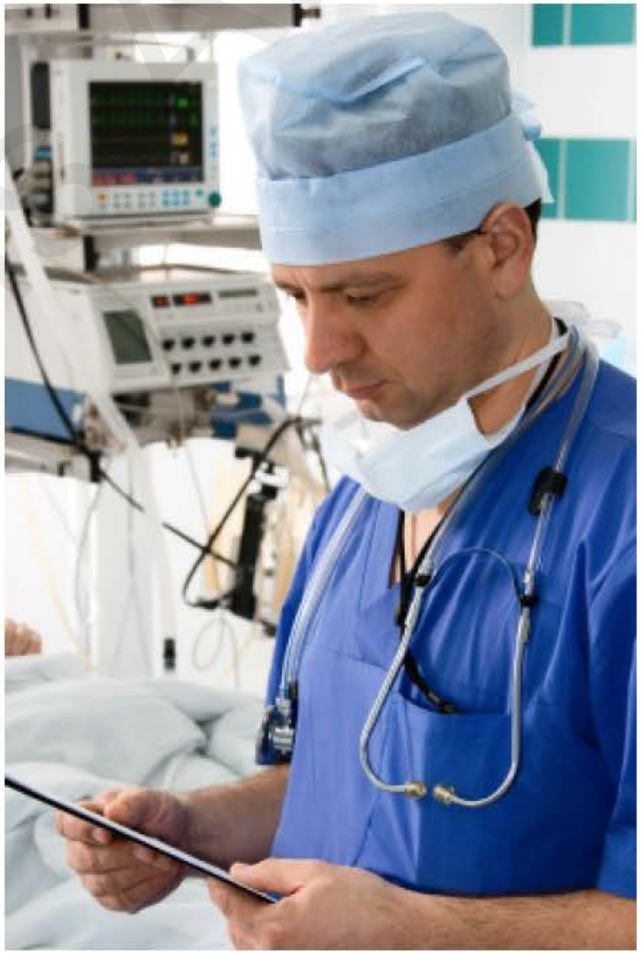
QAdvis

Webinar 2011-01-19

The benefits of a Quality Management System

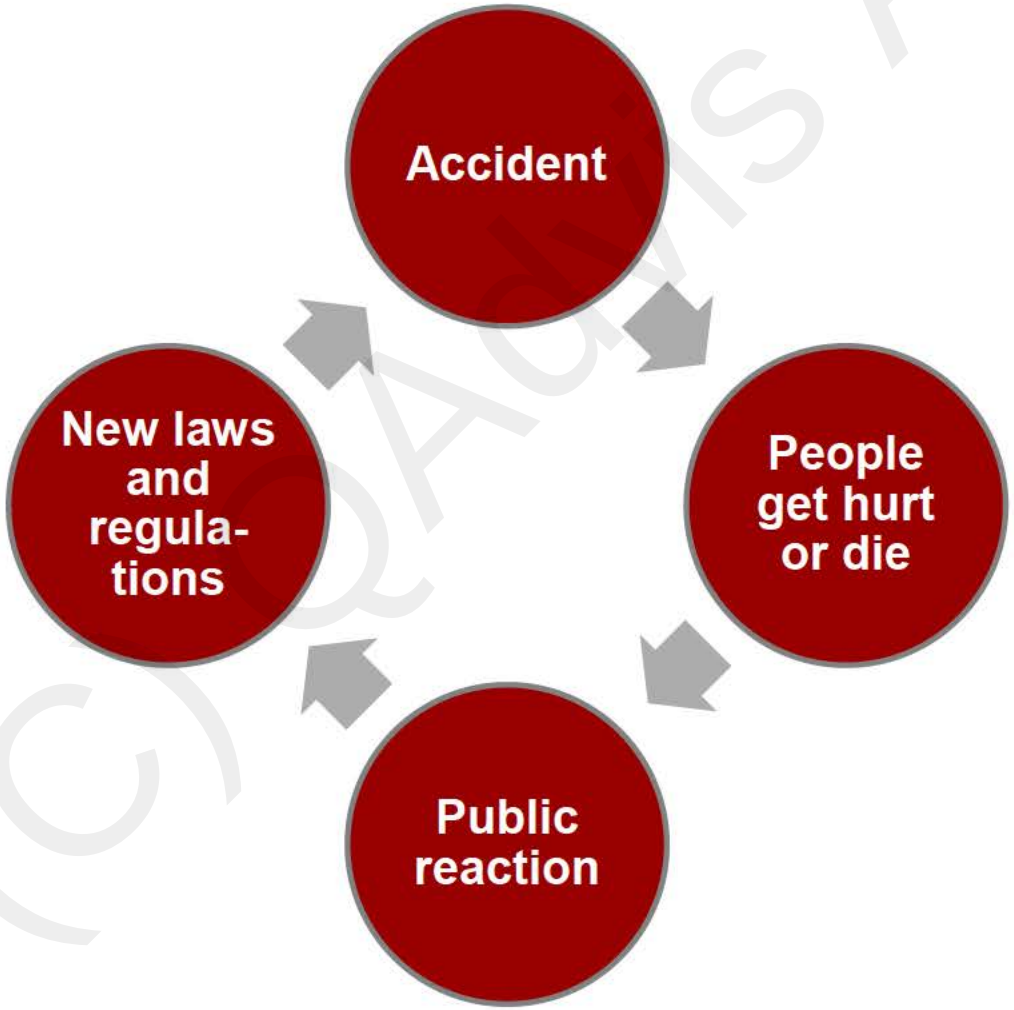


Introduction of the speaker

Robert.Ginsberg@qadvis.com

- 26 years in system development
- 18 years in Medical Device industry
- Participated in > 20 audits, FDA, MDD etc.
- Working member of Cenelek TK-62 and JWG3 (62304)

The bar is raised over time



Wrong information can contribute to injuries and also death

Case report: Socialstyrelsen 2007

”When Sofie came into ER, the treating doctor used the wrong patient journal. In the computerized journal system at the hospital there were two patients with similar names and social security numbers. Based on the contents of the wrong journal Sofie was treated with drugs that led to her death.”

Media report the mishaps, and we as the society don't accept them

News

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Man, 78, died after patient scan mix-up

By **Laura Nightingale**
June 15, 2010

AN elderly man died after undergoing a CT scan with contrast at Frimley Park Hospital that was actually meant for a patient with a similar name.

Ivor Ireland, 78, who was suffering from heart and kidney problems, later underwent emergency dialysis for failing kidneys and subsequently died on the operating table at another hospital.

