Breakfast seminar

Software tool validation

QAdvis seminar Lund 2018-05-09, Stockholm 2018-05-15, Uppsala 2018-05-17

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QAdvis key competence areas

QMS in-the cloud

Turn key QMS
Digital signatures
Efficient and lean
Validated and compliant

System development

Project management
Product software validation
Regulated software validation
Requirement management
Risk management
Verification and validation
Process validation

QA&RA/Clinical Consulting

Interim management
Expert advise
Audits/Mock audits/Due diligence
Warning letters, compliance projects
PMA, 510k, CE-mark
Global regulatory support
Vigilance, recall, post market surveillance
Clinical evaluation and clinical studies

Training/courses

CE-marking
ISO 13485 & 21CFR820
IEC 62304 & IEC 82304-1
IEC 60601-1
IEC 62366-1
SW life cycle
SW risk management
Risk management
And more…

Lean and Six Sigma

Training and Consulting
In cooperation with USA based partner.

European Authorized Representation

Providing European representation for non-EU MedTech companies

Active board member of EAAR: European Association of Authorised Representatives

QAdvis team: Lund and Stockholm

Software tool validation

Agenda

- Background
- Validation based on QSR 820.70(i)
- Validation based on ISO 13485:2016
- Validation of regulated SW
  Why? How? Who?

Background

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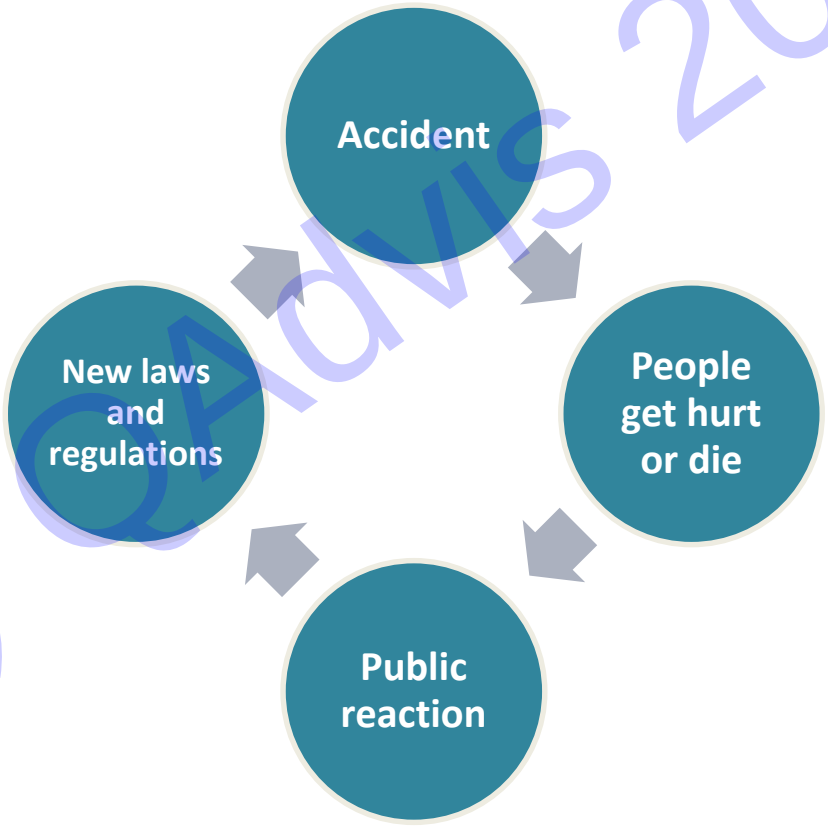
The bar is raised over time



There is an expectation from authorities to do validation of quality related SW

- Indirect effects of the product:
  - Safety and performance
  - Patients and users may get injured
- Data security and integrity
- Compliance

The need for compliance is stated in regulations and standards

- QSR 820.70(i)
- CFR 21 Part 11
- ISO 13485:2016

Validation of software tools based on QSR 820.70(i)

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QSR 820.70
Production and process controls

(i)*Automated processes.*

When **computers or automated data processing** systems are used as **part of production or the quality system**, the manufacturer shall **validate computer software** for its **intended use** according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented.

-> AAMI TIR36:2007

Validation of software tools based on ISO 13485:2016

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ISO 13485:2016

§ 4.1.6

The organization shall document **procedures** for the validation of the application of **computer software used in the quality management system**. Such software applications shall be **validated prior** to initial use and, as appropriate, **after changes** to such software or its application.

The specific approach and activities associated with software validation and revalidation shall be **proportionate to the risk associated** with the use of the software.

