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Optimisation of Medical Device Design Transfer Procedure

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Abstract

A Medical Device Design Transfer (MDDT) is a process of transferring medical device design information from Research and Development (R&D) to Production, for the purpose of producing the medical device. It is worth noting that if the MDDT process takes place prematurely (without doing design verification, design validation, and process validation), it poses a severe risk to start-up medical device organisation. Ultimately, a poorly executed MDDT process can result in quality challenges with manufacturability, repeatability, and consistency during large-scale production of the medical devices. Therefore, this study, conducted at a selected South African organisation, Organisation X, aimed to investigate how the MDDT process can be optimised. The research adopted a qualitative approach. Data was collected using semi-structured interviews. The target population included three key participants, namely, the lead design engineer, the lead manufacturing engineer, and the production manager, who are employees of Organisation X. The interview transcripts were analysed using thematic analysis. A pilot study was used to ensure the validity of this research instrument, and therefore the reliability of the research results. The study's findings revealed that effective MDDT depends on well-structured documentation, availability of skilled resources, effective training and knowledge transfer, clearly defined roles and responsibilities, and cross-functional collaboration. The study identified five potential risks associated with the MDDT process. Consequently, the findings identify four critical steps that should be incorporated into the optimised MDDT procedure. Ultimately, the study emphasises the significance of documenting and transferring tribal knowledge.

Keywords
Medical device design transfer, quality management system, design and development, design control

1. Introduction
Organisation X is a medical device manufacturer in the Western Cape. The lack of a standardisation around the process to transfer medical device design information at the selected organisation (Organisation X), which poses a challenge to effectively and efficiently transfer the design information from the R&D phase to the production phase. The result of ineffective and inefficient transfer can have a severe negative impact on Organisation X, such as product launches being delayed. Furthermore, more importantly, patient safety concerns may arise as product quality and performance may be adversely affected and costs may increase. It is therefore necessary to ensure that the MDDT process is well executed.

A medical device (MD) is equipment that is developed to be used to diagnose, treat, or monitor potential diseases. Medical devices can have a huge impact on the quality of human life. Miclăuş et al. (2020) stated that inadequate medical device design can impose serious risks, such as medical device recalls on the market or patient fatalities. As notably Miclăuş et al. (2020) gave an example of a well-known incident at Pelonomi Hospital, where an inadequate design in a life-support medical device resulted in a patient's death because the device lacked warnings against unplugging from the power source. Therefore, for medical devices to serve the intended purpose they were designed for, they need to be accurate, reliable, and robust to perform according to specification in order to avoid harm to patients. Consequently, medical device regulation is essential. The forementioned regulation primarily aims to ensure that patients have access to high-quality, safe, and effective products. Furthermore, medical device regulation prevents unsafe medical devices from entering the market. According to Guerra-Bretaña and Flórez-Rendón (2018), the objective of regulations governing medical devices is to safeguard both patients and the broader community from hazardous products, while also enhancing public health by introducing cutting-edge products to the market that can provide advantages to patients. It is, therefore, important that regulations are strictly followed to benefit public health by assuring the safety of patients and workers operating the devices.

Against this backdrop, transferring Medical Device Design Information (MDDI) from the Research and Development (R&D) phase to the production phase for regular production can pose significant challenges for a new start-up medical organisation. Abuhav (2018) highlighted that the MDDT process aims to ensure that the design of the medical device is accurately and effectively translated into a final device suitable for its intended use. Additionally, the key element of this process is to verify that all specifications, procedures, and quality requirements are transferred from the R&D phase to production, ensuring consistency, safety, and compliance throughout the production phase. Teixeira (2019) also stated that the goal of the MDDT process is to ensure that design outputs are effectively and correctly translated into production specifications. Similarly, a poor MDDT process can put a patient’s life at risk, or worse, it can result in fatality. Moreover, poor MDDT can result in production problems, such as inconsistency issues in production. These issues result in high percentage failure rates in production, which raise production costs. Often, this occurs when the medical device design information is released, however not mature enough (without preliminary design checks such as design verification, design validation, and process validation) or before the device is ready for mass production. In this case, the readiness status of the medical device is not yet known before the MDDT process takes place.

