Navigating SaMD: The Critical Role of QA in Software-Based Healthcare

Granite State Section – SEP 2025

PRESENTER: SAI RANJITH RAMAKRISHNAN KUMAR (SAI)

My Journey in Quality Engineering

- Quality Engineer with 8+ years in Medical Devices & Robotics.
  - Currently works as Digital Device Quality Engineering Lead (SaMD) at Sanofi
- ASQ Six Sigma Green Belt Certified (SSGB)
- Editorial Review Board Member for:
  - ASQ Quality Management Forum (QMF)
  - ASQ Lean Six Sigma Review (LSSR)
  - ASQ Quality Progress (QP)
- Published Author in ASQ Quality Progress and Quality Magazine.
- Featured in Quality Magazine Podcast & Q&A on AI and medical devices

Agenda

1. **The Quality Landscape in Medical Device Manufacturing**
2. **What is Generative AI ?**
3. **Why Generative AI Matters for Quality Engineers**
4. **Implementation Framework: AI-Assisted Inspection**
5. **Implementation Framework: AI Assisted Documentation**
6. **Implementation Framework: AI Assisted Reports**
7. **Challenges & Watch-Outs**
8. **Key Takeaways !!!!**

The Shift: From Support to Standalone Device

Software is no longer just support—it is the device.

Examples:

a) Mobile app monitoring glucose
b) AI interpreting radiology images
c) Clinical decision-support software

What is SaMD?

IMDRF / FDA :

Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."

Aspect	Software as a Medical Device (SaMD)	Software in a Medical Device (SiMD) *(Not SaMD)*
Definition	Standalone software that performs a medical function	Embedded software that drives or controls a hardware device
Hardware Dependency	Functions independently of hardware	Works only as part of the hardware
Examples	Diagnostic imaging software, mobile health apps, AI clinical decision tool	Pacemaker control software, infusion pump firmware, ventilator operating software
Regulatory View	Regulated as a standalone medical device	Regulated as part of the hardware device

Regulatory Landscape

FDA – USA

- Oversees SaMD under **21 CFR 820 (QSR/Design Controls)**
- Digital Health Center of Excellence provides guidance

IMDRF - Global

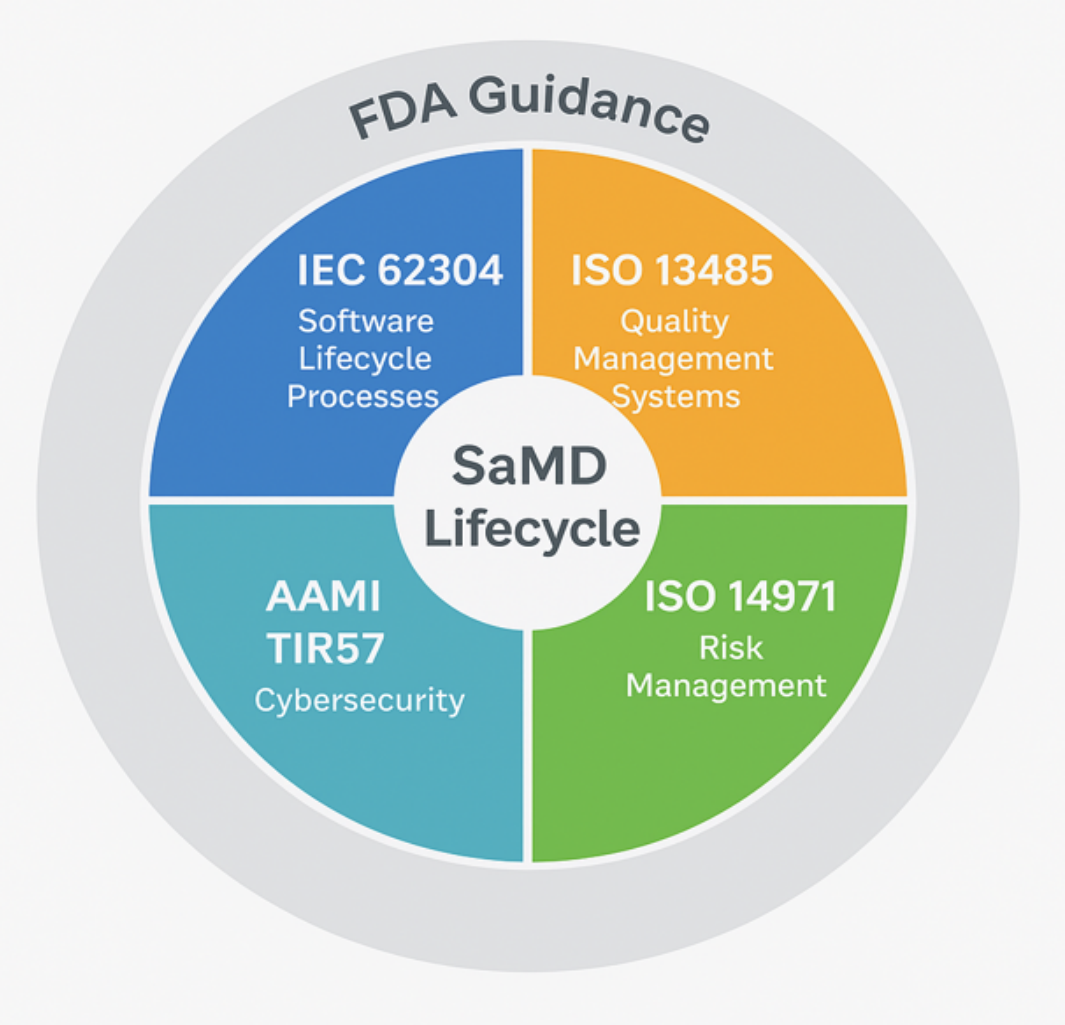
- Established the foundational SaMD definition
- Provided framework for risk categorization & lifecycle approach

