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Medical Software Engineering & Quality Assurance

for Medical Software Engineering, Audit & CAPA Management

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Balancing measures

Innovation

Research

Development

Production

Medical Device Development

Regulatory environment

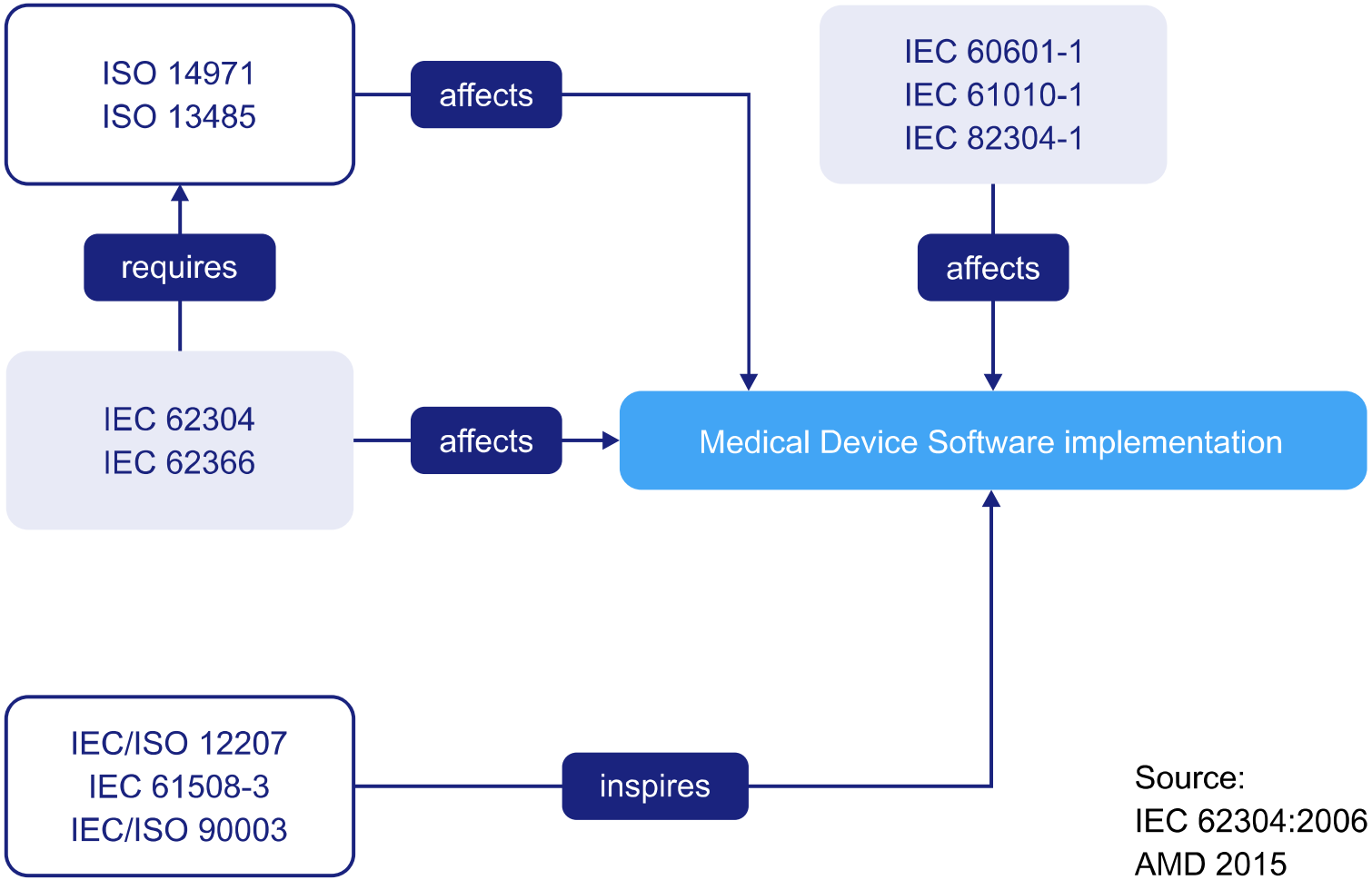
Market / Customer expectations

Medical Device Design and Development

Organizational goals

Challenges

Compliance



Source:
IEC 62304:2006
AMD 2015

Medical Device Development

Daily ‘routine’