Doctors at Frimley Park admitted mixing up Mr Ireland's medical notes with those of a patient with

The revised Medical Device Directive is in effect from 21st of March 2010

- Clinical evaluation
- **Stand alone SW**
- Technical file
- Machine directive
- …

New harmonized standards for MDD & IVDD (27th of Nov 2008)

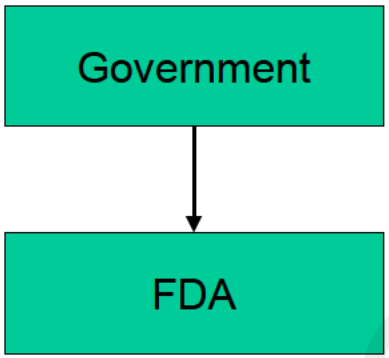
Cenelec	EN 62304:2006 Medical device software — Software life-cycle pro (IEC 62304:2006)
Cenelec	EN 62366:2008 Medical devices — Application of usability engine (IEC 62366:2007)

We can assume that the regulations will continue to evolve

Definition of a Medical device

USA has a centralized system, where FDA plays a central role as a regulator

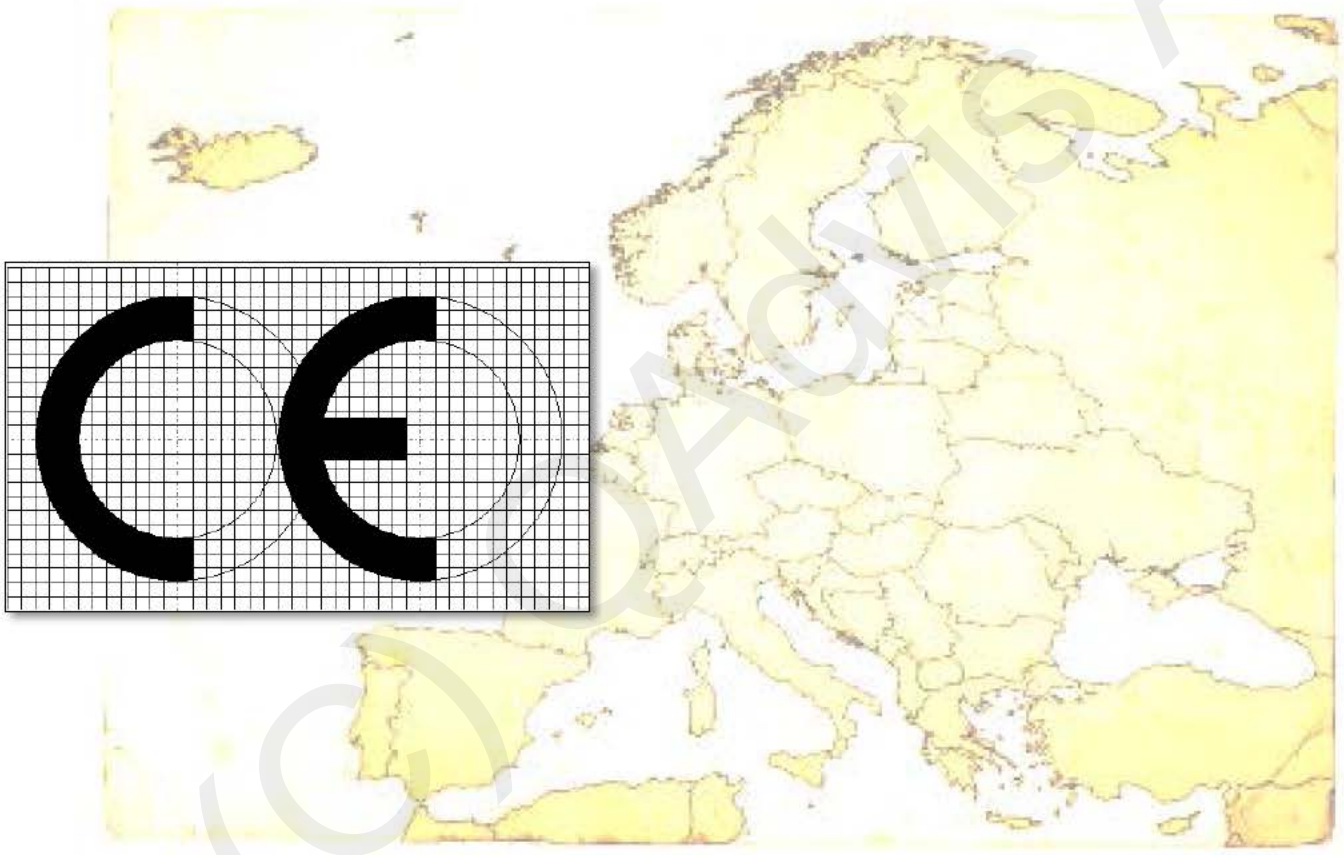
Government



Safe Medical Devices Act

21 CFR 820 (QSR)
21 CFR 11 (Part 11)

The CE mark unifies Europe about regulations



There are a number of regulations, standards and directives to be aware of

And there are a number of documents needed to get the CE-mark

There are three Medical device directives in Europe