EU MDR - Europe

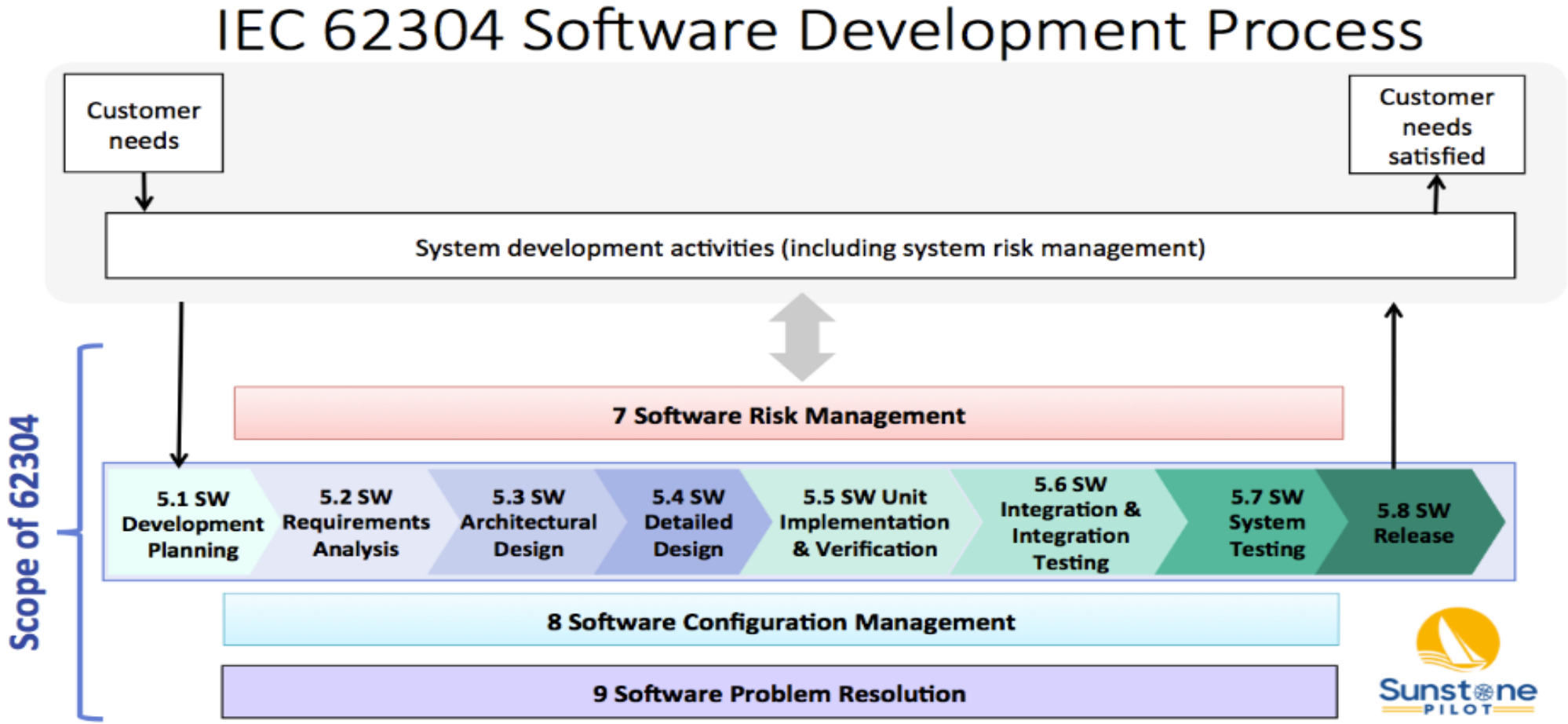
- **Rule 11:** Software classified as medical device based on intended use
- Risk classes: IIa, IIb, or III depending on potential harm