It is worth noting that MDDT process involves converting device design information into feasible production methods and procedures that align with the organisation’s capabilities and its vendors. Schönberger and Hoffstetter (2016) described MDDT as a structured, well-documented procedure that guides how medical devices should be manufactured. Moreover, when implemented effectively, MDDT ensures that the device’s redefined characteristics are consistently achieved and maintained during the production process and remain acceptable. Tranquillo et al. (2022) stated that MDDT signifies the handoff of a completed design and tested prototype to production, which is the last step in the engineering design process. The objective of MDDT is to ensure that everything required for production is successfully transferred from the R&D phase to the production phase. Abuhav (2018) further stated that the MDDT process defines the work done to release the medical device for mass production to the Quality department.

The foregoing emphasized the criticality that medical devices be manufactured in compliance with a recognized quality management system, such as ISO 13485:2016 or equivalent. Jalnasow (2019) advances that ISO 13485:2016 ensures that medical devices consistently meet customer and regulatory expectations and focus on patient safety and quality throughout the entire lifecycle of the medical device. Moreover, ISO 13485:2016 requires organisations to have a documented procedure for transferring medical device design information from R&D to production. However, the standard makes no provision for how organisations are required to do this. Specifically, Clause 7.3.8 of the ISO 13485:2016 standard states that the organisation shall document procedures for the transfer of design and development outputs to production. Although this clause specifies that the transfer should occur, it does not define what the process should look like or what elements must be included. Ultimately, the standard only requires that organisations implement procedures to ensure that design and development outputs are verified as suitable for production before becoming final production specifications and that production capability can meet product requirements. Consequently, this leaves room for interpretation and variation. Each organisation must define and document its approach to MDDT. However, without clear guidance, this process can be inconsistent, incomplete, or inefficient, especially in complex or highly regulated environments. This research study set out to address this research gap at Organisation X.

Ultimately, the lack of standardised MDDT at Organisation X results in inadequate planning, inadequate knowledge transfer, inconsistencies in pilot production, incomplete documentation, and poor post-transfer evaluation. Furthermore, a poor MDDT process can put a patient's life at risk, or worse, it can result in fatality.

1.1 Research Objectives

Therefore, this study aims to develop an optimised MDDT process that can be used to ensure that the medical device design information is adequately transferred from the R&D phase to the routine production phase at Organisation X. To achieve this, the following objectives were set out:

1. To determine the key factors that should be considered during the MDDT from the R&D phase to the routine production phase.
2. To determine the potential risks associated with the MDDT and develop a mitigation strategy.
3. To establish an effective MDDT procedure that can be used to ensure that the medical device design information is adequately transferred from the R&D phase to the routine production phase.

2. Literature Review

2.1. The Steps in MDDT

Prior to any attempts to optimise a MDDT process, it is necessary to understand the basic steps, as seen in Figure 1, that should be included based on the existing literature. Aitchison et al. (2009) stated that MDDT is a critical stage in the development of medical devices and the medical sector, where patient safety, product quality, and regulatory compliance are highly critical. Busby (1998) stated that the key elements of effective MDDT involve considering production considerations in the early stages of the design process and establishing effective communication channels between the design and production teams. Furthermore, Busby (1998) argued that successful MDDT not only depends on documentation and procedures but also on organisational competence to manage knowledge and workflows effectively and efficiently.

Bioaccessla (2024) highlighted stated that the key practices for effective MDDT include early planning (starting the transition of concepts at the early stages of the development cycle), cross-functional collaboration (promoting collaboration between stakeholders involved helps to ensure a smooth transfer process), and proper documentation (it is essential to document detail records of the transfer process. This helps to simplify the review process). Bioaccessla (2024) revealed that the process steps for effective MDDT include planning, document review, production process development, verification and validation, training, and design transfer.

Maney (2024) concurs that medical device transfer is essential as it ensures that the medical device can be manufactured at a large scale, meets the regulatory requirements, and ensures patient safety. Subsequently, Maney (2024) also highlighted that MDDT process ensure smooth collaboration between the R&D and the production team, resulting in efficient production and accelerating the medical device launch to the market. Notably, Maney (2024) also concurs that ISO 13485:2016 regulatory requirements require medical device organisations to establish and document a procedure for transferring design information to production. Furthermore, to ensure that production capabilities align with product requirements, the procedure must ensure that the design output is suitable for large-scale production before finalizing it as production specifications. Maney (2024) outlined that the MDDT process should include design transfer plans and internal preparation (document review). It is essential to review internal documentation and approved suppliers to ensure the documentation is ready for transfer. Training, verification, pilot production, completing design transfer (document control), and lastly, transfer evaluation must follow.

