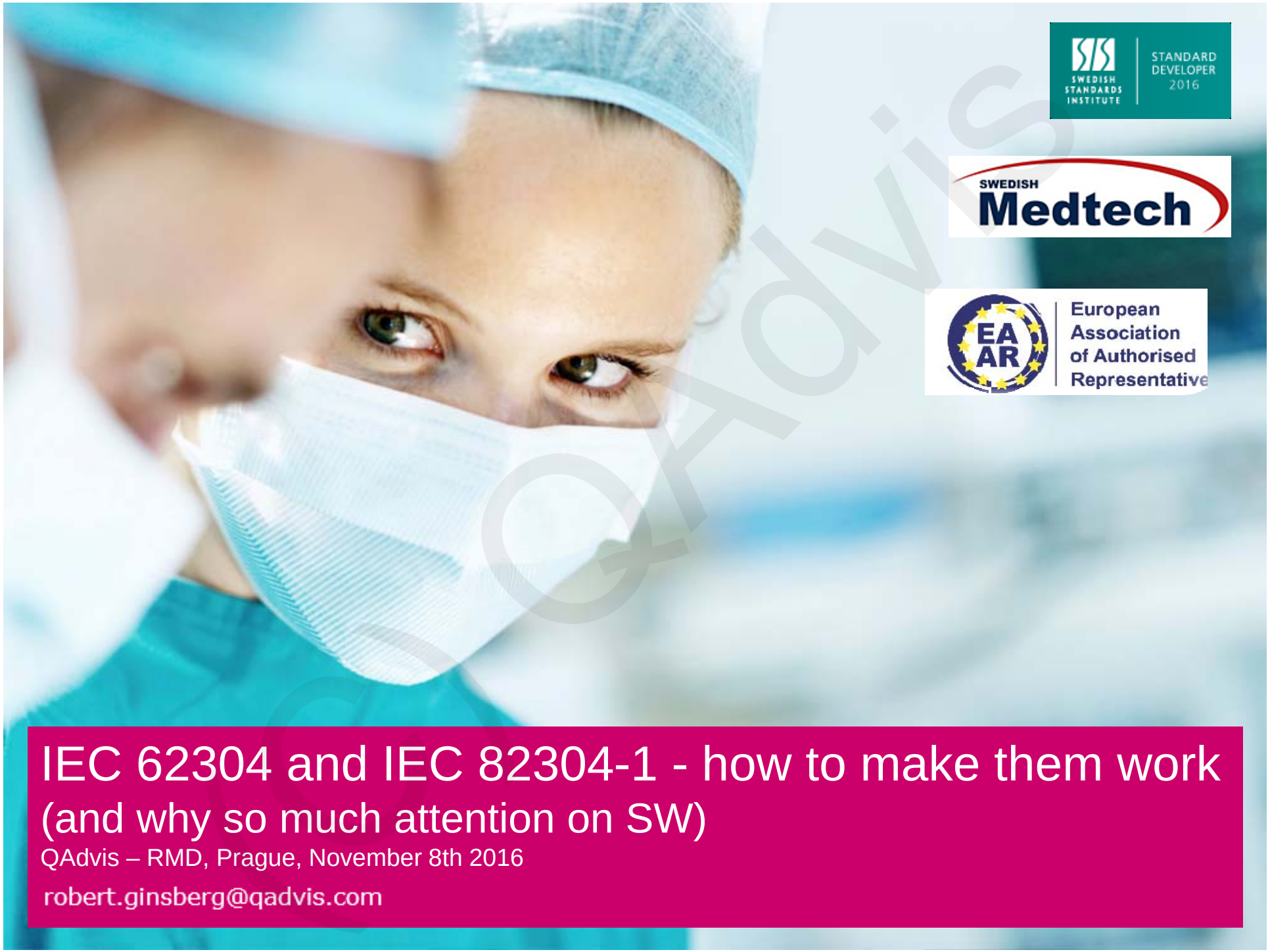


IEC 62304 and IEC 82304-1 - how to make them work

(and why so much attention on SW)

QAdvis – RMD, Prague, November 8th 2016

robert.ginsberg@qadvis.com

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
Computer systems validation
Requirement management
Risk management
Verification and validation
Process validation

QA&RA/Clinical Consulting
Interim management
Expert advise
Audits/Mocks/Due Diligence
Warning letters, compliance projects
PMA, 510k, CE-mark, EC-cert
Global regulatory support
Vigilance, Recalls, PMS
Clinical evaluation and clinical studies

Training/courses
CE-marking
ISO 13485 & QSR
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 US partner.

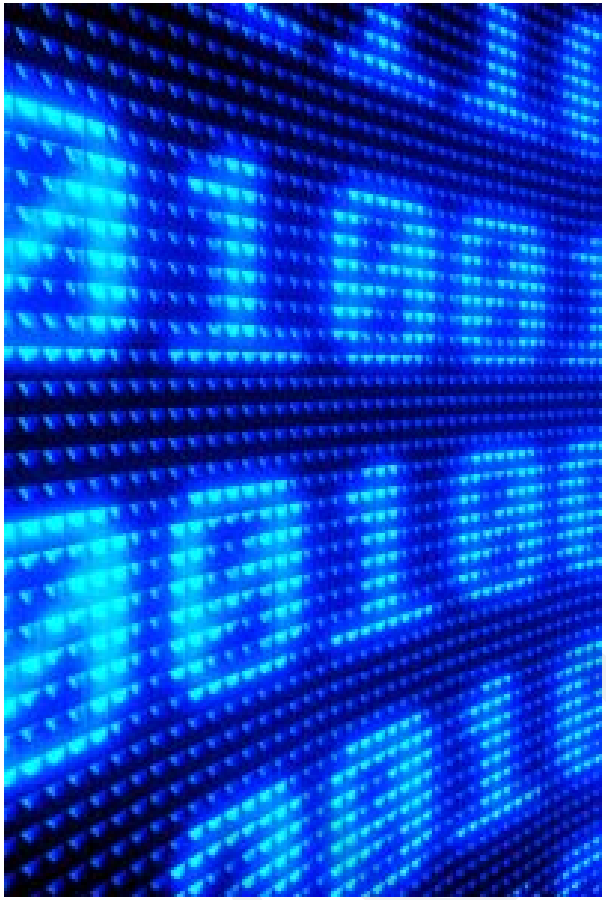
European Authorised Representation
Providing European representation for non-EU MedTech companies
Active member of EAAR: European Association of Authorised Representatives