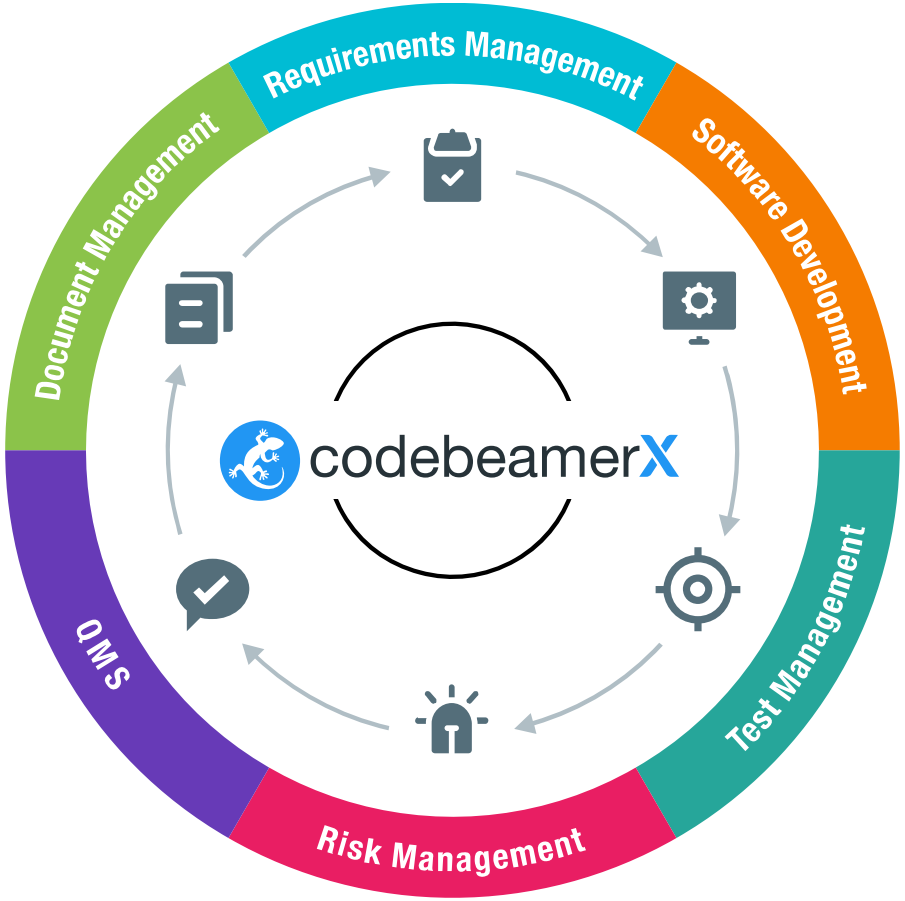
Solution: codebeamer X

Integrated Requirements, Risk, Test and QA Platform for MedTech Development

Medical QMS Process framework

+

Good engineering practices



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Our MedTech solution supports the development of:

US FDA:

Software as a Medical Device (SaMD)

EU:

Medical Device Software (MDSW)

Why Choose codebeamer X for MedTech Development?

Fast Implementation	Audit Support	Domain Experts
		
One Template, Multiple Standards	**Validation Support**	**Easy-access Approvals**
		

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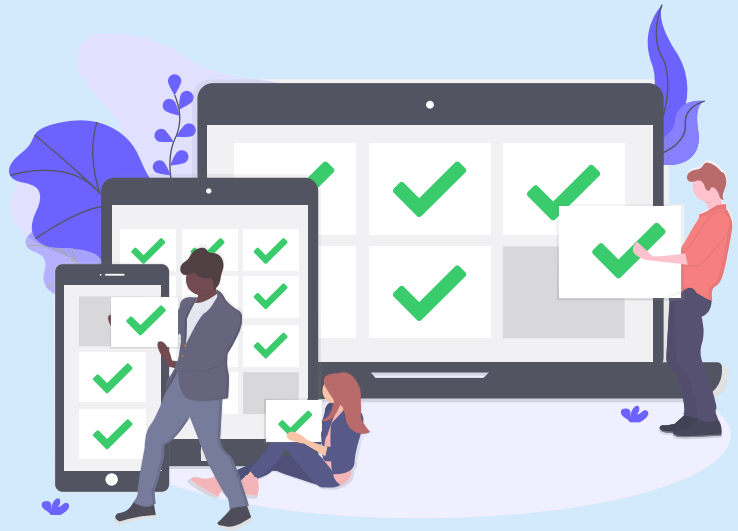
Challenges

Building organizational synergies: Engineering and QAR teams

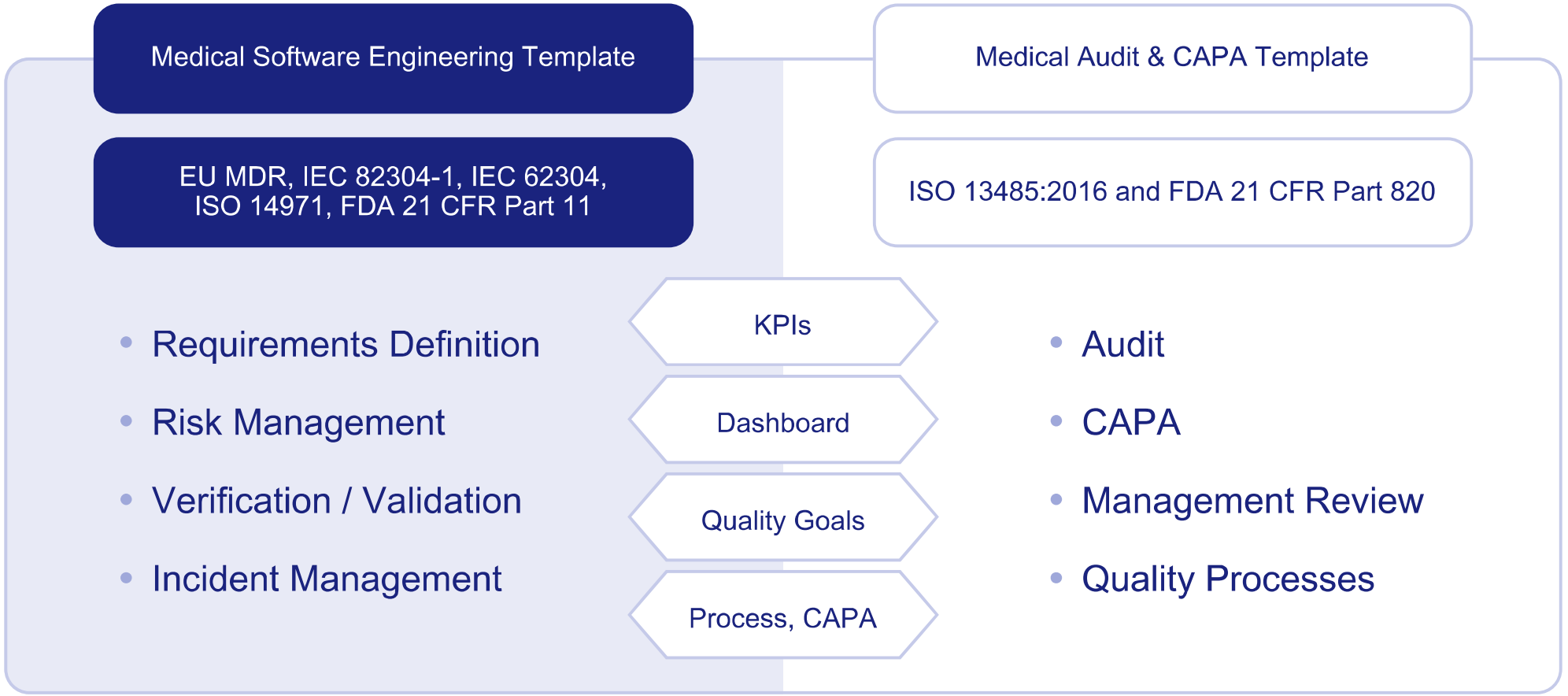
Engineering team



Quality and Regulatory team

What is a Template?

