'Management responsibility' Refer to / taken from Ensuring Compliance: Navigating the EU MDR for Drug-Device Combination Products

This item addresses Management Responsibility

A. QMS Requirements

1. EU Requirements

EU medicinal product Directive 2001/83/EC has the requirements for Single Integral DDC to comply with GSPR Annex I of MDR 2017/745 (Article 117). There is therefore no requirement to comply with **EU MDR 2017/745** Article 10 General obligations of a manufacturer (c) responsibility of the management (ISO 13485 §5). However, complying with **ICH Q10**, section 2 "*Management Responsibility*", ensures that the responsibilities of the (*Senior*) management should be understood and incorporated into pharma company QMS.
There are specific requirements in medicinal product directives related to Qualified Person (SP) responsibilities (Article 51 of Directive 2011/83/EC), including Annex 16 of EU GMP Guide for batch certification

2. US Requirements

21 CFR part 4
Under 21 CFR 820.10 Requirements for a quality management system incorporated from the ISO 13485:2016: §5 Management responsibility ensures executive commitment to quality.

Similarities or Differences

1. Similarities
The management responsibilities are quite similar in EU and US thanks to the alignment on ICH Q10 (Section 2 "Management Responsibility").

2. Differences

- **US Requirements**

In the US, 21 CFR 820.10 Requirements for a quality management system incorporated from the ISO 13485:2016: §5.5.2 Management representative provides more detail on specific requirements for Management Representative.
Under 21 CFR Part 4, if compliance to cGMPs for drug has been demonstrated, then all the Quality Management System requirements for Management Responsibility must be shown to be also satisfied.

- **EU Requirements**

In Europe, in addition to Management Responsibility, QP batch certification and QP responsibilities for medicinal product (Article 51 of Directive 2001/83 and EU Annex 16) should be followed.

The preferred steps you can take to address these differences

Similar to EU manufacturers, **US manufacturers** of Single Integral DDC should document and implement the requirements that a Qualified Person (QP) by review and approval certifies the batch release of each batch of medicinal products for human or veterinary use before it can be released to the market or exported outside the EU. The QP takes the responsibility that the quality, safety, and efficacy of these products are ensured and that the products comply with the regulatory requirements which apply to them. This ensuring also encompasses that the products comply with the EU GMP guidelines, including meeting the standards for manufacturing, testing, and quality control.

B. Background of management responsibility

Management responsibility in a QMS is essential for supporting a quality-centric culture, ensuring resource availability, aligning quality with strategic goals, promoting continuous improvement, maintaining regulatory compliance, and managing risks effectively.

(Text from Section 3: Quality Management Systems (QMS) from an MDR Perspective - Subsection 3: Management Responsibility)

1. ISO 13485:2016 Requirements

The organization must document management responsibilities, including the person responsible for EU-regulatory compliance (see management commitment). Management plays a crucial role in ensuring the effectiveness of the Quality Management System (QMS). Key responsibilities include:

- Leadership and Commitment: Top management must demonstrate leadership and commitment to the QMS by ensuring that quality is a core business strategy component.
- Setting Policies and Objectives: Defining and establishing a quality policy and clear objectives aligned with the business strategy.
- Resource Allocation: Providing the necessary human, technological, and financial resources to implement and maintain the QMS effectively.
- Employee Involvement and Communication: Ensuring that the importance of effective quality management and compliance with the QMS requirements is communicated and understood across the organization.
- Process Approach and System Integration: Managing processes per the QMS requirements and ensuring the system is integrated into the organization's business processes (see .
- Performance Evaluation: Monitoring and measuring the QMS's performance and effectiveness through audits, data analysis, and management reviews.
- Continual Improvement: Ensuring the QMS is regularly reviewed and continually improved.

- Customer Focus: Ensuring customer requirements are determined and met to enhance customer satisfaction and actively managing customer relationships.
- Obligation to Perform Management Reviews (see Management Review)

2. Management Review:

From a QMS-compliance perspective, executive management is responsible for periodically reviewing the Quality Management System (QMS) to ensure it remains suitable, adequate, and effective. These reviews must be documented and conducted at planned intervals to evaluate how well the QMS meets regulatory requirements, customer needs, process goals, and quality policies. The reviews aim to identify opportunities for improvement and necessary changes to the QMS, quality policy, and quality objectives. Records from management reviews shall be maintained and subject to audits and inspections.

Key Requirements:

Frequency and Timing: Management reviews should be held at planned intervals.

Participants: Reviews should involve top management, subject matter experts (SMEs), all managerial levels, and process stakeholders.

Agenda and Documentation: A comprehensive agenda covering the required review inputs per §5.6.2 of ISO 13485:2016, such as performance metrics, customer feedback, process efficiency, compliance status and resource adequacy is essential. Meetings must be formally documented.

Decision-Making and Follow-Up Actions: The review should result in documented outputs, including (1) recommendations for improvement needed to maintain the suitability, adequacy and effectiveness of the QMS and its processes, (2) improvement of product related to customer requirements, (3) changes needed to applicable new or revised regulatory requirements and (4) resource needs. Identified actions must be tracked and implemented, with quarterly follow-ups recommended for effective management.

Tools and Methodologies:

- Balanced Scorecard: Recommended for defining SMART (Specific, Measurable, Achievable, Relevant, Time-bound) quality, regulatory and business objectives that are input for management review.
- Critical review and approval of review input documentation, such as Customer Feedback, Complaint Reports, Reporting to Regulatory Authorities, Internal and Supplier Audit Reports, Analyses of QMS processes, Analysis of Products (including non-conforming product), Corrective and Preventive Action Reports and Overview of New or Revised Regulatory Requirements. These will

be included in FDA inspections starting February 2026, marking a significant change in inspection policies.

Management reviews and adequate follow-up actions ensure the QMS adapts to new or revised regulatory requirements and that the suitability, adequacy and effectiveness of the QMS and its processes are maintained. The process, including improvement actions, will be scrutinized by GMP inspectors during their inspections. This comprehensive approach helps maintain compliance and enhances the overall effectiveness of the QMS.