Modern Software Technologies: Best Practices for Compliance

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SOLITA

We create value from data in a connected world.

Our aim is to create lasting impact by:

→ **Utilizing data and IT**

→ **Combining them with human insight**

→ **Cooperating with our tech partners**

Finland
Helsinki, Tampere, Oulu, Turku, Lahti, Kuopio, Vaasa, Joensuu, Jyväskylä, Pori

Germany
Munich, Berlin

Switzerland
Zurich

Denmark
Copenhagen, Aalborg, Glostrup, Vejle

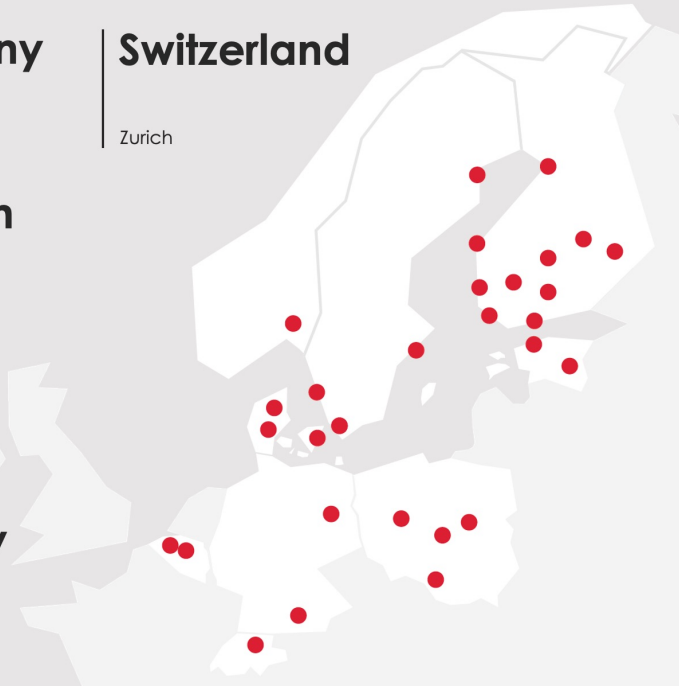
Belgium
Leuven, Ghent

Sweden
Stockholm, Gothenburg, Malmö, Skellefteå

Estonia
Tallinn, Tartu

Poland
Warsaw, Lodz, Poznań, Tychy

Norway
Oslo



GROWTH PER ANNUM APPROX.

20%

TURNOVER IN 2022

200+M

→ **Founded in 1996**

→ **2000+ employees**

→ **9 countries**

→ **30 cities**

1. Software development
2. Strategy
3. Data
4. Design
5. Cloud
6. Connectivity

SOLITA Health

We harness human insight and intelligent technologies to impact many lives.

National infra and key services for social and healthcare

Solutions for data-driven leadership for wellbeing counties

Systems enabling the efficiency of leading hospitals' operations

Stress-free development model for medical software (RegProof®)

AI-based solutions to support HCP's decision-making

Secure data environments for healthcare

SOLITA RegProof®

CERTIFIED MANAGEMENT SYSTEM
eurofins
ISO 13485

€ 34M
revenue in 2023

350+
solitans
in Health projects

REGOPS DEVELOPMENT DIRECTOR, SOLITA HEALTH

Tuomas Granlund

Solita, 2019 ->
- Development director, R&D Solita Health
- Quality Manager & PRRC, QA&RA specialist

Tampere University, 2017 ->
- PhD Candidate, research topic “Calm Compliance in Medical Device Software Development”

Work experience as a lead auditor and product assessor for Notified Body, software, ISO 13485:2016, ISO 9001:2015, IEC 62304, ISO 14971, IEC 62366-1, and IEC 60601-series

15+

Years of working experience in medical device software development and compliance

Background

The paradigm shift

- The change in the software development paradigm
  - Moving away from “traditional” hand-coded development
- Modern agile development practices
  - DevOps, DevSecOps, Cloud-native development
- SaaS-first methodology – prioritization of cloud-based applications over on-prem solutions
  - Simplified deployment, improved scalability, high availability (anywhere, anytime)
- Heavy use of reusable 3rd party components
  - APIs, frameworks, and libraries
- More abstract tools: public cloud-native applications, AI/ML, low-code, GenAI...