Preconfigured Project with Trackers, Workflows, Reports, and Dashboards



- Goal: reduce implementation effort by 80%
- Further customization via Professional Services

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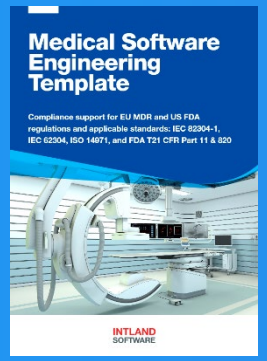
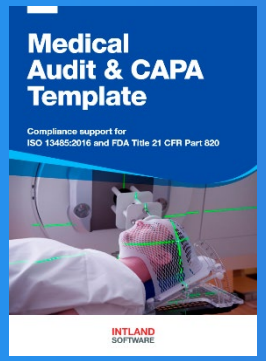
Medical Templates

Process approach

Validated, pre-built process templates





- Medical Software Engineering
- Medical Audit and CAPA management

Custom tailoring

Additional and Custom Use Cases

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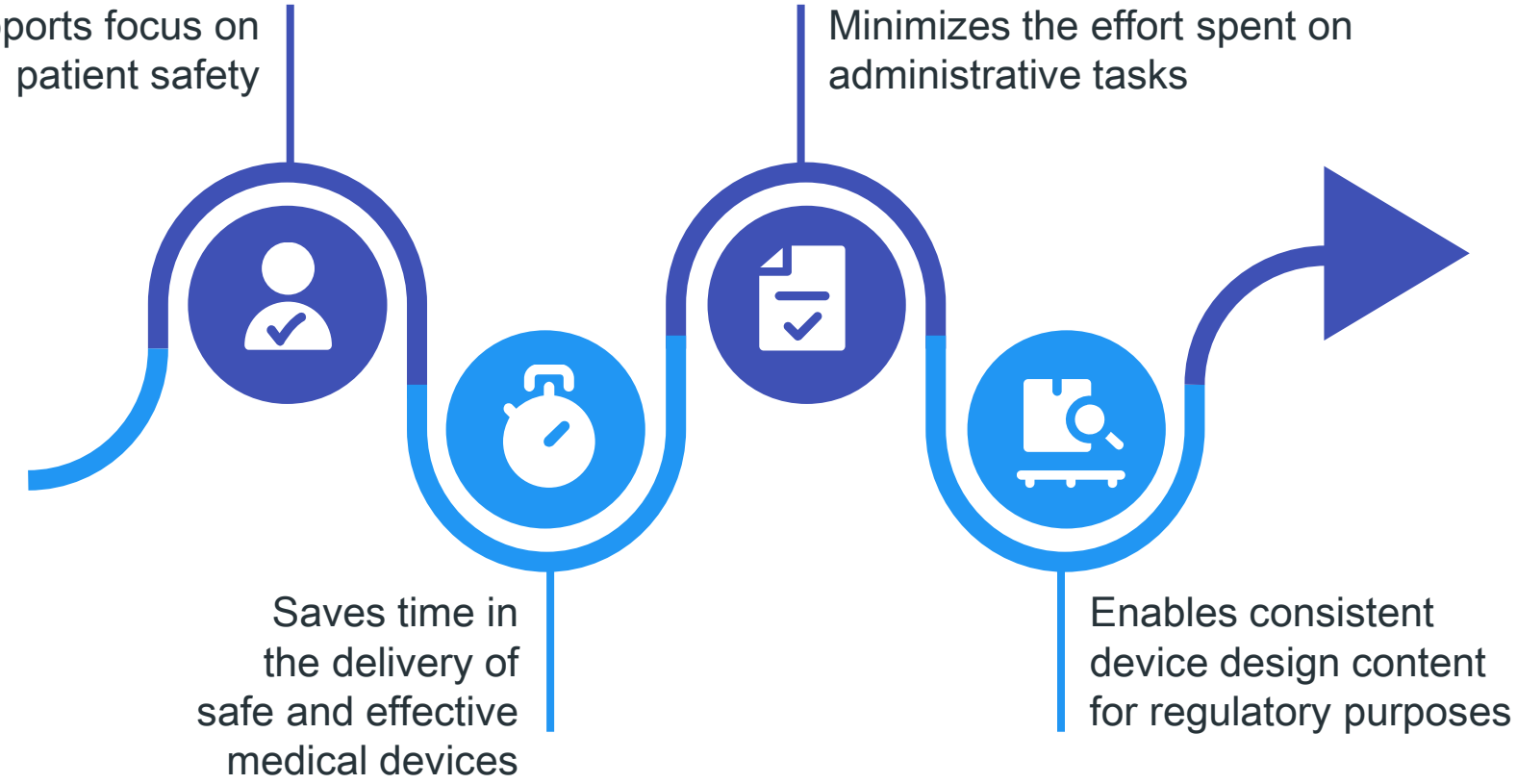
Medical Software Engineering Template