Similarly, Cormican and O'Connor (2007) described the MDDT process as a strategic process used to transfer design information from R&D to production and ensure compliance. It is worth noting that Cormican and O'Connor (2007) argued that MDDT is a complex process that requires detailed planning, implementation, and well-managed to mitigate the risks of poor MDDT. Furthermore, the authors outlined that the MDDT structure should include design transfer preparation and team formation, training plan development, validation planning, transfer project planning, and information and equipment transfer.

Drawing on the views of Bioaccessla (2024), Maney (2024), Cormican and O'Connor (2007), the MDDT process should include design transfer planning, design document review, verification and validation, training and knowledge

transfer, pilot production, document control, and lastly, post-transfer evaluation. Subsequently, Figure 1 below is a graphical depiction of the MDDT process steps based on the literature.

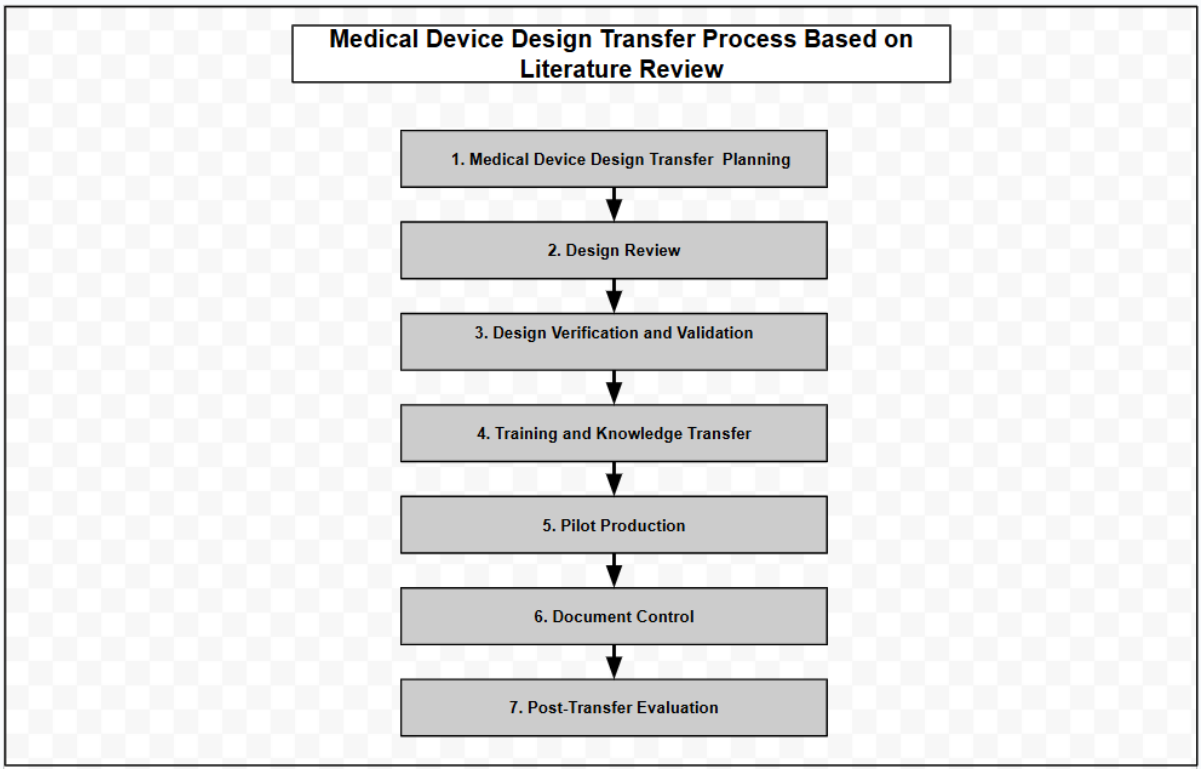

Figure 1. The MDDT Process based on literature (Research, 2025)
(Adapted from Bioaccessla (2024), Maney (2024), and Cormican and O'Connor (2007)