Driving factors behind the change

- Digital transformation
  - New solutions are needed to enable seamless digital engagement on any type of device or interface
- Increasing complexity of software systems
  - Data volume, interconnections, security and resilience needs, evolving business requirements, emerging technologies
- Demand for faster development cycles
  - Competitive landscape, user expectations, developer shortage
- Demand for reduced costs
  - Minimizing the need for extensive hand coding
- Demand for improved quality
  - Battle-proven components and solutions, best practices, coding standards

Modern software technologies

- Modern technology aims to support the core ideas of Agile: continuous improvement, learning, and innovation
- Modern technologies are critical parts of modern software engineering practices
- Technological innovations can take development capabilities to the next level
- There is strong hype for AI-augmented software engineering
  - The tools currently delivering value include, among others, code assistants and test tools

New tech and regulatory approval?

- Regulatory frameworks do not support revolutionary changes
  - The model is more evolutionary
  - There's a very low tolerance for errors; the aim is to protect the general population, not to allow the use of cutting-edge technology
- With new tech, regulatory approval tends to be an incremental process – small steps that are well-understood and, therefore, tolerated
  - With more products with the given tech, the methods of testing and risk reduction get more sophisticated
- Method to **assess the new risks** that the tech creates and objective evidence that the benefits outweigh the risks
  - What is new in this technology, and what potential risks should we be cautious about?
- **Validation** – objective evidence that the outputs of the tech & device are effective and safe
- **Explainability** – new tech needs to be explained within a paradigm that regulatory authorities and the general audience understands

Example: Public cloud computing platforms

- Running a computing infrastructure is challenging and resource-intensive
  - Not often a core competency of an organization
- Public cloud environments offer computing infrastructure on demand
  - Scalability, reliability, security, agility, and functionality
  - Global computing
- In general, public cloud infrastructure provides a platform to create applications quickly
  - Off-the-shelf (native) components create value immediately
  - Providers have considerable resources to operate and improve their services
- The traditional QA method within the MD industry has been planning, controlling, verifying, and validating all changes before deployment
- Public cloud providers are constantly making changes without advance notice
  - The client does not have visibility of the QA activities performed before the deployment
  - Also, rollback decisions are in the provider's control
- Clients give up a degree of control over the platform and it's building blocks
- This breaks the traditional paradigm of maintaining the continuously validated state

Best Practices for Compliance

Recommendations 1/3

- Identify the intended function and essential requirements for a technology
  - **Development platform/tool, Computing environment, a part of the medical device**
  - Consider the requirements in the context of the specific device/project
  - Consider the differences compared to other potential technologies (risk profile) – is this a good fit?
- Identify key risks
  - Level of control (changes), impacts of breaking changes, external dependencies
  - Can the risks be lowered to an acceptable level?