Values



Medical Software Engineering Template

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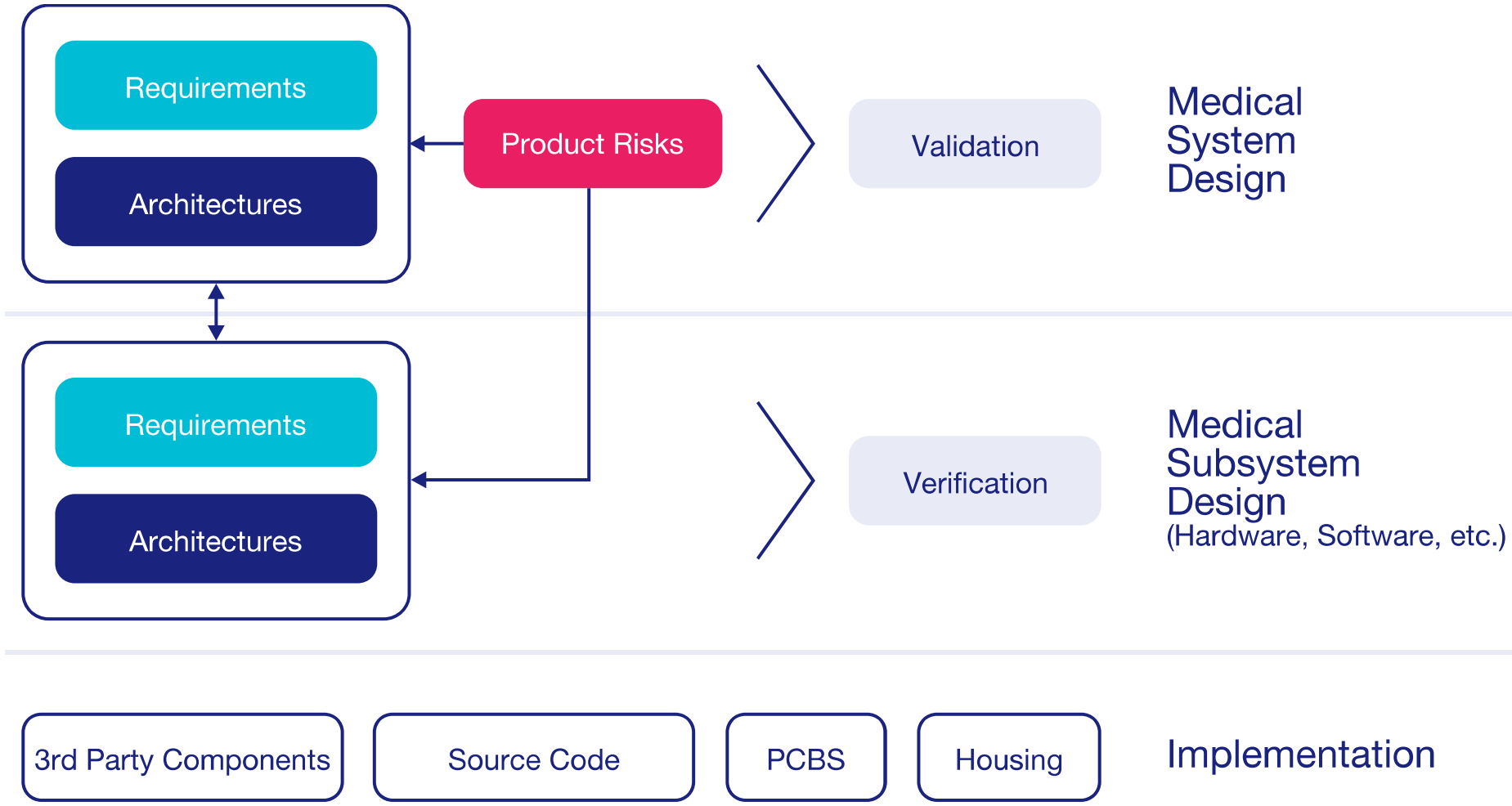
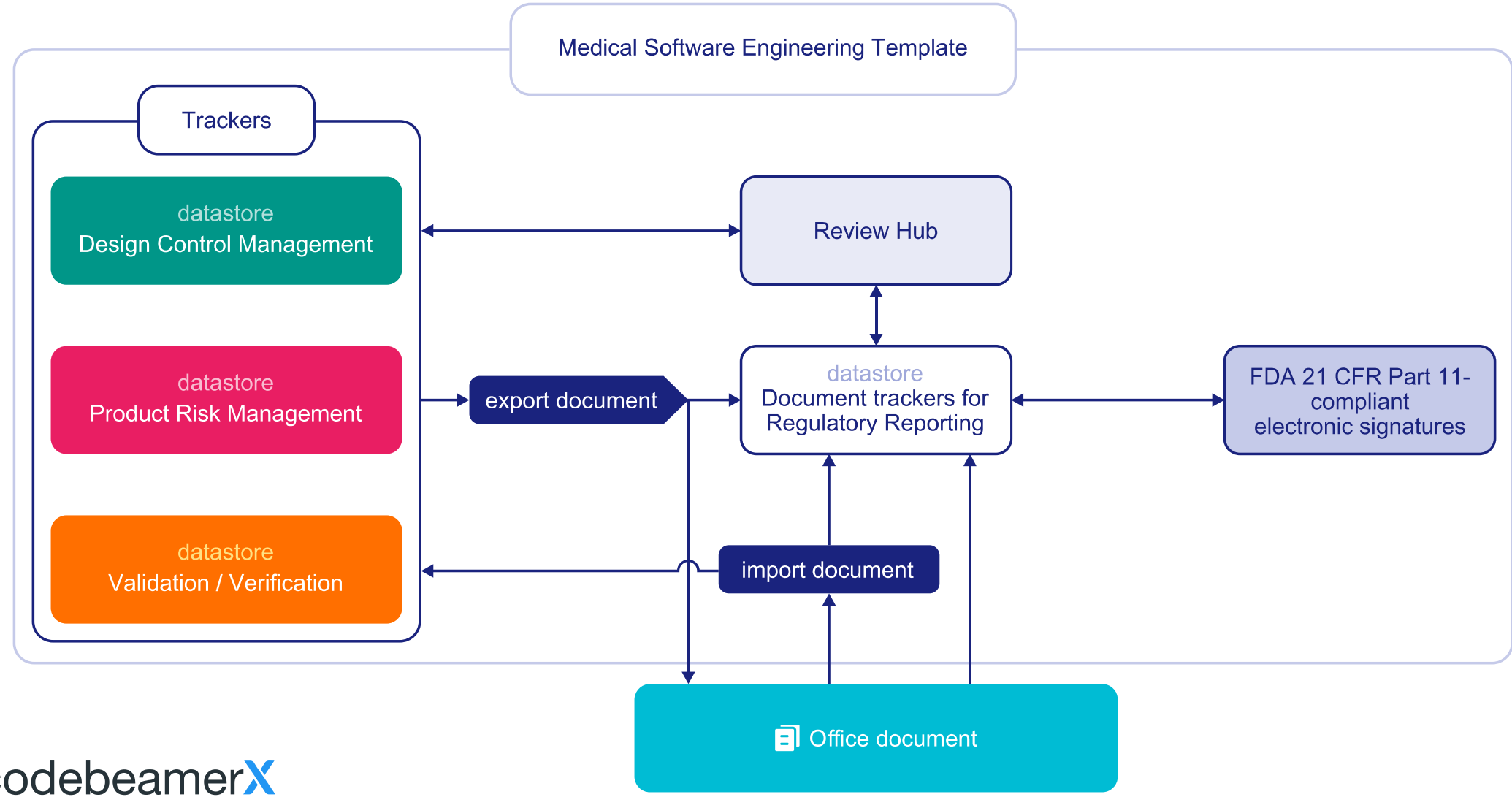
Medical Software Engineering Template