2.2. Risks Faced in Each Step of The MDDT Procedure

According to Shah (2024), during the MDDT procedure, risks are factors that must be taken into consideration to mitigate the consequences of inadequate MDDT. Moreover, if not properly managed, it can compromise device quality, regulatory compliance, and ultimately patient safety. Shah (2024) furthermore argued that several factors contribute to inadequate risk management in medical device development, including insufficient early risk identification, inadequate integration with other development processes, regulatory compliance failure, inadequate ongoing monitoring, and inadequate stakeholder communication. Looking at Figure 1 above and considering the view of several researchers (Geckler (2017); Pullen and Tipton (2019); Singh and Patel (2024); Fries (2017); Abuhav (2018); Shah (2024)), the section below discusses each risk posed to the process steps highlighted by Figure 1 above.

2.2.1 Risk Related to MDDT Planning

Geckler (2017) outlined common risks associated with poorly executing the planning phase, including underestimating the resources needed for the MDDT and failing to identify or overlook key deliverables on time. Furthermore, tight timelines and limited resources often make it difficult to stay within budgets and schedules while maintaining product quality.

2.2.2 Risk Related to Design Review

Pullen and Tipton (2019) stated that the production team is unable to produce consistently and efficiently due to unclear technical specifications or incomplete designs. Inadequate documentation during the MDDT process can result in gaps in quality procedures or protocols, which can affect quality assurance, and this can result in defective medical devices reaching the market. It can also compromise patient safety.

2.2.3 Risk Related to Design Verification and Validation

Misinterpretation of design requirements or specifications poses risks during verification and validation; it can lead to inaccurate verification outcomes, non-compliance, or poor device performance. It is important to ensure that the tests used for validation and verification measure what they are designed to do, as inaccurate testing can lead to false conclusions about the medical device's usability and functionality, thereby compromising patient safety and the quality of the device (Singh and Patel, 2024).

2.2.4 Risk Related to Training and Knowledge Transfer

During the early development stages of the medical device, skilled personnel often use tribal knowledge (design insights that were not properly documented) to build prototypes. As this knowledge is not properly documented, the production team may lack critical insights, leading to poor device quality (Geckler, 2017). According to Fries (2017), the MDDT process must ensure that the knowledge related to the device's design is effectively translated into production specifications.

2.2.5 Risk Related to Pilot Production

In the pilot production phase, small-scale production runs are conducted to generate critical-to-quality data to verify the device's process capabilities. Singh and Patel (2024) stated that pilot production is critical for collecting data to statistically analyse and validate the capabilities of the production processes. Furthermore, pilot production does not represent large-scale production, particularly if it is not carried out under the most challenging conditions. This could result in an inaccurate understanding of the process window and further create challenges in meeting the approval standards and quality issues during the full-scale production process.

2.2.6 Risk Related to Document Control

The success of design transfer depends on the completeness of documentation, such as the device master record and design history record/files (Abuhav, 2018). Moreover, poor documentation during the MDDT procedure can lead to misunderstandings of production instructions and unapproved documentation transferred to production, which can result in several product nonconformities. Pullen and Tipton (2019) argued that the production team is unable to produce consistently and efficiently due to unclear technical specifications or incomplete designs.

2.2.7 Risk Related to Post-transfer Evaluation

It is important to make sure that the MDDT is implemented and executed correctly and effectively to ensure that the device is manufactured in accordance with the design specifications, meets its intended use, and complies with regulatory requirements. According to Public Health (2020, cited in Shah, 2024), managing risk associated with new medical product development is essential; failures often arise due to the inability to anticipate and mitigate technical uncertainties and regulatory challenges early in the development process. As previously stated, Shah (2024) argued that regulatory compliance failure and inadequate ongoing monitoring contribute to poor risk management in medical device development

3. Methodology

This study employs a qualitative methods approach. This approach was adopted to gain an in-depth, meaningful understanding of complex processes and experiences that cannot be captured with a quantitative approach. Notably, Ahmad et al. (2019) and Castellan (2010) point out that quantitative research is typically used to identify trends through the analysis of numerical data. Since this study set out to establish how the MDDT process can be optimized, it was necessary to explore what was going wrong in the current process and why it went wrong. Qualitative research is therefore deemed as more suited for being able to highlight the root cause of why something is happening. The use of qualitative data offers a more comprehensive approach to uncovering the reasons why something is happening. Subsequently, this approach offers flexibility to explore deeper into the participants' responses and uncover underlying issues such as communication gaps, unclear responsibilities, and capture the context-specific practices of the organisation.