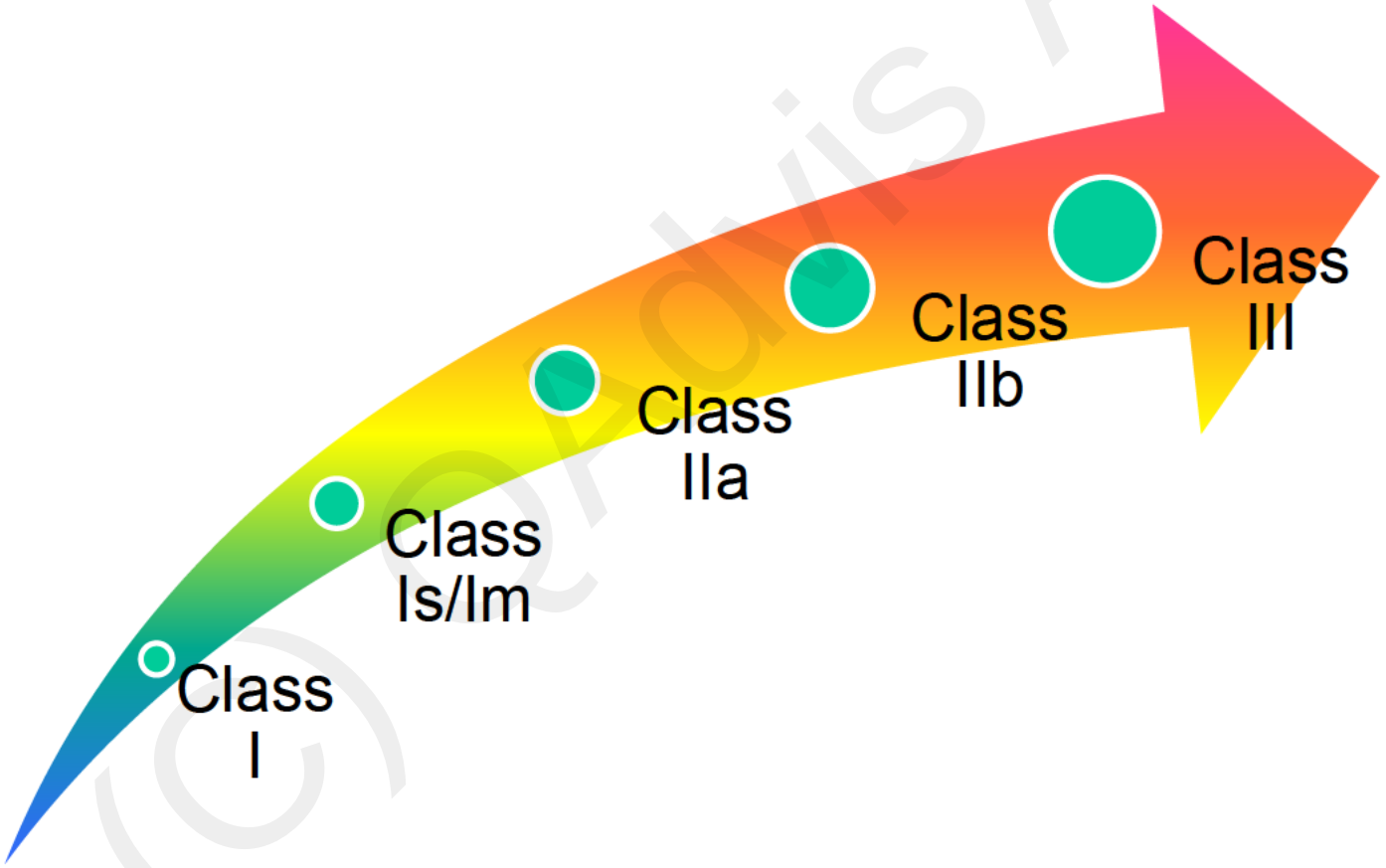
Medical device directives

AIMD

IVDD

MDD

The product classification is based on risk to patients



There are two tracks that have to be taken striving for the CE mark

Organization

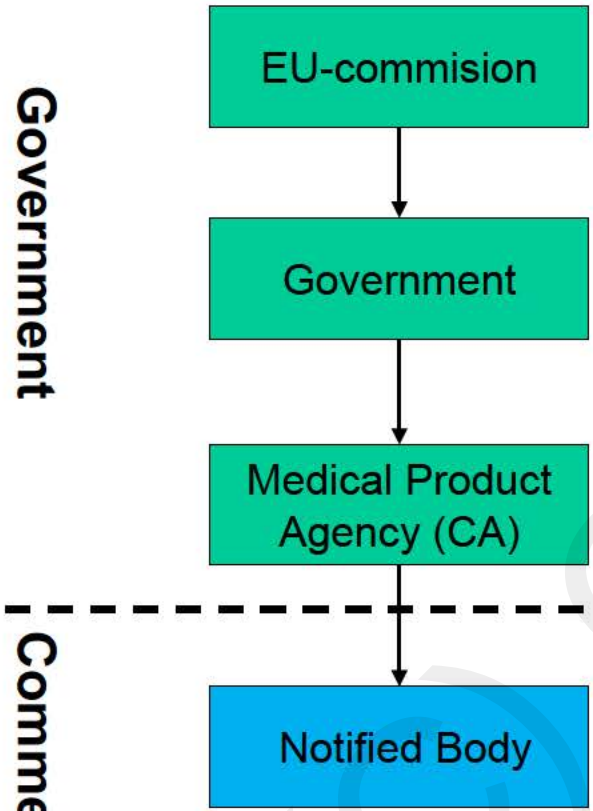
- Develop Q system
- Proof that it works
- Audit by NB
- QMS certificate

CE

Product

- Fulfill essential requirements
- Use harmonized standards
- Prove compliance
- Technical file
- EC certificate

The CE marking system calls for the need of a Notified Body



90/385/EEC **AIMD**
93/42/EEC **MDD**
98/79/EEC **IVDD**

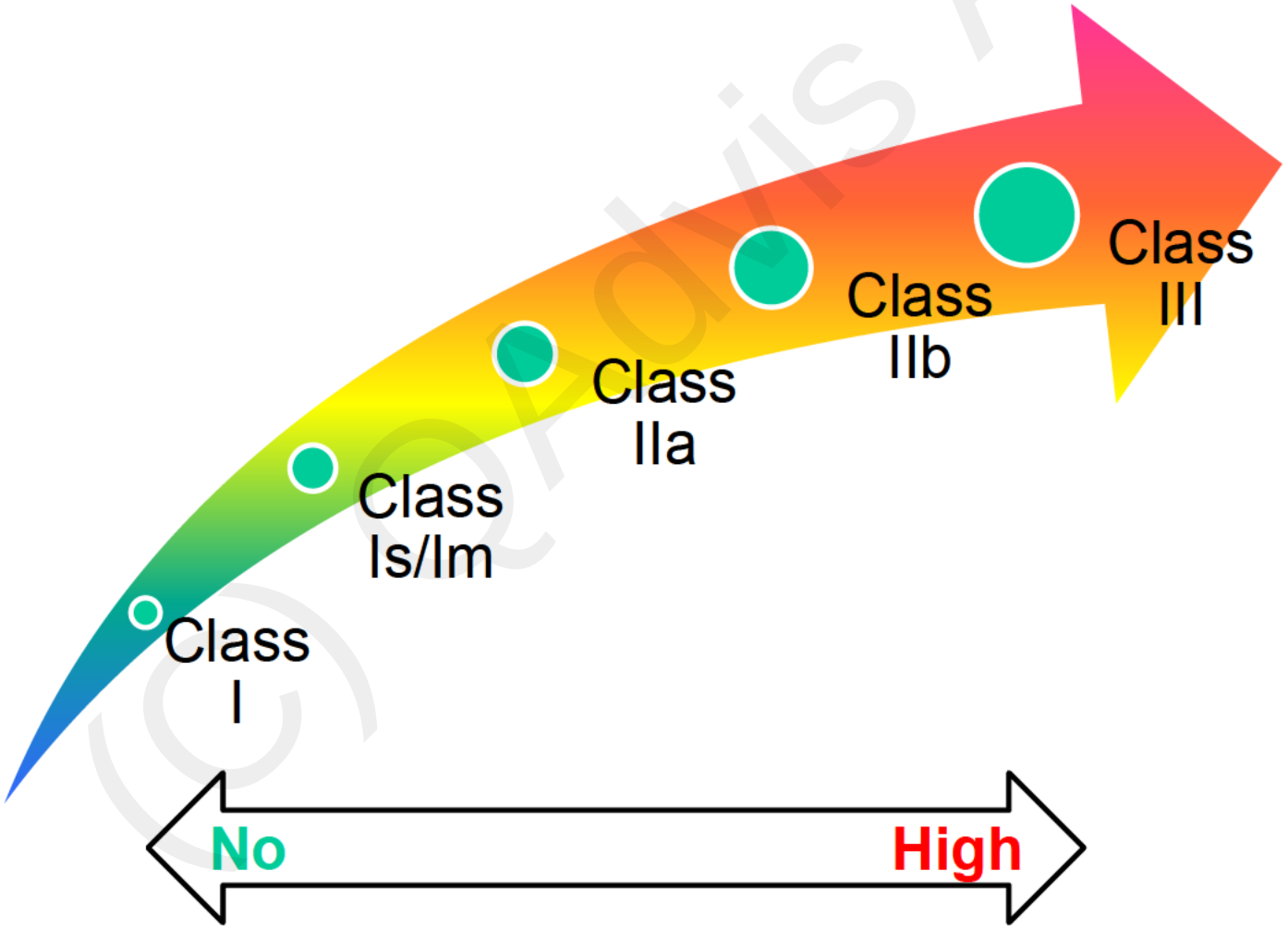
SFS 1993:584

LVFS 2001:5 AIMD
LVFS 2003:11 MD
LVFS 2001:7 IVD
LVFS 2001:8 Vigilance

Example: Swedish implementation

Example: Intertek, BSI, DNV, KEMA and more

The involvement of a Notified Body increases with patient risk



A CE-marked component makes the life much easier for the manufacturer

The first step to get the CE mark is to find the class of your products

For Medical devices under MDD:

Class	Description of route	NB mandatory
Class III Class IIb	Full Quality Management System	Yes
Class IIa Clas Is Class Im	Full Quality Management System Parts of QMS in Production testing	Yes
Class I	Full QMS (Certified) Full QMS (Not certified) Self certification for relevant parts of QMS	No

Many manufacturers with SW based products end up with the full QMS

For Medical devices under MDD:

Class	Description of route	NB mandatory
Class III Class IIb	Full Quality Management System	Yes
Class IIa Clas Is Class im	Full Quality Management System ~~Parts of QMS in Production testing~~	Yes
Class I	Full QMS (Certified) Full QMS (Not certified) ~~Self certification for relevant parts of QMS~~	No

There is a similar schema for In-Vitro devices

For IVDs:

Class	Description of route	NB mandatory
List A	Full Quality system Partly Quality system + Production testing	Yes
List B	Full Quality system Partly Quality system + Production testing Product testing	Yes
Self-Test IVDs	Full Quality system Partly Quality system + Production testing Product testing Design examination	Yes
General	Self certification (Full QMS … Partly)	No

Also here manufacturers of IVDs with SW end up with a full QMS

For IVDs:

Class	Description of route	NB mandatory
List A	Full Quality system ~~Partly Quality system + Production testing~~	Yes
List B	Full Quality system ~~Partly Quality system + Production testing~~ ~~Product testing~~	Yes
Self-Test IVDs	Full Quality system ~~Partly Quality system + Production testing~~ ~~Product testing~~ ~~Design examination~~	Yes
General	Self certification (Full QMS ~~… Partly~~)	No

All routes have common components of control

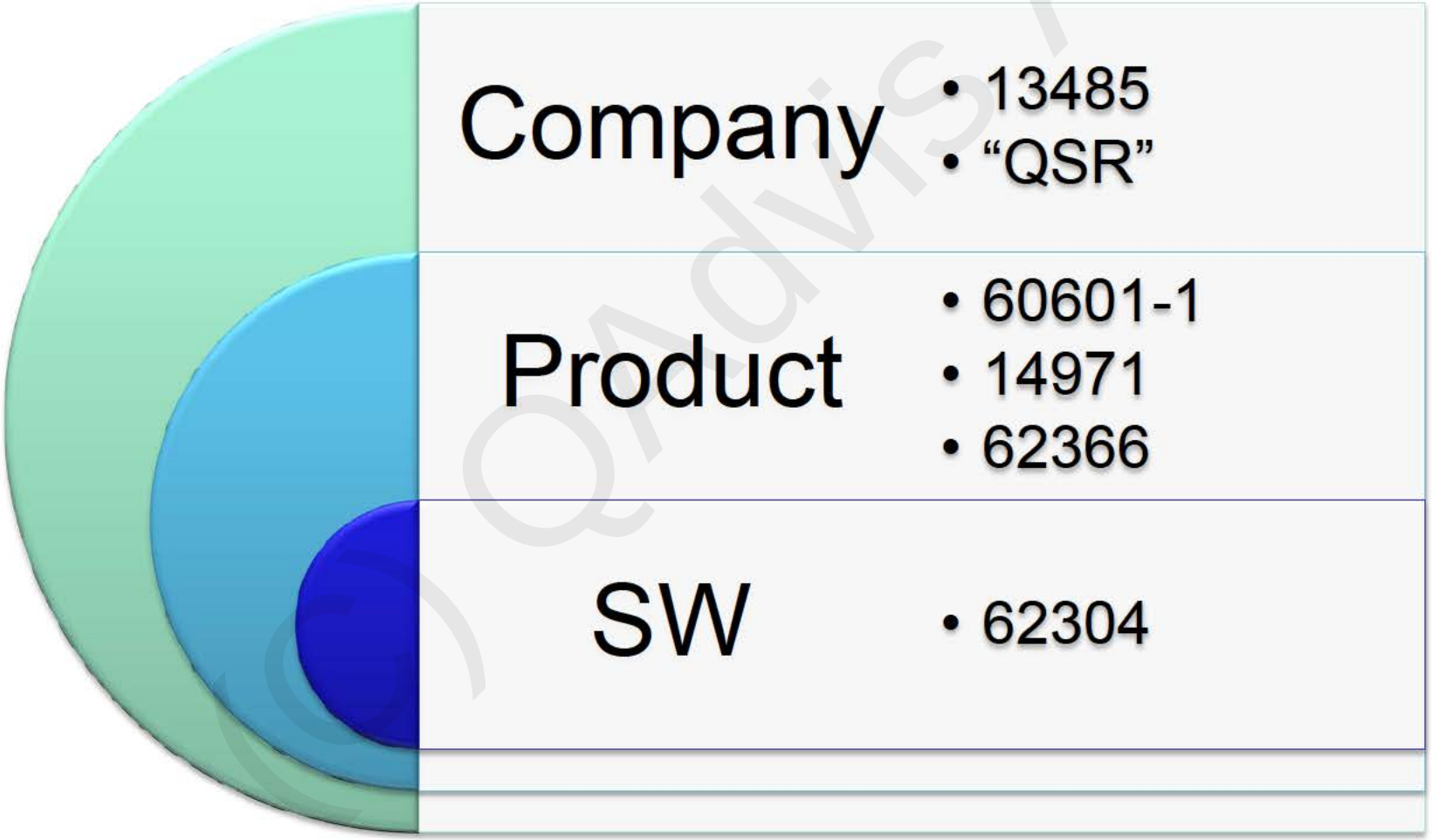
	Self declaration	NB verifies	Full QMS
Fulfil essential requirements	✓	✓	✓
Harmonized standards	✓	✓	✓
Risk management	✓	✓	✓
Post market surveillance	✓	✓	✓
Vigiliance	✓	✓	✓
Certification	✓	✓	✓
Archiving	✓	✓	✓

