

Agile and QMS

Friends or Foes?

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Baz Luhrmann - Wear Sunscreen

*"If I could offer you only one tip for the future, **sunscreen** would be it".*

*"The long-term benefits of **sunscreen** have been proved by scientists, whereas the rest of my advice has no basis more reliable than **my own meandering experience**".*

everybody's free
(to wear **SUNSCREEN**)
THE SUNSCREEN SONG
(class of '99)

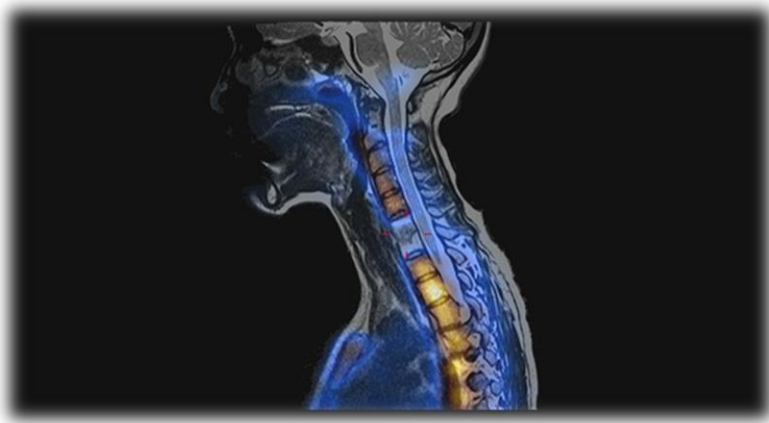
About GE



Founded in **1889**
by **Thomas Edison**

>**300,000** employees
in over **100** countries.

GE Healthcare Nuclear Medicine

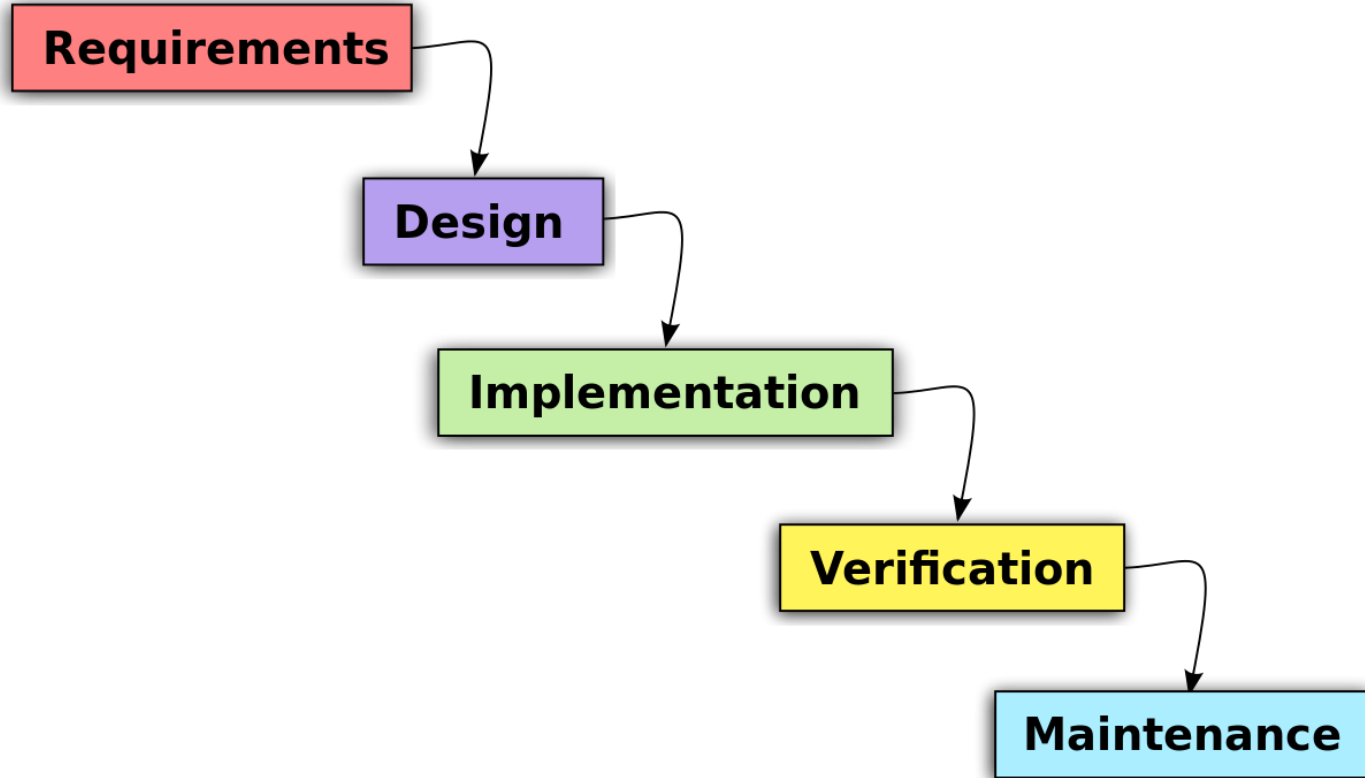


FDA Regulation of Medical Devices

- **21** Code of Federal Regulations (CFR), Part **820**, Quality System Regulation
- **Sec. 820.40 - Document Controls**
- **Sec. 820.30 - Design Controls**
 - (a) General - establish and maintain design procedures
 - (b) Design and development planning
 - (c) Design input
 - (d) Design output
 - (e) Design review
 - (f) Design verification
 - (g) Design validation
 - (h) Design Transfer
 - (i) Design Changes
 - (j) Design History File

Serial Waterfall Process?

