussions on software innovations or logistics services for e-retailers. The inclusion and exclusion criteria employed have been presented in Table 1 and the flow of the systematic literature review conducted and the databases used have been depicted in Figure 1.

Table 1. Inclusion and exclusion criteria applied when filtering the studies

Inclusion Criteria	Exclusion Criteria
• Studies published 2015 - November 2024	• Retracted studies
• Studies must be journal articles, review articles or conference papers obtained from the following databases: Scopus, ScienceDirect or Google Scholar	• Duplicate studies
• Studies must discuss consumer products	• Non-English studies

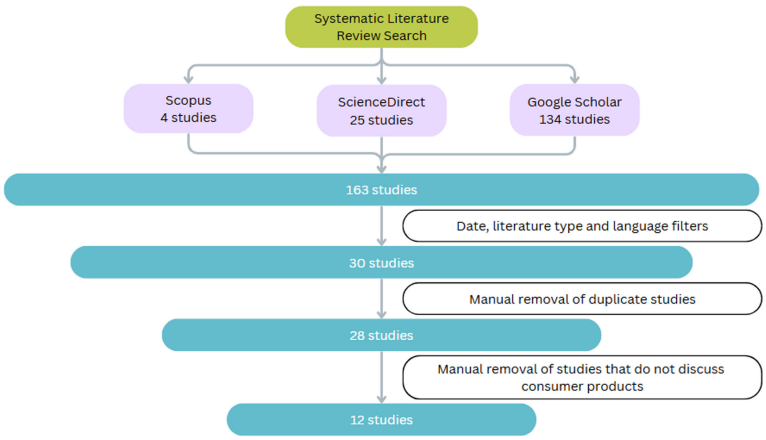

Figure 1. Flow of the systematic literature review search

Of the 12 studies returned, a sample of 6 have been considered for discussion within this paper that address product development and their contributions to design support for engineers. A user-centred approach is emphasised in the ASSIST-OTCPP framework for over-the-counter pharmaceutical (OTCP) packaging developed by Camilleri et al. (2023). This framework actively supports engineers through stakeholder engagement, consumer insights and a structured computer-based tool for decision-making. Similarly, Berry et al. (2024) discuss the successful development of a novel strategy to scale-up health innovation in Zambia, aimed at treating diarrhoea in children under five years of age using a co-packaged oral rehydration salts and zinc (ORSZ) product. This strategy highlights product testing and participatory approaches but lacks an overall structured design tool for engineers. Whilst elements such as the design of the packaged ORSZ product are considered, the strategy discussed does not delve into the risk management of such a product when used by children or other users.

A study on bioprinting medical devices by Li et al. (2022) focusses on quality management and regulatory compliance, providing little direct support to the engineer. Two of the studies reviewed implement Life Cycle Assessment (LCA) and Multi-Criteria Decision Analysis (MCDA) to guide design engineers in material selection. Ingrao et al. (2015) discuss using LCA to model the environmental impacts of using PLA trays for fresh-food packaging. Similarly, the eco-design framework for bio-based materials developed by Müller-Carneiro et al. (2023) focusses on integrating LCA and MCDA for sustainability evaluation. Both these studies focus on the environmental impacts of their products, but do not discuss any design support that can be provided to engineers. Finally, Parisi et al. (2018) discuss their research on Interactive, Connected and Smart (ICS) materials which explores material properties and aesthetics but no explicit design support for engineers is provided.

Since 2015, research on design support for engineers within the pharmaceutical packaging industry has been minimal, highlighting the need for further study. No research found has addressed balancing risk management and multi-user experience in pharmaceutical packaging design. This paper aims to bridge this gap by introducing the **P**roduct **SU**pport when balancing **R**isk **M**anagement and multi-**U**ser e**X**perience (PSURMUX) framework as a foundation for an intelligent computer-based design support tool. The framework considers multiple users, focussing on older people as primary end users, with caregivers and nurses as secondary users. Despite this boundary, this study's findings remain relevant to users with disabilities and/or chronic conditions.

2.2. Methodology

To develop the PSURMUX framework, the methodology illustrated in Figure 2 has been employed. The methodology is characterised by five phases of data collection, including obtaining data from packaging design engineers, quality and risk professionals, as well as potential end users. Evaluation studies shall also be incorporated with packaging designers in the later stages of this research. This paper focuses on the studies conducted with the first two categories. The first study with packaging design engineers was aimed at obtaining critical data pertaining to the requirements necessary for the development of the PSURMUX framework. The second study was conducted with quality and risk professionals in the pharmaceutical packaging industry and was aimed at obtaining data related to the quality and risk profession in order to create a generic persona who could be referred back to during future studies.

