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DIGITAL TRANSFORMS PHYSICAL

Medical Audit & CAPA Template

Compliance support for ISO 13485:2016 and FDA Title 21 CFR Part 820

codebeamer™

The Medical Audit & CAPA Template

Due to rigorous quality standards, developers of medical technology face stringent requirements on the design, development, manufacturing, and post-market surveillance of their digital healthcare products.

This **Medical Audit & CAPA Template** helps you tackle internal and external quality audits with ease. Compliance assessments are greatly simplified thanks to the preconfigured artifacts, processes, and traceable links between work items that this template provides out of the box.

The template simplifies audit preparation & execution, and enables you to manage Corrective and Preventive Actions in a convenient and fully traceable manner.

Why use the Medical Audit & CAPA Template?

1

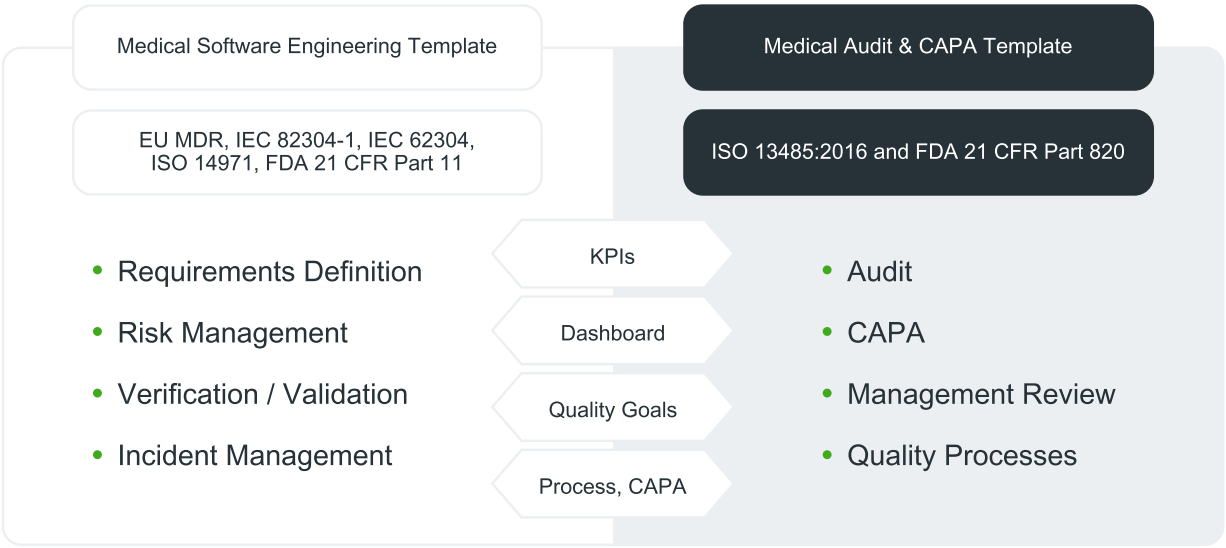
Simplified compliance audits
Plan and schedule audits, and build comprehensive and actionable audit checklists. Execute compliance audits in a central quality control platform.

2

Actionable continuous improvement
Manage all customer complaints, feedback, non-conformities, improvement potentials, Root Cause Analyis, and CAPA in an integrated system.

