**ISO 13485:2018 Management Overview Executive Summary**

**Medical devices — Quality management systems — Requirements for regulatory purposes**

# Introduction

## General Overview

ISO 13485:2018 specifies comprehensive requirements for quality management systems where organizations need to demonstrate their ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. This standard represents a strategic organizational decision that addresses the complete life-cycle of medical devices, including design and development, production, storage and distribution, installation, servicing, and final decommissioning. The quality management system must be integrated into organizational processes with particular emphasis on regulatory compliance and risk management.

## Process Approach

The standard is based on a process approach to quality management, emphasizing the importance of understanding and meeting requirements, considering processes in terms of added value, obtaining results of process performance and effectiveness, and improving processes based on objective measurement. This systematic approach ensures consistent delivery of safe and effective medical devices.

## Relationship with ISO 9001

While this is a stand-alone standard, it is based on ISO 9001:2008 principles but includes specific requirements for medical device organizations and excludes some ISO 9001 requirements not appropriate as regulatory requirements. Organizations conforming to ISO 13485 cannot claim ISO 9001 conformity unless all ISO 9001 requirements are met.

# Section 1: Scope

ISO 13485:2018 specifies requirements for quality management systems applicable to organizations involved in one or more stages of the medical device life-cycle, regardless of size or type. The standard can be used by suppliers or external parties providing products or services to medical device organizations. Requirements apply to all organizational activities that affect product conformity, including outsourced processes which remain the organization's responsibility through monitoring, maintaining, and controlling.

# Section 2: Normative References

The standard references ISO 9000:2015 (Quality management systems — Fundamentals and vocabulary), providing foundational terminology and concepts essential for understanding quality management principles in the medical device context.

# Section 3: Terms and Definitions

Key definitions include medical device, manufacturer, authorized representative, distributor, importer, clinical evaluation, post-market surveillance, risk, risk management, sterile medical device, implantable medical device, and medical device family. These terms establish the foundation for understanding regulatory requirements and organizational responsibilities throughout the medical device life-cycle.

# Section 4: Quality Management System

## General Requirements

Organizations must document, implement, and maintain a quality management system that demonstrates effectiveness in accordance with standard and regulatory requirements. The system must establish processes needed for the quality management system, apply risk-based approach to process control, determine process sequence and interaction, and manage changes to processes with impact evaluation.

## Documentation Requirements

The quality management system documentation must include quality policy and objectives, quality manual, documented procedures and records, documents determined necessary for effective process control, and other documentation specified by regulatory requirements. Medical device files must be established for each device type or family, containing comprehensive documentation demonstrating conformity and regulatory compliance.

## Document and Record Control

Documented procedures must define controls for document review and approval, distribution control, change management, and obsolete document prevention. Records must be maintained to provide evidence of conformity and effective operation, with controls for identification, storage, security, retrieval, retention, and disposition. Record retention must be at least the medical device lifetime or as specified by regulatory requirements.

# Section 5: Management Responsibility

## Management Commitment

Top management must provide evidence of commitment through communicating the importance of meeting customer and regulatory requirements, establishing quality policy, ensuring quality objectives establishment, conducting management reviews, and ensuring resource availability.

## Customer Focus and Quality Policy

Management must ensure customer requirements and regulatory requirements are determined and met. The quality policy must be appropriate to organizational purpose, include commitment to compliance and effectiveness maintenance, provide framework for objectives, be communicated and understood, and reviewed for continuing suitability.

## Planning and Organization

Quality objectives must be established at relevant functions and levels, be measurable and consistent with policy. Planning must ensure quality management system requirements are met and system integrity is maintained during changes. Responsibilities and authorities must be defined, documented, and communicated, with management representative appointed for system oversight.

## Management Review

Management reviews must be conducted at documented planned intervals to ensure continuing suitability, adequacy, and effectiveness. Review inputs must include feedback, complaint handling, regulatory reporting, audits, process and product monitoring, corrective and preventive actions, previous review follow-up, changes affecting the system, recommendations for improvement, and new or revised regulatory requirements.

# Section 6: Resource Management

## Resource Provision and Human Resources

Organizations must determine and provide resources needed for quality management system implementation, maintenance, and meeting regulatory and customer requirements. Personnel must be competent based on appropriate education, training, skills, and experience, with documented processes for establishing competence, providing training, and ensuring awareness.

## Infrastructure and Work Environment

Infrastructure requirements must be documented to achieve product conformity, prevent product mix-up, and ensure orderly handling. This includes buildings, workspace, utilities, process equipment, and supporting services. Work environment requirements must be documented when conditions can affect product quality, including health, cleanliness, and clothing requirements for personnel.

## Contamination Control

Arrangements must be planned and documented for controlling contaminated or potentially contaminated products to prevent contamination of work environment, personnel, or product. For sterile medical devices, requirements for microorganism and particulate matter control must be documented and maintained during assembly or packaging processes.