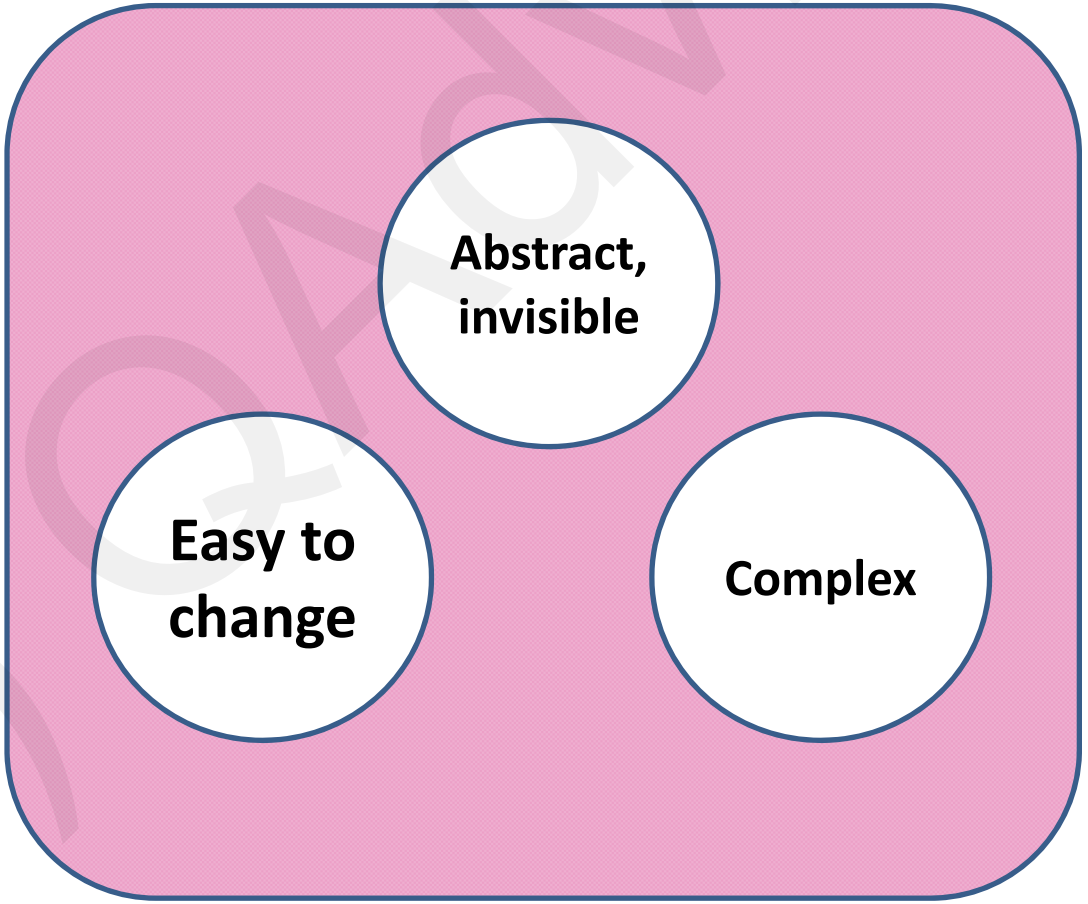
Presentation of the speaker Robert Ginsberg

- 30+ years in SW Development
- 25+ years in Medical Device SW
- Certified Lead auditor (ISO 13485 & QSR)
- Co-author to IEC 62304, 82304, 80001-1, 80002-1, 80002-2
- Working member of Cenelek TK-62
- Certified Scrum Master


MEDICAL
Health Care
Doctor
Hospital
Pharmacist
Nurse
Dentist
First Aid
Surgeon
Emergency

What makes software so special?





Can wrong patient information contribute to death?

Case report: Swedish SoS 2007

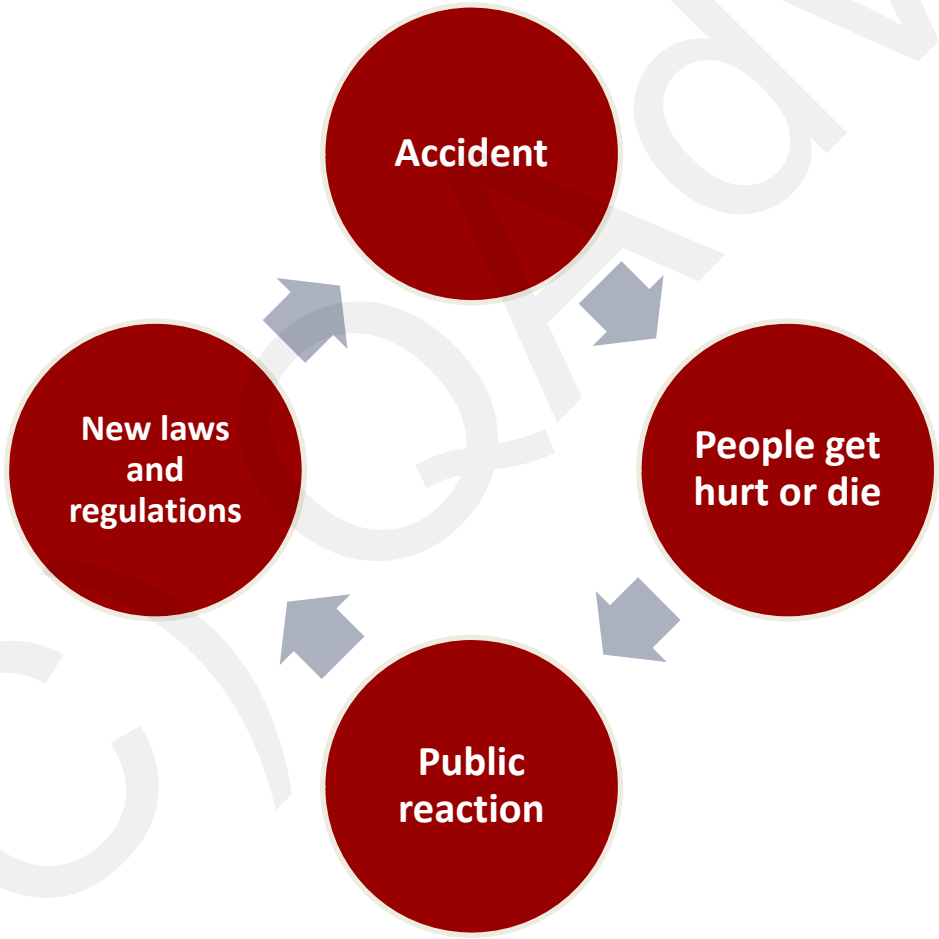
”When Sofie came into ER, the treating doctor used the wrong patient record.

In the electronic patient record system at the hospital there were two patients with similar names and social security numbers.

Based on the contents of the wrong record Sofie was treated with drugs that led to her death.”

Swedish SoS **=** National Board of Health and Welfare
Ref: https://www.vardfokus.se/tidningen/2007/nr-4-2007-4/tva-patienters-journaler-forvaxlades-pa-sjukhuset/

The bar is raised over time



Expectations from authorities are based on historical events

- Example: upcoming MDR & IVDR
- Objective evidence
  - ✓ Software validation
  - ✓ Device verification
  - ✓ Device validation
- Safety and effectiveness
  - ✓ Risk analysis
  - ✓ Clinical evaluation
- Designated individuals responsible

