Regulatory aspects of medical devices

Einar Heiberg, einar@heiberg.se

1

Conflicts of interest

- Founder and owner of Medviso AB
- Co-founder and co-owner of IMITS AB
- Consultant to Imacor AB

2

Purpose of the lecture

- Get basic knowledge about regulatory system for medical device.

3

Before we start: Numeric Analysis challenge

21 820 13485 14155 14971 19011 27002 62304 62366

4

Regulations covering medical device software

21 CFR 820
ISO 13485
ISO 14155
ISO 14971
ISO 19011
ISO 27002
ISO 62304
ISO 62366

5

What are medical devices?

- Is this a medical device?

6

What are medical devices?

- Is this a medical device?
- Depends on the software and how it is intended to be used
- Is software only a medical device?

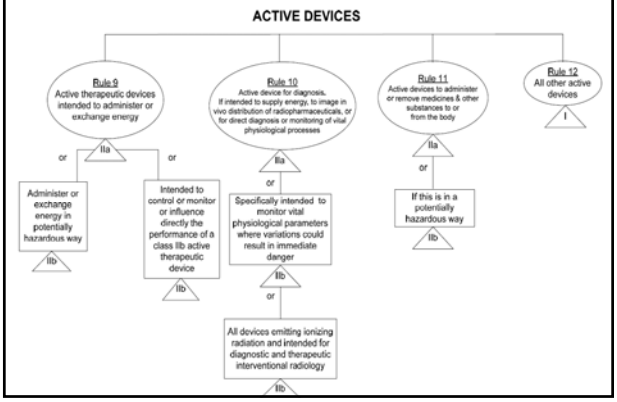
7

How are medical devices classified

- Non-invasive devices
- Short term invasive devices
- Long term invasive devices
- Active devices

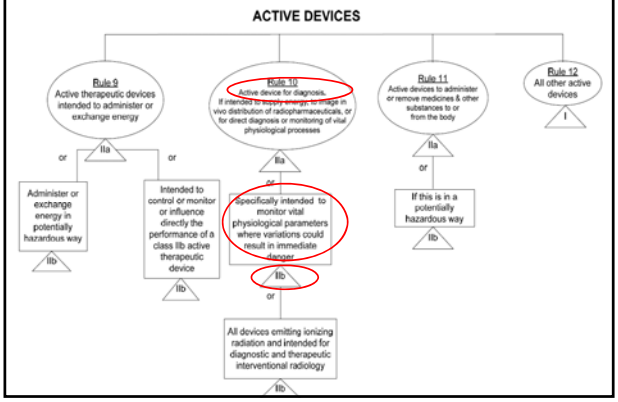
8

Classification (EU)



9

Classification (EU)



10

What regulations are there?

- European union CE-mark and the Medical Device Directive (MDD 93/42 EEC)
- USA have (FDA) Food and Drug Administration.
- Canada: Canadian Medical Device Conformity Assessment System (CMDCA)
- China: CFDA (system is currently revised)

…

11

MDD 93/42 EEC

- Have to conform to several standards (exact list depends on type of device)
- Medical device manufacturing requires a quality management system (ISO13485)
- Depending on device you need to follow specified standards

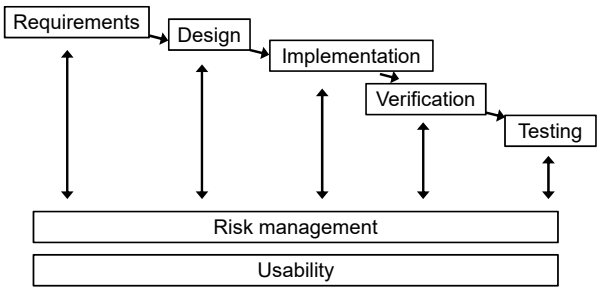
12

What is a Quality Management System?

- Documented procedures on how all things in the company are performed that affects quality.
- Medviso have 27 documented operational procedures covering; design, continual improvements, risk analysis, documentation, testing, purchasing, distribution…
- Started with commercially available system that we have adopted during the years

13

Development process under regulatory systems



14

Development process under regulatory systems

- Traceability is the key. All steps in the chain should be traceable.
- Solution to this challenge is to use a electronic version control system with an integrated issue tracker.
- Many documents needs to be formally approved. Digital signature systems (that are regulatory compliant) is a big help.

15

Implications

- Everything starts with good formulated requirements and well balanced claims
- Instructions for use is a key document
- User manual needs to be available on most of the European languages (countries have different rules).
- Write your operating procedures with great care to avoid unnecessary work.

16

Structure of an FDA application

- 510(k) notion
- Core section is indications for use and substantial equivalence
- 20 sections
- 62 appendices (about 1 500 pages).
- Fix sum to FDA (~30 000 SEK) + yearly fee of about ~30 000 SEK
- Small company is less 100M USD turnover.
- Review cycle is about 90 days.

17

FDA and machine learning

- FDA will likely not within the coming decade approve systems that continuous to learn after they are dispatched
- Once the system is improved it needs to be re-released

18

CE-mark process

- Different routes
- Certification against ISO 134685 followed by an inspection of the “Technical File”.
- Technical File is a collection of documents describing the development and validation of the product.
- Important part of the Technical File is to ensure that all essential requirements for the device are fulfilled. This is done by for each criteria have an objective documentation.
- Review is done by third party notified body (paid by the hour of about 2 000 SEK). Cost of the review was about 150 000 SEK. Yearly cost about 50 000 SEK.

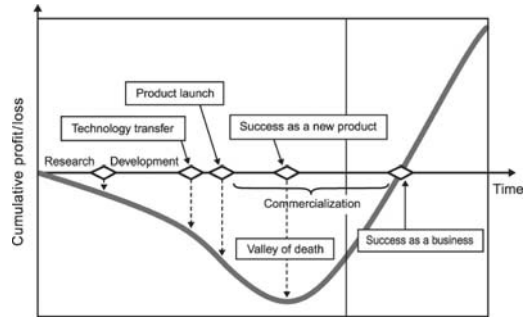
19

Taking software from research to commercialization

- As soon as possible when you realize that you need approval, implement a Quality Management System.
- Revision control is key.
- ”Re-design” the software with all documentation. Take the old code go through all documentation steps in order.
- Hospitals can of course evaluate software without approval. However, you are not allowed to market it without approval.

20

Valley of Death



21