DEPARTMENT OF BIOMEDICAL ENGINEERING

VI Semester

24BM501 BIOMEDICAL DEVICE DESIGN

5.2 Quality Management Systems (QMS)

➢Introduction

A **Quality Management System (QMS)** is the formalised set of policies, processes, procedures, responsibilities and resources through which an organisation directs and controls its activities to consistently meet customer and regulatory requirements. In the medical-device industry the QMS is not optional: it is the legal basis on which regulators (FDA, CDSCO, Notified Bodies) judge whether a manufacturer can reliably produce safe and effective devices. The principle is that **quality must be designed and built into the device**, not merely inspected at the end.

Definitions

- ✓ **Quality:** degree to which a set of inherent characteristics of a device fulfils requirements (ISO 9000).
- ✓ **Quality assurance (QA):** planned and systematic activities that give confidence that quality requirements will be met (prevention).
- ✓ **Quality control (QC):** operational techniques such as inspection and testing to verify that requirements are met (detection).
- ✓ **Good Manufacturing Practice (GMP):** minimum practices for hygiene, process control, equipment, personnel and records during manufacture.
- ✓ **Verification:** "Did we build the device right?" – confirming that outputs meet design inputs. **Validation:** "Did we build the right device?" – confirming that the device meets user needs and intended use.

➢Quality Management Principles

Principle (ISO 9000)	Meaning for a device company
Customer focus	Understand clinician and patient needs; handle complaints and feedback
Leadership	Top management defines the quality policy and provides resources
Engagement of people	Trained, competent staff who own quality
Process approach	Manage activities as interrelated processes (design, purchasing, production, service)
Improvement	CAPA, audits and management review drive continuous improvement

Principle (ISO 9000)	Meaning for a device company
Evidence-based decision making	Decisions based on data from testing, complaints and surveillance
Relationship management	Control of suppliers and contract manufacturers