In-the-state-of-control

Standards play a central role in the regulatory environment

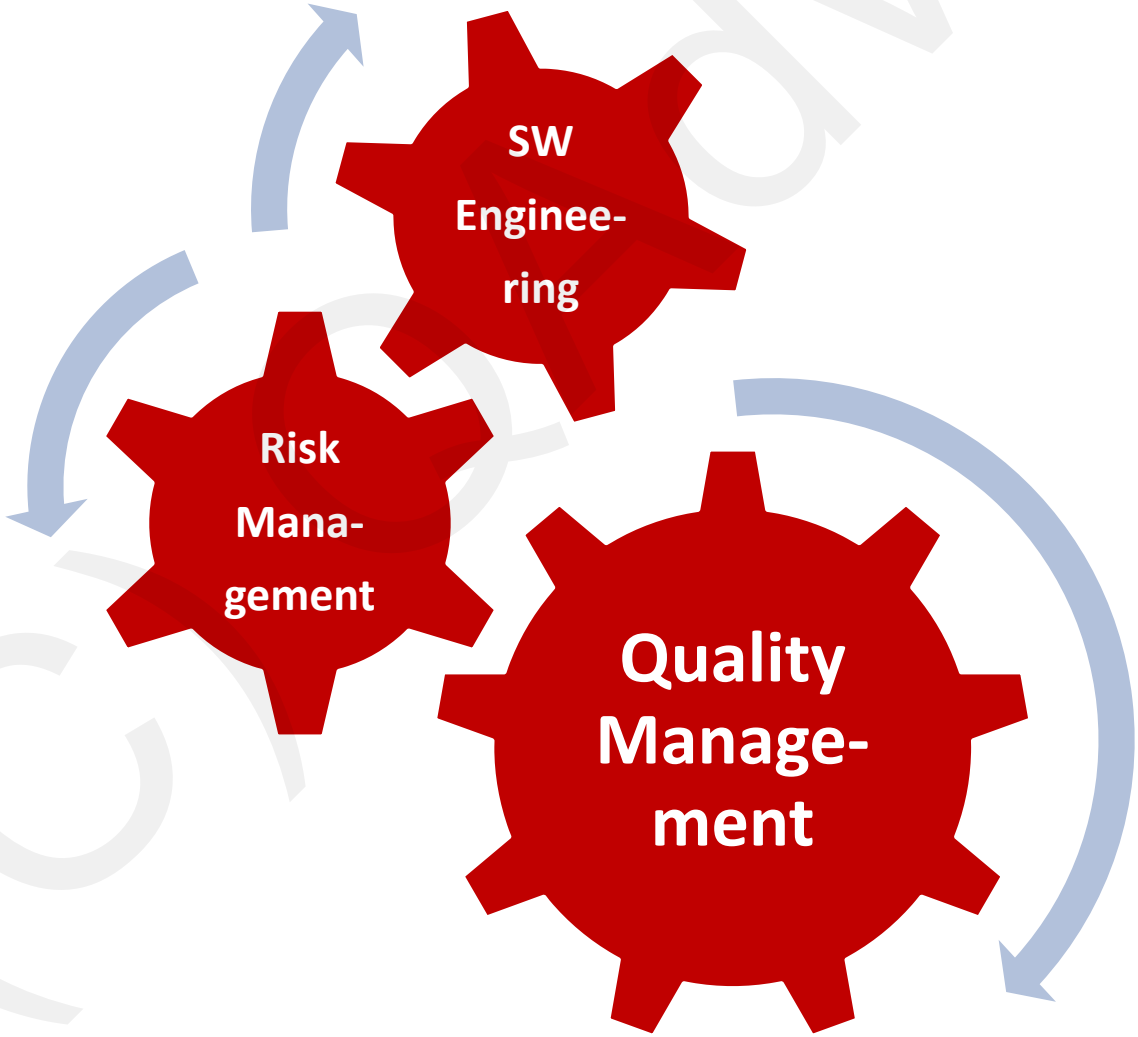
IEC 62304: Medical device software –
Software life cycle processes

A SW process standard

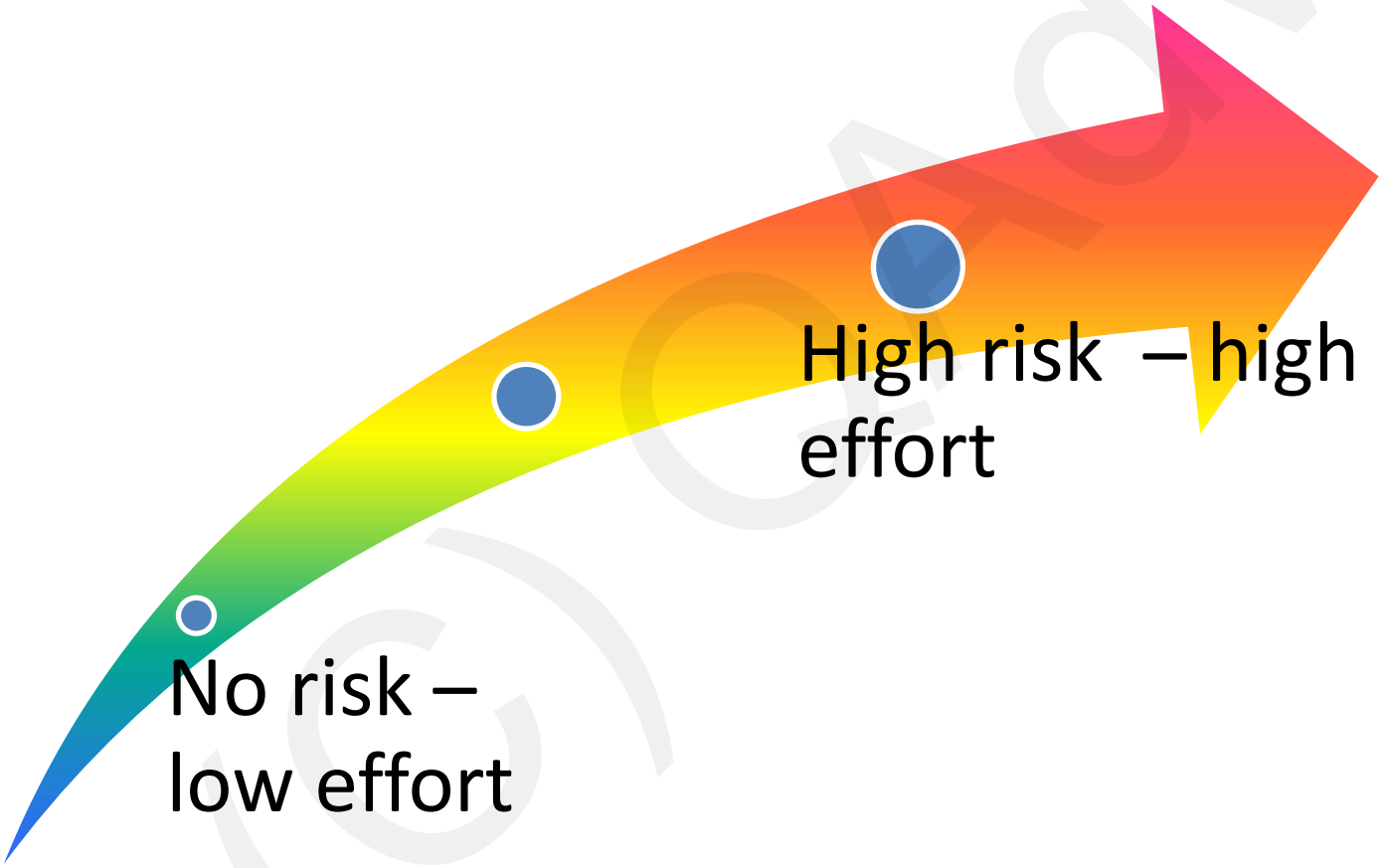
ISO 14971 that defines the risk management process is the basis of IEC 62304 (Ed 1.1)

Risk analysis	• Identification of Intended use • Identification of Hazards, Hazardous situations and Harms • Estimation of Risk(s)
Risk evaluation	
Risk control	• Option analysis • Implementation of risk control measures • Risk/benefit analysis • Risks from risk control measures
Residual risk	
Risk management report	
(Post-) Production	• Service records & Complaints & Clinical data