You need to prove the fulfillment of the Essential requirements in MDD/IVDD/AIMD

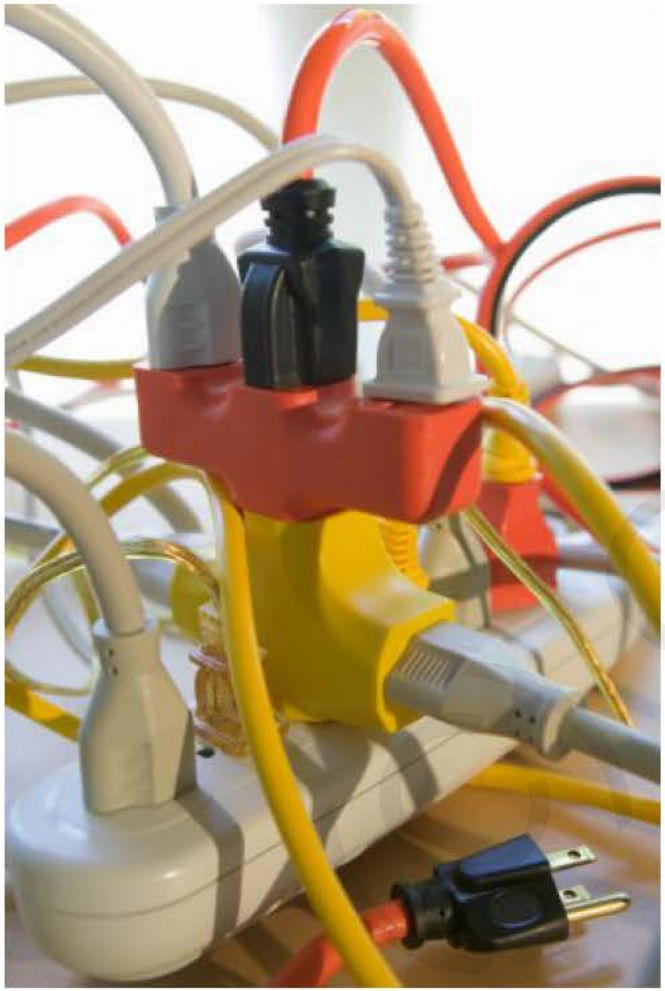
4. Essential Requirements Checklist

Essential Requirements	A/NA	Horizontal Standards
I. GENERAL REQUIREMENTS 1. The device must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	A	ISO 13485 ISO 14971
1 The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their	A	IEC 62366 ISO 13485 ISO 14971

Harmonized standards fulfill the Essential requirements

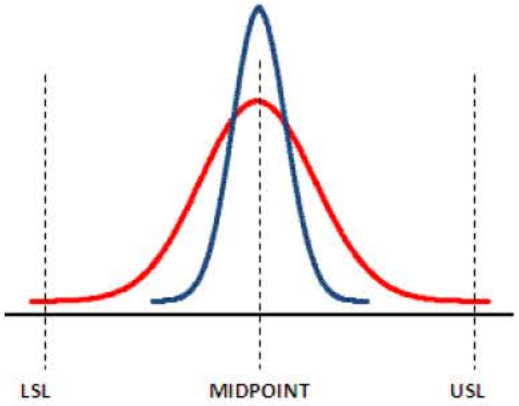


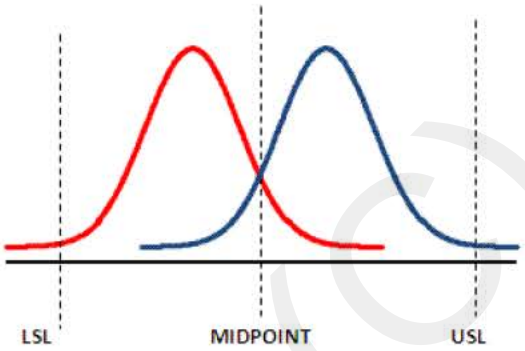
Complying to standards is voluntary, but …



- Presumption of conformity
- Alternatives
  - Equal
  - Better
- In reality “mandatory”

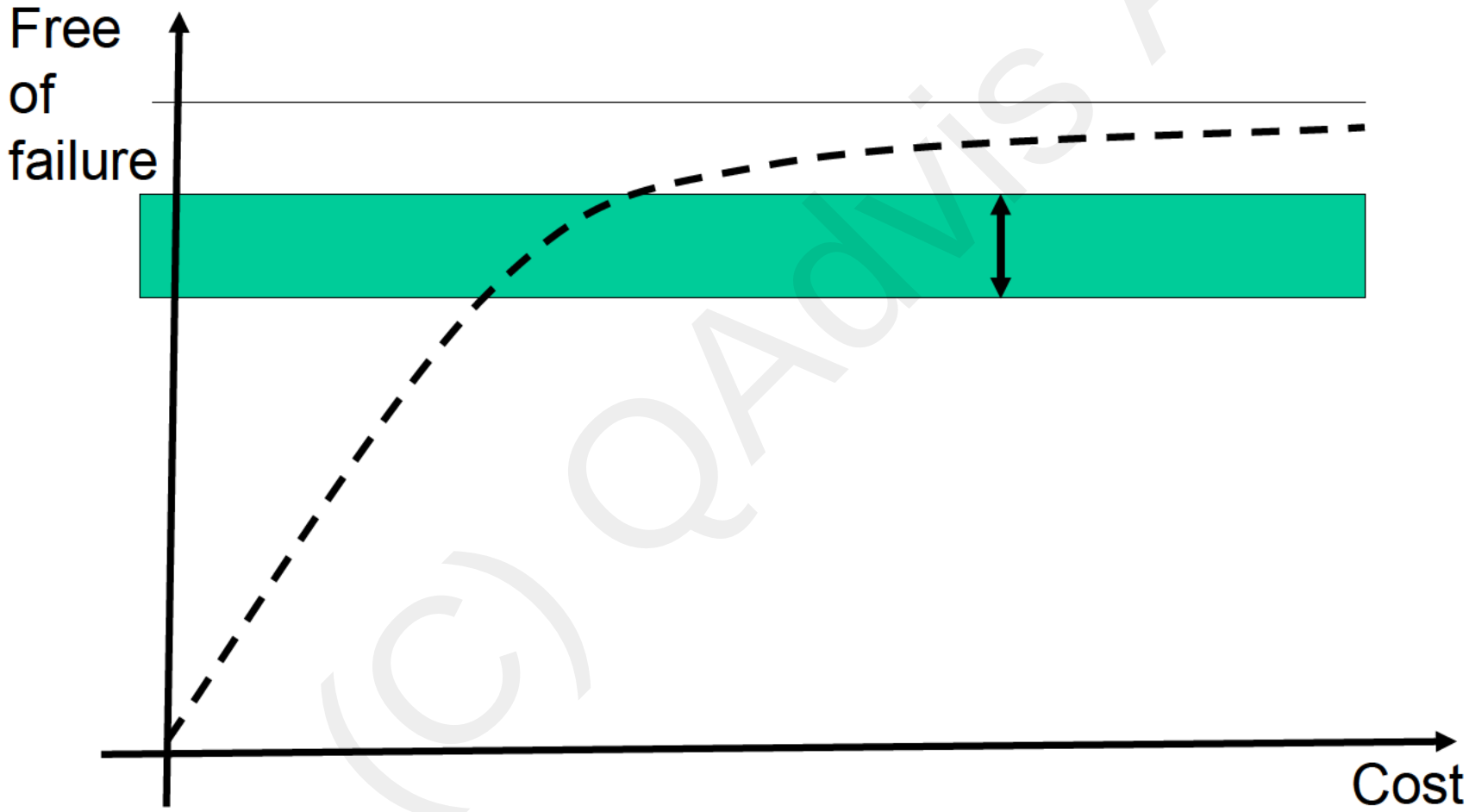
Why do we need a quality system?