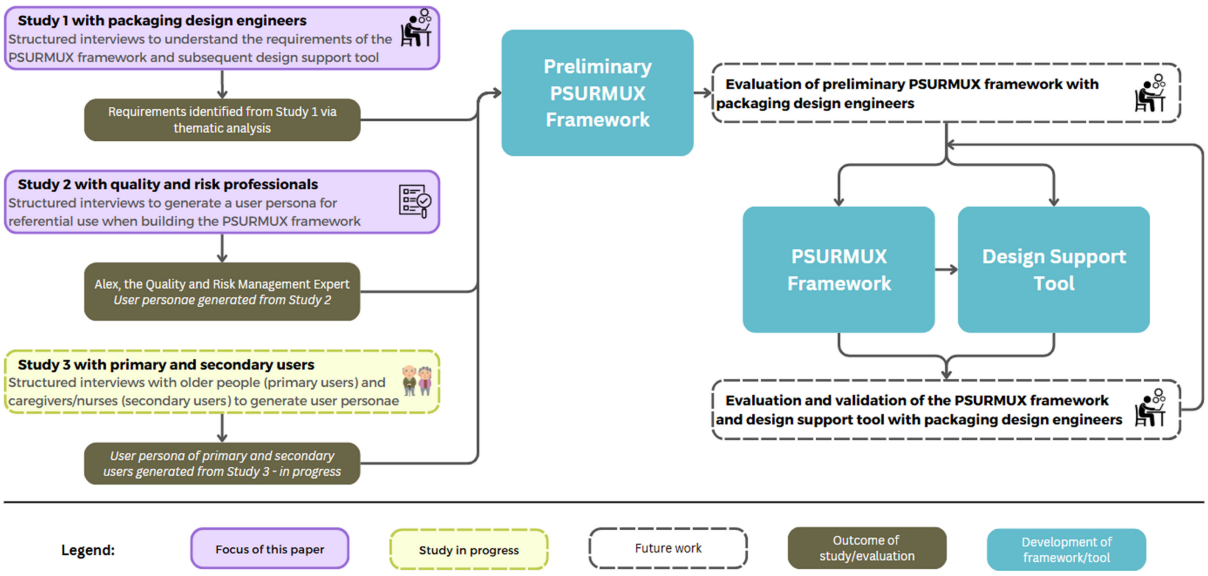

Figure 2. Interaction between study outcomes and development of the PSURMUX framework

2.2.1. Participants

Both studies consisted of structured 45–60-minute interviews without recordings, collecting text-based qualitative and quantitative data through Likert scales, multiple choice, and open-ended questions. The first study, held with seven packaging design engineers, targeted the participants' experience with designing pharmaceutical packaging, the challenges faced during their design process, and what they would require from a design support tool aimed at providing support when balancing multi-user experience and risk management. The second study, held with five quality and risk professionals, aimed to obtain information on day-to-day work life which was then analysed and used to generate the user persona. All participants were contacted and recruited directly by the authors via telephone or email. During both studies, all participants were assigned a code to ensure anonymity throughout the entirety of the research. These have been presented in Table 2 for both studies, along with basic participant information, namely gender, age bracket and years of experience.

Table 2. Participant information for studies 1 and 2

Study 1				**Study 2**			
Participant Code	*Gender*	*Age Bracket*	*Years of Experience*	*Participant Code*	*Gender*	*Age Bracket*	*Years of Experience*
DE1	F	51 - 60	> 10 years	QRP1	F	46 - 55	> 10 years
DE2	M	31 - 40	> 10 years	QRP2	M	36 - 45	> 10 years
DE3	M	41 - 50	> 10 years	QRP3	M	26 - 35	5-10 years
DE4	M	22 - 30	6-10 years	QRP4	M	26 - 35	5-10 years
DE5	M	51 - 60	> 10 years	QRP5	M	46 - 55	> 10 years
DE6	F	41 - 50	> 10 years				
DE7	M	31 - 40	6-10 years				

An ethics form (ENG-2023-00111) was submitted to the authors' institution for both studies. Structured interview questions were validated by five experts from academia and the pharmaceutical packaging industry, with feedback prompting adjustments such as removing irrelevant questions, adding images for clarity and rewording for better comprehension. The collected qualitative data was then analysed using thematic analysis to identify key themes and patterns.