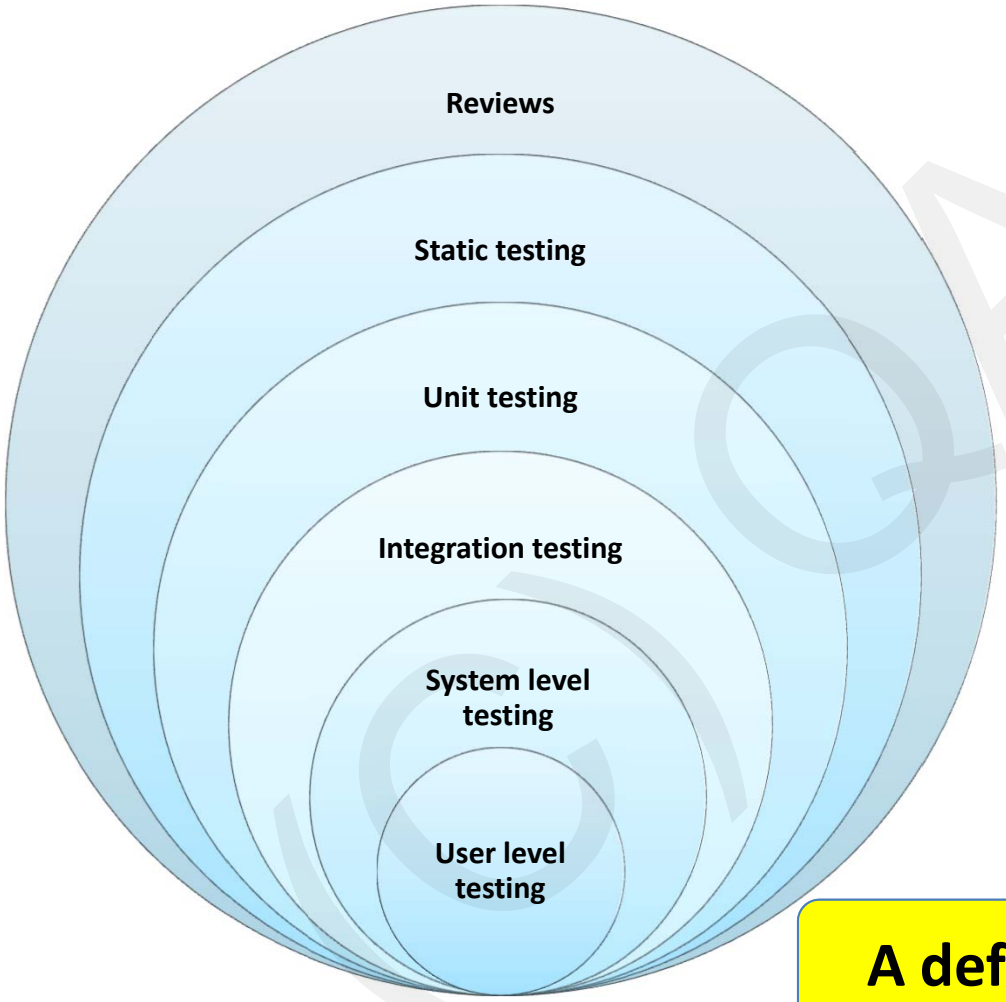
IEC 62304 philosophy is based on three basic principles



Your validation effort should be dynamic regarding rigor and detail based on risk



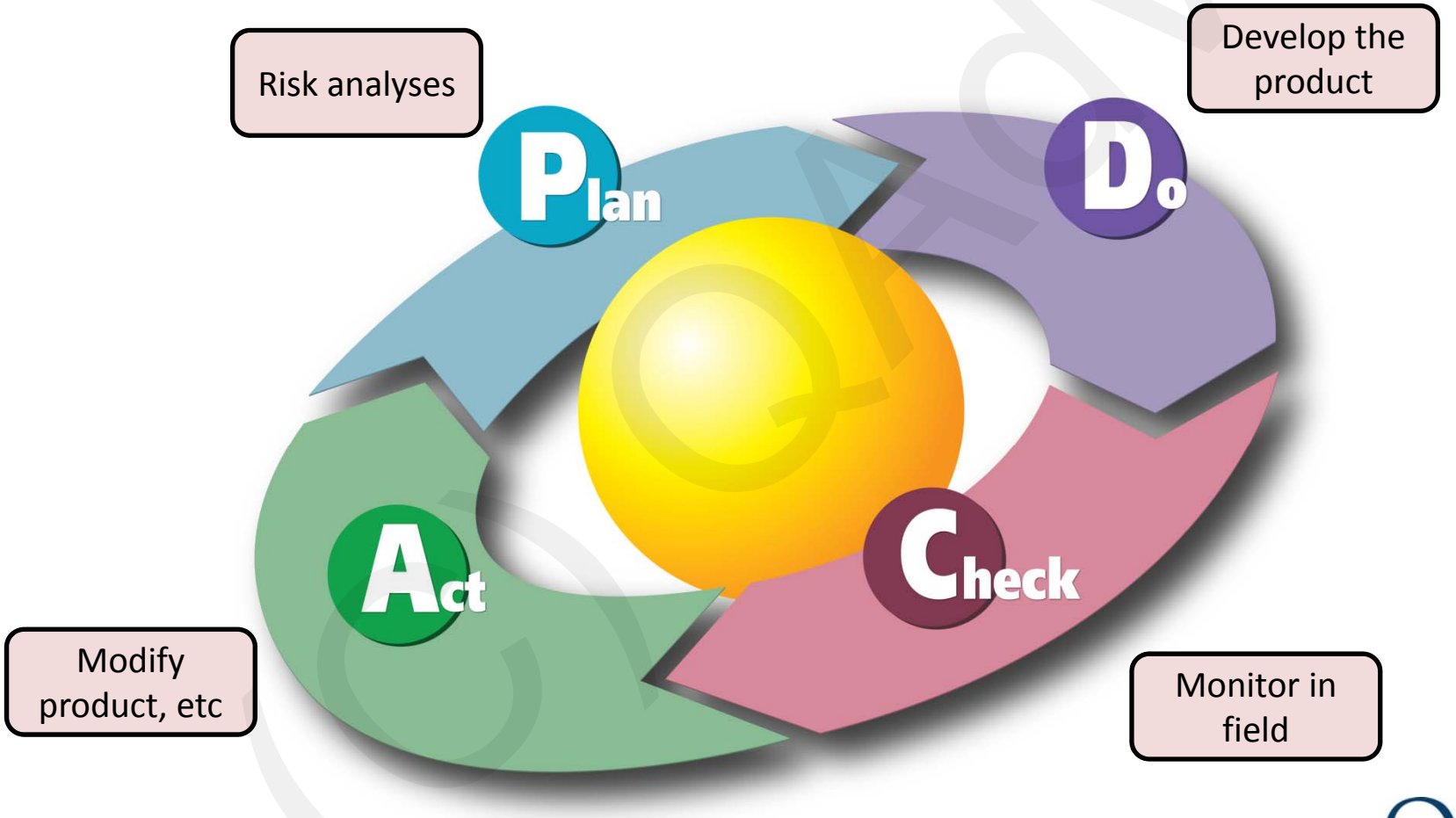
Reading IEC 62304 - how much is enough ?



- ✓ Coverage of minimal process requirements
- ✓ Results from the risk analyses set the level of V&V
- ✓ The traceability assures and demonstrates coverage
- ✓ Field data supports your strategy

A defendable story!

