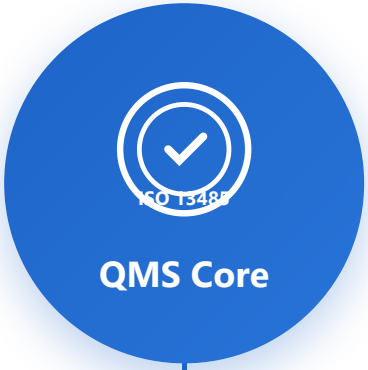
Quality Management System



Design Controls

Risk Management

Document Control

CAPA Systems

Design Controls

Overview

Design Controls ensure that medical devices are developed systematically with documented procedures that verify the design meets user needs and intended uses. This is a critical FDA requirement under 21 CFR Part 820.30.

Key Objectives

- Ensure products meet user needs and specifications
- Identify and mitigate design flaws early
- Maintain traceability throughout development
- Comply with regulatory requirements

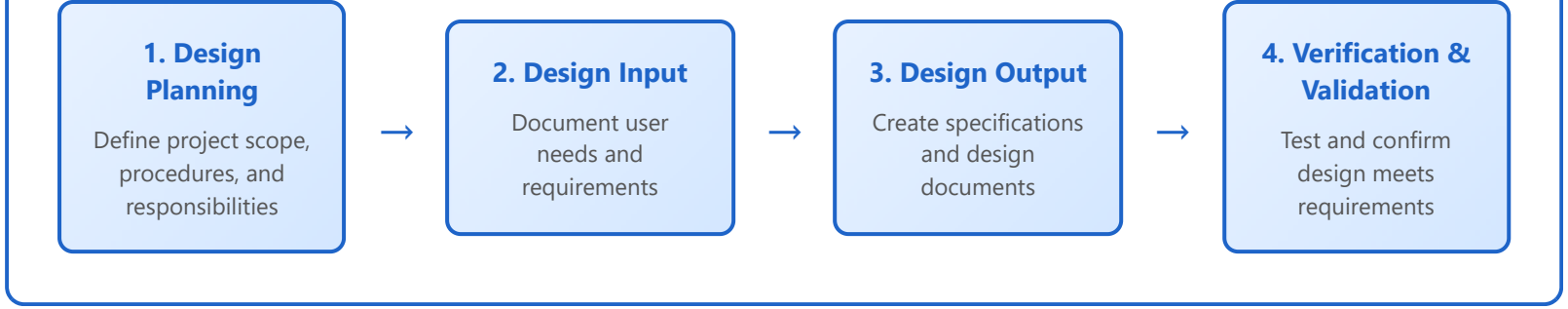
Critical Elements

- **Design Planning:** Establishing procedures and responsibilities
- **Design Input:** User needs and technical requirements
- **Design Output:** Specifications and drawings
- **Design Review:** Formal assessment at milestones
- **Design Verification:** Testing against specifications
- **Design Validation:** Confirming user needs are met

Benefits

- Reduced development costs and time-to-market
- Fewer post-market failures and recalls
- Enhanced product quality and safety
- Regulatory compliance and easier audits

Design Control Process Flow



Key Insight: Design Controls create a structured framework that transforms user needs into safe, effective medical devices while ensuring regulatory compliance and reducing development risks.

Risk Management

Overview

Risk Management is a systematic approach to identifying, evaluating, controlling, and monitoring risks throughout a medical device's lifecycle. It follows ISO 14971 standards to ensure patient safety and product effectiveness.

ISO 14971 Framework

- **Risk Analysis:** Identify hazards and estimate risks
- **Risk Evaluation:** Determine acceptability of risks
- **Risk Control:** Implement mitigation measures
- **Residual Risk:** Evaluate remaining risks
- **Risk Review:** Continuous monitoring

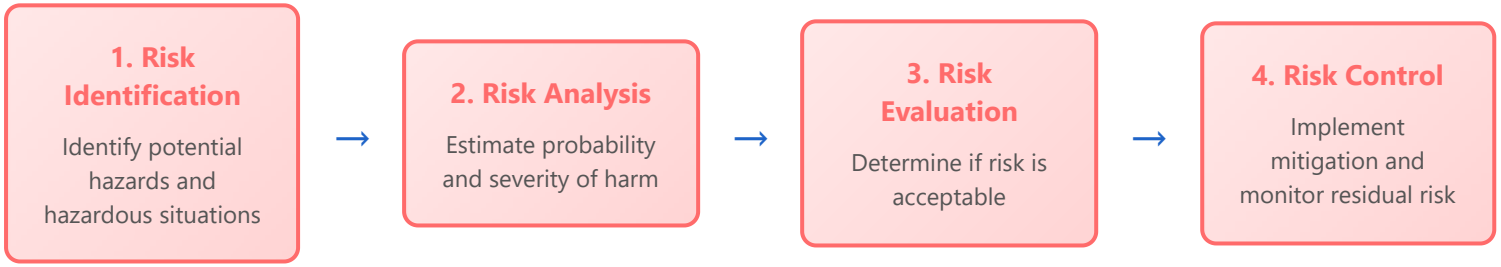
Risk Assessment Tools

- **FMEA:** Failure Modes and Effects Analysis
- **FTA:** Fault Tree Analysis
- **HAZOP:** Hazard and Operability Study
- **Risk Matrix:** Probability vs. Severity mapping

Risk Control Measures

- **Inherent Safety:** Design out the hazard
- **Protective Measures:** Guards, alarms, interlocks
- **Information for Safety:** Warnings, training
- Hierarchy: Elimination > Engineering > Administrative

Risk Management Process



Critical Point: Effective risk management is not a one-time activity but a continuous process throughout the entire product lifecycle, from concept to post-market surveillance.

