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

This item addresses management commitment (ISO 13485 § 5.1), resource management (ISO 13485 § 6), and purchasing controls (ISO 13485 § 7.4),

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:
(d) resource management (ISO 13485 §6) and Purchasing controls (ISO 13485 §7.4), including selection and control of supplier and subcontractors.
However, ICH Q10, section 2.7 "*Management of Outsourced Activities and Purchased Materials*" have requirements that apply to Single Integral DDC product.

2. US Requirements

21 CFR Part 4

- **21 CFR 820.10** Requirements for a quality management system incorporated from the ISO 13485:2016: §5 Management responsibilities
- **21 CFR 820.10** Requirements for a quality management system incorporated from the ISO 13485:2016: §6.2 Human resources describes the requirements for personnel
- **721 CFR 820.10** Requirements for a quality management system incorporated from the ISO 13485:2016: §7.4 Purchasing describes the purchasing controls

Similarities and Differences
Similarities
EU MDR2017/745, ICHQ10 and 21 CFR 820 have similar requirements for Resource management and Purchasing controls.

Differences
Under 21 CFR 820.10 Requirements for a quality management system incorporated from the ISO 13485:2016: §6.2 Human resources, ensure that personnel are made aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

The preferred step to address this difference is to include training relevant to device defects.

B. Background of Management commitment (ISO 13485 § 5.1)

Management commitment is crucial for setting the tone and direction of the QMS of manufacturers of devices, ensuring adequate resources, fostering a culture of quality, driving compliance and continuous improvement, managing risks effectively, and achieving customer satisfaction.

(Text from Section 3: Quality Management Systems (QMS) from an MDR Perspective - Subsection 3: Management Responsibility)
The organization must document management responsibilities, including the person responsible for EU-regulatory compliance.
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)

C. Background of Resource Management (ISO 13485 § 6)

Effective resource management ensures that all necessary personnel, training, financial resources, equipment, documentation, and processes are in place and properly managed to meet regulatory compliance. This comprehensive approach helps organizations maintain high standards of quality and safety while adhering to regulatory requirements.

(Text from Section 3: Quality Management Systems (QMS) from an MDR Perspective - Subsection 4: Resource Management)

Resource Management with Emphasis on Regulatory Compliance: The QMS must address resource management, ensuring that adequate personnel, equipment, and training are provided.

Resource Management is a critical aspect of the Quality Management System (QMS) as outlined by standards like ISO 13485:2016, 21 CFR 820 QMSR and MDR. It involves ensuring that all necessary resources are provided and managed to achieve the desired quality objectives and regulatory compliance.

Human Resources: Ensure that personnel performing work affecting product quality are competent based on appropriate education, training, skills, and experience. This involves identifying training needs, providing necessary training, and maintaining records of training and competence.

Roles and Responsibilities: Clearly define roles, responsibilities, and authorities within the organization to ensure that all tasks are performed effectively. Make sure that a Person Responsible for Regulatory Compliance is appointed per the MDR requirements (Article 15), who possesses the requisite expertise in the field of medical devices. See responsibilities of the Person Responsible for Regulatory Compliance.

Responsibilities of the Person Responsible for Regulatory Compliance:

The person responsible for regulatory compliance shall at least be responsible for ensuring that:

(a) the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released;

(b) the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date;

(c) the post-market surveillance obligations are complied with in accordance with Article 10(10);

(d) the reporting obligations referred to in Articles 87 to 91 of the MDR are fulfilled;

(e) in the case of investigational devices, a signed statement by the manufacturer to confirm that the investigational device meets all general safety and performance requirements, except for those aspects being

specifically studied in the clinical investigation (Section 4.1 of Chapter II of Annex XV of the MDR).

Facilities and Workspace: Provide and maintain suitable facilities and workspace that meet regulatory requirements and support the production of safe and effective medical devices

Infrastructure: Provide suitable facilities and equipment. Ensure equipment is maintained, calibrated, and validated per regulatory standards.

Work Environment: (1) Health, Safety, and Environmental Conditions: Create and maintain a work environment that supports product quality and conforms to applicable health, safety, and environmental regulations; (2) Cleanliness and Contamination Control: Implement procedures to control cleanliness and contamination, particularly in controlled environments such as cleanrooms.

Information Systems: (1) Documentation and Data Management: Ensure the availability of appropriate documentation and data management systems to support quality processes. This includes maintaining records, managing data integrity, and ensuring data security; (2) IT Infrastructure: Provide and maintain an IT infrastructure that supports the effective management of quality-related data and processes.

Financial Resources: (1) Budgeting and Financial Planning: Allocate sufficient financial resources to support the QMS, including funding for training, infrastructure maintenance, and compliance activities; (2) Cost Management: Implement cost management practices to ensure efficient use of resources while maintaining quality standards.

External Resources: (1) Supplier Management: Establish and maintain criteria for the selection, evaluation, and re-evaluation of suppliers and ensure that suppliers and service providers meet the required quality standards and regulatory requirements; (2) Outsourcing and Partnerships: Manage relationships with outsourced partners and contractors to ensure that they comply with the relevant aspects of the QMS

Monitoring and Measurement: (1) Develop key performance indicators (KPIs) to assess resource management effectiveness. This includes tracking training effectiveness, equipment performance, and supplier quality; (2) Regularly review performance data to identify areas for improvement (also see Management Review).

By effectively managing resources, organizations can ensure that they have the necessary tools, personnel, and support to consistently produce high-quality medical devices that meet regulatory requirements and customer expectations.

D. Background of Purchasing Controls (ISO 13485 § 7.4)

Effective purchasing controls and supplier management are essential for mitigating risks, ensuring regulatory compliance, maintaining quality assurance, providing documentation and traceability, facilitating market access, and building customer confidence

(Taken from Section 3: Quality Management Systems (QMS) from an MDR Perspective - Subsection Product Realization)

Implementing effective purchasing controls and supplier management offers several regulatory benefits:

1. Risk Mitigation: To comply with regulatory requirements for supplier management, product-risk criteria must be defined and implemented. Proper supplier management helps identify and mitigate risks associated with the supply chain. This ensures that any potential issues are addressed proactively, reducing the likelihood of non-compliance with regulatory standards.
2. Regulatory Compliance: Adhering to purchasing controls ensures that all procurement activities meet regulatory requirements. This includes selecting suppliers who comply with relevant standards, such as ISO 13485:2016 for medical devices.
3. Quality Assurance: Effective supplier management ensures that all suppliers and subcontractors comply with regulatory and quality requirements, thereby guaranteeing that purchased products meet established quality standards and regulatory criteria. This involves evaluating, selecting and monitoring suppliers. Depending on the criticality of the product or service provided by the supplier, this may include regularly auditing of the supplier. Regular supplier evaluations and audits help maintain high-quality standards and compliance.
   Supplier Audit Reports will be included in FDA inspections starting February 2026, marking a significant change in FDA inspection policies.
4. Documentation and Traceability: Proper purchasing controls include maintaining comprehensive documentation of procurement activities. This documentation is crucial for demonstrating compliance during regulatory audits and inspections.
   Identification and traceability may involve .suppliers of distribution services or distributors
5. Market Access: Compliance with regulatory requirements through effective

purchasing controls and supplier management facilitates market access. Regulatory bodies are more likely to approve products from companies that demonstrate robust supplier management practices.

6. Customer Confidence: Ensuring that suppliers meet regulatory standards enhances customer confidence in the safety and efficacy of products. This can lead to increased customer satisfaction and loyalty.