Records of such activities shall be maintained.

-> ISO/TR 80002:2 2017

Validation of regulated SW
Why? How? Who?

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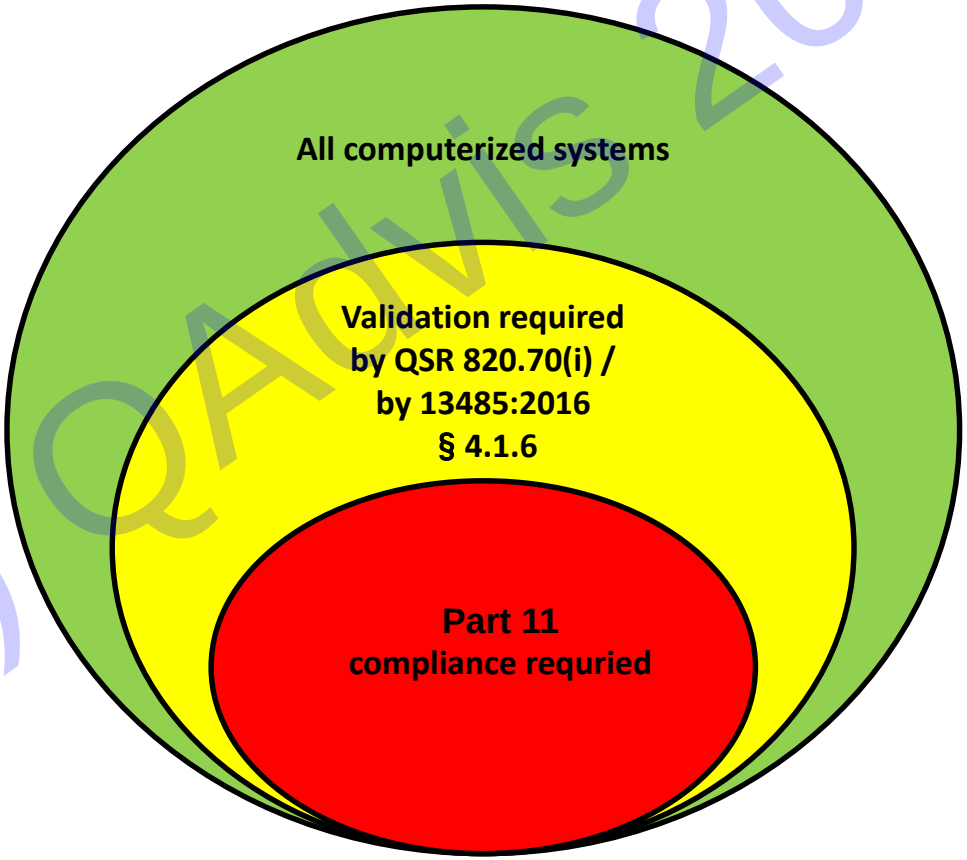
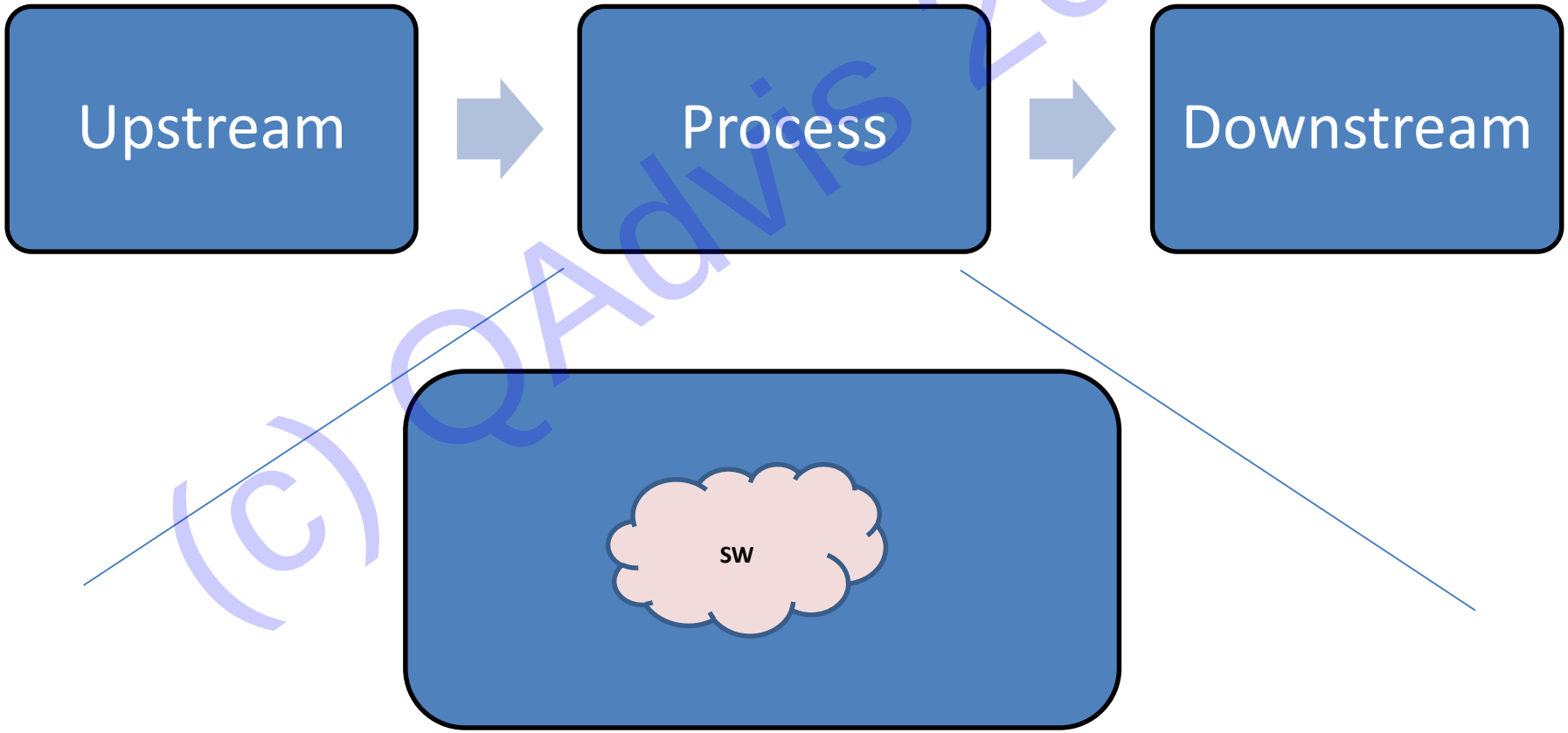
The need for validation is based on the intended use of SW



