Session 9:

Quality Management and Prequalification

World Health Organization

UNFPA

PATH
A catalyst for global health

Session Objectives

- Place international standards within quality management context
- Discuss intent and scope of key quality management standards
- Link quality management with prequalification requirements

Quality Management

- Includes all elements of organizational management that affect product quality
- Does not include activities that have no effect on product quality

Brainstorm

- Identify at least five components of a quality management system

Essential Components of a Quality Management System

- A well-established quality management system will have documented:
  - Quality objectives
  - Management responsibilities
  - Training procedures
  - Process and quality assurance procedures
  - Record-keeping
  - Remedial action in case of quality problems

ISO 9000 and 13485

- ISO 9000: Quality management systems
- ISO 13485:
  - Specifically for medical devices
  - More prescriptive than ISO 9001
  - More emphasis on risk assessment

Quality Management and Prequalification

- Prequalification involves examination of documentary evidence to verify the integrity of the product manufactured and compliance with ISO 13485
    - Through review of the Site Master File Summary
    - Through review of the Product Dossier
    - Through on-site inspection
- WHO specification 3.3: Pre-qualification “verifies that the manufacturer has the quality assurance and management system”

The ISO 9000 Series

- Getting a certificate is one thing
- Getting the benefit in terms of operation is another

ISO 9000
Fundamental Principles

8 quality management principles:

- Customer focus
- Leadership
- Involvement of people
- Process approach
- System approach to management
- Continual improvement
- Factual approach to decision making
- Mutually beneficial supplier relationships

ISO 13485

- Clause 4: The quality management system
- Clause 5: Management responsibility
- Clause 6: Resource management
- Clause 7: Product realization
- Clause 8: Measurement, analysis, and improvement

Making ISO 9000 Work for You

- Be committed to the principles of ISO 9000
- Document your operation as it exists
- Be prepared to justify your decisions

Small Group Discussion

- Discuss how your factory applies specified clauses of ISO 13485

WARNING: This material is only a summary of the standard; do not use this material as a substitute for the complete official standard document.

Summary of ISO 13485: Quality Management Standard for Medical Devices

Clause 4: Systemic Requirements

Summary

- You must have a system of documentation that covers your policy, procedures, and product specifications.
- You must keep records of production and testing.
- You must keep the system up-to-date and usable.

Details

- **4.1**: Must work out what is needed for the system, how to operate and control it, and make sure that it can work.
- **4.2**: Must have documents about the system (including policy and objectives, quality manual, procedures, records, legally required documents, etc.).
- Documents must be controlled.
- Must have file that fully defines each product (product dossier).

Clause 5: Management Requirements

Summary

- Top management is responsible for ensuring that the system is created, operated, and developed.

Details

- **5.1**: Management must provide evidence of commitment to quality system.
- **5.2**: Must ensure that customer requirements are determined and met.
- **5.3**: Must ensure appropriate quality policy which maintains the quality system and reviews quality objectives and policy.
- **5.4**: Management responsible for planning any changes.
- **5.5**: Management must define, document, and communicate responsibilities. There must be internal communication systems.
- **5.6**: There must be management reviews.

Clause 6: Resource Requirements

Summary

- The organization must provide the necessary buildings, staff, and other resources to allow the quality system to develop and function.

Details

- **6.1**: Organization must provide resources needed to effectively run the quality system and meet regulatory and customer requirements
- **6.2**: Must have competent, trained, and experienced staff. Must evaluate and maintain records of training.
- **6.3**: Must provide necessary buildings, utilities, equipment, and support. Must document the requirements for and record the implementation of maintenance.
- **6.4**: Must pay attention to work environment if it could affect quality.

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Clause 7: Realization Requirements

Summary

- Manufacturing must be planned to meet specifications, customer, and regulatory requirements.
- Processes must be validated to show they do that.
- Must maintain full documentation.
- Product must be traceable through factory.

Manufacture: General

- Product realization (manufacture) procedures and facilities to be planned, including validation, tests, and appropriate records.
- Must establish requirements for risk management and perform risk assessments.
- Must determine and review customer and statutory requirements, and keep records of the requirements.
- Must have effective ways of communicating with clients.

Design

- Must have written procedures for design and development, including reviews and validation.
- Must determine design requirements.
- Design outputs must meet requirements and provide information for production.
- Must have acceptance criteria.
- Must have design reviews.

Quality Control

- Must have criteria for purchasing.
- Must ensure that purchased product conforms to requirements.
- Production to be done under suitable conditions with suitable monitoring and record-keeping.
- Keep records of product cleaning, if appropriate.
- Must determine and establish the monitoring and measurements needed to demonstrate conformity.
- Must calibrate as needed and identify to show status if calibration.
- Prevent damage to calibration.
- Assess validity of previous results if calibration found faulty.

Process Set Up

- Production processes to be validated (unless output can be verified by monitoring).
- Software used in production to be validated before initial use.
- Must preserve product as required during production.

Traceability

- Product to be identified during production.
- Must have procedures for traceability of product, and identify product status (pass/fail).

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Clause 8: Remedial Requirements

Summary

- Process product quality and quality system and must be monitored.
- Data collected must be analyzed.
- Opportunities for corrective action must be identified.
- Must have procedures for corrective and preventative actions and implement them when necessary.
- Must review corrective and preventative actions.

Monitoring

- Must monitor whether or not customer requirements are met.
- Must conduct internal audits of quality management system.
- Must monitor quality management system.
- Must monitor quality of product during production and keep appropriate records.
- Nonconforming products must be controlled to prevent unintended delivery or use.

Analysis

- Must collect and analyze appropriate data for:
  - Feedback from clients (including complaints)
  - Conformity to requirements
  - Trends in production
  - Opportunities for corrective action
  - Suppliers

Corrective and Preventive Actions

- Must have procedure and take action to eliminate nonconformities and prevent recurrence.
- Review corrective actions.
- Determine and implement preventive actions to eliminate nonconformities.
- Review preventive actions.

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The ISO 9000 Series

Fundamental Principles

- Customer focus
- Leadership
- Involvement of people
- Process approach
- System approach to management
- Continual improvement
- Factual approach to decision making
- Mutually beneficial supplier relationships

1. **Customer Focus**

   Organizations depend on their customers and should:

   – Understand current and future customer needs

   – Meet customer requirements

   – Strive to exceed customer expectations

2. **Leadership**

   Leaders:

   – Establish unity of purpose

   – Provide organizational direction

   – Create and maintain environments that support employee involvement in achieving organizational objectives

3. **Involvement of People**

   People at all levels are the essence of an organization—their full involvement enables their abilities to benefit the organization as a whole.

4. **Process Approach**

   Managing activities as a process produces a desired result more efficiently.

5. **System Approach to Management**

   Identifying, understanding, and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

6. **Continual Improvement**

   Continual improvement of the organization's overall performance should be a permanent organizational objective.

7. **Factual Approach to Decision Making**

   Effective decisions are based on the analysis of data and information.

8. **Mutually Beneficial Supplier Relationships**

   An organization and its suppliers are interdependent, and a mutually beneficial relationship enhances the ability of both to create value.