➢QMS Documentation

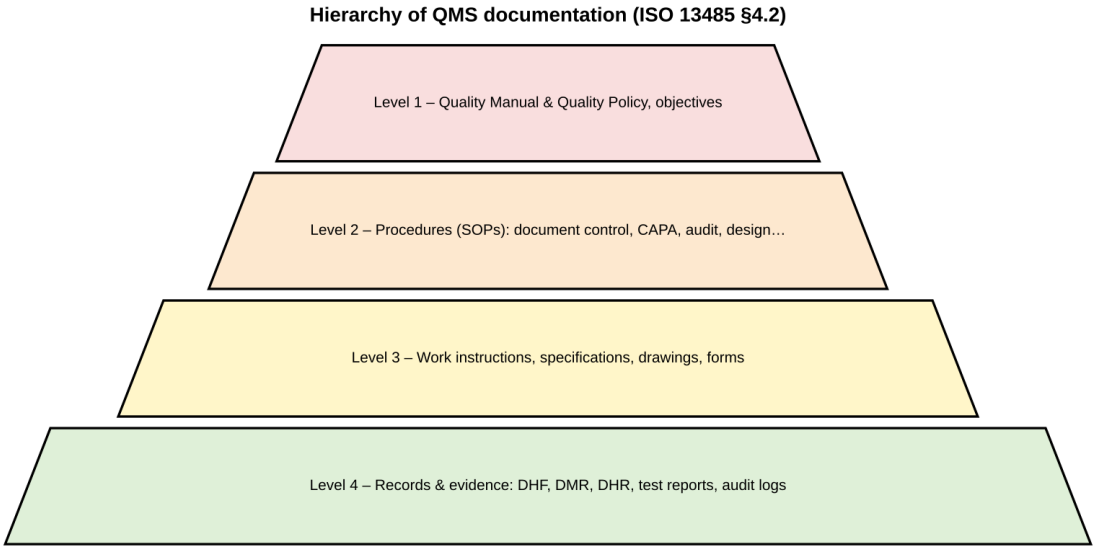

Fig. 5.8 Hierarchy of QMS documentation

- ✓ **Quality manual and quality policy:** scope of the QMS, justification of exclusions, and top-management commitment.
- ✓ **Documented procedures (SOPs):** mandatory for document control, record control, internal audit, non-conforming product, CAPA, complaint handling, training, purchasing, design control and risk management.
- ✓ **Medical Device File (MDF) / Technical file:** product specification, labelling, manufacturing and testing procedures, installation and servicing instructions for each device type. In FDA terminology this was split into the **DHF (Design History File)**, **DMR (Device Master Record)** and **DHR (Device History Record)**.
- ✓ **Document control:** documents are approved, versioned, reviewed, available at point of use and protected against obsolete use.
- ✓ **Records:** legible, retained for at least the lifetime of the device (not less than 2 years in the US; often 5–10+ years or longer for implants) – including batch records, calibration records and training records.

➢Design and Development Controls

Design controls (ISO 13485 clause 7.3, 21 CFR 820 design controls, MDR Annex II) make the development process disciplined and traceable. Every requirement must be traced to a design output, a verification test and a validation activity (the **traceability matrix**).

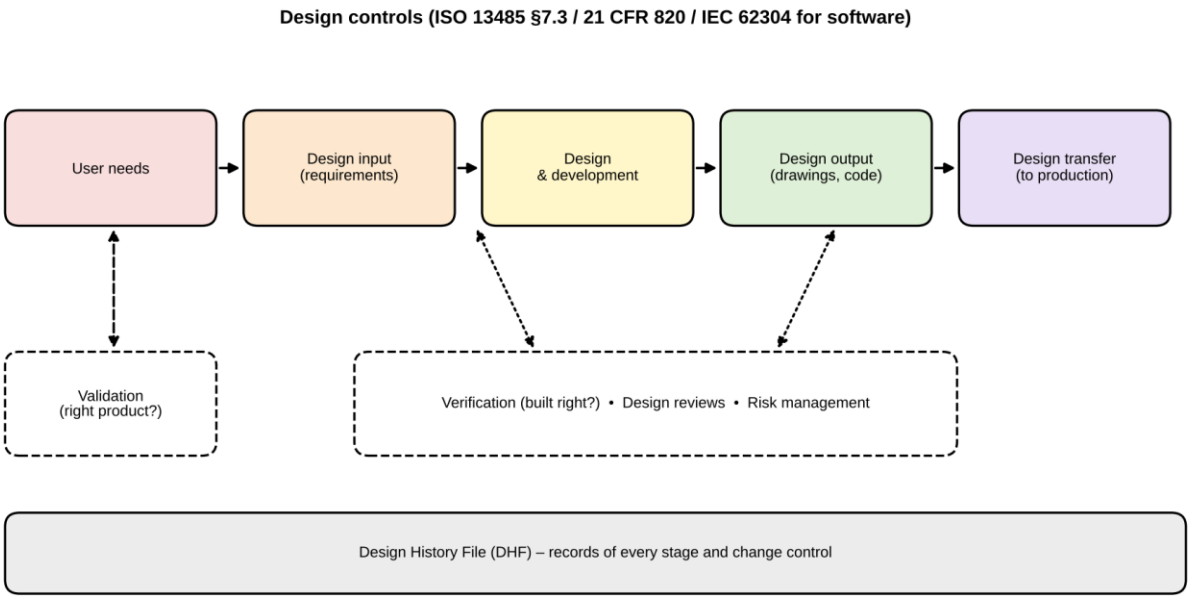

Fig. 5.9 Design control process

1. **Design and development planning:** stages, responsibilities, reviews, verification and validation activities.
2. **Design inputs:** functional, performance, safety, regulatory and usability requirements, derived from user needs and risk analysis.
3. **Design outputs:** drawings, software code, specifications, acceptance criteria – must meet inputs and be traceable.
4. **Design review:** formal documented reviews at suitable stages by cross-functional experts.
5. **Design verification:** bench tests, simulations and inspections confirm outputs meet inputs (e.g. IEC 60601 tests).
6. **Design validation:** confirmation under defined operating conditions on representative product, including clinical evaluation and usability testing.
7. **Design transfer:** ensuring the design is correctly converted into production specifications.
8. **Design changes:** identified, reviewed, verified/validated and approved before implementation (change control).