Medical device design



Medical Software Engineering Template

DHF/RMF/TF compilation, Part 11 approvals



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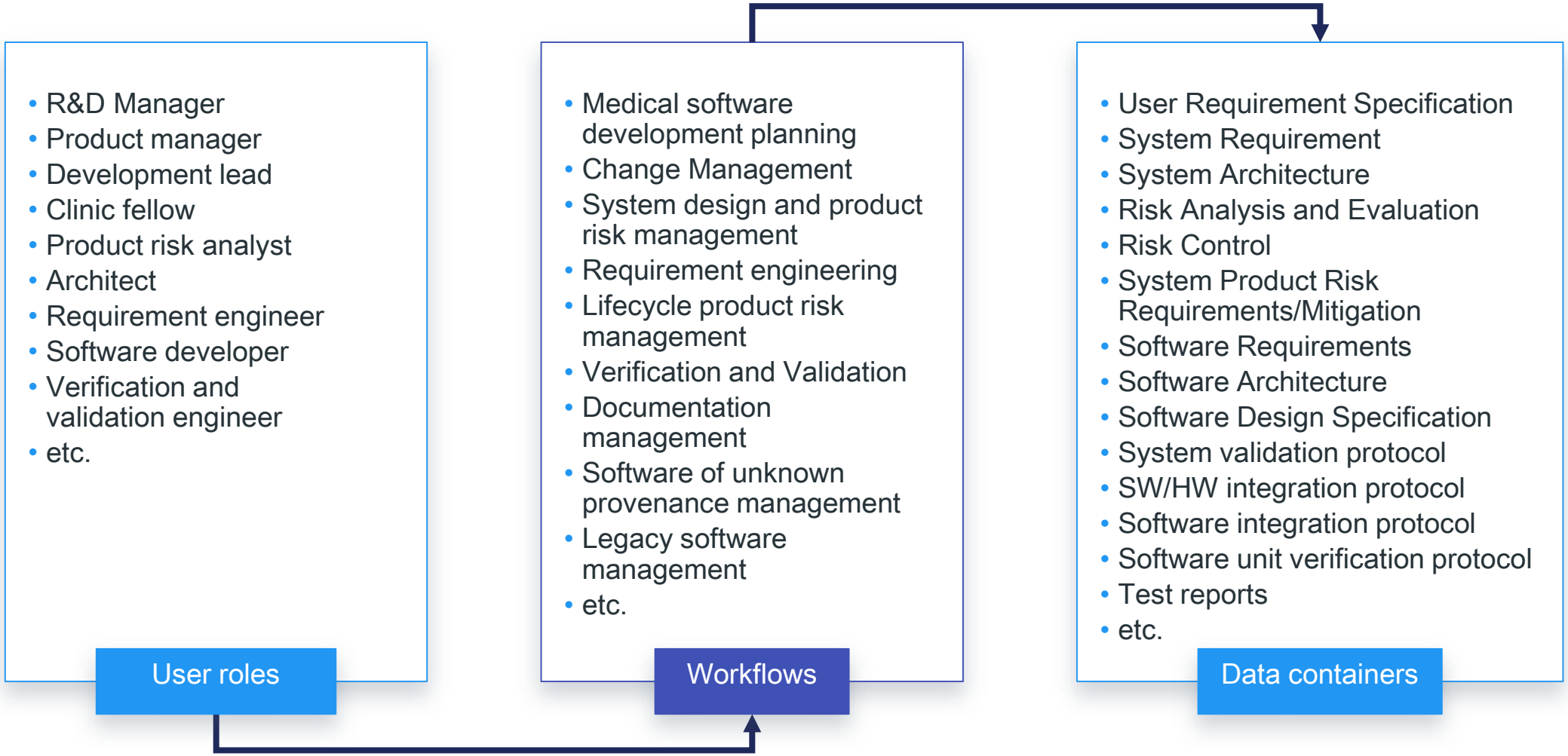
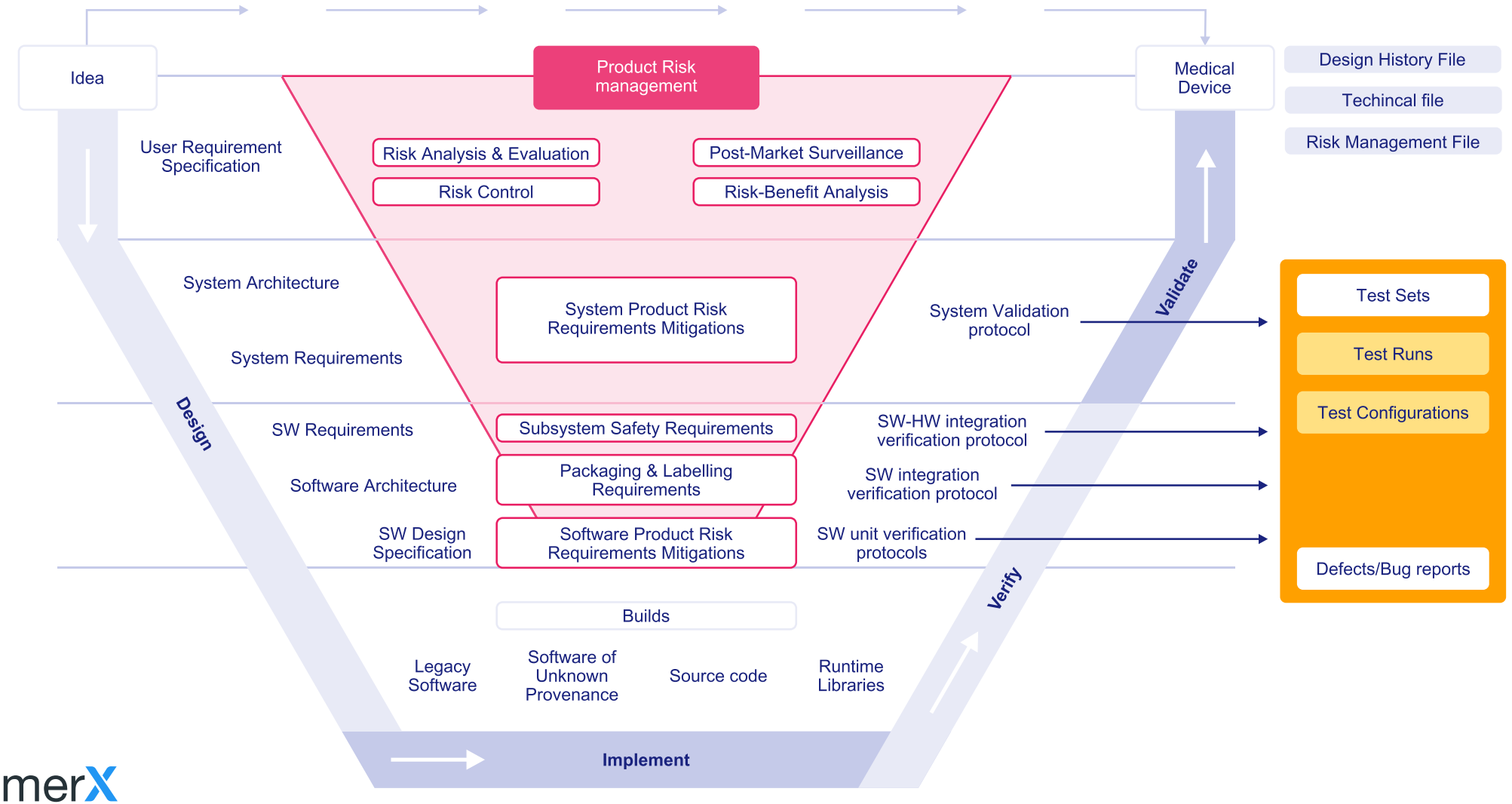
Medical Software Engineering Template