Quality management is the basis in the medical device regulations

There is an optimal ratio between quality and cost



The content of ISO 13485 affects most parts of your company

- 0 Introduction
- 1 Scope
- 2 Normative references
- 3 Terms and definitions
- 4 Quality management system
- 5 Management responsibility
- 6 Resource management
- 7 Product realization
- 8 Measurement, analysis and improvement

The last four chapters in ISO 13485 are tightly connected to each other

0 Introduction

1 Scope

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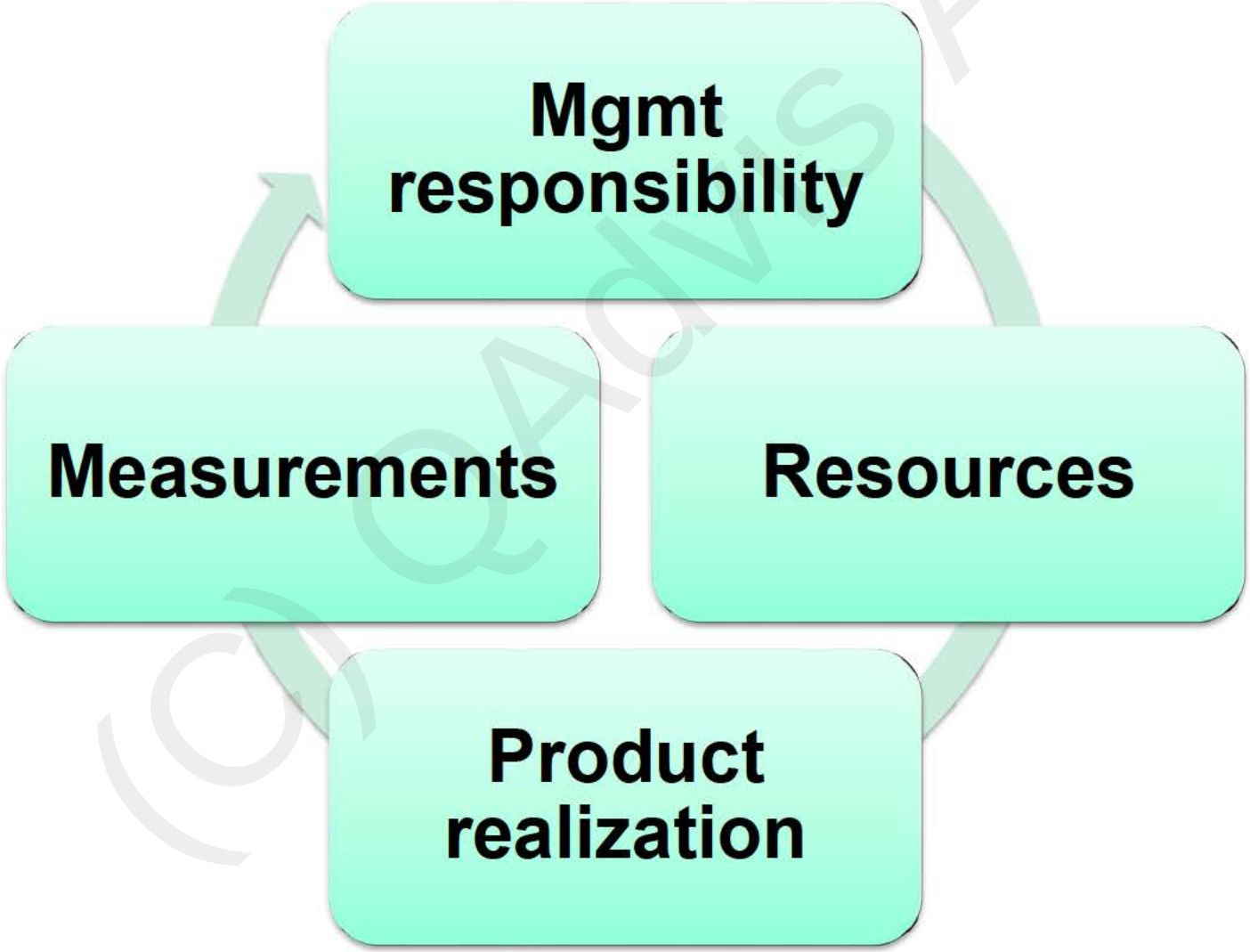
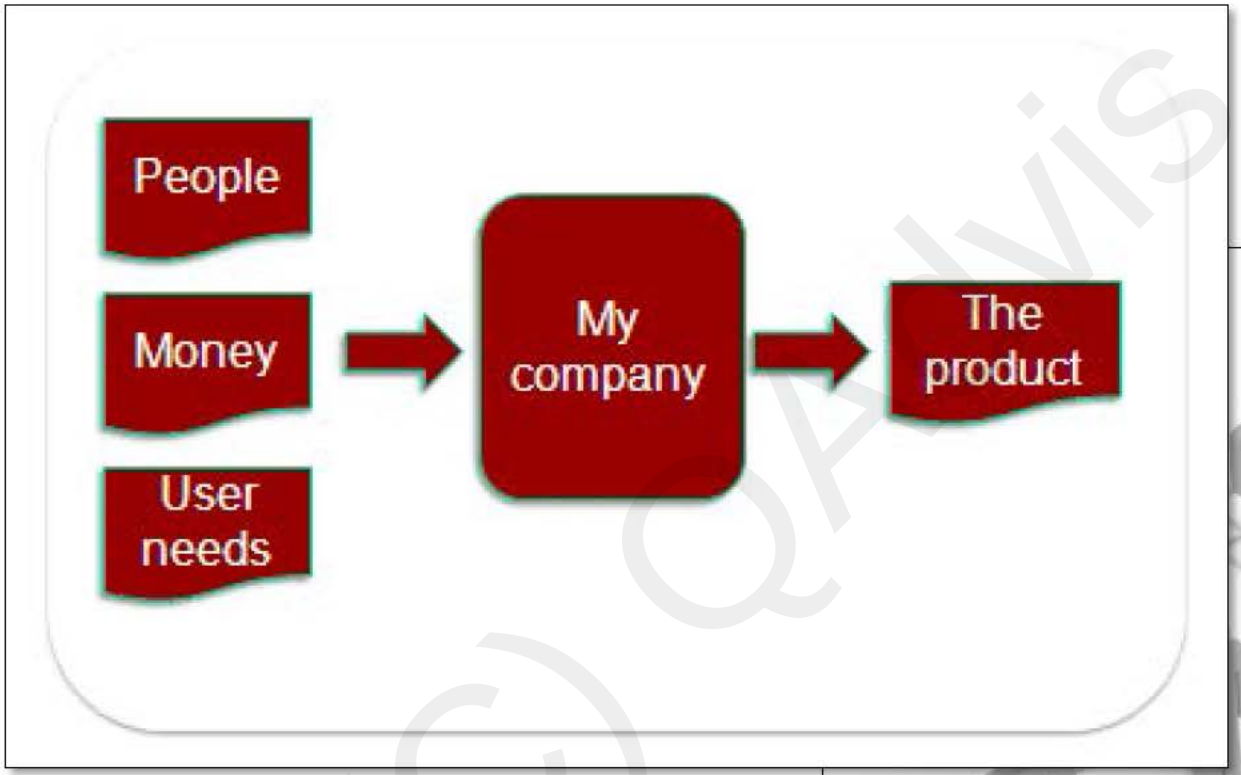
7 Product realization