4. Data Collection and Analysis

The target population of this study consists of only three key interviewees who occupy roles that are significant to the development of the medical device in Organisation X. The three participants were purposefully selected because of their expertise, their extensive experience, and previous involvement in the MDDT process. Each participant has more

than 10 years of working experience in a medical device production organisation and has gained experience through direct exposure to MDDT projects. These employees are the Lead Design Engineer, Lead Manufacturing Engineer, and the Production Manager. A census sampling was used. Singh and Singh (2015) stated that when all the individuals in a target population are used, it is a census sample.

To collect data, the interviews were conducted through the Microsoft Teams online application platform. Semi-structured interviews were used because of the capability to facilitate in-depth exploration and, thereafter, an understanding of the problem. As part of ethical considerations of this study, before starting the interview, the informed consent process was outlined to participants. After the interviews, the Microsoft Team made a transcription available. However, to ensure the accuracy of the data collected by the transcription, the researcher verified the transcript against the audio recordings and made corrections to guarantee the legitimacy of the research data collected during this study.

Thematic analysis of the data took place after the data was transcribed and cleaned. As defined by Castleberry Nolen (2018), thematic analysis is a qualitative research method for identifying, analysing, and reporting the patterns (themes) within the data. The process involves systematically organizing and interpreting textual data to find meaningful patterns or themes. Thematic analysis was used to gain a comprehensive understanding of the research study problem and sub-questions, enabling the researcher to meet the research objectives. A six-phase framework thematic analysis was followed as provided by Braun and Clarke (2006). These phases included becoming familiar with the data, generating initial codes, searching for themes, reviewing themes, defining and naming themes, and writing up. As for the research validity, before conducting the main data collection, a pilot study was conducted to assess the validity of the semi-structured interview, as it was the tool used for data collection. By doing so, this ensured that the research findings are reliable, trustworthy, meaningful, and further aligned with the study's objectives.

5. Research Findings Related to the Research Objectives

5.1 Findings Related to the Research Objective 1

The research data identified four key factors that should be taken into consideration during the MDDT from the R&D phase to the routine production. In particular, the first is well-structured documentation, which is clear, easy to follow, complete, and approved. The second factor is cross-functional collaboration between the design and production teams. The third key factor is training and knowledge transfer, which was also reported to play a pivotal role in the transfer of design information, while the final factor is defined roles and responsibilities. The findings from the research participants highlighted that these factors are essential to the effectiveness of the MDDT procedure.

5.2 Findings Related to the Research Objective 2

The data from the research participants for Research Objective 2 in this study revealed five significant risks associated with the MDDT procedure. These include the loss of tribal knowledge (this refers to device design insight knowledge that was not properly documented), insufficient resource allocation, timeline delays, unclear technical specifications, and poor communication. The data collected reveal that these are potential risks that have an impact on the effectiveness of the MDDT procedure. Ultimately, to ensure the effectiveness of the MDDT procedure, these risks must be mitigated.

5.3 Findings Related to the Research Objective 3

The analysed research data shows that for MDDT to be effective, it must include four key elements in its process. These elements should include training and knowledge transfer, the availability of skilled resources, defining roles and responsibilities, and defined critical steps. These elements were considered essential by the research participants to ensure that device design information is adequately transferred from the research and development phase to the routine production phase. Four critical steps were identified as important to improve the effectiveness of the design transfer procedure. These steps included: (i) defining the scope of the MDDT, (ii) forming the MDDT team, (iii) assessing the MDDT readiness and gap analysis, and (iv) assessing the production readiness.

6. Discussion of Research Findings Related to the Research Objectives

6.1 Discussion of Findings Related to the Research Objective 1

With reference to the first research objective, which was to determine the key factors that should be considered during the MDDT from the R&D Phase to the Routine Production Phase, this study deduced that there is alignment between the literature by different scholars and the research findings. Notably, both the authors and research participants

highlighted four factors crucial to the success and effectiveness of the MDDT process. These factors are well-structured documentation, cross-functional collaboration, training and knowledge transfer, and defining roles and responsibilities.