Fundamentals



Medical Software Engineering Template

Logical Data Model



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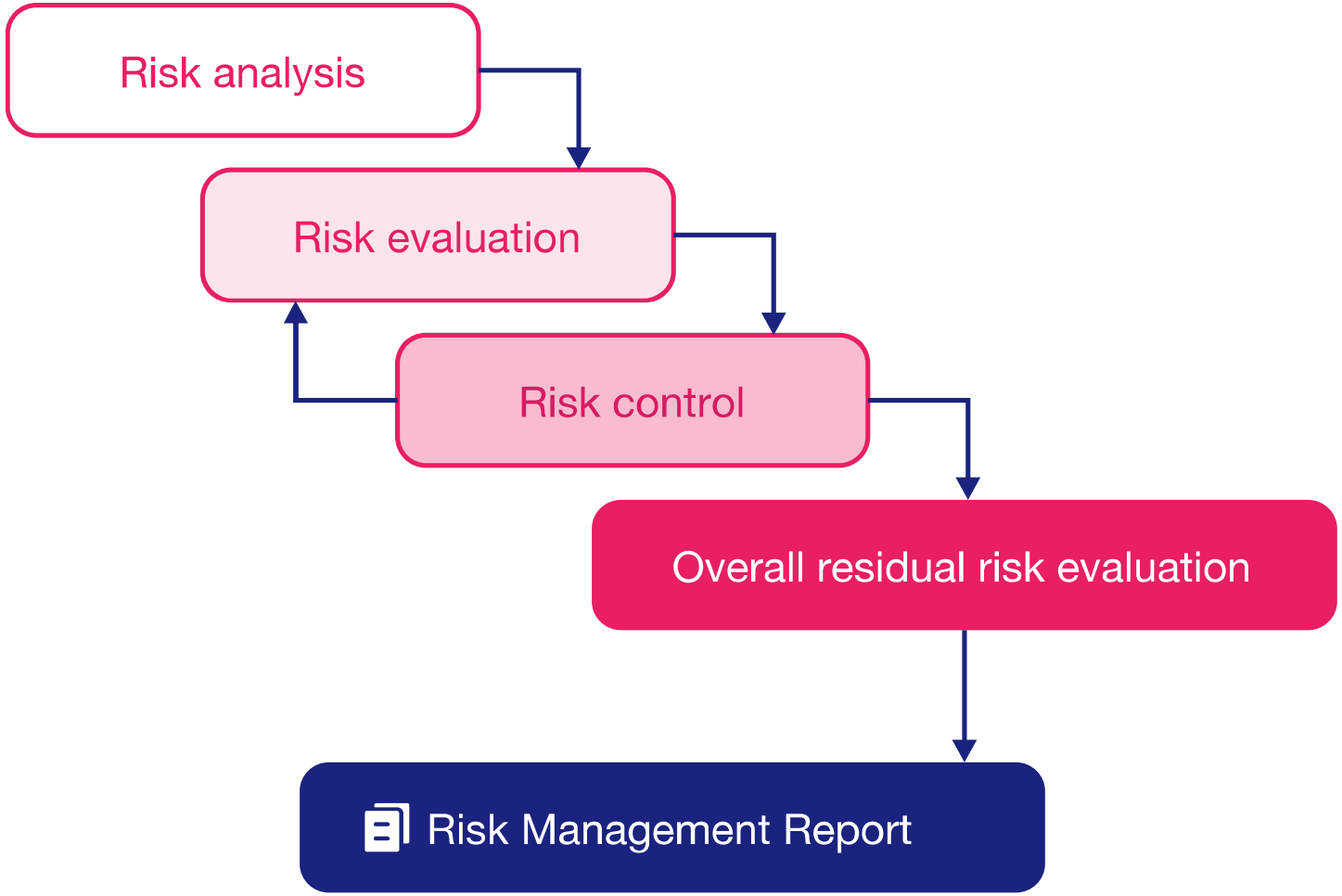
Product Risk Management