A regulated SW is supporting a regulated company process



Examples of software that has to be validated

R & D

- Automated Software Test System
- A simple spreadsheet
- A (not so) simple spreadsheet
- C/C++ language compiler

Manufacturing

- PLC for manufacturing equipment
- Automated welding system
- Automated welding process control system
- Automated vision system
- Pick and place system
- Parametric sterilizer

Quality

- Nonconforming material reporting system—Total system upgrade
- Software for scheduling nonconforming material report review board meetings
- Approved vendor list system
- Calibration management software

Example of a risk based analysis of validation requirements of regulated SW

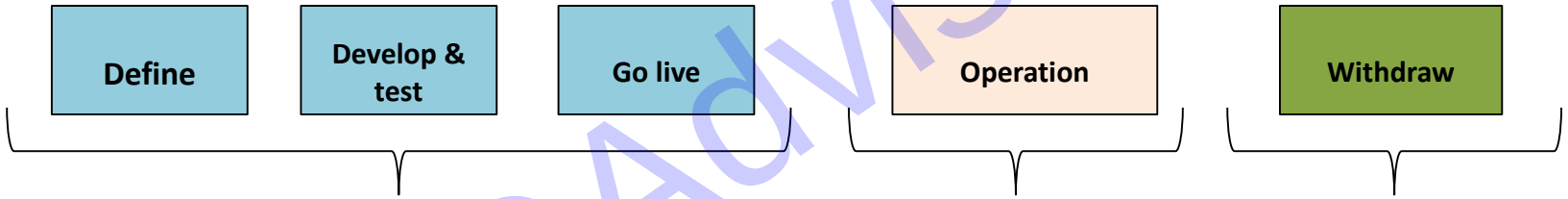
Function/Record	Risk of harm to humans	Regulatory Risk	Environmental risk	Validation Level
Word processor	No	No	No	None
Training database	No	Low	No	Low
Compiler	Medium	Low	No	Medium
Risk management file	Medium	High	No	High

Validation level	Description
Low	Configuration management of file
Medium	Validation according to a plan, record
High	Validation according to a plan, report

Definitions are important, but are often vaguely used

Validation means **confirmation** by examination and provision of **objective evidence,** that the particular requirements for a specific **intended use** can be consistently fulfilled.

SW validation, what is included?



