Challenges of Software Certification in the Medical Technology Industry

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Overview

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About me: Ilian Boyadjiev

- Student at TUM: Information Systems (Wirtschaftsinformatik) 2018 – 2022
  - MatrNr. 03682704
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- Became acquainted with Fortiss GmbH in 2020/2021
  - H. Ruess, Grundlagen der Programm- und Systementwicklung (IN2078)
- Seminar: Service Engineering
- Working student at Catenate GmbH since 2018
  - Backend software development for a business software tool (usage in marketing and sales)
  - Affinity for various project management tasks

General information about the writing process

- Formatting and tools:
  - LaTeX-Template and citation rules: https://www.in.tum.de/fuer-studierende/pruefungen-und-formalitaeten/abschlussarbeit/
  - Overleaf
  - Shared file storage by LRZ Sync+Share
- Language: English
- Official start date: 15.02.2022
- Official submission date: 15.07.2022
- Supervisor: Prof. Dr. Florian Matthes
- Advisors: Dian Balta, Yannick Landeck

Situation and context

- Medical devices are a fundamental component of every health care system
- Probability of failure → need for certification
- MDR effective since May 2021 (before that Medical Device Directive was effective)
- New major change to classification: practically there are no devices under Class I anymore
  → most devices are classified one class higher than before
  → need to involve a Notified Body

Prototype

- Manufacturer creates a new medical device

Technical documentation

- Device description,
- Device specification,
- Manuf. information,
- Clinical evaluation,
- Risk Management & analysis,
- Verification & validation records, ...

ASSESSMENT

Evaluation of:

- Tech. documentation
- Intended purpose
- Clinical data
- Safety & performance requirements
- Verification & validation
- ...

Product on market

- Time-to-market is delayed
- Innovation is challenged
- Increased amount of invested resources (both for manufacturer and Notified Body)

Research questions

From a startup perspective, we should research how obligations of the Regulation need to be fulfilled in order to place compliant devices on the market.

- What are the **main challenges** of MDR compliance?
  - Completeness of documentation, consistency of information
  - A method to **continuously verify** the technical documentation
  - Common reasons for rejection, why are there even challenges

- What **processes** are already in place to deal with the challenges?
  - Large scale manufacturing requires an **approach** to **continuously** ensure MDR compliance
  - What kind of processes are involved and what **tools/approaches** are involved
  - Who are the involved **stakeholders, roles**?
  - Transition process from MDD to MDR

- How can a **startup** bring a new product onto the Market?
  - Agile project management approaches are **not** really applicable to compliance projects
  - What processes are needed for small scale manufacturers

Main goal: Market analysis and identification of challenges, processes and strategies to ensure compliance with MDR

Approach

In order to successfully identify and categorize business procceses

- A series of **semi-structured interviews** should be conducted
- With **large** manufacturers like Arthrex GmbH, founded in Munich, 1981
- And **small** manufacturers (start ups)
- TUM Venture Labs

Approach

A **poster/landmap** is to be created that should contain

- a **summarized overview** of the main research topics and challenges,
- the **results** of the research
- the necessary process steps, measures and documents to successfully and efficiently develop a new compliant medical device from scratch.
- The landmap should serve as a **framework** applicable to startups.

In order to get a better grasp of the topics, the following sources are to be used

- R. Thür, S. Panten, and L. Vogler. “Medical Device Knowledge Units.” avasis solutions GmbH,
- Ben-Menahem, S.M., Nistor-Gallo, R., Macia, G. et al. "How the new European regulation on medical devices will affect innovation" (2020)
- T. Lukas, K. Sohrabi, V. Gross, M. Scholtes. "Health Software Product or Software as Medical Device" (2021)
- J. Mantas. "Legal Challenges for IT Service Providers in Pharmacogenomics." (2020)
- R. Ramki. “Regulatory Projects and Agile — Can they go together?” (2019)
- D. Beerbaum. “Applying Agile Methodology to Regulatory Compliance Projects in the Financial Industry: A Case Study Research.” (2020)
- Monir El Azzouzi. "Medical Device Easy Podcast"
- and more

Discussion

Thank you for your attention.