Traditional Quality System



What is Agile?



No Planning

No Documentation

Agile = Scrum

No Architecture

No Requirements

For Small Projects Only



Coexistence?

Design and Development Planning



Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process. The plans shall be reviewed, updated, and approved as design and development evolves.

21 CFR 820, Section 30(b)

Does Not Prescribe Specific Methods or Tools

Design Input



Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient.

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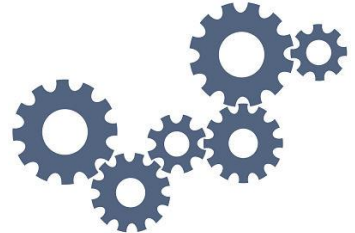
The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s).

21 CFR 820, Section 30(c)

Does Not Prescribe Specific Methods or Tools

The QSR in general, and Design Controls in particular, **do not define** a development process or prescribe a specific development methodology or a specific software development lifecycle.

Rather, they **specify** controls that must be **integrated** into the manufacturer's development processes, methodology, and lifecycle.



The Agile Manifesto

We are uncovering better ways of developing software by doing it and helping others do it. Through this work we have come to value:

Individuals and Interactions

Working Software

Customer Collaboration

Responding to Change

over

Processes and Tools

Comprehensive Documentation

Contract Negotiation

Following a Plan

That is, while there is value in the items on the right, we value the items on the left more.

Does Not Prescribe Specific Methods or Tools

Agile and Regulatory perspectives both value
High-Quality software.

Agile focuses on meeting the **needs** of the **customer**.

Regulatory focuses on **safety** and **performance**.



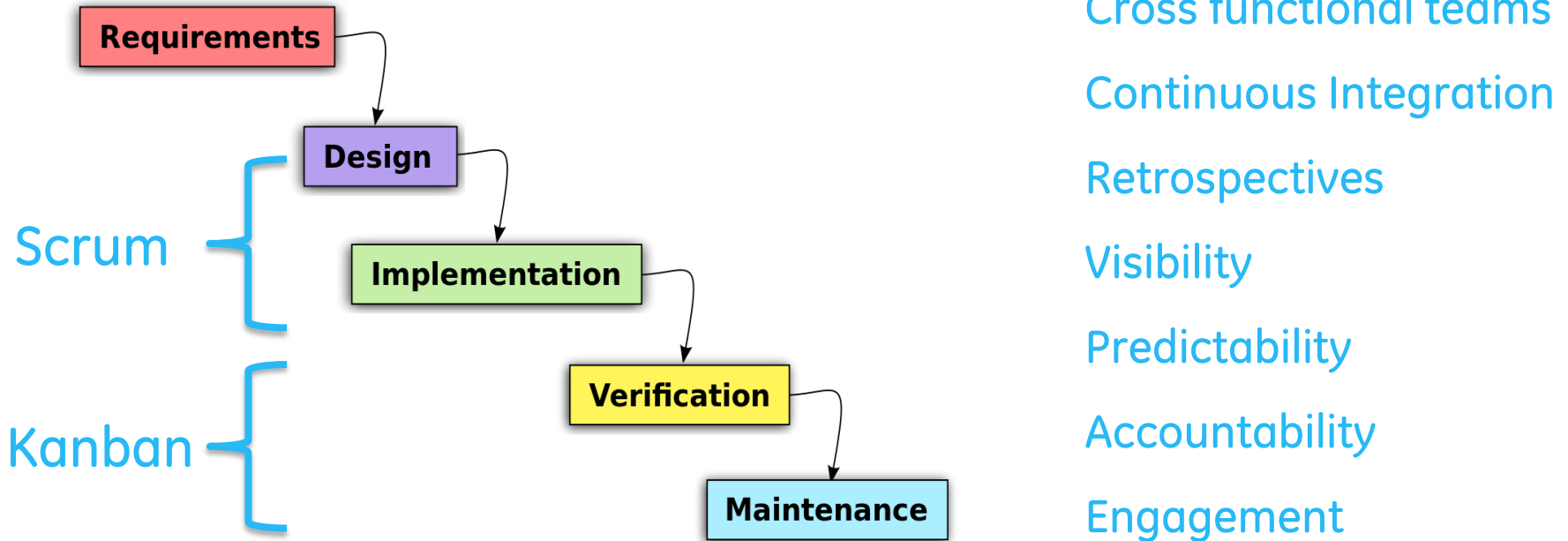
So What's the Problem?

- Traditional Quality Systems are built for **Waterfall**.
 - Not simple to change
- Product Development is not only **Software**.
 - How you adapt Agile for Hardware or System Engineering?
- It's Organization **Culture** change



Agile @ GE Healthcare NM

No change in QMS, following the existing process.



Further Reading

Technical Information Report - AAMI TIR45:2012

“Guidance on the use of AGILE practices in the development of medical device software”

AAMI - Association for the Advancement of Medical Instrumentation

"But trust me on the sunscreen".

