Regulatory aspects of medical devices

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Conflicts of interest

• Founder and owner of Medviso AB
• Co-founder and co-owner of IMITS AB
• Consultant to Imacor AB
Purpose of the lecture

• Get basic knowledge about regulatory system for medical device.
Before we start:
Numeric Analysis challenge

21   820 13485 14155 14971
19011 27002 62304   62366
Regulations covering medical device software

21 CFR 820
ISO 13485
ISO 14155
ISO 14971
ISO 19011
ISO 27002
ISO 62304
ISO 62366
What are medical devices?

• Is this a medical device?
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?
How are medical devices classified

- Non-invasive devices
- Short term invasive devices
- Long term invasive devices
- Active devices
Classification (EU)

ACTIVE DEVICES

**Rule 9**  
Active therapeutic devices intended to administer or exchange energy

- Administer or exchange energy in potentially hazardous way
  - IIb

- Intended to control or monitor or influence directly the performance of a class IIb active therapeutic device
  - IIb

**Rule 10**  
Active device for diagnosis. If intended to supply energy, to image in vivo distribution of radiopharmaceuticals, or for direct diagnosis or monitoring of vital physiological processes

- Specifically intended to monitor vital physiological parameters where variations could result in immediate danger
  - IIa

- or
  - IIb

**Rule 11**  
Active devices to administer or remove medicines & other substances to or from the body

- If this is in a potentially hazardous way
  - IIb

**Rule 12**  
All other active devices

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)
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
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
Development process under regulatory systems

- Requirements
- Design
- Implementation
- Verification
- Testing

Risk management

Usability
Development process under regulatory systems

• Traceability is the key. All steps in the chain should be traceable.

• Solution to this challenge is to use an electronic version control system with an integrated issue tracker.

• Many documents need to be formally approved. Digital signature systems (that are regulatory compliant) is a big help.
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.
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.
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.
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.
Valley of Death