3

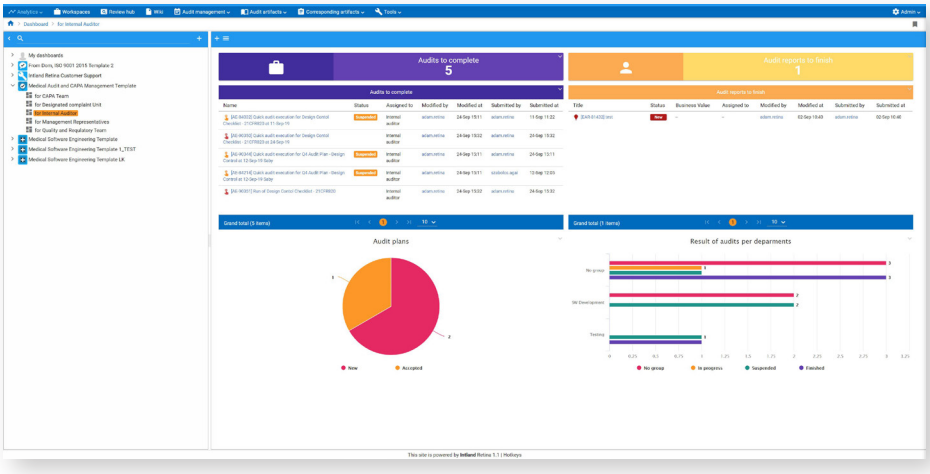
Integrated quality and regulatory management
Maintain a shared and integrated information management system for all your audit activities. Tie in engineering process control using the Medical Software Engineering Template.

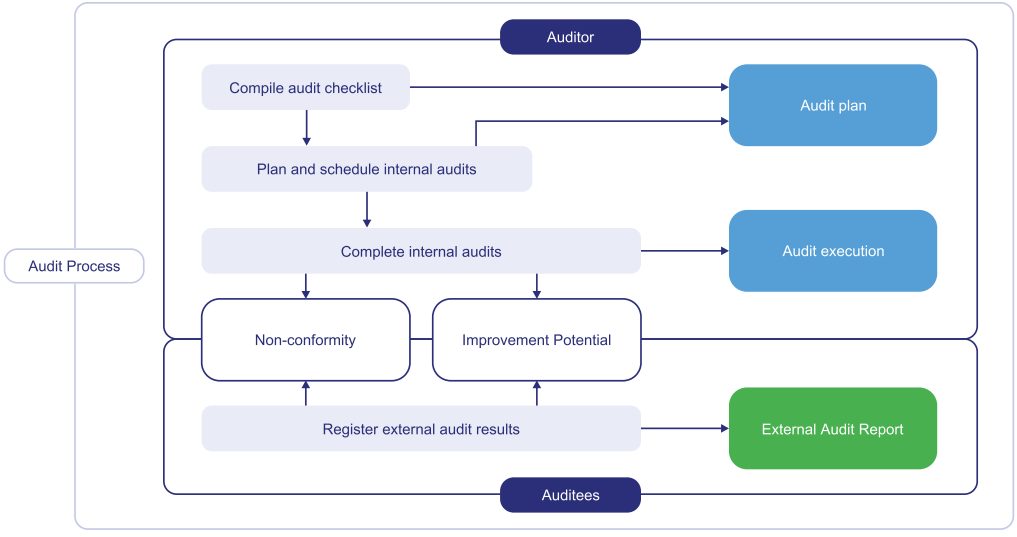


Capabilities of the Medical Audit & CAPA Template

All-in-one Audit Management

This template supports your entire audit management lifecycle for MedTech regulations. The template provides predefined artifacts and processes to accelerate compliance verification, and best practices to help you perform audits effectively. Compile re-usable audit checklists for various medical standards. Plan and manage audits in a traceable manner. Customize audit dashboards for immediate access to detailed information and high-level visual data analytics charts. Use this template to provide auditors with an efficient platform to record audit evidence during audits.