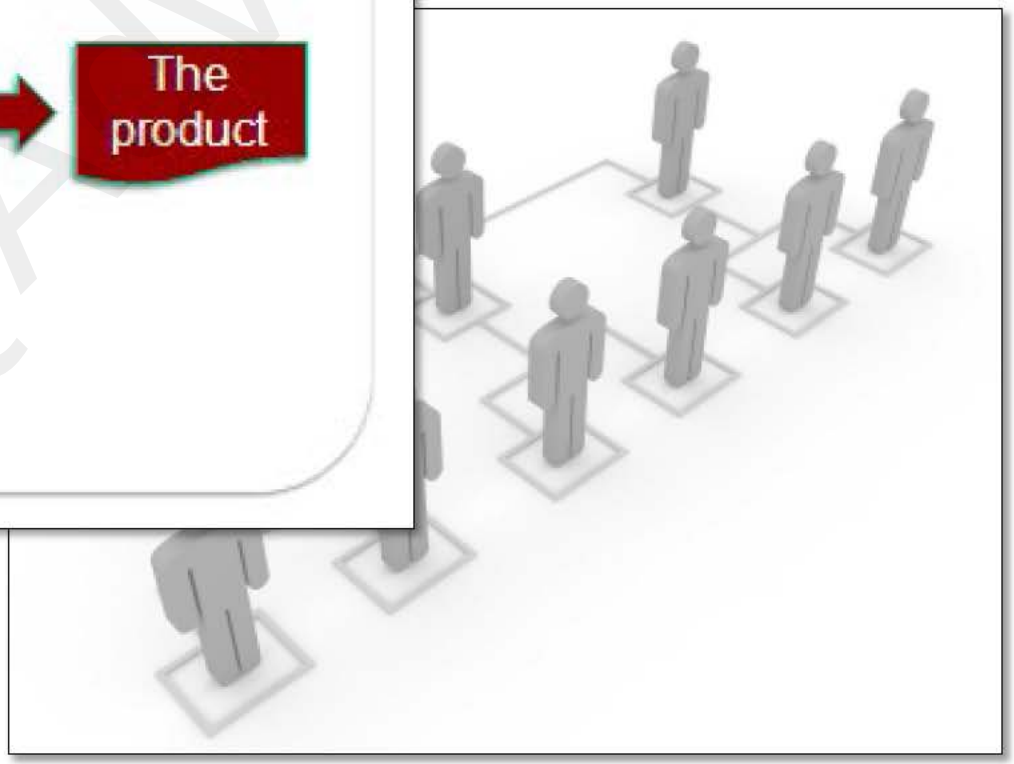
8 Measurement, analysis and improvement

There is a never ending loop with these four entities involved

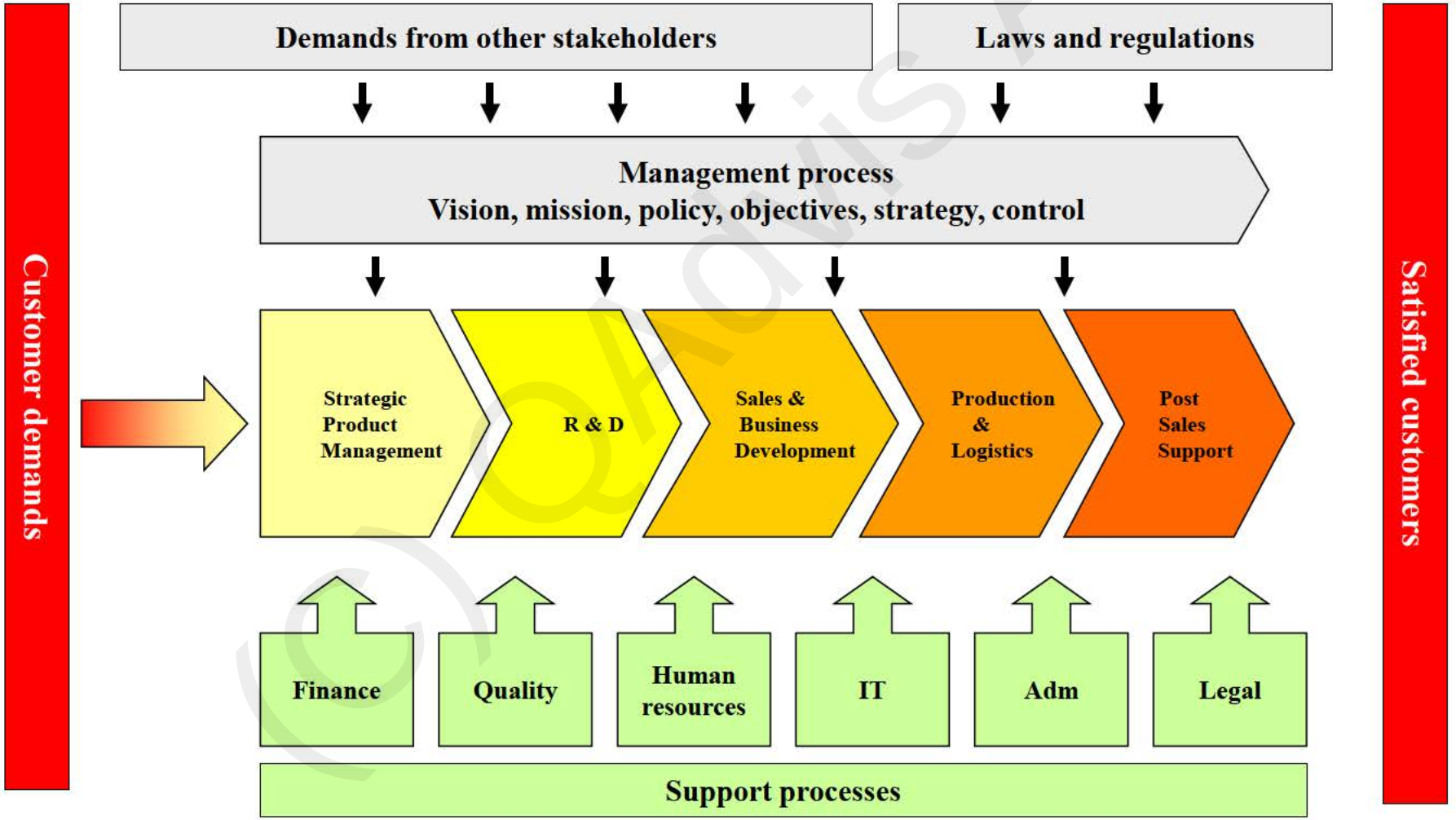


ISO 13485 calls for definitions of the company processes





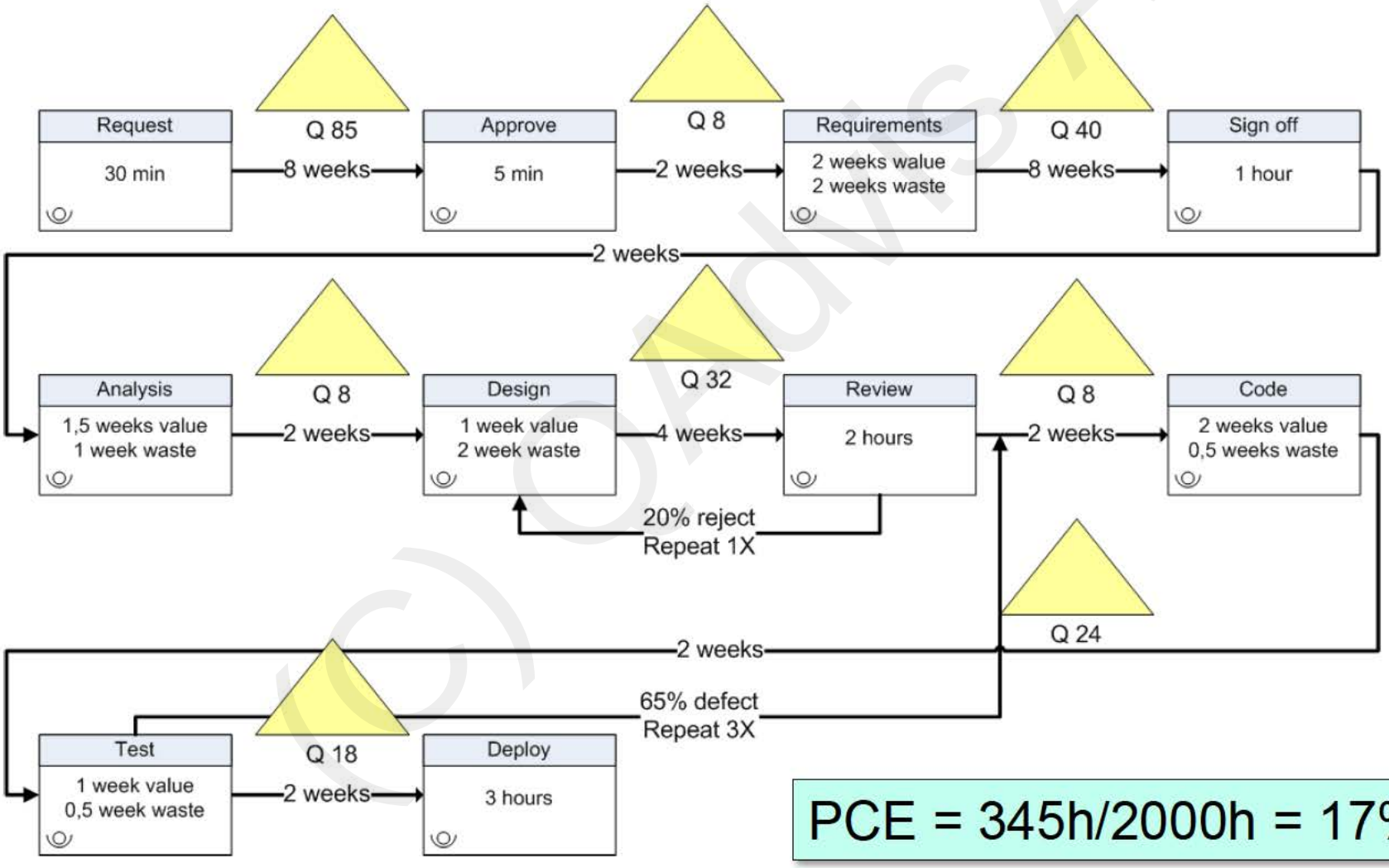
Modeling the whole company is a large task



How can QMS related activities improve your business?

A Lean process improvement technique is value stream mapping

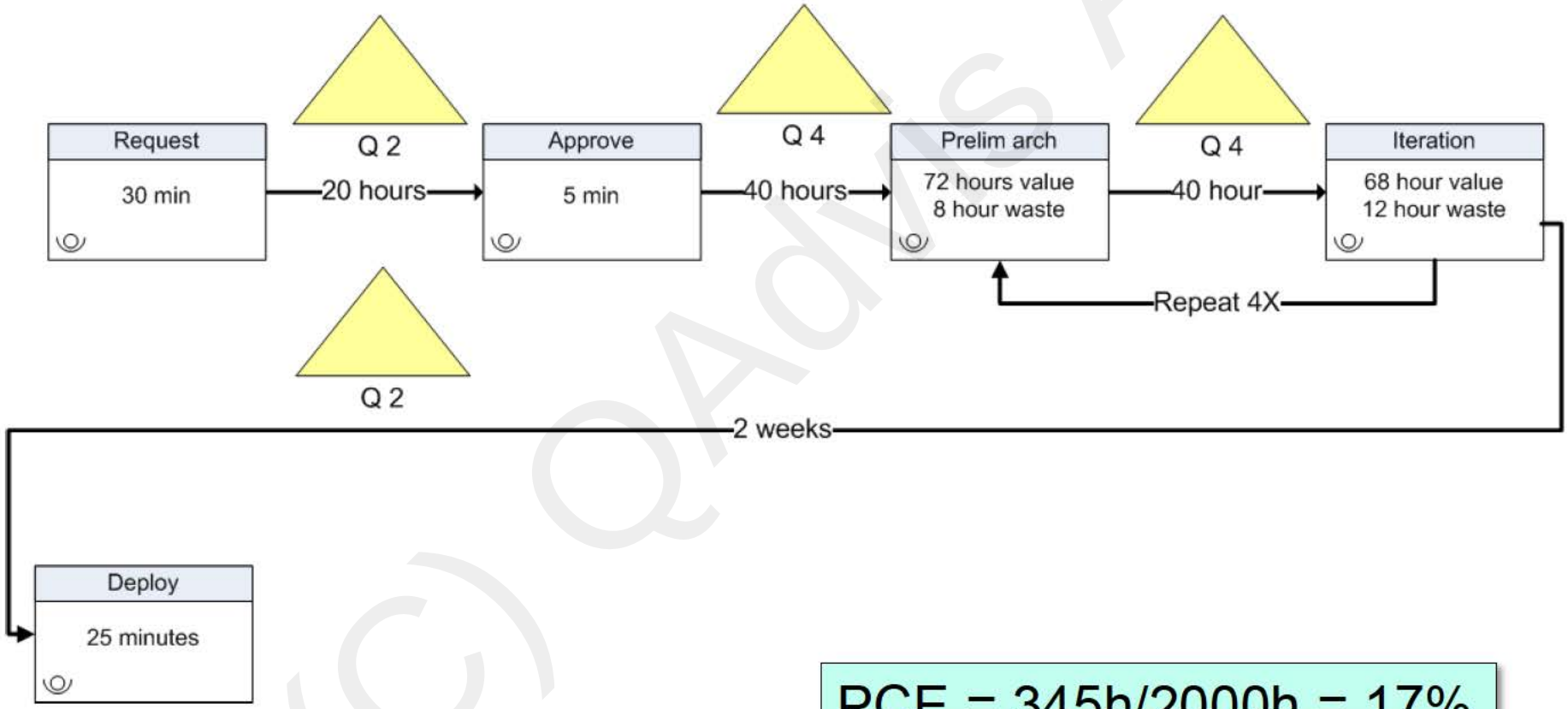
Example of value stream mapping of a process



PCE = 345h/2000h = 17%

We can refactor the process using a work cell approach

The refactored process is much more efficient



~~PCE = 345h/2000h = 17%~~

PCE = 345h/521h = 66%

Continuous improvements of the QMS can improve your business

- Changes take time
- Avoid intensive improvement programs
- Small steps
- Compliance and productivity
- Consider IT support from the first start

Our offer

- Implementation of QMS
- Development of product documentation
- Risk management
- Software validation
- Change management
- Training

QAdvis