Regarding well-structured documentation, both the literature from different scholars and the research participants agree that its quality is a foundation for the success of the MDDT process. Conversely, both the literature and the research participants highlighted the importance of cross-functional collaboration between the design, production, and quality teams in the effectiveness and success of the MDDT process. Both emphasized that effective cross-collaboration across the teams ensures that the risks are well managed. Subsequently, different authors emphasised that training and knowledge transfer is a complex process, yet a critical process in the MDDT process. While the research participant stressed the importance of adequately transferring critical knowledge from the design team to the production team. Although literature shows less emphasis on the significance of defining roles and responsibilities in the success of the MDDT process, it recognises the need to transfer responsibilities to the production team during the MDDT process. On the other hand, the research participants emphasised the significance of defining roles and responsibilities in the MDDT process.

6.2 Discussion of Findings Related to the Research Objective 2

In terms of research objective two, which was to determine the potential risks associated with the MDDT and develop a mitigation strategy, this study found that both the literature and the findings of the research participants hold similar views regarding the potential risks associated with the MDDT process and the appropriate mitigation strategies. With the loss of tribal knowledge being the first major risk in the MDDT process, identified. Literature highlighted that often critical knowledge can be lost when transitioning from the design phase to the production phase. This aligns with the findings of participants 1 and 2. Notably, on the other hand, participant 3 claims that critical device design knowledge is lost because of staff turnover. This signifies the significance of documenting tribal knowledge during the MDDT process.

Literature returned that insufficient resource allocation affects the MDDT process. Often, critical tasks are overlooked or not identified. This aligns with the views of both Participant 1 and Participant 2. Moreover, different scholars argued that inadequate planning results in production inefficiencies and timeline delays. This aligns with the findings of the three participants. Subsequently, the scholars argued about the impact and consequences of unclear technical specifications transferred to the production team during the MDDT process, which affects production efficiency and product quality. This is consistent with the views of both Participants 2 and 3. Lastly, scholars, participants 1 and 3, identified poor communication as a risk in the MDDT process. They emphasised that poor communication led to misunderstanding and delay, which also increases cost.

6.3 Discussion of Findings Related to the Research Objective 3

Lastly, the third research objective was to establish an effective MDDT procedure that can be used to ensure that the medical device design information is adequately transferred from the R&D phase to the routine production phase. A consensus was noted between the literature of numerous scholars and the findings of the research participants. It is worth noting that both the literature and the findings of this study returned that four elements are significant in ensuring the quality and reliability of design information during the MDDT procedure. This includes (i) training and knowledge transfer, (ii) availability of skilled resources, (iii) defining roles and responsibilities, and (iv) critical steps.

Regarding training and knowledge transfer, the different scholars and research participants emphasised the importance of ensuring the quality and reliability of medical device design information from the R&D phase to the production phase. Moreover, the literature emphasised the impact of poor knowledge transfer, leading to production inefficiencies, quality issues, and regulatory non-compliance issues. While the three participants shared practical evidence of the impact of poor training and knowledge transfer. Notably, the availability of skilled resources was identified as the second element. Literature by various scholars highlighted the significance of skilled resources in the MDDT process. Subsequently, inadequately skilled resources in the MDDT process contribute to delayed timelines, poor planning, increased costs, and compromised quality. This aligns with the findings of research Participants 1, 2, and 3. While the three emphasised that defining roles and responsibilities will improve clarity and avoid duplication of tasks. However, as previously stated, it is worth noting that less emphasis is placed on the significance of defining roles and responsibilities. It is also worth noting that Kinsel (2012) stated that the MDDT activities should include the transfer of responsibilities.

Critical steps in the MDDT process were identified as the last element. Several scholars outlined seven key steps necessary to ensure the success of the MDDT process. This includes: (i) design transfer planning, (ii) design document review, (iii) verification and validation, (iv) training and knowledge transfer, (v) pilot production, (vi) document control, and (vii) post-transfer evaluation. The three research participants concur that the seven steps identified by the scholars are the minimum steps necessary in the MDDT process. Collectively, Participant 1, Participant 2, and Participant 3 identified four additional critical steps that will further strengthen the MDDT process if they are incorporated. These steps are (i) defining the scope of MDDT, (ii) formulating the MDDT team, (iii) assessing the MDDT readiness and gap analysis, and (iv) assessing production readiness. Three participants argued that these steps should be adopted to strengthen the MDDT process.

