WORKSHOP FROM GARAGE TO MARKET

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Practicalities

• Is it a Medical Device (MDD, AIMD, IVD)?

• What class Medical Device ?0
  • Quality System constellation
  • Notified Body interaction

• The Project
  • The Device
    • Directive requirements, standards, labelling
    • Upload and maintenance in appstore
    • Device changes
  • The Quality System
Is it a Medical Device

• Needs to meet definition of Medical Device (likely MDD but can also be AIMD or IVD)
  • as supplemented by EU guidance documents on
    • MEDDEV 2.4/1 Classification of medical devices
    • MEDDEV 2.1/6 Qualification and Classification of stand alone software
  • and in accordance with National guidelines
    • UK MHRA guidelines
    • Swedisch Competent Authority: Proposal for guidelines regarding classification of software based information systems used in health care
    • Netherlands IGZ very limited guidelines
Is it a medical device?

- Medical device is any [article including software] whether used alone or in combination with device including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application,
- intended by the manufacturer to be used for human beings for the purpose of
  - diagnosis, prevention, monitoring, treatment or alleviation/compensation of disease or handicap
  - investigation, replacement or modification of the anatomy or of a physiological process
  - control of conception
- General purpose software used in healthcare setting is not medical device (recital 6 Directive 2007/47)
- Accessories to devices are regulated as devices in their own right
MEDDEV 2.1/6
medical devices
simple version

1. Computer program?
2. Stand alone?
3. What action does it perform on data? [beyond storage, archival, lossless compression, simple search]
4. For benefit of individual patients?
5. Intended purpose in scope of MDD?
6. Accessory?
MEDDEV 2.1/6 IVDs simple version

1. In scope MDD?
2. In scope IVDD?
3. Data obtained only from IVD?
4. Data obtained from medical device?
5. Accessory?
6. Accessory?
Health and Well-being?

• EU concept of medical device is binary – yes or no?
• Medical as opposed to general health/well-being -> no EU position yet
• Green Paper from European Commission
• EU Court (Brain Products case C-219/11) on definition of “medical device”:
  • requires “medical context” as opposed to non-medical use, e.g. in sports
  • regulate from a public health protection perspective (risk to user)
Regulatory slippery slope

Avoid scope creep of intended purpose as result of use of changing functionality description (e.g. expanding scope of functionality over time) – use of language in label, instructions and marketing is crucial.
What class? (MDD only)

- Classification according to Annex IX MDD (guidance MEDDEV 2.4/1 Classification of medical devices)
- Confirm classification with third party experts or Notified Body
- Wrong classification makes device illegal

Class I allows for self certification

Class IIa, IIb, require

1) approval of the Tech File by the Notified Body
2) approval of the EN ISO 13485 certified Quality System
What class? (MDD only)

**ACTIVE DEVICES**

- **Rule 9**
  - Active therapeutic devices intended to administer or exchange energy
  - Administer or exchange energy in potentially hazardous way

- **Rule 10**
  - Active device for diagnosis
  - Intended to control or monitor or influence directly the performance of a class IIb active therapeutic device
  - Specifically intended to monitor vital physiological parameters where variations could result in immediate danger

- **Rule 11**
  - Active devices to administer or remove medicines & other substances to or from the body
  - If this is in a potentially hazardous way

- **Rule 12**
  - All other active devices
Route to CE mark MDD and AIMDD

CONFORMITY ASSESSMENT PROCEDURE
+ CERTIFICATES FOR AIMD AND MDD

ANNEX 2
Full Quality Assurance System
Design Dossier
Examination by Notified Body
EC Declaration of Conformity
Evaluation and Surveillance by the Notified Body

ANNEX 2
Full Quality Assurance System
Technical File
EC Declaration of Conformity

ANNEX 3
EC Type Examination
Examination done by the Notified Body

ANNEX 4
Statistical Verification
EC Verification
Evaluation and Surveillance by the Notified Body
approval done by Notified Body

ANNEX 4
Production Quality Assurance
EC Declaration of Conformity
approval done by Notified Body