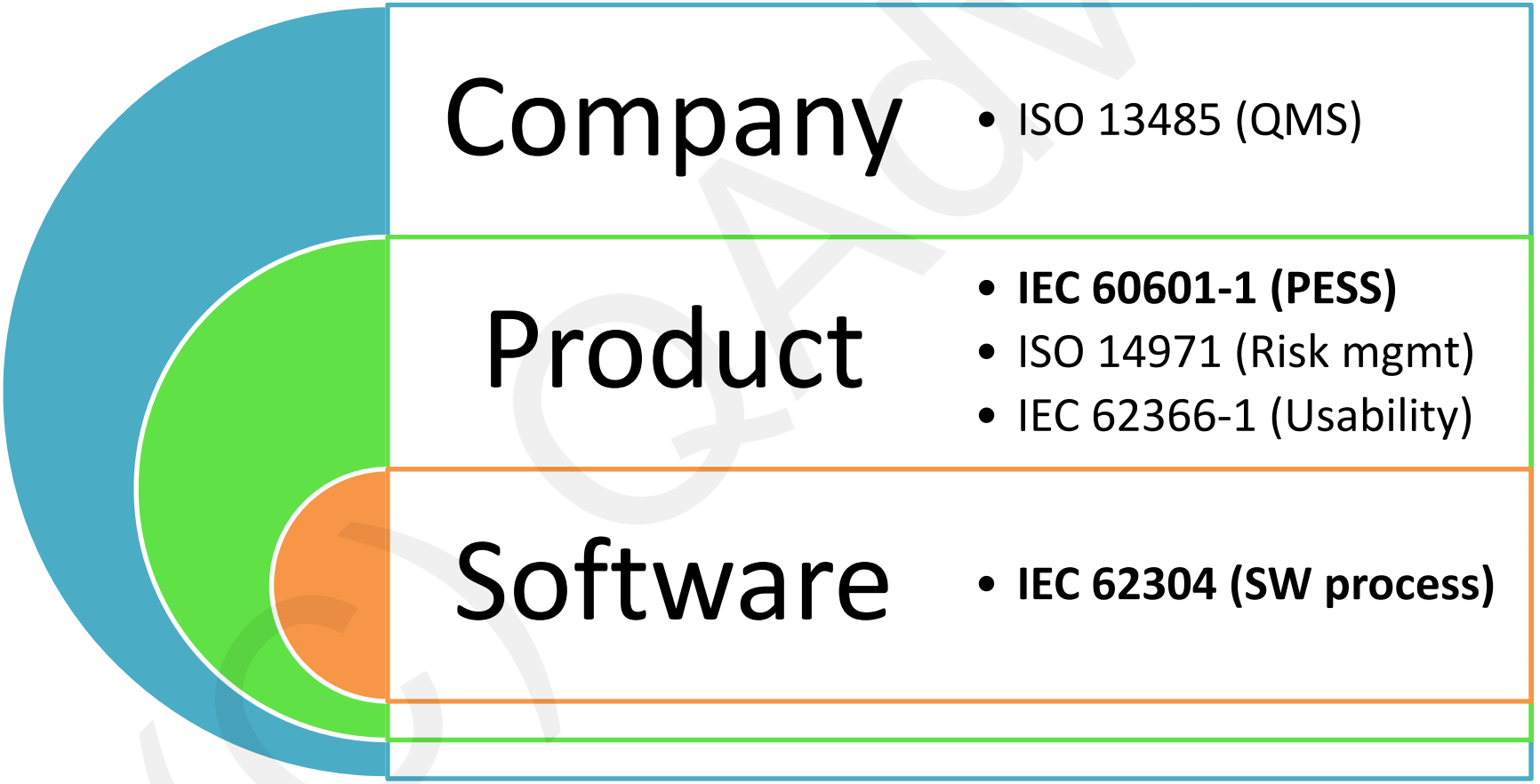
You should use field data to defend your story



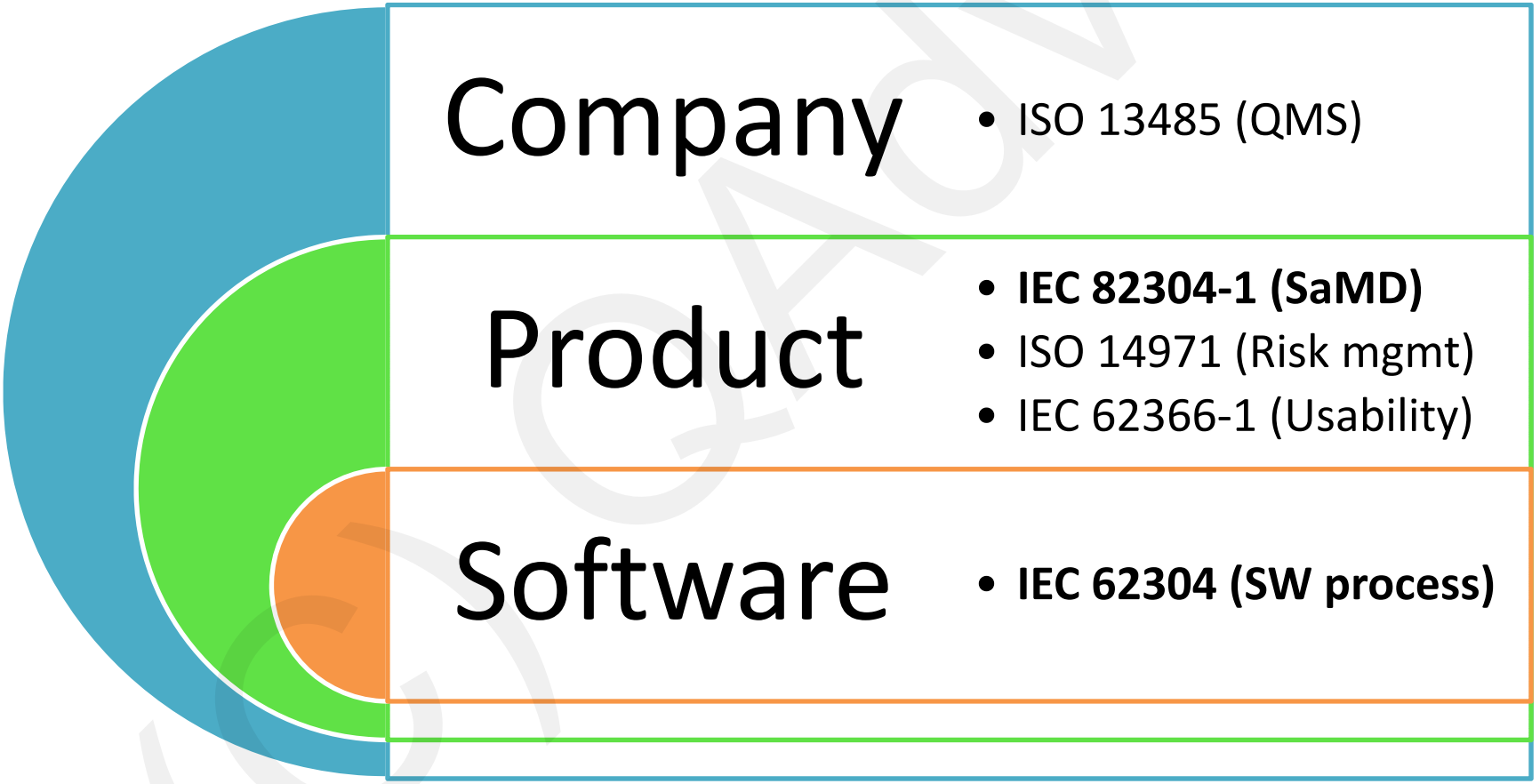
IEC 82304-1: Health software – Part 1: General requirements for product safety

How will it fit in next to other standards?