2.2.2. Thematic analysis

Thematic analysis is used to analyse qualitative data to identify and interpret patterns, or 'themes', within the data. Braun et al. (2019) developed a is a six-phase approach for this method: (1) Familiarisation -

immersing oneself in the data through repeated reading, listening and viewing; (2) Coding - systematically categorising data; (3) Theme construction - identifying patterns based on researcher interpretation; (4) Theme revision - ensuring alignment with a central concept; (5) Definition - refining themes for clarity; and (6) Reporting - evaluating theme effectiveness individually and in the dataset. For each study, the data was transcribed and the scripts were re-read for familiarisation. Each transcript was then coded via the MAXQDA Analytics Pro software for qualitative data analysis (MAXQDA, 2023). The transcribed scripts were coded and analysed with the assistance of the integrated Artificial Intelligence (AI) tool. Following analysis, the results were reviewed by the researcher. For the first study with designers, the identified themes have been presented as requirements for the framework.
When using MAXQDA, the integrated AI system can assist the user by providing suggestions, summarising documents and paraphrasing sections in a document. The use of AI in qualitative data analysis can assist a researcher by providing an opinion without the same emotions and biases as the researcher, which are inherently human in nature. This was established during the 2024 MAXQDA International Conference (MQIC), where discussions on the opportunities and challenges of AI in research were held (MAXQDA, 2024).

2.2.3. Use of user persona

Personas represent user needs, fostering and influencing product design. They can be used to define product requirements, serving as a foundation when building a product design specification (PDS). Personas can be referred to when validating product requirements as they aid in identify issues such as requirement redundancy, and potentially, risks associated with requirements (Salminen et al., 2022).
In the second study conducted, a user persona was generated as a result of thematic analysis to establish to have an expert on quality and risk management to refer to in future studies. This shall then be used when building the PSURMUX framework, and when creating the consequent design support tool. The user persona generated is presented in Section 3.2.2.

3. Study results

This section presents the results of the studies conducted as: (1) requirements for the PSURMUX framework resulting from the study with packaging designers (Section 3.1) and (2) the themes identified, and persona generated from the study with quality and risk professionals (Section 3.2).

3.1. Study with packaging design engineers

3.3.1. Requirements identified from the thematic analysis

Seven requirements have been extracted and deemed necessary to implement when developing the PSURMUX framework, and the subsequent design support tool, to help design pharmaceutical packaging products. A sample of the codebook generated for this study is provided in Table 3.

Table 3. Sample of the codebook used during study 1

Code	Description	Example	Associated Theme
Inclusion of diverse user groups	Incorporation of guidelines to design for multiple users.	"*A tailored framework would help ensure the design accommodates their* [the potential users] *specific needs . . .*" (DE1)	Support for user-centred design and accessibility
Support for AI	Agreement that AI should be incorporated into the framework to enhance decision-making and risk analysis.	"*The capability of AI is surely something to consider for this process and may lead to significant benefits*." (DE2)	Incorporation of AI for enhanced risk assessment and efficiency

Requirement 1: Support for user-centred design and accessibility: The framework should include guidelines for designing packaging for diverse users, including older people, nurses, caregivers, and people with disabilities, ensuring safety and accessibility for all. DE1 stated that *"a tailored framework would help ensure the design accommodates their* [the potential users] *specific needs, improving safety,*

usability, and accessibility". To prevent user injury and accommodate physical limitations, DE1 and DE3 noted that the PSURMUX framework should provide the best possible practices for ease of opening and usability. Similarly, the design support tool should be able to assess risks related to accessibility and ease of use, such as packaging features potentially leading to user injury. As recommended by DE4 and DE6, the design support tool should enable packaging designers to input user feedback and usability test results to inform the risk analysis.

Requirement 2: Incorporation of AI for enhanced risk assessment and efficiency: All participants, save for DE5 and DE7, expressed that they would want AI to be incorporated into the PSURMUX framework and design support tool. The participants who agreed noted that the implementation of AI should be the future of the industry. DE2 and DE3 respectively mentioned how *"the capability of AI is surely something to consider for this process and may lead to significant benefits"* and that *"it is the future of this industry - human/AI collaboration is becoming a must in assuring high-quality outcomes"*. DE7 remained neutral, stating that he *"fails to see how the current AI, based on LLM* [Large Language Model]*, can be of use in such cases where precision is a must"*. On the other hand, DE5 was against the integration of AI within the framework and/or design support tool, with his reason being that *"they* [AI systems] *aren't intelligent"*. The participants who agreed noted that guidance should be provided on using the AI system within the framework and how this should provide predictive risk analysis. The areas in which AI can be used to assist in decision-making and the areas where human expertise is necessary should be detailed within the framework. The participants noted that with the incorporation of AI, suggestions should be made by the AI for the severity, probability and detectability of a risk, with mitigation measures included, as part of the risk analysis. Despite the integrated AI system, the design engineer should be able to review, adjust, and validate any recommendations.