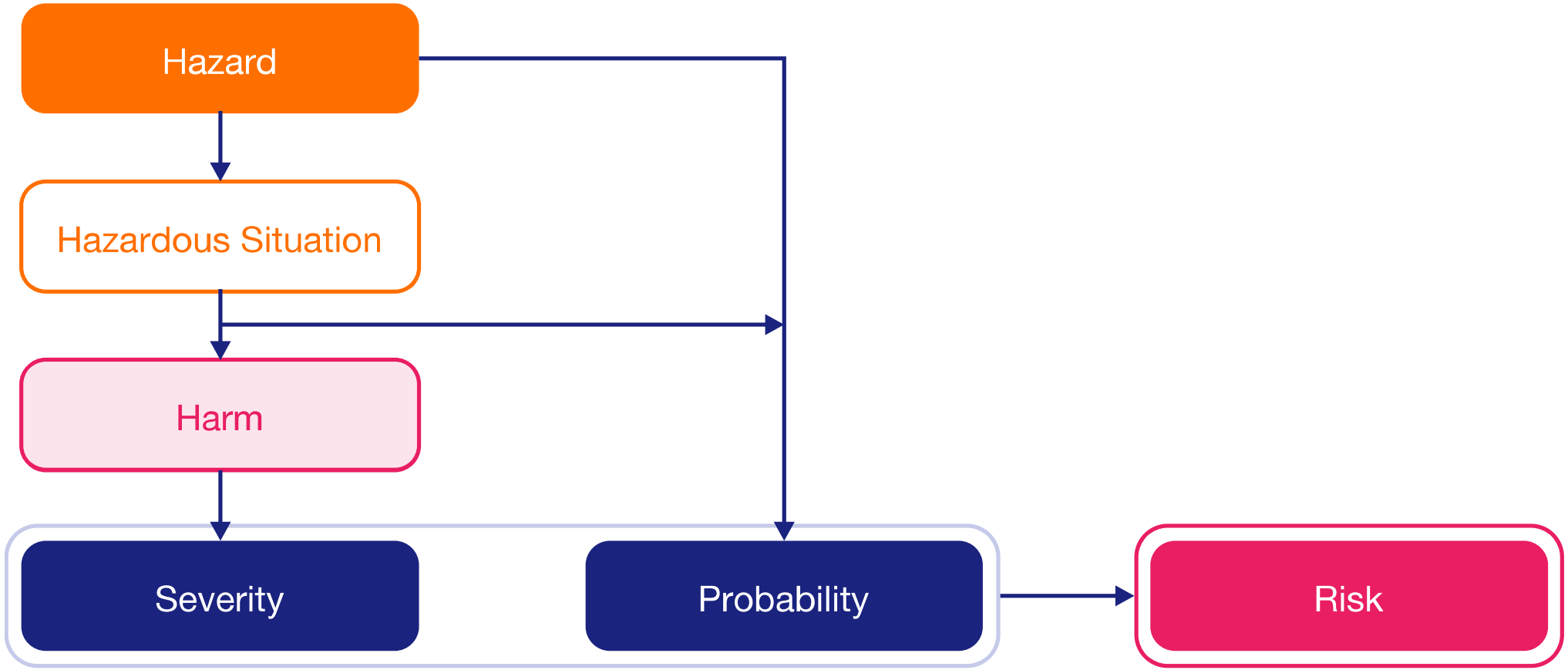
Demonstration

Product Risk Management



Demonstration

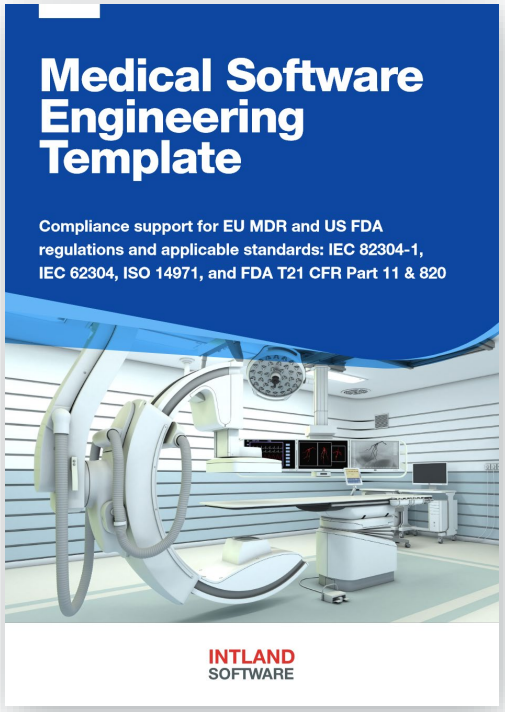
Product Risk Management



Source: ISO 14971:2012

Tool Validation

Validation Requirements



Compliance framework

Medical Software Engineering Template 1.0 for codebeamer X

- IEC 82304-1:2016 Health software - Part 1: General requirements for product safety
- IEC 62304:2006 Medical device software – Software life cycle processes
- EN ISO 14971:2012 Medical devices – Application of risk management to medical devices
- FDA Title 21 CFR Part 11 - Sec. 11.50 Signature manifestations
- FDA Title 21 CFR Part 11 – Sec. 11.200 Electronic signature components and controls

Medical Audit & CAPA Template 1.0 for codebeamer X

- ISO 13485:2016
- FDA Title 21 CFR Part 820
- FDA Title 21 CFR Part 11 - Sec. 11.50 Signature manifestations
- FDA Title 21 CFR Part 11 – Sec. 11.200 Electronic signature components and controls

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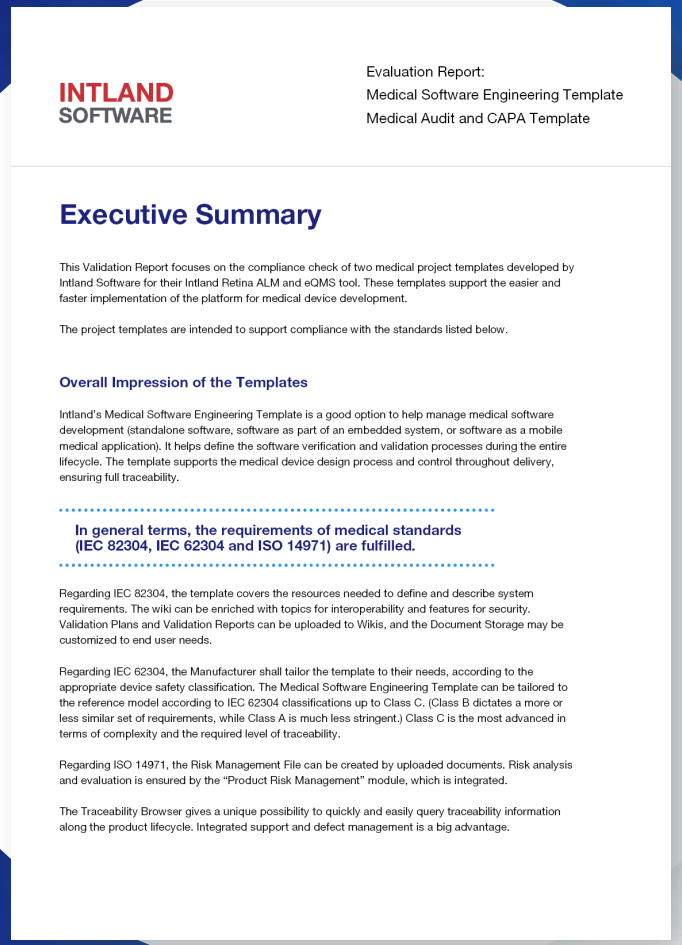

INTLAND SOFTWARE

Evaluation Report:
Medical Software Engineering Template
Medical Audit and CAPA Template

Executive Summary

This Validation Report focuses on the compliance check of two medical project templates developed by Intland Software for their Intland Retina ALM and eQMS tool. These templates support the easier and faster implementation of the platform for medical device development.

The project templates are intended to support compliance with the standards listed below.

Overall Impression of the Templates

Intland's Medical Software Engineering Template is a good option to help manage medical software development (standalone software, software as part of an embedded system, or software as a mobile medical application). It helps define the software verification and validation processes during the entire lifecycle. The template supports the medical device design process and control throughout delivery, ensuring full traceability.

