Session 9:
Quality Management and Prequalification
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
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.
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 the 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).
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.
The ISO 9000 Series

Fundamental Principles
- Customer focus
- Leadership
- Involvement of people
- Process approach
- System approach to management
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- 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.

The WHO Prequalification Programme for Condoms: A Workshop for Male Latex Condom Manufacturers