Establish a validated state

Maintain the validated state

Control of changes

Monitor

Ensure future access to records

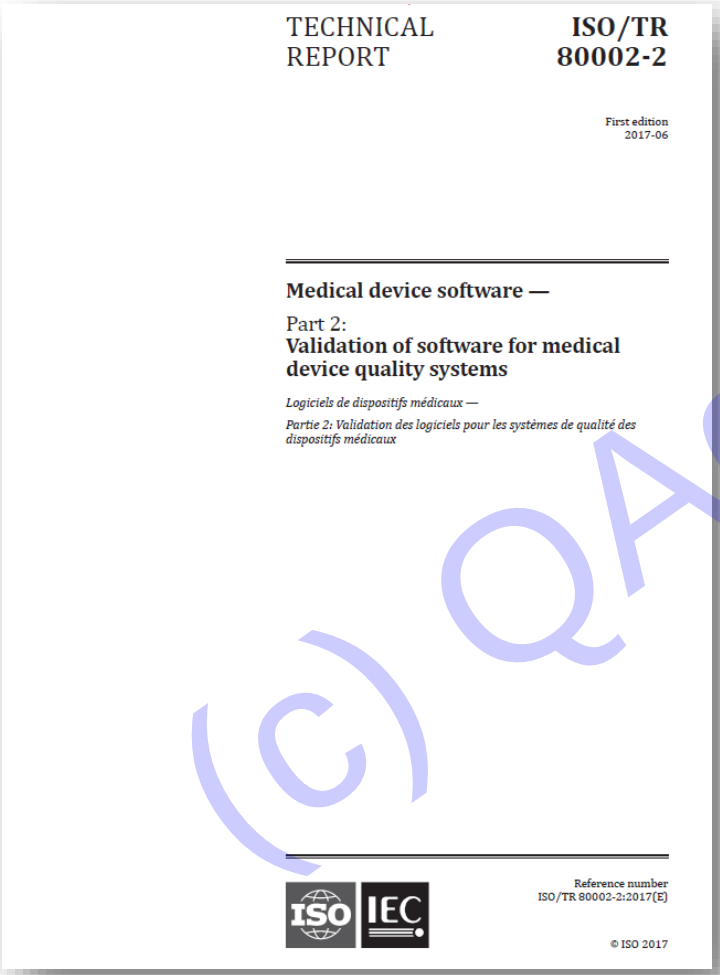
There are several sources of information available

- General Principles of Software Validation (FDA Guideline) — What!
- AAMI TIR 36 Validation of software for regulated processes (AAMI Guideline) — How!
- 13485:2016 Medical devices-QMS-Requirements for regulated purposes — What!
- ISO/TR 80002-2:2017 Validation of software for medical device quality system — How!

TIR 36 – Key concepts

- Intended use
- Risk management
- Level of effort
- Critical thinking
- Toolbox
- Documentation
- Changes

ISO/TR 80002-2 – Key concepts


TECHNICAL REPORT

ISO/TR 80002-2

First edition 2017-06

Medical device software —

Part 2:
Validation of software for medical device quality systems

Logiciels de dispositifs médicaux —

Partie 2: Validation des logiciels pour les systèmes de qualité des dispositifs médicaux

ISO IEC

Reference number ISO/TR 80002-2:2017(E)

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- Intended use
- Risk management
- Level of effort
- Critical thinking
- Toolbox
- Documentation
- Changes

Intended use – is this software regulated?

- Purpose of process
- Purpose of system
  - Basic requirements?
  - How dependent you are of the system?
  - What should it not be used for?

Regulatory use assessment is crucial to decide validation needs

a.Could the failure or latent flaws of the software affect the safety or quality of medical devices?

b.Does the software automate or execute an activity required by regulation (in particular, the requirements of the 13485 or QSR)?

c.Does the software generate or manage data to be used in or support of a regulatory submission?

d.Does the software generate or manage records that are required by a regulation?

