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Short communication

Managing significant changes in Medical Device Quality Management System during the transition period

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Introduction

The medical device industry is undergoing continuous transformation driven by evolving regulatory expectations, technological innovation, and increased focus on patient safety. During the transitional period, the implementation of the new regulatory framework EU MDR 2017/745 (EU MDR) within Medical Device Quality Management Systems (MD QMS) must adapt rapidly while maintaining compliance and product integrity.

Managing significant changes within the MD QMS during this period presents unique challenges, including balancing operational continuity with regulatory alignment, mitigating risks, and ensuring the effective involvement of relevant parties.

A structured and risk-based approach to change management is critical to ensure that modifications to processes, documentation, and controls during the transition period do not compromise quality, performance or compliance of legacy medical devices.

Change management within MD QMS

At Alkaloid AD Skopje, as a manufacturer of legacy medical devices concentrates for hemodialysis marketed under the brand *Aminal*, the change management process within the MD QMS as a part of Integrated Management System (IMS) is designed to ensure continued compliance, product safety, and performance throughout the EU MDR transition period. This process is structured and risk-based, integrating the requirements of medical devices legislation (ISO 13485, 2016).

All proposed changes, whether related to suppliers, service providers, manufacturing processes, incoming materials, documentation, or quality control processes, are systematically evaluated through a formalized change control procedure. This includes the classification of changes based on their potential impact on device safety, performance, and regulatory compliance as non-significant, substantial, and significant changes.

Each change undergoes a documented risk assessment, as well as verification and validation activities, and is approved by designated cross-functional members of the Change Control team (ISO 13485, 2016).

Management of significant changes within MD QMS during transition period

This study analyzes the management of significant changes within MD QMS during transition period, with a particular focus on compliance with the

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requirements of EU MDR. The transition from legacy directives to the EU MDR introduces substantial regulatory, technical, and organizational challenges, requiring manufacturers to implement comprehensive and well-controlled change management processes. These changes often affect core MD QMS elements, including risk management, clinical evaluation, post-market surveillance (PMS), and technical documentation.

Within the transition period established under Article 120 of EU MDR, manufacturers must ensure that no significant changes are introduced to legacy devices or their MD QMS without appropriate regulatory oversight (Regulation EU 2017/745, 2017, MDCG 2020-3 Rev.1, MDCG 2021-25 Rev.1).

In this context, the introduction of a new supplier for primary packaging was assessed through a structured change control process. The change was initially categorized as potentially significant due to its impact on device integrity and biocompatibility, as well as on overall compliance with essential safety and performance requirements (MDCG 2020-3 Rev.1, MDCG 2021-25 Rev.1).

A comprehensive risk-based evaluation was performed, including supplier qualification, material compatibility studies, validation of packaging processes, and assessment of biocompatibility impact. Changes affecting new suppliers, particularly those producing a new type of packaging material, are generally presumed significant unless justified otherwise (MDCG 2020-3 Rev.1).

Consequently, ALKALOID AD Skopje, as the manufacturer of legacy medical devices, engaged proactively with its Notified Body (NB), submitting a formal change notification containing the required documentation and justification demonstrating that the change does not adversely affect conformity with the applicable Directives still governing the legacy device under Article 120(3) (Regulation EU 2017/745).

Following a detailed review, the NB concluded that the change, while relevant, was adequately controlled and supported by objective evidence demonstrating equivalence in performance and compliance. The NB's approval confirmed that the introduction of the new primary packaging supplier did not constitute a prohibited significant change under Article 120, thereby allowing the manufacturer to maintain the validity of the issued certificates during the transition period. This case highlights the importance of early NB collaboration, robust change management procedures, and alignment with MDCG 2021-25 expectations to ensure continued compliance and uninterrupted market access while transitioning towards full EU MDR conformity.

Conclusion

Effective management of significant changes within MD QMS during the EU MDR transition period requires a structured, risk-based, and well-documented approach aligned with regulatory expectations. The presented case demonstrates that, through systematic evaluation, robust activities, and proactive collaboration with the Notified Body, manufacturers can successfully implement necessary changes without compromising compliance, device safety, or performance. Adherence to ISO 13485 and MDCG guidance, combined with early regulatory involvement, enables the continued validity of legacy device certification and ensures uninterrupted market access while progressing toward full EU MDR conformity.

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