Requirement 3: Incorporation of regulatory compliance and market-specific requirements: Up-to-date regulatory guidance should be provided through the framework based on the target market/s to *"help us* [the designers] *understand what the requirement of each market is"* (DE4). This would include specific standards such as those for packaging labelling and safety requirements, tailored to distinct regional regulations. As noted by DE1, *"a framework that provides up-to-date regulatory guidelines for different markets would simplify the design process, helping designers focus on creating effective packaging"*. A compliance checklist or reference list, including guidelines from the EU and FDA, should be included to aid packaging designers meet both local and international standards. It was noted that integrating regulatory compliance as a factor in risk assessments within the design support tool would allow designers to identify and prioritise any risks related to regulatory requirements, thus streamlining their process.

Requirement 4: Guidance on material selection and environmental stability: Material selection guidelines, based on product requirements, have been deemed necessary to incorporate into the PSURMUX framework by all participants, save for DE2 and DE5, who remained neutral on the matter and noted that it *"entirely depends on the project objectives"* (DE5). Despite agreeing, DE6 noted that *"such a framework should take into consideration the stability requirements of the product being packaged"*. Guidelines should cover material durability, environmental stability and pharmaceutical compatibility. The design support tool should assess risks such as material degradation due to humidity or temperature changes and suggest mitigation strategies to ensure integrity.

Requirement 5: Risk mitigation and quality control for product integrity: DE1, DE3 and DE4 agreed that the PSURMUX framework should provide a step-by-step risk mitigation process for all design stages, based on the systematic approach to engineering design established by Pahl and Beitz (1988). DE2 agreed but stated he would not want the framework to cover the conceptual design phase of the design process as *"conceptual design may include abstract processes that would be restricted with the introduction of the AI tool"*. DE6 suggested implementing the framework in the task clarification and detailed design stages. DE5 and DE7 both stated they would want the framework to solely cover the task clarification stage, reasoning that *"the earlier one knows the risks, the better"* (DE7). Critical risks like tamper-evidence, contamination, sealing integrity and transport damage should be addressed. Guidelines aligned with Good Manufacturing Practices (GMP) should be included to offer mitigating actions that ensure packaging integrity.

Requirement 6: Integration with production constraints and manufacturing capabilities: All seven participants agreed that it is important to incorporate guidelines on production feasibility within the framework that include aspects such as alignment with machinery capabilities, material compatibility, as

well as production constraints such as printing colour limitations. DE1 emphasised that *"manufacturing is one of the three main factors ...* [which is influenced by] *... design, as it is what allows us* [the designers] *to materialise our ideas and ensures scalability and feasibility. To implement our designs, we must definitely rely on manufacturing capabilities, regardless of whether they can be innovated"*. Similarly, DE3 stated that *"it is useless to design a packaging product which cannot be physically produced or design it full of colours and the printer is restricted with its printing colour capabilities"*. The framework should thus incorporate suggestions aimed at optimising production efficiency, potentially lowering costs and improving overall equipment effectiveness and performance.

Requirement 7: Structured documentation and collaboration across teams: DE6 and DE7 mentioned how the PSURMUX framework should support standardised documentation, with templates for data input from various departments, facilitating the tracking of design decisions and improving communication. Clear guidelines for inputting and reviewing points should be provided to foster cross-functional collaboration among stakeholders. As recommended by DE1 and DE6, collaborative input from various stakeholders should be facilitated via the design support tool to enable contribution of insights between teams on potential design flaws and risks.

3.2. Study with quality and risk professionals

3.2.1. Themes identified from the thematic analysis

Five themes were extracted and deemed necessary to build an adequate user persona that reflects quality and risk professionals. A sample of the codebook generated for this study is provided in Table 4.