📜 **“Global regulators differ in detail but align on one principle: SaMD = Medical Device.”**

Standards Governing SaMD



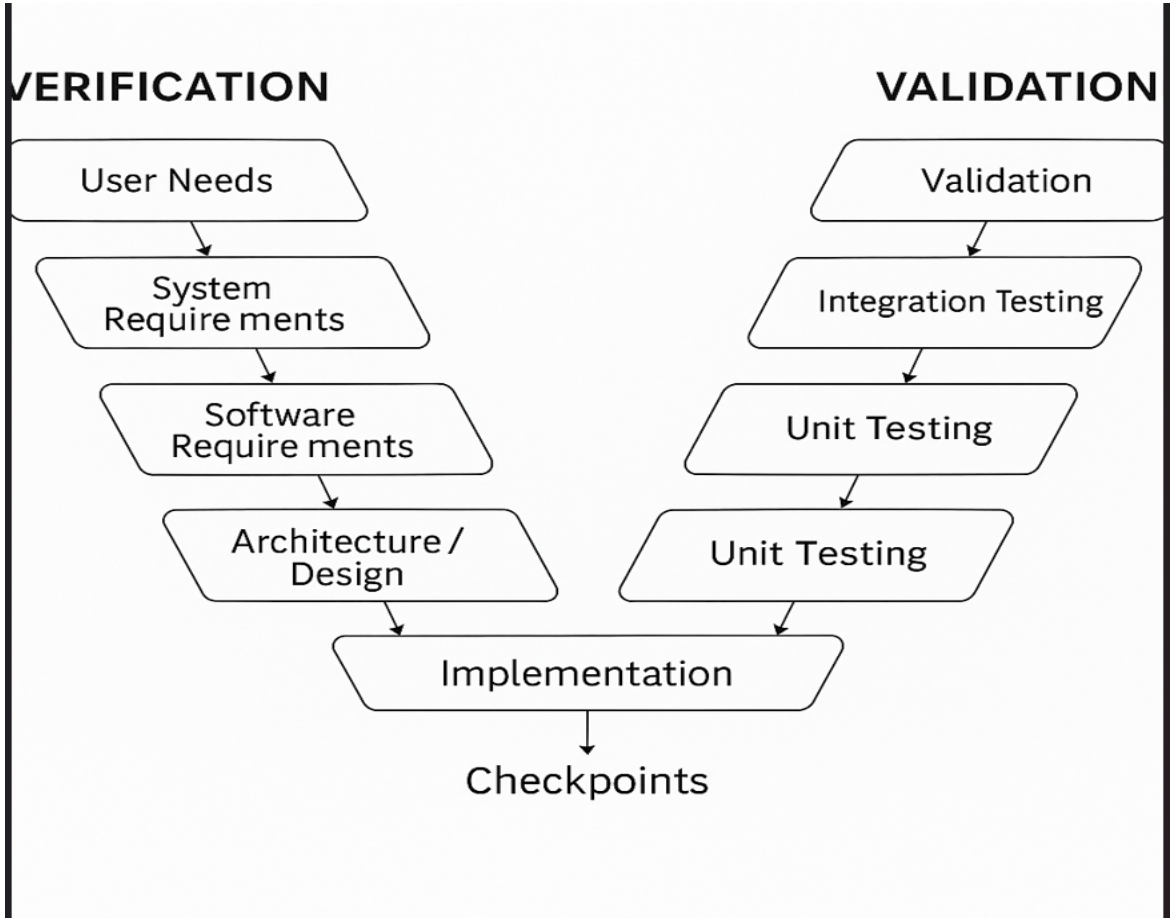
SaMD Lifecycle Process



Reference: https://sunstonepilot.com/2018/09/fda-software-guidances-and-the-iec-62304-software-standard/