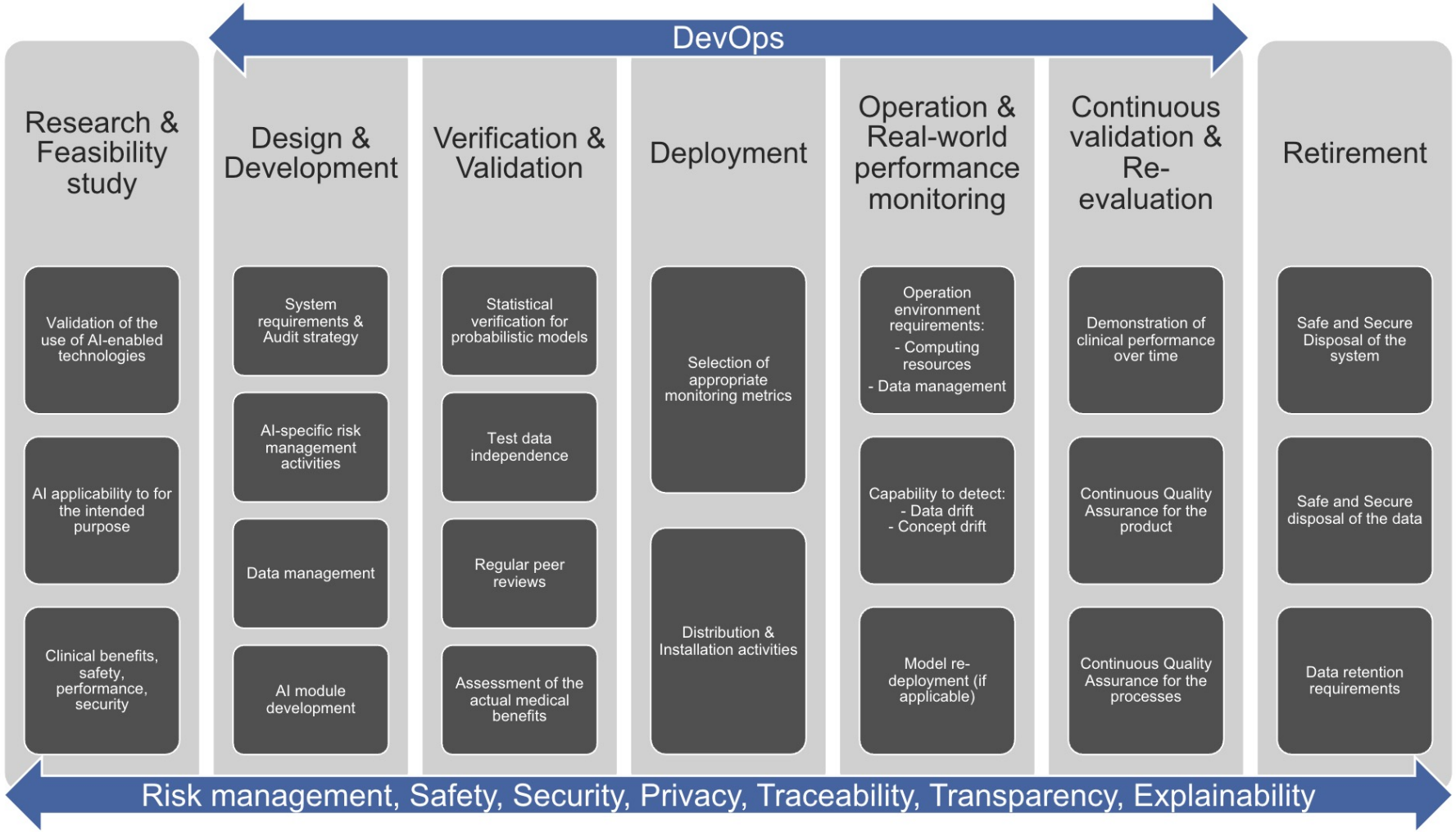
Recommendations 2/3

- Create a strategy to fulfill identified requirements, mitigate risks, and ensure an adequate level of control (technical perspective)
  - Changes (notifications, approvals, detection)
  - Change patterns, detection period
  - Mitigation activities, monitoring, time and resources (risk-based approach)
- Create a strategy for supplier management (QMS perspective)
  - MD / Health references, certificates, SLAs, service plans, (documented) quality practices, pre-notifications & customer communication
  - -> What do we expect from the vendor, and what additional measures do we need to implement

Recommendations 3/3

- Create a monitoring process
  - To detect changes (KPIs, smoke tests, etc.)
  - To understand the impact of changes (need to trigger more tests, assessment of the outputs against baseline)
- Create a maintenance process to address changes
  - Rapid problem-resolution process
  - Fallback process (if possible), other failover strategies
  - Post-incident analysis for continuous improvement (monitoring, impact assessment, risk management, risk mitigations)
- Continually improve the resiliency of the device

Example: lifecycle model for AI-driven device



Thank you!

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