University of St.Gallen

Institute of Technology Management

Compliance in QC Labs

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Orientation Round (add-on) – Compliance/Overcompliance
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Ensuring Compliance in Pharmaceutical Laboratories

The QCEx discussions show: Compliance forms the bedrock of operational success, as without adherence to stringent regulatory standards, pharmaceutical businesses face significant risks. In essence, compliance isn't just important - it's the license to operate. Ensuring compliance requires a robust framework centered around e.g., the right methods and training, digital integration of processes, and a holistic laboratory strategy. This framework supports the alignment of local operations with global standards, safeguarding against violations while fostering continuous improvement. Hence, compliance requires a strategic approach employing people, such as business process managers to map and present workflows to ensure clarity during inspections. Transparency helps streamline audits and builds confidence among regulators.

A critical aspect of compliance is maintaining consistency between regulatory test methods and laboratory test methods. While internal adjustments to laboratory procedures may be necessary, they should not stand in conflict with regulatory requirements. Any local changes require approval from the global team, emphasizing the importance of uniformity in test documentation to prevent discrepancies. Limiting the involvement of global teams in inspections, as demonstrated by some QCEx participants, can prevent unnecessary complications and maintain focus on local processes. Moreover, scientific rigor is essential as laboratories must conduct studies to validate the accuracy and reliability of their methods. The presented case studies showed that regulatory changes, aimed at standardization, have revealed the challenges of poorly executed approaches. Similarly, eliminating local documents in favor of globally consistent ones reduces the risk of non-compliance and strengthens laboratory integrity. Participants reported challenges around documentation gaps and risk assessments as regulatory documents are not always state-of-the-art, and health authorities are skeptical of risk assessments. Moreover, they showed that building trust with health authorities is essential and requires proactive engagement through exchanges, pre-discussions, and clear proposals to foster robust and acceptable processes. In that regard, the discussions also revealed that regulatory expectations are evolving. Collaboration and competition between health authorities coupled with hybrid inspections are representative of the growing complexity of compliance. Companies must not only master their processes but also understand related operations and global regulatory specifics.

Health authorities increasingly expect companies to experiment with AI tools. The integration of such tools offers transformative potential but also demands caution. While AI can analyze laboratory investigation reports in mere seconds - a task that takes human experts several hours - it is not currently recognized as a compliant cGMP tool. As a pilot program initiated in one of the showcase companies demonstrates, AI solutions can provide suggestions and even identify root causes. However, human oversight remains crucial to validate AI outputs, ensuring accountability and accuracy. The future of AI in compliance holds promise but requires careful implementation. Training programs must accompany AI deployment to equip staff with the skills to use these technologies effectively. Furthermore, regulatory alignment will be necessary for AI-driven solutions to gain full acceptance, potentially enabling AI to autonomously draft reports and optimize workflows.

Ultimately, compliance is both a challenge and an opportunity. By leveraging innovation while upholding rigorous standards, pharmaceutical laboratories can not only meet regulatory demands but also pioneer advancements in efficiency and quality. Thereby, compliance in the pharmaceutical industry is non-negotiable, serving as the foundation of trust, quality, and business sustainability. All QCEx participants agree that compliance is a continuous journey.