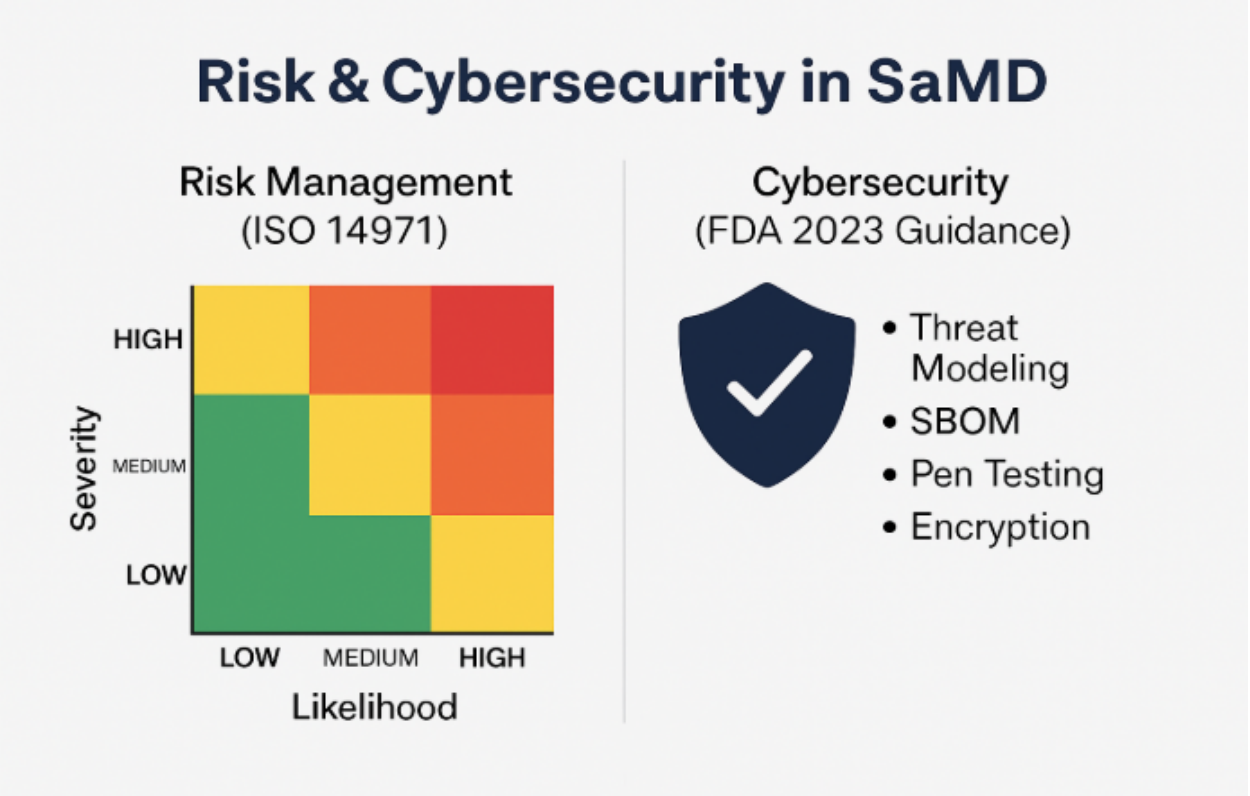
SaMD V&V

“Did we build it right?”