Document Control

Overview

Document Control ensures that all QMS documents are properly created, reviewed, approved, distributed, and maintained. It guarantees that the correct versions of documents are available where needed and obsolete documents are removed from use.

Core Requirements

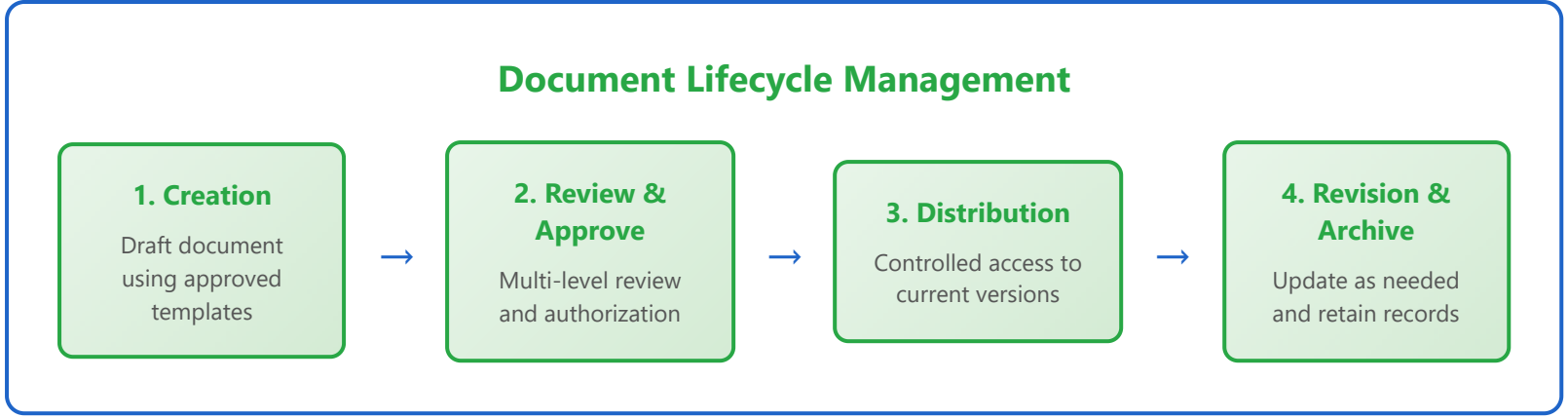
- Document identification and version control
- Review and approval before issuance
- Controlled distribution and access
- Regular review and updates
- Obsolete document removal
- Change control and traceability

Document Hierarchy

- **Level 1:** Quality Manual - Overall QMS policy
- **Level 2:** Procedures - How to perform activities
- **Level 3:** Work Instructions - Detailed step-by-step
- **Level 4:** Records - Evidence of activities

Best Practices

- Use electronic document management systems (eDMS)
- Implement automated workflows for approvals
- Maintain audit trails for all changes
- Regular training on document procedures
- Periodic document review cycles



Essential Principle: "If it isn't documented, it didn't happen." Proper document control ensures traceability, compliance, and serves as objective evidence during regulatory inspections.

CAPA Systems (Corrective and Preventive Action)

Overview

CAPA is a systematic approach to investigating, resolving, and preventing quality problems. It addresses both existing nonconformities (corrective) and potential issues (preventive) to drive continuous improvement in the QMS.

Corrective Action (CA)

- Addresses existing problems or nonconformities
- Eliminates the cause of detected issues
- Prevents recurrence of problems
- **Example:** Device failure investigation and fix

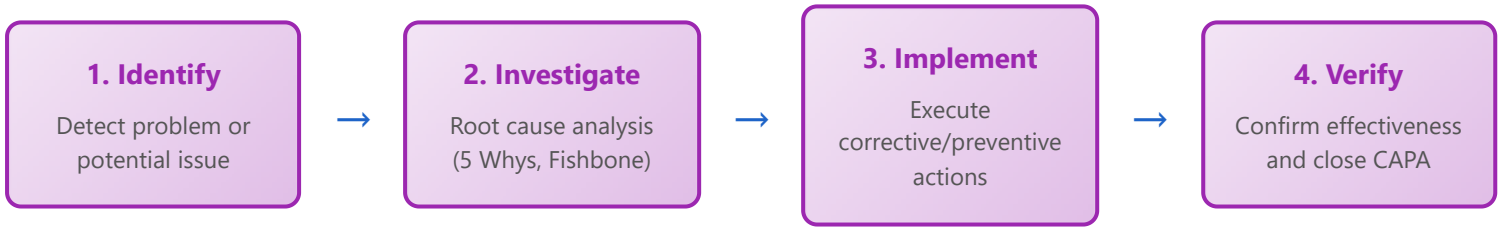
Preventive Action (PA)

- Identifies potential problems before they occur
- Proactive risk mitigation
- Based on trend analysis and monitoring
- **Example:** Addressing component aging concerns

CAPA Triggers

- Customer complaints and feedback
- Internal audit findings
- Nonconforming products or processes
- Quality metrics and trend analysis
- Post-market surveillance data
- Regulatory inspection observations

CAPA Process Flow



Success Factor: Effective CAPA requires thorough root cause analysis, not just addressing symptoms. Use tools like 5 Whys, Fishbone diagrams, and Pareto analysis to identify true underlying causes.