Table 4. Sample of the codebook used during study 2

Code	Description	Example	Associated Theme
Regulatory Compliance	Ensuring adherence to industry regulations to maintain product quality and safety.	"*Quality is not something that should be improved on, it is either good or bad quality*." (QRP4)	Commitment to Quality Control and Compliance
Risk Mitigation	Identifying and reducing risks in production and packaging to prevent defects, recalls, or contamination.	"*Biggest risk is cross-contamination*." (QRP3)	Commitment to Quality Control and Compliance

Theme 1: Commitment to quality control and compliance: All five participants emphasised that ensuring and maintaining quality is of high priority. Quality is not just an aspect to improve on to these professionals, it is a fundamental measure that *"is not something that should be improved on, it is either good or bad quality"* (QRP4). Compliance with internal and regulatory standards, including industry certifications such as ISO 9001 and GMP, is crucial. It also requires thorough documentation and systematic record-keeping, as well as addressing customer complaints. All participants noted that their tasks related to risk identification and mitigation are critical and include managing risks such as cross-contamination.

Theme 2: Balancing cost efficiency with quality: Pressure to cut costs was noted among all participants, with QRP1 stating that *"competition is high so cost reduction is important, but not at the expense of quality"*. Competition is one of the drivers for cost efficiency, and cost-saving initiatives such as the introduction of augmented reality (AR) to streamline processes, as elaborated by QRP1, have been implemented in some companies to support efficiency. QRP 4 explained how various key performance indices (KPIs) are designed to meet both financial and quality metrics, such as cycle times and Corrective And Preventive Action (CAPA) closures, respectively. These reflect the dual objectives of quality and risk professionals: quality and productivity, which can be challenging to balance with limited resources and high safety standards. QRP3 noted *"a struggle is that resources are limited, so issues sometimes need to be compartmentalised"*.

Theme 3: Challenging regulatory and audit landscape: QRP1, QRP2 and QRP3 noted that the regulatory environment is particularly demanding, with certain regulatory audits being *"very demanding ... high expectations for the audit and low company resources"*.

QRP3 also stated that *"client audits are sometimes worse than certification audits"* due to clients having high and specific standards that may be difficult to meet without extensive resources. The need to compartmentalise issues due to limited resources therefore adds to the challenge. Managing quality also requires coordination with external suppliers, which are often large and international. QRP3 noted that since *"suppliers are big and foreign, company complaints are not always considered, they are overlooked"*. External pressures and supplier dependencies can be highlighted, which impact the ability to meet both internal and external quality standards. It was also noted by QRP5 that compliance challenges are not solely resource-based but also depend on the availability of skilled personnel with the necessary knowledge to navigate regulatory requirements.

Theme 4: Dependence on, and optimisation of, tools and systems: All participants, save for QRP5, noted that, in general, they tend to rely heavily on quality and risk management software such as TrackWise (quality management system) and SAP (software used for quality control) to aid in maintaining comprehensive quality records and documenting each stage of the quality management process. QRP5 stated that *"we* [QRP5's company] *don't use any software, everything is hand-calculated"*. This can increase workload and the potential for error, and QRP5 noted that he was not satisfied with the matter. All five participants stated that they make use of analytical methods such as the Ishikawa method, PARETO analysis and Failure Mode and Effect Analysis (FMEA) to investigate non-conformities and provide a structured approach to risk and quality control. QRP1 and QRP2 noted that quality checks are integrated into production machines at their company, which shows the close relationships with engineering and validation teams to ensure that every part of the production process is adherent to quality standards.

Theme 5: Collaboration and team support as key motivators: All five participants highlighted the importance of teamwork and QRP5 stated that *"the team is very hands-on in terms of how challenges are handled and mitigated"*, stressing the importance of a collaborative environment. A strong team helps navigate challenging work conditions, external pressures and high expectations. QRP2, for instance, highlighted that the team, inclusive of shop floor and departmental teams, is a significant motivator in his role. All participants agreed that they feel rewarded when successfully mitigating risks or resolving quality-related issues. QRP4 also noted that this motivation extends beyond his company to the broader impact within the entire supply chain, reflecting his commitment to safety and reliability. Additionally, QRP5 noted that employee retention indirectly contributes to quality as more experienced employees are better acquainted with processes and machinery, leading to fewer errors and greater consistency in quality output.