Relevant standards for SW as part of a medical device according to MDD

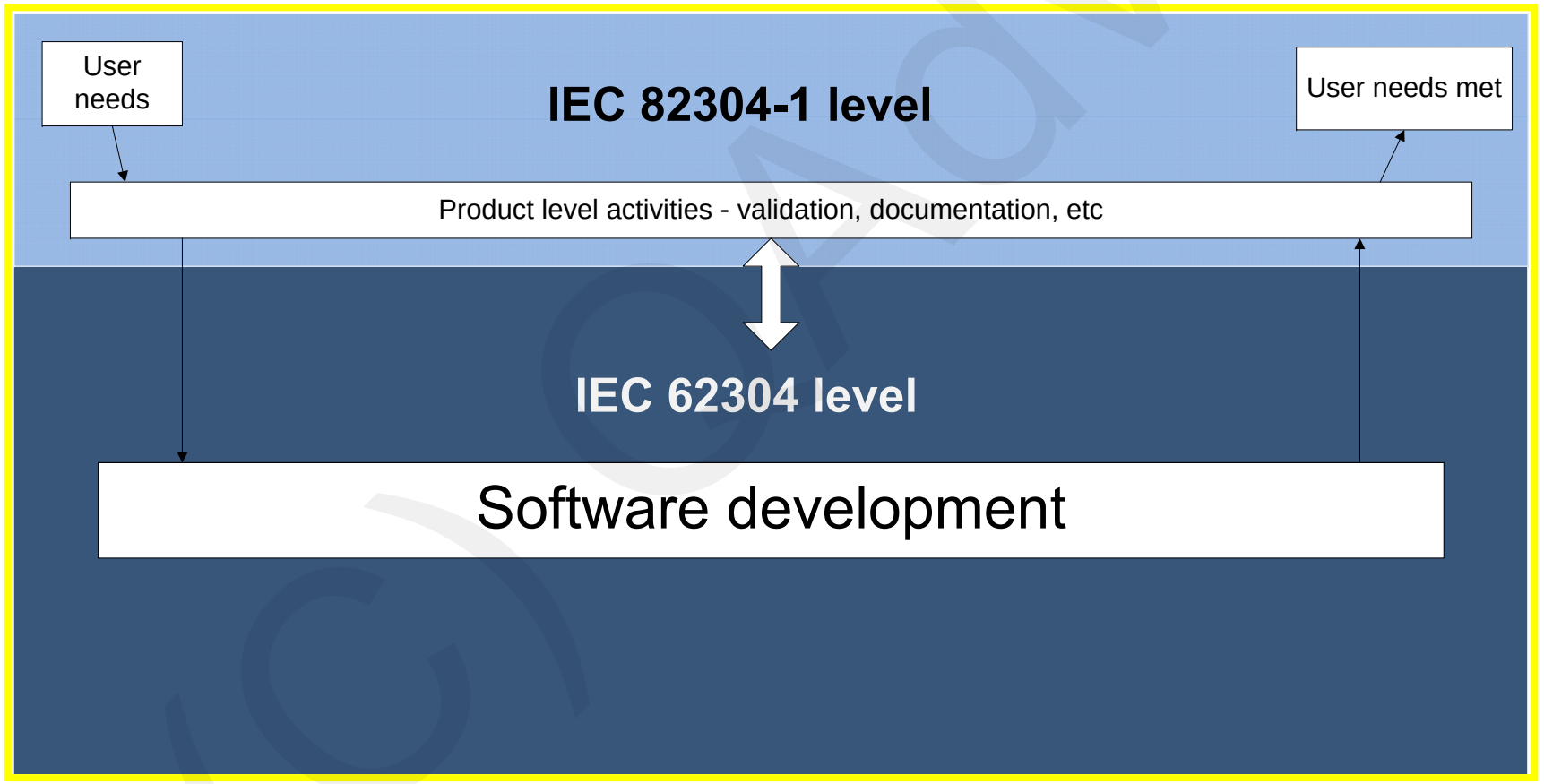


Relevant standards for SW as medical device (SaMD) according to MDD

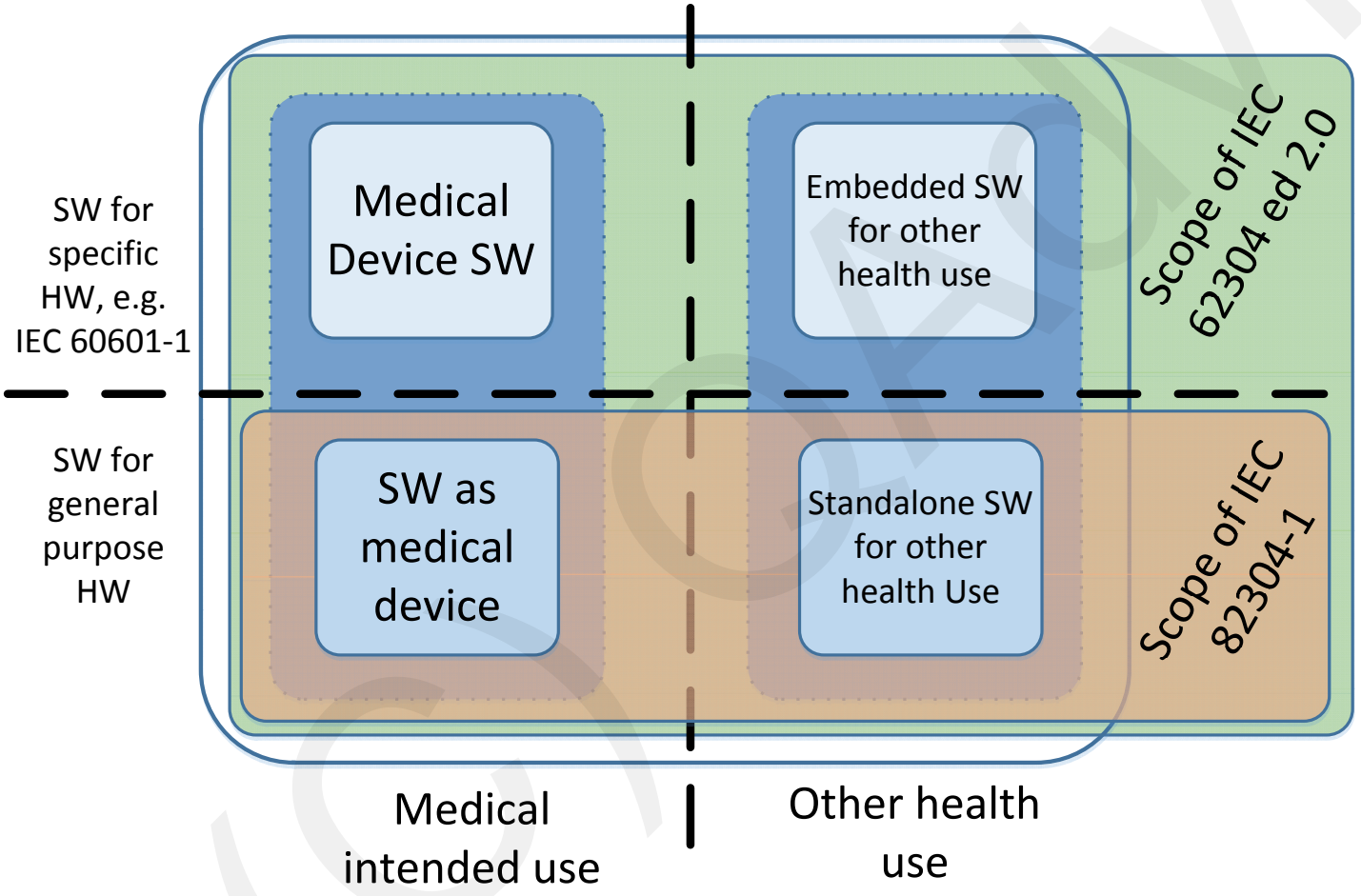


IEC 82304-1: Health Software – Part 1: General requirements for product safety

The structure of IEC 62304 is aligned with system level standards as IEC 60601-1 and IEC 82304-1