In general terms, the requirements of medical standards (IEC 82304, IEC 62304 and ISO 14971) are fulfilled.

Regarding IEC 82304, the template covers the resources needed to define and describe system requirements. The wiki can be enriched with topics for interoperability and features for security. Validation Plans and Validation Reports can be uploaded to Wikis, and the Document Storage may be customized to end user needs.

Regarding IEC 62304, the Manufacturer shall tailor the template to their needs, according to the appropriate device safety classification. The Medical Software Engineering Template can be tailored to the reference model according to IEC 62304 classifications up to Class C. (Class B dictates a more or less similar set of requirements, while Class A is much less stringent.) Class C is the most advanced in terms of complexity and the required level of traceability.

Regarding ISO 14971, the Risk Management File can be created by uploaded documents. Risk analysis and evaluation is ensured by the "Product Risk Management" module, which is integrated.

The Traceability Browser gives a unique possibility to quickly and easily query traceability information along the product lifecycle. Integrated support and defect management is a big advantage.

- Easier definition of lifecycle-wide verification and validation processes
- Simplified compliance with IEC 82304, IEC 62304 (up to Class C) and ISO 14971
- Product Risk Management capabilities to analyze and evaluate risks & to maintain your Risk Management file
- One-click traceability: handle all traceability issues along the product lifecycle
- Integrated support and defect management
- Medical Audit and CAPA Template for ISO 13485 or FDA 21 CFR Part 820-compliant QMS implementation

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