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Short communication

Innovation culture development in regulated GMP change control

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Introduction

The Change Control (CC) process is a basic but essential component of the Pharmaceutical Quality System (PQS), ensuring that all changes affecting product quality, patient safety, and regulatory compliance are systematically assessed, approved, implemented, and evaluated for their effectiveness. In GMP-regulated environment, organizations must balance strict regulatory compliance with the need for operational efficiency and innovation.

At Alkaloid AD Skopje, the existing Change Control process is fully aligned with cGMP, ICH Q10, ICH Q9, ISO 9001 and other applicable requirements. However, operational challenges such as prolonged cycle times, manual workflows, limited digitalization, and insufficient cross-functional integration can reduce process efficiency and agility. This paper analyzes current gaps and proposes a Target Operating Model focused on digital transformation, risk-based governance, and development of an innovation-oriented quality culture.

Materials and methods

Regulatory and process review

A comprehensive review of existing SOPs (SOP000310) and regulatory frameworks (EU GMP, ICH Q9, Q10, Q12) was conducted to assess the compliance and process structure.

GAP analysis and stakeholder assessment

A structured GAP analysis identified strengths and weaknesses in the current Change Control process. Stakeholder expectations (internal and external) were evaluated to determine alignment, communication effectiveness, and accountability.

Benchmarking and model development

Industry best practices were analyzed, focusing on digitalization, risk-based decision-making, and cross-functional collaboration. Based on these findings, a future-state Target Operating Model was developed

Results and discussion

The analysis confirmed that the existing CC process demonstrates strong compliance, clear governance, and defined responsibilities. However, several important weaknesses were identified, including extended cycle times, backlog accumulation, manual tracking systems, limited use of data analytics, and weak integration with project management.

Benchmarking results show that leading pharmaceutical companies improve efficiency through risk-based workflows, digital Quality

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Management Systems (eQMS), and real-time KPI monitoring. Organizations adopting such models report cycle time reductions of 25–40% and improved audit readiness.

The proposed Target Operating Model introduces:

- Digital workflow management through eQMS
- AI-supported risk assessment and classification for timely decision-making
- Parallel review processes instead of sequential approvals
- Real-time monitoring dashboards and KPI governance
- Strengthened cross-functional collaboration and accountability

Additionally, the model emphasizes cultural transformation. Traditional GMP environments tend to be risk-averse and compliance-driven, which can limit innovation. The proposed Innovation Culture Framework promotes leadership alignment, accountability, collaboration, and continuous improvement, positioning Change Control to be recognized as a driver of operational excellence rather than an administrative requirement.

Key performance targets include reduction of closure time to ≤90 days, backlog reduction (<5% open >90 days), and on-time task completion ≥95%.

Conclusion

Although the Change Control system at ALKALOID AD Skopje is fully GMP-compliant, significant opportunities exist to improve efficiency, transparency, and agility. The identified operational gaps highlight the need for a more modern, digitally enabled, and risk-based approach.

The proposed Target Operating Model demonstrates that regulatory compliance and innovation are not conflicting objectives but can be integrated through effective governance, digitalization, and a strong quality culture. Implementation of the model is expected to reduce cycle times, improve process visibility, strengthen accountability, and enhance employee engagement.

Ultimately, the transformation of Change Control into a digitally supported, risk-based, and innovation-driven capability will support long-term organizational performance while ensuring the highest standards of product quality and patient safety.

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