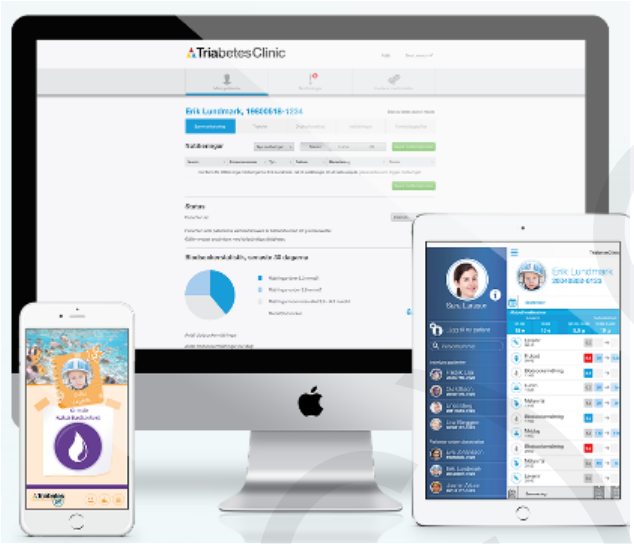


The scope of IEC 82304-1 (and IEC 62304 ed 2) is intended to also cover Health SW



HEALTH SOFTWARE - software intended to be used specifically for managing, maintaining or improving HEALTH of individual persons, or the delivery of care

IEC 82304-1 is mainly a product standard for health software



- SW for general computing platforms
- Health software product validation
- Safety & security
- Manufacturers
- Entire lifecycle

IEC 82304-1 is for software running on general computing platforms

SW for general computing platforms

- Standalone software
- Software medical device
- Software-only products
- SaaS, Software as a Service
- SaMD, Software as a Medical Device (IMRDF)

IEC 82304-1 is addressing safety and security

Safety

Freedom from unacceptable risk

Security

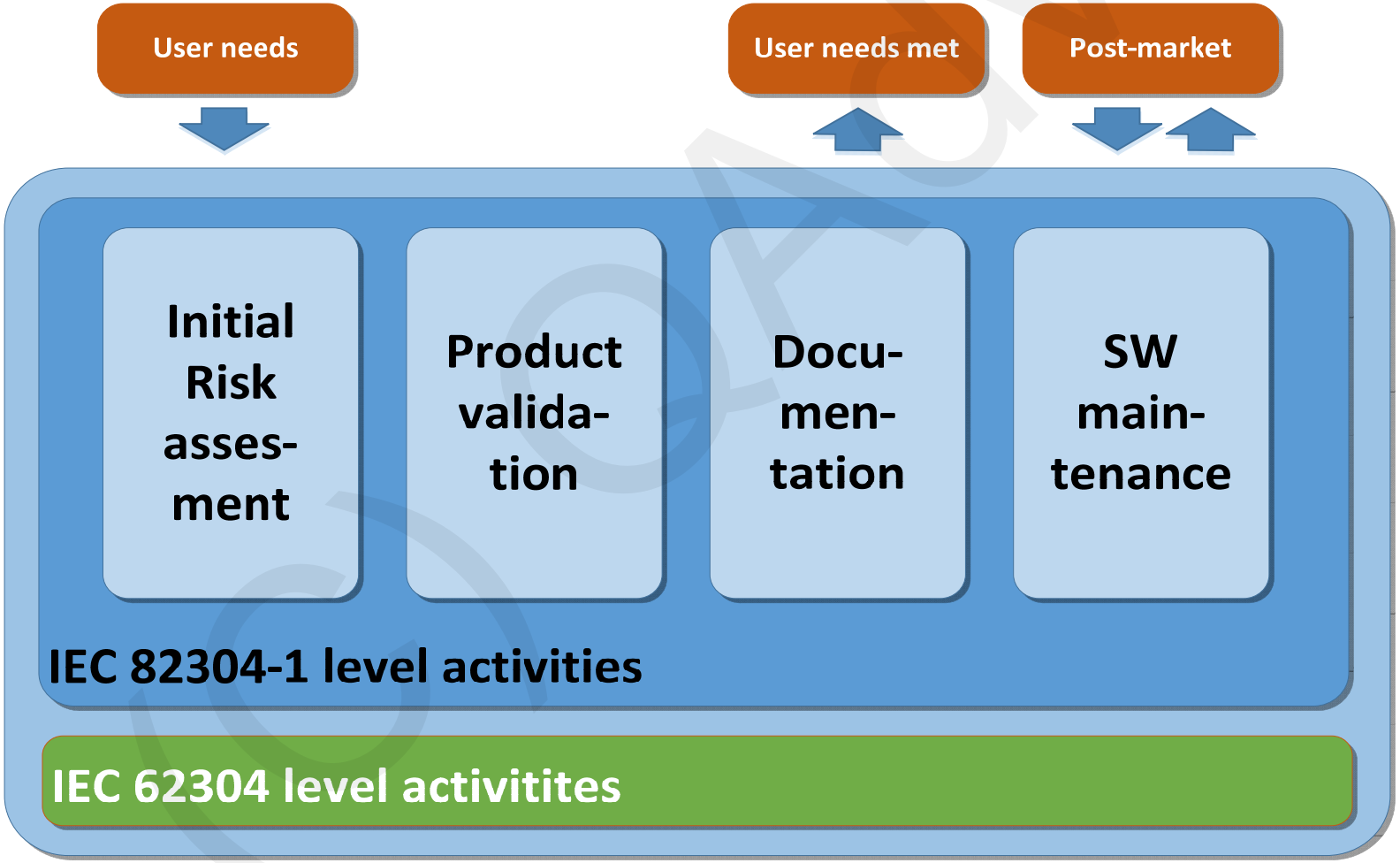
Protection of information and data so that unauthorized persons or systems cannot read or modify them and authorized persons or systems have access to them

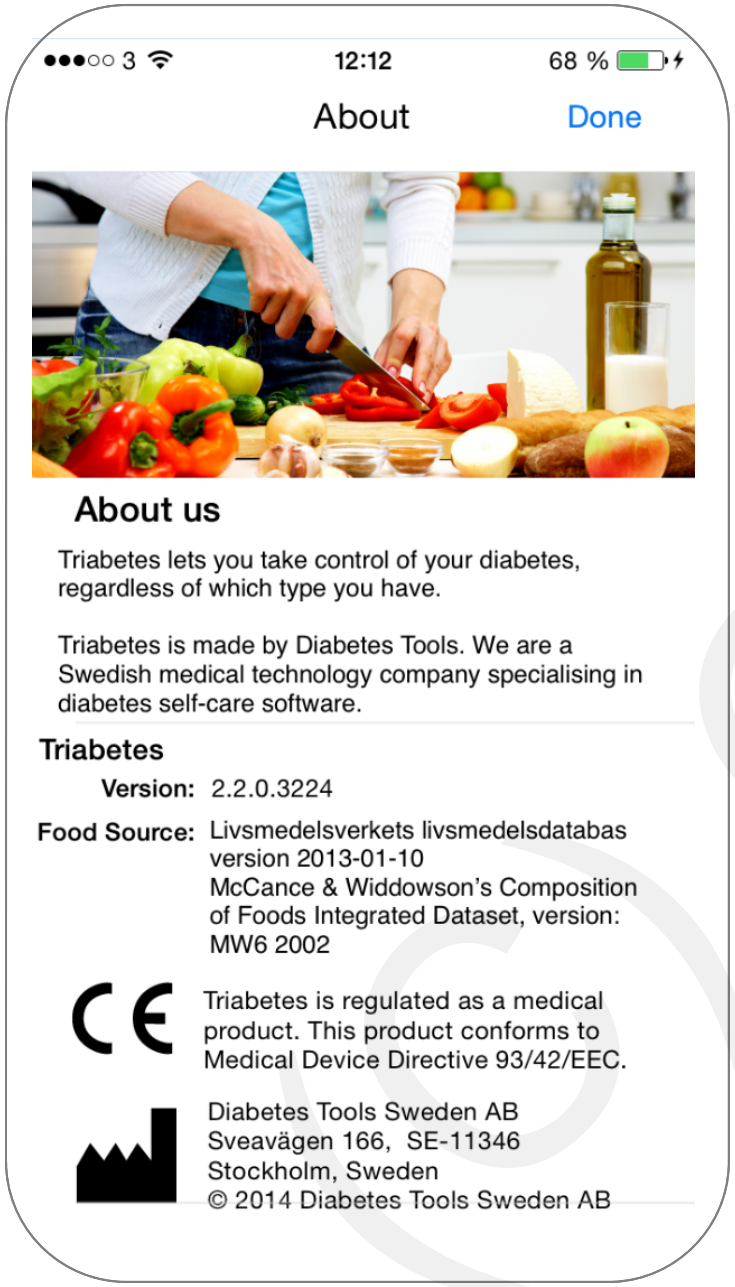
IEC 82304-1 is expecting a manufacturer to be identified