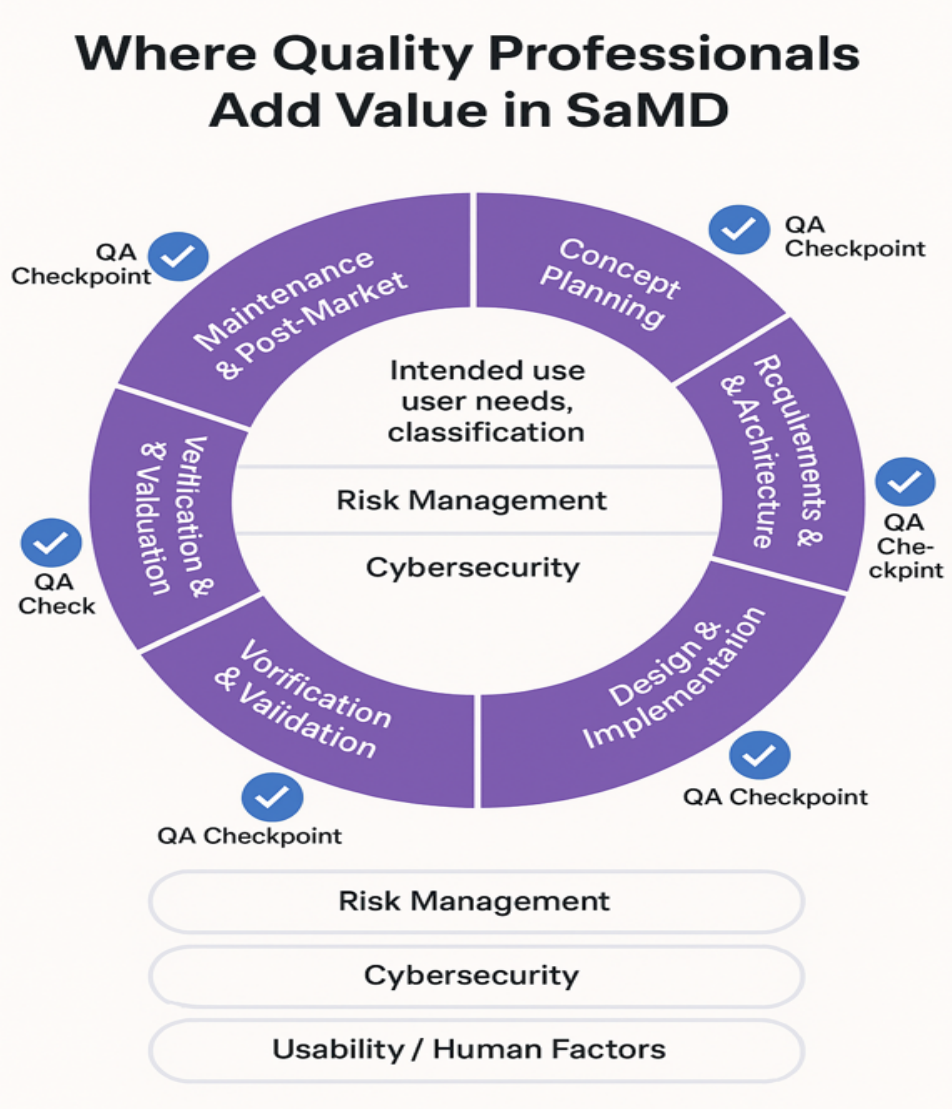
“Did we build the right product?”

Risk Management & Cybersecurity



““In SaMD, patient safety = product reliability + cybersecurity resilience.”

The Critical Role of QA/QE



Implementation Framework: AI Assisted Reports

- **Plan V&V Early**
  Integrate verification & validation into project planning
- **Maintain Living Risk Files**
  Keep risk management documents continuously updated
- **Strengthen Cybersecurity Discipline**
  Adopt Secure Product Development Framework (SPDF)
- **Collaborate Across Teams**
  Work closely with software developers, clinicians,
- **Use Checklists & Traceability Tools**
  Apply IEC 62304 compliance checklists

“Proactive quality practices prevent compliance gaps and protect patients.”

Conclusion

- **SaMD is Transforming Healthcare**
  - Expands beyond hardware → software as the device itself
  - Growth in AI, mobile apps, cloud tools

- **Regulations & Standards Are Clear**
  - FDA, IMDRF, EU MDR treat SaMD as a medical device
  - IEC 62304, ISO 13485, ISO 14971 anchor compliance

- **Quality Professionals Are Critical**
  - Ensure safety, effectiveness, compliance, and trust
  - Active role across lifecycle, not just oversight

“Quality is not a checkbox — it’s the foundation of SaMD success.”

“Your Turn: Questions, Comments, Curiosities?”

✨ *“Remember: The only bad question is the one left undocumented . 😉 ”*