

Calytra Insights #1: Updates to ISO 13485:2024 and ISO 14971:2025

1.0 Purpose:

This document provides a detailed analysis of the key changes in ISO 13485:2024 and ISO 14971:2025 relative to their previous versions. It aims to clarify how these revisions affect medical device development, regulatory compliance, and risk management. The document is designed to help manufacturers, quality assurance teams, and regulatory professionals navigate new requirements efficiently and strategically.

2.0 Scope:

The insights focus on explicit differences between the new and prior revisions of ISO 13485 and ISO 14971, highlighting their impact on risk management, supplier oversight, post-market surveillance, cybersecurity, and benefit-risk analysis. The document outlines actionable steps for manufacturers to adapt their processes, ensuring compliance, and maintaining competitiveness in an evolving regulatory landscape.

3.0 Insight Summary

ISO 13485:2024 Enhancements: Expanded risk-based thinking, supplier management, and integration of post-market surveillance into quality management systems. The update strengthens alignment with MDR/IVDR and U.S. FDA regulations, emphasizing cybersecurity and digital health considerations.

ISO 14971:2025 Refinements: Increased focus on cybersecurity risks, continuous risk management across the entire product lifecycle, and more rigorous benefit-risk documentation. The standard aligns with digital health regulations and requires stakeholder collaboration for risk assessments.

Implications for Manufacturers: Companies must enhance supplier agreements, automate post-market surveillance data integration, implement lifecycle cybersecurity protocols, and strengthen benefit-risk documentation processes. These changes will lead to higher compliance costs but improve long-term device safety, marketability, and regulatory approval success.

3.1. ISO 13485:2016 Revision (2024)

The 2024 revision of ISO 13485 introduces several changes that differentiate it from its 2016 predecessor described in **Table 1**.

Table 1: Summary of Changes to ISO 13485

Ref	Challenge	Change
1	Integration of Expanded Risk-Based Thinking	The previous version introduced risk-based thinking, but the 2024 revision mandates its application across every quality process, not just design and manufacturing. This now includes supplier evaluations, complaint handling, and PMS.

Ref	Challenge	Change
2	Revised Supplier Management Requirements	While the 2016 version focused broadly on supplier control, the 2024 update specifies the need for formal agreements outlining supplier obligations for regulatory compliance, with ongoing performance assessments.
3	Post-Market Surveillance Integration	A major addition in 2024 is the requirement to systematically link PMS data with design and risk management processes. The earlier version lacked this explicit integration.
4	Global Regulatory Harmonization	The 2024 revision aligns with MDR/IVDR updates, creating more stringent documentation requirements for quality system compliance.
5	Focus on Digital Health and Cybersecurity	Addressing gaps in the 2016 standard, the new version explicitly requires cybersecurity and software validation procedures for digital health devices.

3.2. Impact on Medical Device Development

- **Increased Documentation Requirements:** Manufacturers must now document risk-based decisions and PMS integrations more thoroughly, necessitating enhanced quality management systems.
- **Stronger Supplier Oversight:** Companies will need to dedicate additional resources to supplier audits and agreements, increasing compliance workloads but improving accountability.
- **Shorter Design Iterations:** With PMS feedback loops tied to risk management, device updates will become more iterative and responsive to real-world performance.

3.3. Advice for Manufacturers

- **Expand Risk Management Integration:**
 - Develop standardized workflows to embed risk management in supplier evaluation, process controls, and post-market activities.
 - Invest in training for teams to document risk-based decisions comprehensively.
- **Revamp Supplier Management Protocols:**
 - Create detailed supplier agreements with clear quality and compliance metrics.
 - Implement ongoing supplier audits and real-time performance monitoring tools.
- **Leverage PMS Data Effectively:**
 - Automate PMS data collection and establish clear protocols to analyze and feed this data into design and risk controls.
 - Use PMS insights to prioritize iterative design improvements for faster market adjustments.

3.4. ISO 13485:2016 Revision (2024)

The 2025 revision of ISO 14971 introduces more explicit distinctions relative to the 2019 version described in **Table 2**.

Table 2: Summary of Changes to ISO 13485

Ref	Challenge	Change
1	Expanded Scope of Risk Management	The updated standard explicitly addresses cybersecurity risks, covering threats from data breaches, hacking, and software vulnerabilities.
2	Lifecycle-Wide Focus	Continuous risk management now applies explicitly beyond the production phase, requiring manufacturers to document risk controls during post-market operations, such as software updates and cybersecurity patches
3	Benefit-Risk Analysis Updates	More detailed requirements for documenting benefit-risk analyses, directly tying them to clinical evidence and intended use.
4	Alignment with Digital Standards	Integration with ISO/IEC 81001 ensures compatibility with digital health device requirements, which was not explicitly addressed in 2019.
5	Stakeholder Inclusion	Explicit inclusion of diverse stakeholders in risk assessment processes, fostering broader perspectives on residual risks.

3.5. Impact on Medical Device Development

- **New Cybersecurity Obligations:** Teams will need to incorporate cybersecurity risk assessments and controls throughout development and post-market phases.
- **Enhanced Post-Market Investment:** Continuous risk management demands more resources for lifecycle support, including routine updates and security patches.
- **Greater Documentation Complexity:** The expanded focus on benefit-risk analysis necessitates additional clinical validation and justification of residual risks.

3.6. Advice for Manufacturers

- **Build Cybersecurity Expertise:**
 - Establish dedicated cybersecurity teams to assess, mitigate, and monitor software-related risks.
 - Create a cybersecurity incident response plan and integrate it into post-market risk controls.
- **Implement Lifecycle Monitoring Tools:**

- Adopt software tools that continuously track risk controls and residual risks throughout the device lifecycle.
- Set up protocols for routine risk file updates tied to PMS data.
- **Enhance Collaboration for Risk Assessments:**
 - Actively engage clinicians, patients, and regulators during risk evaluations to ensure a well-rounded analysis.
 - Use stakeholder feedback to refine benefit-risk justifications.
- **Streamline Benefit-Risk Documentation:**
 - Develop templates and workflows for systematically linking clinical evidence with residual risk justifications.
 - Leverage automation to reduce manual effort in benefit-risk analysis reporting.

4.0 Conclusion: A Step Toward Safer, Smarter Medical Devices

The updates to ISO 13485:2024 and ISO 14971:2025 represent a shift toward more explicit, actionable quality and risk management requirements. By adopting these revised standards, manufacturers can enhance compliance, improve device safety, and remain competitive in an evolving regulatory landscape. Proactive adaptation will not only ensure smoother market approvals but also foster trust among regulators, clinicians, and patients.