7. Recommendations for an Optimised Medical Device Design Transfer

Collectively, the critical steps returned in this research study were adopted as the foundation of the optimised MDDT process from the research and development phase to the production phase. Ultimately, the four new steps will be added to the existing MDDT process flow. Figure 2 below shows the optimised MDDT process flow with the new steps written in red. The procedure is now optimised to mitigate the consequences of the lack of a standardised and well-regulated process for MDDT from the R&D phase to the production phase (Figure 2).

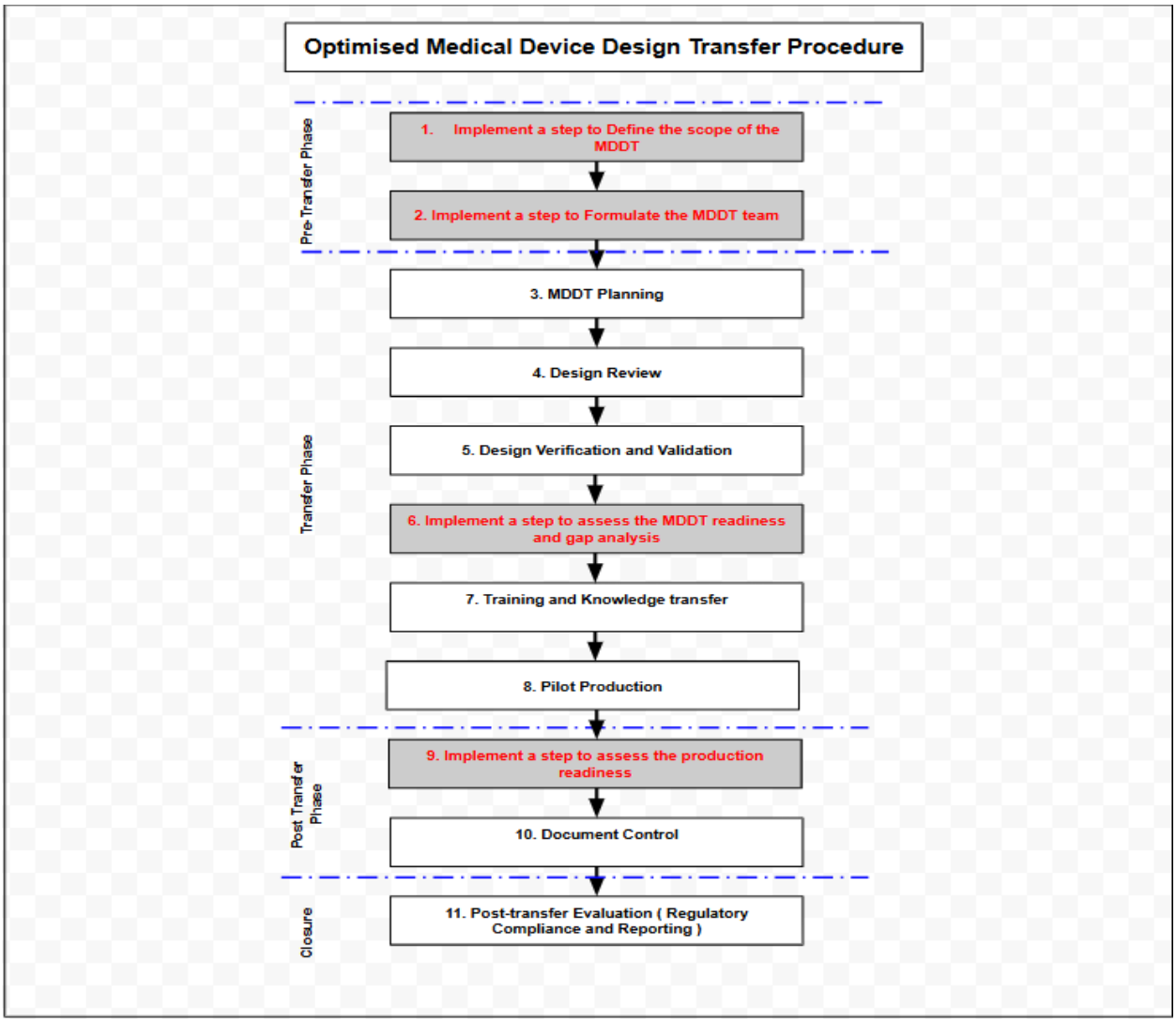

Figure 2. Optimised medical device design transfer procedure (Researcher 2025)