3.2.2. Quality and risk persona generated

Based on the thematic analysis, a generic persona named Alex was created. Alex serves as an expert on risk management in the pharmaceutical packaging industry, providing a reference for developing the PSURMUX framework and its design support tool. Alex is a highly experienced quality and risk management specialist in the pharmaceutical packaging industry, skilled in ISO 9001 and GMP standards. He is responsible for identifying and mitigating risks, managing product quality, and ensuring regulatory compliance. Alex's main goals are: (1) maintaining high product quality and compliance with regulatory standards, (2) reducing production costs, and (3) surpassing both financial and non-financial KPIs. Alex's main challenges are: (1) managing strict audits and regulatory requirements within a resource-limited environment, (2) dealing with foreign suppliers who may overlook issues raised, and (3) balancing cost reduction with the uncompromising demands for quality and safety.
Proficient in tools like TrackWise, SAP, and methods such as Ishikawa, PARETO analysis, CAPA and FMEA, Alex thrives in team collaboration and solving complex risk-related problems. He is motivated by the impact of quality control on employee satisfaction and retention, as well as link between consistent process quality and reduced error rates.

4. Discussion

The studies conducted aim to fuel the ongoing research into the development of the PSURMUX design support framework, and consequently, a design support tool that implements the framework, as presented in Figure 2. The first study with packaging design engineers identified seven key requirements essential for a well-founded framework and design support tool. These elements are not only crucial for

developing the framework but can also be applied throughout the product design process, making them highly relevant for packaging designers in industry. Similarly, Alex, the persona developed from the second study with quality and risk professionals, embodies five central themes that reflect the responsibilities, challenges and motivations of the quality and risk profession. Alex provides a focussed perspective, helping design engineers meet the expectations of quality and risk professionals. Through Alex, design engineers can align their pharmaceutical packaging products with the complex priorities of quality and risk professionals. Combining Alex's insights with the requirements from the first study offers an integrated approach to designing pharmaceutical packaging products.

Considering that the studies conducted are aimed at fuelling the framework and design support tool, which are still under research, the requirements and themes identified throughout this paper can be leveraged by packaging design engineers as valuable and actionable resources that can be used to streamline the pharmaceutical packaging design process. By addressing regulatory compliance, usability, production constraints and advanced risk assessment, engineers are provided with a means to balance technical demands with user-centred outcomes. This would ultimately lead to the creation of safer, more efficient and market-ready packaging solutions. Considering, for instance, a pharmaceutical company designing child-resistant packaging, leveraging the risk assessment and regulatory compliance requirements, one can ensure that the packaging meets international safety standards whilst minimising usability challenges for users who are older people. Similarly, incorporating the persona of Alex allows engineers to tailor designs that align with industry expectations for product integrity, mitigating risks related to tamper-evidence and cross-contamination.

By combining the user-centred requirements identified in the first study with Alex's insights from the second study, engineers can gain a comprehensive approach to pharmaceutical packaging design. This integrated method enhances efficiency, compliance and safety, ultimately leading to innovative and marker-ready solutions that satisfy both end users and regulatory bodies.

4.1. Study limitations

The main limitation faced during this study was the small sample size. The local pool of packaging design engineers and quality and risk professionals in the pharmaceutical packaging industry is limited, considering the country's size and number of pharmaceutical packaging companies.

4.2. Future work

Studies with primary and secondary users are being conducted and are aimed at understanding the day-to-day experience of older people (primary users) as well as nurses and caregivers (secondary users) when using pharmaceutical packaging, which will consequently lead to the generation of primary and secondary user personae. These studies aim to fuel the development of the PSURMUX framework, and consequently, a design support tool. Evaluation studies for the framework and design support tool are planned to be conducted in the future, as depicted in Figure 2 (Section 2.2).

5. Conclusion

The main contribution of this paper is the identification of key requirements for developing a design support framework to assist packaging design engineers in creating pharmaceutical packaging products. At present, designers have limited resources and little research addresses balancing risk management and multi-user experience in such designs. This paper aims to begin bridging this gap. In addition to the ongoing development of the PSURMUX framework, the outcomes of the studies discussed can be independently utilised by designers as needed. The requirements identified, such as the support for multi-user centred design, the incorporation of AI and risk mitigation and quality control, provide a strong foundation for developing the PSURMUX framework to create safer, more efficient packaging solutions. In addition to this, the user persona 'Alex' provides an understanding into the needs, motivations and challenges faced by quality and risk professionals which can be used as a reference by design engineers to ensure that packaging solutions are aligned with real-world demands for compliance. Future research and studies will continue to investigate the balance between multi-user experience, risk identification and management, and product design support in pharmaceutical packaging design.

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