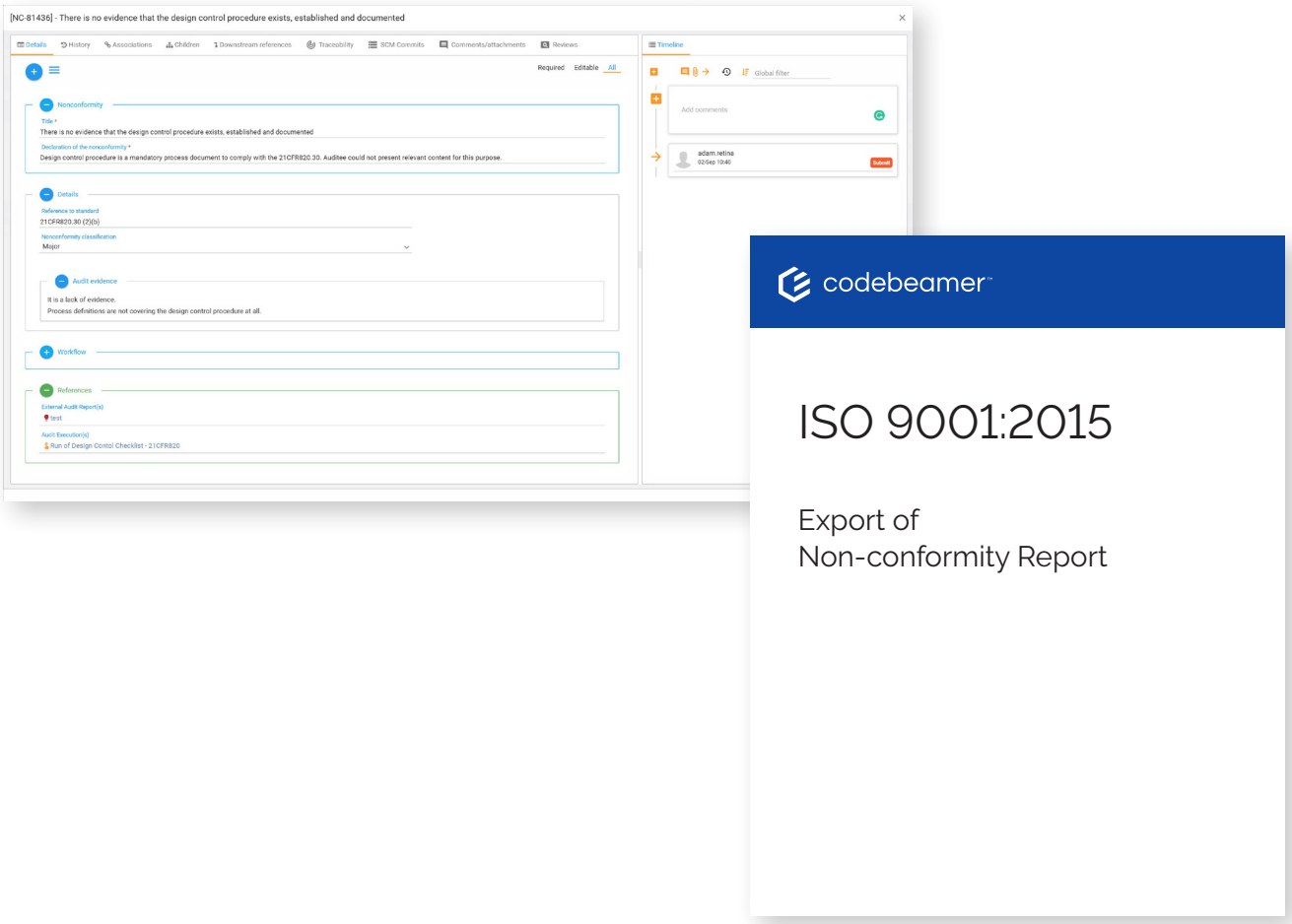


Non-conformity and Improvement Management

Record and manage non-conformities and any potential for improvement in a central platform using the Medical Audit & CAPA Template. Link audit reports to non-conformities and improvement artifacts to trace them through their lifecycles. Define custom workflows for non-conformities and improvements.

Root Cause Analysis

Analyze non-conformities and record the results of Root Cause Analysis in this template. Couple RCA with the investigation of customer complaints, and trace improvement actions from identification to execution.



