Challenges of software certification for startups in the medical technology industry

Ilian Boyadjiev, 18.07.2022, Bachelor Thesis Final Presentation

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Overview

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2. MDR Background
3. Methodology
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   - Identified Challenges for Start-ups
   - Stakeholder analysis
   - Framework to Approach MDR Certification
   - Timeline of MDR Certification
6. Conclusion

Motivation

- Medical devices are a fundamental component of every health care system
- To avoid failures the need for standardization is raised
- MDR replaces a previous directive with the main goal of introducing industry standards
- MDR calls for urgent business transformations

MDR Background

- Effective since May 2021

- Main goals of MDR
  - increase safety for patients
  - improve quality of medical devices on the market
  - standardization of medical devices across the European Economic Area

- Major changes compared to MDD:
  - new rules for classification of medical devices
    → most devices are classified one class higher than before
    → need to involve a Notified Body in the certification process
  - stricter control on Post-Market Surveillance plans
  - more requirements for the technical documentation
  - registration in the EUDAMED database

MDR Background

- According to the classification of the manufactured device, the obligations for manufacturers are:
  - apply a conformity assessment procedure and draw up a Declaration of Conformity
  - to appoint a Person Responsible for Regulatory Compliance (PRRC)
  - to conduct clinical evaluations
  - implement a QMS and RMS
  - implement a UDI mechanism
  - compile technical documentation
  - conduct Post-Market Surveillance and Clinical Follow-ups

Class I	Class IIa	Class IIb	Class III
Low risk	Low to medium risk	Medium to high risk	High risk
E.g. tongue depressors, FFP2 face masks, etc.	E.g. software with monitoring and/or diagnostic functions	E.g. software that monitors physiological processes	E.g. implants, defibrillators

Methodology: Research questions

1. What are the main challenges of MDR compliance?
   → Literature review
   → Goal: Identify pain-points for small manufacturers

2. What processes are already in place to deal with the challenges?
   → Semi-structured interviews
   → Goal: overview of the certification process, identify roles in the certification process and find how are challenges overcome

3. How can a start-up bring a new product onto the market?
   → Apply framework
   → Goal: streamline the necessary process steps towards certification according to MDR

Challenges for SMEs

Lack of clarity towards MDR requirements and obligations

- New classification rules
- Resources to discover what obligations apply
- Identify the necessary roles and activities

Source: N. McDevitt. “Challenges for the Regulatory Affairs Function in Demonstrating Compliance for Existing CE Marked Devices to the New EU Medical Devices Regulation 2017/745.” en. In: (2019),

Challenges for SMEs

Distribution of accountability
between the roles involved in the manufacturing process

Critical suppliers needs to comply with MDR

Using frameworks and libraries

Challenges for SMEs

Increase in certification costs

- Hire staff and allocate resources
- Case study: 5% - 10% of revenues go into certification
- In general, SMEs manufacture a small range of products

→ Mergers and acquisitions of medical companies can be expected

Source: P. Maresova, L. Rezny, L. Peter, L. Hajek, and F. Lefley. “Do Regulatory Changes Seriously Affect the Medical Devices Industry? Evidence From the Czech Republic.” eng. In: Frontiers in public health 9 (Apr. 2021)

Technical Documentation

Challenge: Completeness in content

- Documents missing
- Information missing

Required according to MDR Annex II + III

Device description, incl:

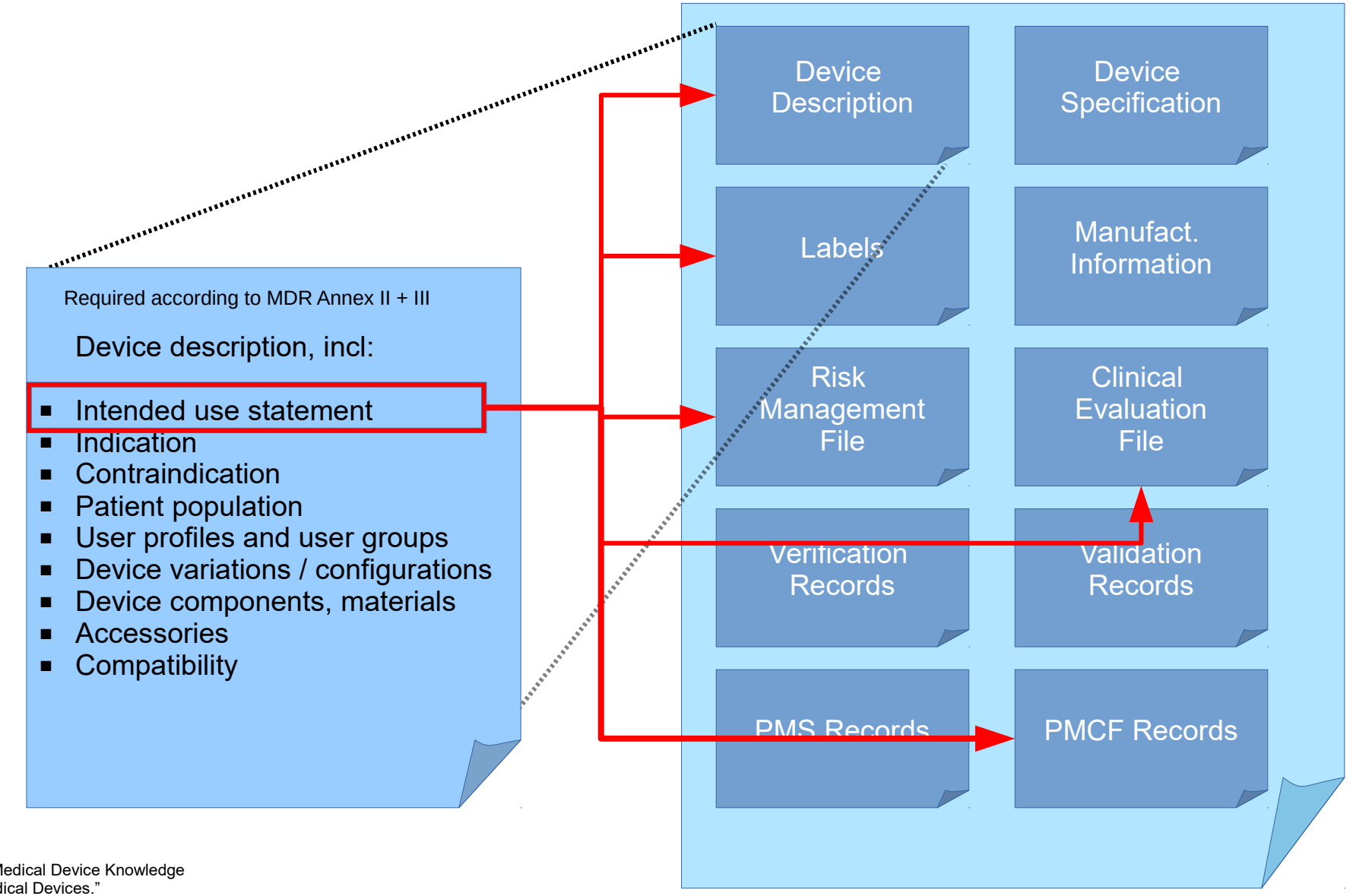
- ✔ Intended use statement
- ✔ Indication
- ✔ Contraindication
- ✔ Patient population
- ✔ User profiles and user groups
- ✗ Device variations / configurations
- ✔ Device components, materials
- ✔ Accessories
- ✗ Compatibility

Source: avasis solutions GmbH, R. Thür, S. Panten, and L. Vogler. “Medical Device Knowledge Units – A smart way to digitalize the Technical Documentation for Medical Devices.”

Technical Documentation

Challenge:
Consistency of information

- At least 37% of information is reused in at least one other document
- Information should be transferred across documents in a reliable way



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Technical Documentation

Challenge: Traceability across documents

- Changes must be traceable across all documents
- It must be clear how and which changes were triggered
- The change process needs to be managed, so that changes are controlled, carried out consistently, and completed.

