

Robust Audit Programs

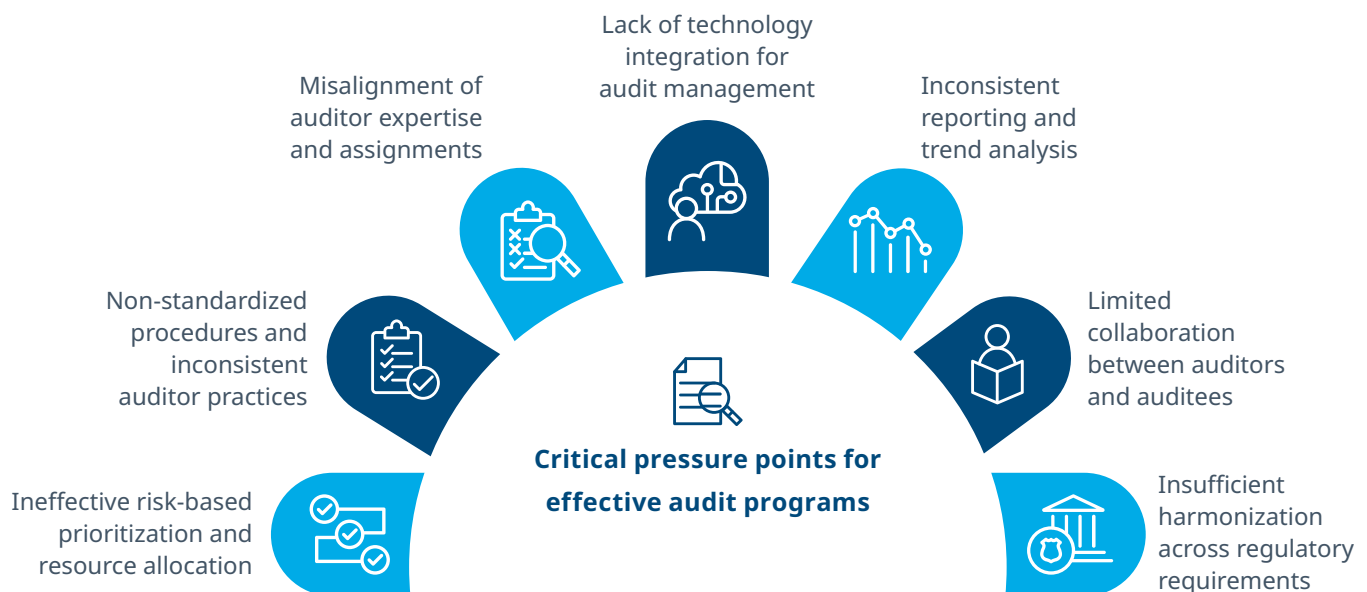
Driving smarter business decisions

Overview

Establishing an effective quality management system is essential for any manufacturer in medical devices, in-vitro diagnostics, or pharmaceuticals. Robust internal audit programs — supported by consulting expertise, comprehensive services, and advanced technology and analytics — enable organizations to evaluate quality management effectiveness, drive continuous improvement, and inform strategic business decisions.



Common audit program deficiencies



IQVIA consulting and services

IQVIA provides consulting and professional services to supplement manufacturers' internal resources. Our consultants support internal, external (supplier), and mock regulatory audits, bringing impartial industry expertise and best practices for companies working across a range of geographies including the U.S., Europe, Japan, Latin America, the Middle East, and Asia-Pacific:

- Gap analysis against global regulations and standards, with recommendations for audit program improvement
- Prioritization of actions based on ROI and compliance needs
- Training and professional development for audit teams
- Strategic resource allocation and role alignment

Technology solutions

Our audit programs are powered by SmartSolve® eQMS technology, which delivers:

- Automated audit planning, execution, and follow-up
- Streamlined management of findings and corrective actions
- Automated notifications and calendar integration
- Consistent CAPA escalation for high-risk findings
- Built-in summary reports and trend analysis
- Integration with ancillary systems for comprehensive data management

Optimized audit program: People, process, technology, performance

A truly optimized audit program connects consulting, services, and technology to facilitate continuous improvement:



People:

Optimized assignments, ongoing training, clear expectations



Process:

Risk-based approach, standardized procedures, consistent categorization and follow-up



Technology:

Automation, analytics, and integration for efficiency and effectiveness



Performance:

Drive a culture of quality and pivot into data driven strategic operations

About SmartSolve®:

SmartSolve is an AI-enabled, Microsoft Azure-based platform that helps Life Sciences organizations streamline and automate global quality management and regulatory compliance. [SmartSolve® eQMS](#) centralizes enterprise-wide quality processes, from design and manufacturing to post-market surveillance, while [SmartSolve® RIM](#) manages regulatory submissions, product registrations and health authority interactions. Built on industry best practices, SmartSolve connects teams, data, and workflows in a single platform to drive an optimized focus on patient safety, product quality and commercial performance.



Elements of a robust audit program

- Trending and tracking metrics
- Risk-based audit scope and depth
- Positive auditor/auditee relationships
- Skills and competencies alignment
- Common database and harmonized procedures
- Auditor consistency and strategic resource allocation

Conclusion

Well-run audit programs — supported by expert consulting, tailored services, and advanced technology — are valuable assets that reveal insights for better business decisions and global regulatory compliance. This, in turn, enables an enhanced focus on patient safety and commercial performance. [Contact](#) IQVIA to design and implement your audit program with the support of experienced consultants, proven services, and leading technology solutions.

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