➢Risk Management in the QMS (ISO 14971)

ISO 13485 requires a risk-based approach to every process, and **ISO 14971:2019** gives the standard process for **medical device risk management**. Risk is the combination of the **probability of occurrence of harm** and the **severity** of that harm. The goal is to reduce risk **as far as possible** and to demonstrate that residual risk is acceptable when weighed against clinical benefit.

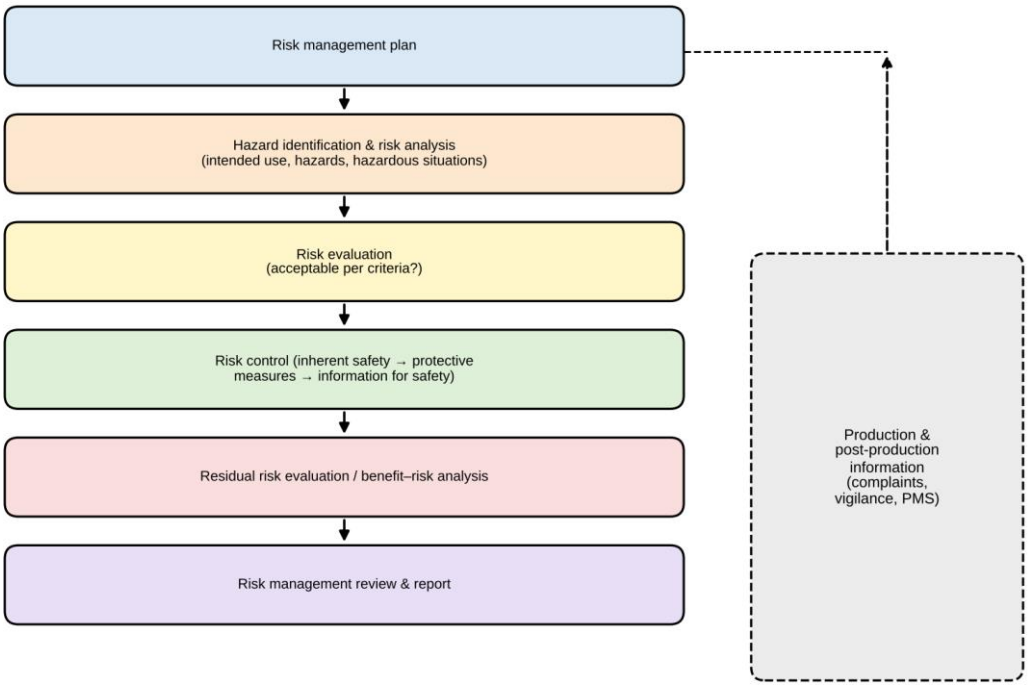

Fig. 5.10 Risk management process (ISO 14971)

Risk = Severity of harm × Probability of occurrence

Tool	Purpose
PHA – Preliminary Hazard Analysis	Early identification of hazards in concept stage
FMEA – Failure Mode and Effects Analysis	Bottom-up analysis of component/process failures; RPN = Severity × Occurrence × Detection
FTA – Fault Tree Analysis	Top-down analysis of how an undesired event can occur
HAZOP / use-error analysis	Systematic study of deviations and user errors

Risk control hierarchy: (1) inherently safe design, (2) protective measures in the device or manufacturing process (alarms, interlocks, fuses), (3) information for safety (warnings, training). Labelling is the last resort, not the first.

➢Purchasing and Supplier Control

✓ Suppliers are **evaluated, approved and monitored** according to their effect on product quality; a **Approved Supplier List (ASL)** is maintained.

✓ **Quality agreements** define specifications, change notification, audit rights and record retention.

✓ **Incoming inspection** with sampling plans (AQL, ISO 2859) or certificates of conformity.

➢Production and Service Provision

✓ **Process validation – IQ, OQ, PQ:** *Installation Qualification* (equipment installed correctly), *Operational Qualification* (works across the operating range), *Performance Qualification*

(consistently makes conforming product). Required for processes whose output cannot be fully verified, such as sterilisation, sealing, welding and moulding.