- **Implement a step to define the scope of the MDDT (pre-transfer phase)**

Now, implementing a step to define the scope of the MDDT is necessary to minimize challenges, such as misalignment of expectations and premature transfer of devices. Implementing this step as part of the optimised procedure will ensure that the scope is defined before the transfer process commences. The stakeholders involved must define and agree on what will be transferred and the expected deliverables. This will reduce miscommunication, a lack of clarity, and prevent incomplete MDDT from the R&D phase to the production phase.

- **Implement a step to formulate the MDDT team (pre-transfer phase)**

Notably, the findings revealed that a lack of resources and undefined roles and responsibilities were a major risk for the MDDT process at Organisation X. Without a designated team, responsibilities are not clearly defined, resulting in gaps in accountability, as blame games often occurred. This step will ensure that, before the start of the design transfer, an MDDT team is formed with designated roles and responsibilities. This can be accomplished by identifying key role players and employees with suitable experience and skills. This will enhance the process by ensuring accountability and avoiding abdication of responsibilities.

- **Implement a step to assess the MDDT readiness and Gap Analysis (transfer phase)**

Findings indicated that design transfer processes were initiated at Organisation X without adequately evaluating the readiness of the device design. This resulted in issues picked up in the pilot production phase, causing delays. Implementing a step to assess the MDDT readiness and Gap analysis will allow the design team to confirm the completeness of the design and identify missing design elements, such as incomplete documentation and unresolved design issues.

- **Implement a step to assess production readiness (post-transfer phase)**

The study's findings revealed that the pilot production phase was often challenged by issues such as a high rejection rate, process inefficiency, and supplier-related issues. Such challenges may be carried over to routine production if not addressed. Implementing a step to assess the production readiness will ensure that the organisation evaluates and confirms that suppliers, equipment, facilities, technical specifications, and personnel are ready for scaled-up production. This step will enhance the procedure by ensuring that the large-scale production capabilities after the pilot production phase are evaluated. Ultimately, this will improve the overall production efficiency.

8. Transferability of the Research Study

While this research study ultimately recommends the adoption and implementation of the optimised MDDT procedure for all medical device designs that are to be transferred from the R&D phase to the production phase, it should be noted that the optimised process was developed based on the current regulatory landscape at Organisation X. It is therefore also recommended that the optimised procedure be reviewed for its relevance to future changes in the regulatory landscape. Despite the fact that the MDDT procedure cannot be generalized across medical device manufacturing industries, it is, however, recommended that a newly started-up medical device organisation can adopt this procedure as a guideline to transfer the medical device design information from the R&D phase to the production phase.

Finally, this research study was conducted at Organisation X, and the findings were based on the employees' experience in the medical device design process within Organisation X. Therefore, the output of this study cannot be generalised across the broader medical device organisation.

9. Conclusion

The research study concluded that the success of an effective MDDT depends on four critical factors to ensure that the medical device design information is transferred from the R&D phase to the routine production phase. Moreover, the study also concluded that there are several risks that compromise efficiency, quality, timelines, and regulatory compliance during the MDDT process. These risks must be mitigated to ensure efficiency, quality, and regulatory compliance. The study also concludes that to ensure the quality and reliability of the design information during the MDDT process, four elements are essential. The study confirms that the key elements are (i) effective training and knowledge, (ii) availability of skilled resources, (iii) defined roles and responsibilities, and (iv) critical steps. In addition to critical steps, the study further contributes to existing knowledge by emphasising the significance of (i)

defining the scope of the MDDT, (ii) formulating a design transfer team, (iii) assessing MDDT readiness and gap analysis, and (iv) assessing production readiness.

Ultimately, the purpose of this study was to investigate how the MDDT procedure can be optimised to mitigate the consequences of the lack of a standardised and well-regulated process for MDDT from the R&D phase to the production phase. The literature review on MDDT guided the data collection, analysis, and interpretation of findings, enabling the researcher to answer all the research questions and achieve the research objectives

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