# Section 7: Product Realization

## Planning and Customer-Related Processes

Product realization planning must be consistent with other quality management system processes and include risk management documentation. Customer-related processes must determine requirements including delivery and post-delivery activities, regulatory requirements, user training needs, and additional organizational requirements.

## Design and Development

Comprehensive design and development procedures must be documented, including planning with stages, reviews, verification, validation, and transfer activities. Design inputs must include functional, performance, usability, and safety requirements, regulatory requirements, risk management outputs, and previous design information. Design outputs must meet input requirements, provide appropriate information for production, contain acceptance criteria, and specify characteristics essential for safe use.

## Design Controls

Design and development review, verification, and validation must be performed according to planned arrangements. Clinical evaluations or performance evaluations must be performed as part of validation. Design transfer procedures must ensure outputs are suitable for manufacturing. Design changes must be controlled with significance determination and appropriate review, verification, and validation.

## Purchasing and Production

Purchasing processes must ensure purchased products conform to specifications, with supplier evaluation based on ability to meet requirements, performance, and risk associated with the medical device. Production and service provision must be planned, carried out, monitored, and controlled with comprehensive controls including documentation, infrastructure qualification, monitoring implementation, equipment availability, labelling and packaging operations, and release activities.

# Section 8: Measurement, Analysis and Improvement

## Monitoring and Measurement

Organizations must plan and implement monitoring, measurement, analysis, and improvement processes to demonstrate product conformity, ensure quality management system conformity, and maintain effectiveness. Feedback processes must gather information from production and post-production activities, serving as input to risk management and improvement processes.

## Complaint Handling and Regulatory Reporting

Documented procedures for timely complaint handling must include requirements for receiving, recording, evaluating, investigating, determining regulatory reporting needs, handling complaint-related products, and determining correction or corrective action needs. Procedures for regulatory authority reporting must be documented when required by applicable regulations.

## Internal Audits and Data Analysis

Internal audits must be conducted at planned intervals to determine quality management system conformity and effective implementation. Data analysis procedures must determine, collect, and analyze appropriate data to demonstrate system suitability, adequacy, and effectiveness, including feedback, product conformity, process and product characteristics, supplier performance, audits, and service reports.

## Improvement Processes

Organizations must identify and implement changes necessary to ensure and maintain continued suitability, adequacy, and effectiveness through quality policy, objectives, audit results, post-market surveillance, data analysis, corrective actions, preventive actions, and management review. Corrective action procedures must define requirements for reviewing nonconformities, determining causes, evaluating action needs, implementing actions, verifying effectiveness, and ensuring actions don't adversely affect regulatory requirements or device safety and performance.

# Section 9: Control of Nonconforming Product

## General Controls

Organizations must ensure nonconforming products are identified and controlled to prevent unintended use or delivery. Evaluation must include determination of investigation needs and external party notification. Procedures must define controls and responsibilities for identification, documentation, segregation, evaluation, and disposition.

## Response Actions

Actions for nonconforming products detected before delivery include eliminating nonconformity, precluding original intended use, or authorizing use under concession with proper justification and regulatory compliance. For products detected after delivery, appropriate actions must be taken considering effects or potential effects, with procedures for issuing advisory notices according to regulatory requirements.

# Annex A: Comparison with Previous Edition

The standard includes significant changes from ISO 13485:2003, including enhanced requirements for organizational context consideration, risk-based approach application, regulatory requirements integration, process approach expansion, design and development requirements enhancement, purchasing process strengthening, production control improvements, measurement and monitoring expansion, and improvement process enhancement.

# Annex B: Correspondence with ISO 9001:2015

The standard maintains correspondence with ISO 9001:2015 structure while including medical device-specific requirements and excluding certain ISO 9001 requirements not appropriate for regulatory purposes. This enables organizations to understand relationships between standards while maintaining focus on medical device regulatory compliance.

## Key Success Factors

1. **Regulatory Focus**: Deep understanding of applicable regulatory requirements and integration into all quality management system processes
2. **Risk Management**: Comprehensive risk management approach throughout product realization processes
3. **Life-cycle Thinking**: Consideration of complete medical device life-cycle from design through disposal
4. **Process Approach**: Systematic process approach ensuring consistent product realization and regulatory compliance
5. **Continual Improvement**: Regular monitoring, measurement, and improvement ensuring system effectiveness and regulatory compliance maintenance

## Implementation Benefits

* **Regulatory Compliance**: Systematic approach to meeting medical device regulatory requirements globally
* **Product Safety**: Enhanced assurance of medical device safety and performance through systematic controls
* **Market Access**: Facilitation of global market access through internationally recognized quality management system
* **Risk Mitigation**: Systematic risk management reducing potential for product recalls and regulatory non-compliance
* **Operational Excellence**: Improved operational efficiency through systematic process approach and continual improvement
* **Stakeholder Confidence**: Enhanced confidence from customers, regulators, and other stakeholders in organizational capability
* **Competitive Advantage**: Quality management system providing market differentiation and customer assurance