- ✓ **Sterile devices:** validated sterilisation (ethylene oxide ISO 11135, radiation ISO 11137, steam ISO 17665) and packaging (ISO 11607); controlled cleanroom environments (ISO 14644).
- ✓ **Identification and traceability:** lot/serial numbers, UDI; full traceability for implants down to the patient.
- ✓ **Calibration:** monitoring and measuring equipment is calibrated against national or international standards at defined intervals (NABL / NIST traceable).
- ✓ **Labelling and packaging control:** prevents mix-ups and ensures correct instructions for use.
- ✓ **Servicing and installation records** for devices that need field service.

➢Measurement, Analysis and Improvement

Complaint handling, vigilance and post-market surveillance

Every complaint is recorded, evaluated and investigated; those meeting reporting criteria are notified to regulators (MDR reports in US, MvPI in India, vigilance in EU). Data from complaints, service records, literature and clinical follow-up feed back into risk management.

Internal audit and management review

- ✓ **Internal audits** at planned intervals check that the QMS conforms to ISO 13485 and is effectively implemented; auditors are independent of the area audited.
- ✓ **Management review** by top management evaluates audit results, feedback, process performance, CAPA status, regulatory changes and resource needs.
- ✓ **External audits:** Notified Body, MDSAP, FDA inspection and CDSCO audit.

Corrective and Preventive Action (CAPA)

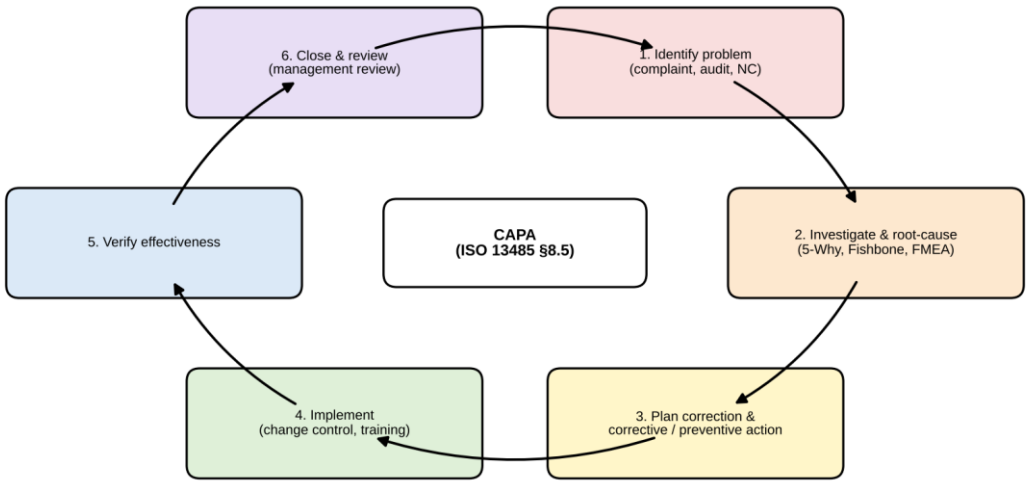

Fig. 5.11 CAPA cycle

- ✓ **Correction:** immediate action to eliminate a detected non-conformity (e.g. rework a batch).

- ✓ **Corrective action:** eliminates the **root cause** of a detected non-conformity to prevent recurrence.
- ✓ **Preventive action:** eliminates the cause of a **potential** non-conformity.
- ✓ **Root-cause tools:** 5-Why, Ishikawa (fishbone), Pareto analysis, FMEA, fault tree.

Quality tools and improvement methods

Tool / method	Use
Statistical Process Control (SPC) charts	Monitor process variation in production
Six Sigma (DMAIC)	Reduce defects: Define–Measure–Analyse–Improve–Control
Lean manufacturing / 5S	Remove waste, organise workplace
Pareto chart, histogram, scatter plot	Prioritise causes and visualise data
Quality metrics: first-pass yield, complaint rate, CAPA closure time, audit findings	Measure QMS performance