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Perspective

Navigating risk in biological quality testing: A guide for emerging laboratories

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Biological products are inherently complex and highly sensitive to variations in testing conditions, rendering quality control (QC) testing laboratories particularly vulnerable to high-impact operational, analytical, and biosafety risks. Despite the emphasis on risk-based thinking in international standards, a structured laboratory-specific framework for identifying, assessing, and mitigating risks in biological product QC testing remains insufficiently articulated. This article presents a simplified approach for proactive identification of testing-related and occupational health risks, along with their mitigation and conversion into opportunities. The concept aligns with internationally accepted standards, including ISO/IEC Guide 51, ISO 31000:2018, ISO/IEC 17025:2017, and ICH Q9 guidelines. Implementation of this framework enhances the reliability of results, strengthens regulatory compliance, and improves patient and occupational safety. By addressing the gap in structured risk assessment for biological QC laboratories, the article provides practical guidance for implementing ISO/IEC 17025:2017 Clause 8.5 and enables continuous improvement through systematically converting identified risks into opportunities.

Keywords Biological products; ICH Q9; ISO/IEC 17025; Risk assessment; Risk priority number; Quality control laboratories