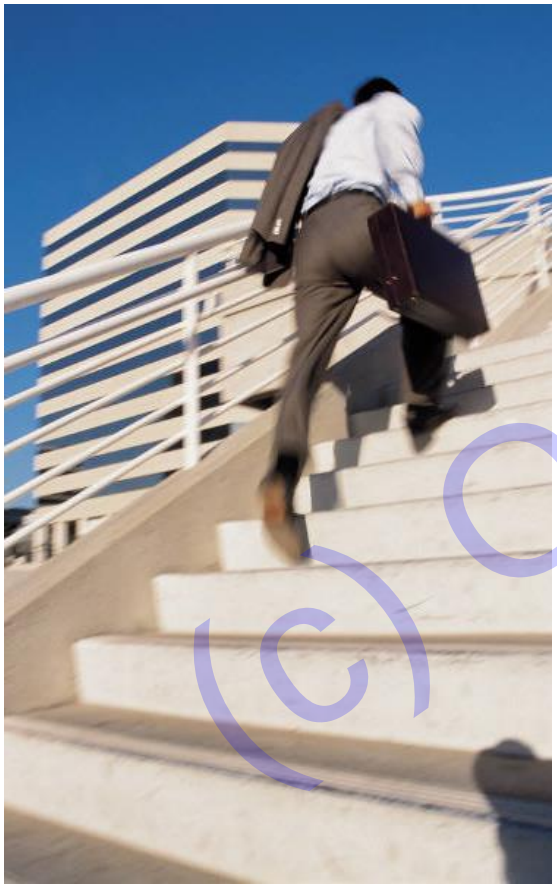
e.Is the software used to execute or record an electronic signature required by regulation?

Risk management is the cornerstone in the validation effort

- What are the process risks?
- What can go wrong?
  - System errors
  - Use errors
  - Errors in the interface to other systems?
- Will errors and mistakes be detected?
- How to reduce risks?

Two kinds of risk analysis

The level of effort and confidence needed differ



- Based on intended use
- Risk level
- Critical thinking

Wide range of different software

- Off-The-Shelf
  - Unmodified
  - Configurable
  - Modified
- Custom software
  - In-house developed
  - Purchased externally
- Stand-alone or in a network
- Simple or complex

Toolbox - examples

- Software life cycle
  - Requirments
  - Architetcure & Design
  - Test & review
  - Release
- Different types of tests
- Analysis of known anomalies
- Supplier evaluation or audit
- Training
- Monitoring

Procedure – example

- Classification of a software tool
  - Determine if the software is within the scope and the level of validation – Intended Use
    - Establish a Master Validation Plan
    - List software to be validated in the Master Validation Plan
  - Determine the level of validation
    - Intended Use
    - Process description
    - Initial risk assessment
- Planning, execution and reporting
  - Define the validation effort based on the risk level
    - Separate plan or sufficient with the Master Validation Plan
- Maintenance
- Retirement

Validation Plan content (MVP or separate)

Description of the process

Intended use

Description of the software

Documentation of the risk assessment

Other documentation

Training

Backup and recovery

Security

CM

Requirements

Verification

Validation

Example: To get an Off-the-shelf Customer Complaints System into the validated state

Process analysis

Define Intended Use & requirements at user level

Risk analysis

Risk Control Measures

System description

Supplier evaluation

Black box testing of requirements

Version control

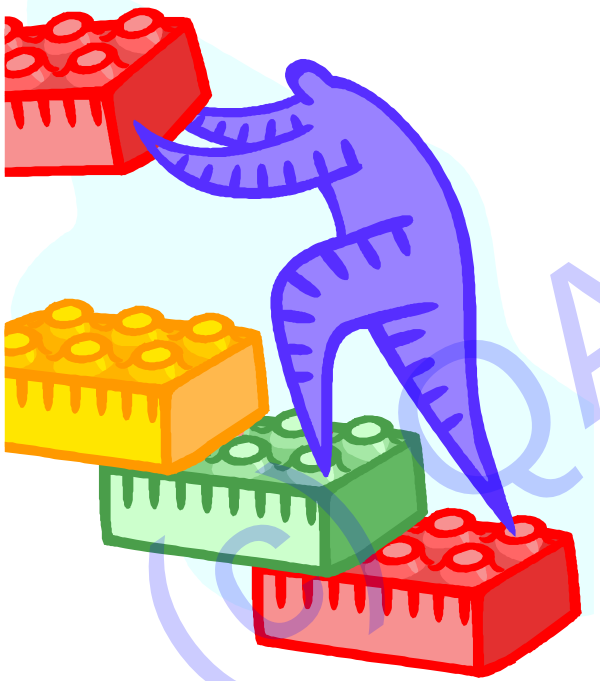
Change control process in place

”Customer Complaint System Validation Document”

The validation documentation has to be archived

- Plan
- Records
- Summary report

The changes has to be controlled



- Software changes

  - New versions
  - Change control
  - Regression test

- Change of use over time?

- Re-validation required?

Thank you for your attention!
Questions & Answers

QAdvis can support you as needed

- Deployment of QMS
- Mentorship CSV
- Risk management
- Courses
  - ISO 13485:2016
  - Risk management & SW risk management
- Internal trainings

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