Manufacturer

Natural or legal person with responsibility for the design, development, packaging, or labelling of a health software product, or adapting a health software product before it is placed on the market or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party

IEC 82304-1 is tightly interconnected with IEC 62304





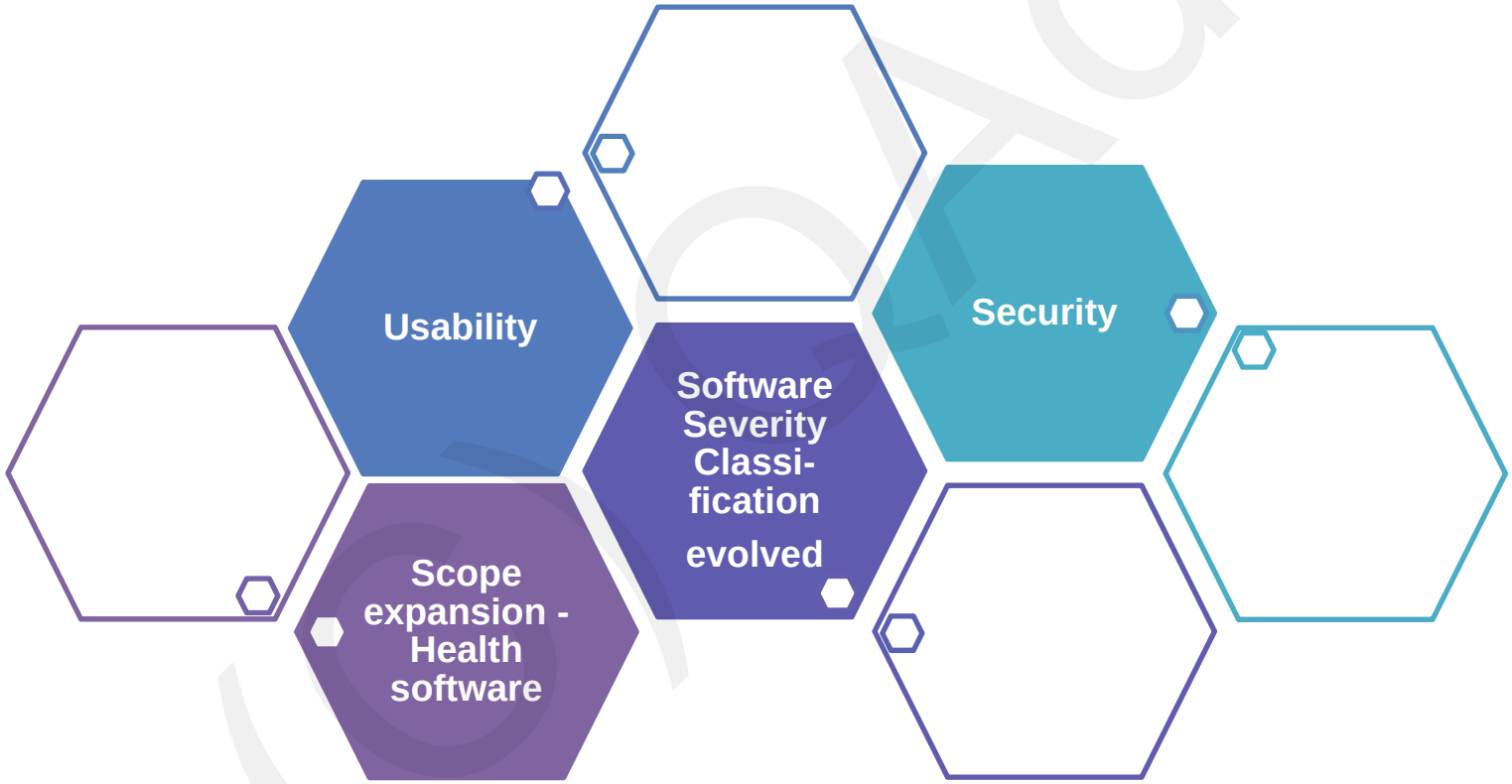
IEC 82304-1 calls for health SW product identification

- Manufacturer name and trademark
- Product name and type reference
- Version identifier

IEC 82304-1 calls for health software accompanying documents

- Manufacturer contact information
- Product identification and Version
- Instructions for use
- Technical description

IEC 62304 Edition 2 is on its way (early 2018?)



What's next?
MDR and IVDR

There is a new classification rule in MDR for software – 10a

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes, is in class IIa, except if such decisions have an impact that may directly or indirectly cause:

- the death or an irreversible deterioration of the state of health, in which case it is in class III;

- a serious deterioration of the state of health or a surgical intervention, in which case it is in class IIb.

Software intended to monitor physiological processes is in class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, in which case it is in class IIb.

All other software is in class I.

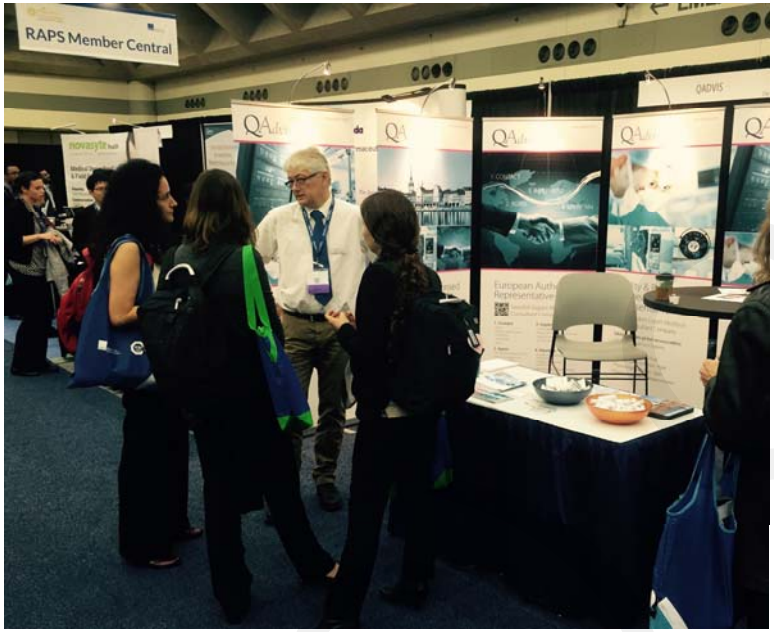
Summary

- Focus should be on design, defect prevention and SW reliability
- A solid approach to software risk management is fundamental
  - Software architecture and design
  - Usability
  - Security
- Tool support is crucial to achieve high productivity in SW development
  - Static analysis
  - Test automation
  - Risk and requirements management
- Field data needed as part of your “defendable story”

The regulatory storm is ahead of us. Don’t wait – act now!

Q&A

QAdvis can support you as needed



IEC 82304-1 and IEC 62304

- Gap analysis
- Implementation
- Compliance assessment
- Training
- Software risk management
- Static analysis program
- Tool implementation
- EAR services

Contact: robert.ginsberg@qadvis.com
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