Compliance Auditing

Compliance auditing is the process of **systematically verifying** compliance with regulatory requirements

🏢 Internal Audit

Self-compliance inspection

🔍 External Audit

Third-party certification body review

🏛️ Regulatory Audit

FDA, EMA and other authority inspections

Audit Checklist Items

- **QMS (ISO 13485):** Quality Management System conformity
- **Design Control:** Design input, verification, and validation documents
- **Risk Management (ISO 14971):** Risk analysis and mitigation measures
- **Software Verification:** IEC 62304 compliance
- **Clinical Evaluation:** Securing sufficient clinical evidence
- **Labeling:** Appropriateness of instructions for use and warning labels
- **CAPA:** Corrective and Preventive Action System
- **Complaint Handling:** Complaint management process

📋 Document Preparation

Complete DHF, DMR, Design History File, etc.

🎯 Continuous Improvement

Process improvement based on audit findings

💡 **Key Point:** It is important to maintain regulatory readiness through regular internal audits and to identify and resolve issues in advance before external audits