ANNEX 5
EC Declaration of Conformity
approval done by Notified Body

ANNEX 6
Product Quality Assurance
EC Declaration of Conformity
approval done by Notified Body
Self-certification with documentation available

ANNEX 7
EC Declaration of Conformity
CE-Mark with Identification-number of Notified Body
CE-Mark
Route to CE mark IVD
The project

It’s a medical device, so get acquainted with

• Essential Requirements
• Harmonized Standards
  • Software lifecycle, usability, clinical evidence
• Change Control
• Control over subcontractors
• EU Language Requirements
• Associated Directive Requirements (R&TTE)
• Declaration of Conformity
• Manufacturer/Authorized Representative
  • Establishment
  • Responsibilities
    • Compliance to Directives
    • Post Market Surveillance
    • Communication to Competent Authorities / Notified Bodies
• Role of Competent Authority
The project

Minimum following medical device standards apply that related to software

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN 62304:2006</td>
<td>Medical device software - Software life-cycle processes</td>
</tr>
<tr>
<td>EN 62366:2008</td>
<td>Medical devices – application of usability engineering to medical devices</td>
</tr>
<tr>
<td>EN ISO 14971:2012</td>
<td>Medical devices – application of risk management to medical devices</td>
</tr>
<tr>
<td>MEDDEV. 2.7.1 - 3</td>
<td>CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES</td>
</tr>
<tr>
<td>EN 980:2008</td>
<td>Symbols for use in the labelling of medical devices</td>
</tr>
<tr>
<td>EN1041:2008</td>
<td>Information supplied by the manufacturer with medical devices</td>
</tr>
<tr>
<td>&lt;tbd&gt;</td>
<td>&lt;any application specific (harmonized) standard&gt;</td>
</tr>
</tbody>
</table>
The project

Challenges

• What if app has already been (largely) built?
• What if app is already in the appstore?
• What if the modelling per EN 62304 does not fit your process?
• What if you don’t have the application specific test facilities (e.g. at hearing applications, diabetic control)
• Is the usability data and clinical data meeting the expectations?
• The IFU

• EU personal (health) data regime
  • Perform Privacy Impact Assessment (PIA)
  • Implement privacy by design
  • Fulfill requirements for international personal data transfers
  • Make national notifications
  • Hosting agreement should be data protection law compliant
  • Privacy policy / informed consent
The project

• Upload in appstore / Google Play when CE marked (not before)

• Meet EU language requirements for medical devices (we only have 24 languages)

• How to implement corrective action technically?

• Does update affect the Technical File?
The project

Quality System

- For Class I devices the Quality System dimensions particularly focus on Change Control, Post Market Surveillance, communication to Competent Authorities (Annex VII)

- For Class IIa and Class IIb devices the manufacturer shall establish a (EN ISO 13485 based) Quality System
The project

The EN ISO 13485 based Quality System

• For Class IIa and Class IIb devices the manufacturer shall establish an (EN ISO 13485 based) Quality System
• This Quality System + the app designed and manufactured under that Quality System shall be audited by a Notified Body
  • Audit on the Tech File
  • Audit on the Quality System

Selection process of the Notified Body

• Discuss with more than one Notified Body
• Field of Expertise
• Select one of the “big ones”
The project

The EN ISO 13485 based Quality System requires at minimum Quality Manual plus a set of SOPs for

- Document Control
- Management Review
- Resource management
- Internal Audit
- Product Realization
- Purchasing
- Change Control
- Complaint Management
- CAPA
- Risk Management
- Training
- Clinical Evaluation
- Usability
- Calibration and Maintenance

- Plan for 10-12 months lead time
The project

CE certified, and then?

- Address changes in product, changes in regulations in Tech File (and communicate to Notified Body as required)
- Actively implement Post Market Surveillance
- Implement vigilance
- Continues training employees on regulated environment
- Maintain control over crucial subcontractors and critical suppliers
- Expect unannounced audits (class IIa/IIb)
THANKS FOR YOUR ATTENTION

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