Corrective Actions, Preventive Actions

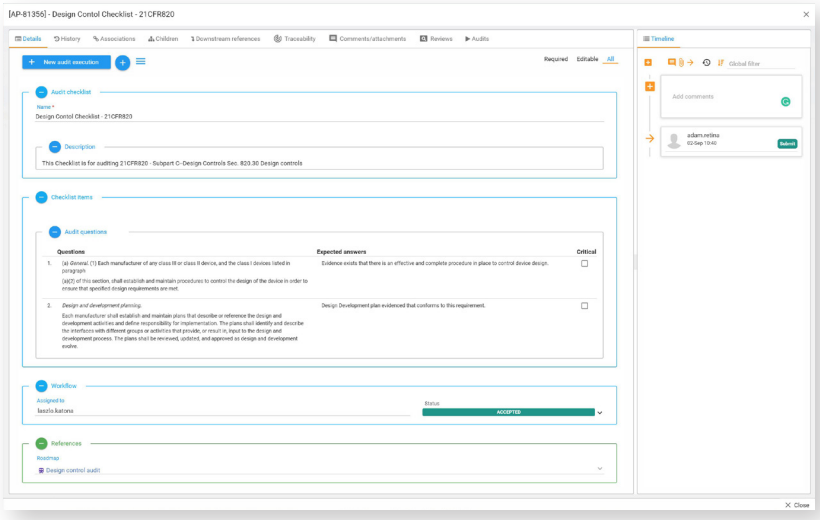
Provide your CAPA team with a comprehensive platform to compile action plans for corrective actions based on RCA. Use the Medical Audit & CAPA Template to attach timing and efficiency check results to the original action plans. Record Preventive Actions using preconfigured artifacts to manage improvement potentials. Trace Corrective and Preventive Actions back to non-conformities and improvement potentials, as well as to corresponding audit reports.

Complaint Registration, Adverse Incident Reporting

Use this template to manage your complaint file compilation repository based on the key requirements of the FDA 21CFR820.198. Extend investigation records of complaint files to RCA and towards Adverse Incident Reporting. Maintain all Adverse Incident Record documents in this template with optinal FDA 21CFR11-compliant electronic signatures.

Management Review Record

Record management review records by integrating review items including Corrective and Preventive actions, complaint records, and adverse incident reporting. Record and monitor review action items in a timely manner using the Medical Audit & CAPA Template.



Templates

Start quickly and accelerate your ROI using preconfigured templates. Templates are easy to use, and you can adapt them flexibly to suit your organization's individual needs.

- Document Management Template
- Requirements Management Template
- Test Management Template
- **Medical Software Engineering Template**
- Pharma GAMP®5 Template
- Customer Relationship Management (CRM) Template
- ISO 9001:2015 QMS Template
- Scrum Agile Template
- Customer Support Template
- **Medical Audit & CAPA Template**
- SAFe® Template
- Agile Marketing Template

Download our Medtronic case study to learn how the world's largest medical technology company reaches compliance in a scaled Agile development environment

Integrations

Connect your fragmented tool environment in a central development platform through out-of-the-box integrations. Reduce hidden costs and the tedious manual work of creating integrations. Enjoy full traceability and data consistency, and slash tool maintenance costs.

JUnit, eclipse, Jenkins, Docker, Trello, Bitbucket, Jira, JMeter, Red Hat OpenShift, Cantata, Enterprise Architect, ReqIF, Quality Center, kubernetes, Word, Excel, Project, DAV, plasticscm, TeamCity, Vector, git, GitLab, MATLAB Simulink, GitHub

Our solutions are successfully used by:

Medtronic, SAMSUNG, Inivata, STEPHAN, NewYork-Presbyterian, sysmex, medin A Hamilton Medical Company, Rakuten Medical, COSYLAB, TrakCel, MicroDiscovery, bigfoot BIOMEDICAL, spōk, DITABIS

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Validation Kits

Codebeamer's Validation Kits are valuable tools for safety-critical product development teams with regulatory compliance needs.

- **Tool Validation Kit**
  Use this kit to simplify and accelerate tool qualification and validation in regulated product development.
- **Title 21 CFR Part 11 Validation Kit**
  Rely on this tool to prove compliance with 21CFR11 requirements about electronic records management.

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