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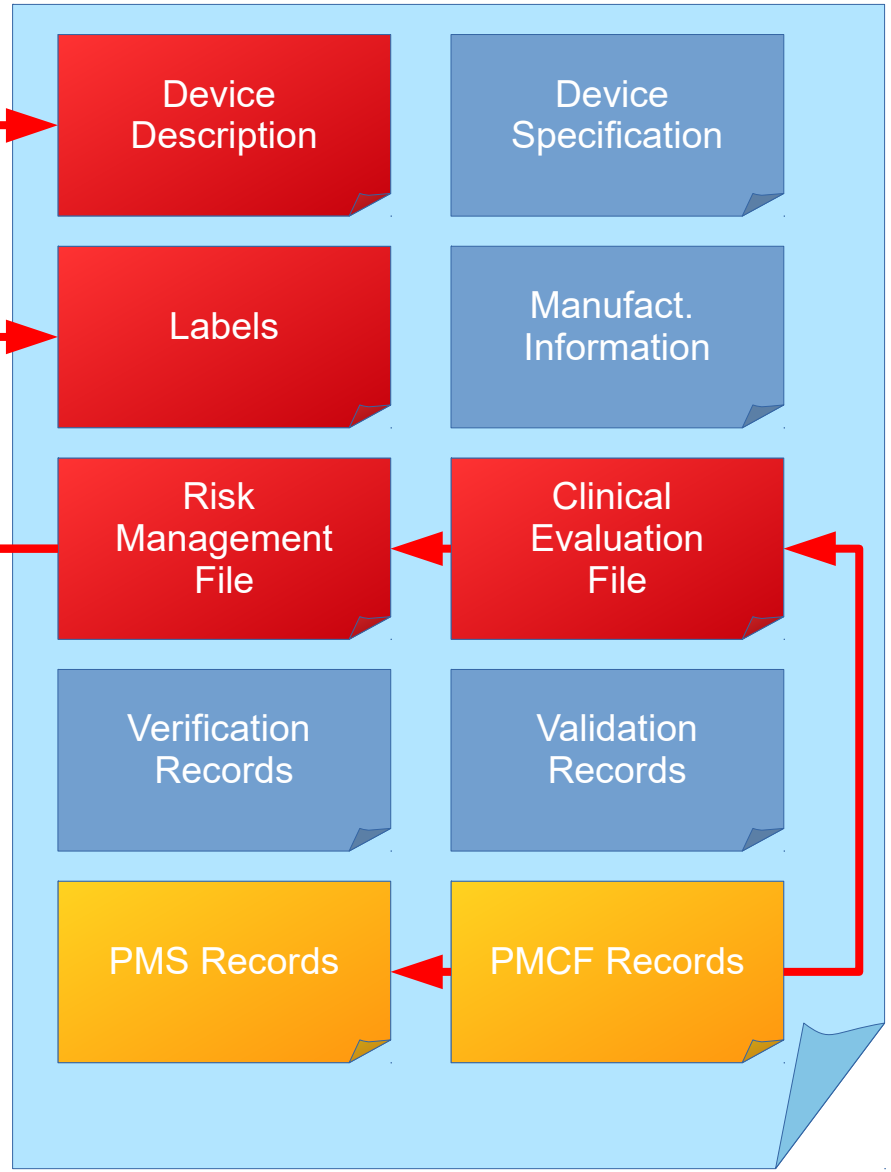


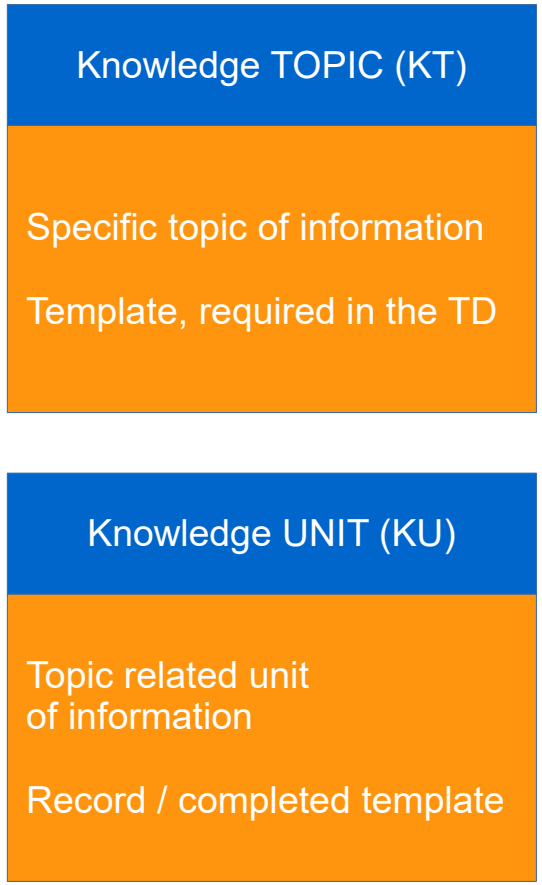
Source: avasis solutions GmbH, R. Thür, S. Panten, and L. Vogler. “Medical Device Knowledge Units – A smart way to digitalize the Technical Documentation for Medical Devices.”

Technical Documentation

Medical Device Knowledge Units

- „an innovative, open source ***data model*** for the medical device industry, whereby the contents of the technical documentation of medical devices can be efficiently mapped in digital form.“ (Avasis, MDKU, 2021)
- Idea: transfer of documents to individual ***knowledge units*** (KU), managed in a database.
- Knowledge units are assigned to topics (e.g. risk management, clinical evaluation, etc.) and are reused as required.

The creation and maintenance of technical documentation documents is **simplified** and **accelerated** through the use of existing knowledge units. In addition, **redundancies and inconsistencies are avoided**.



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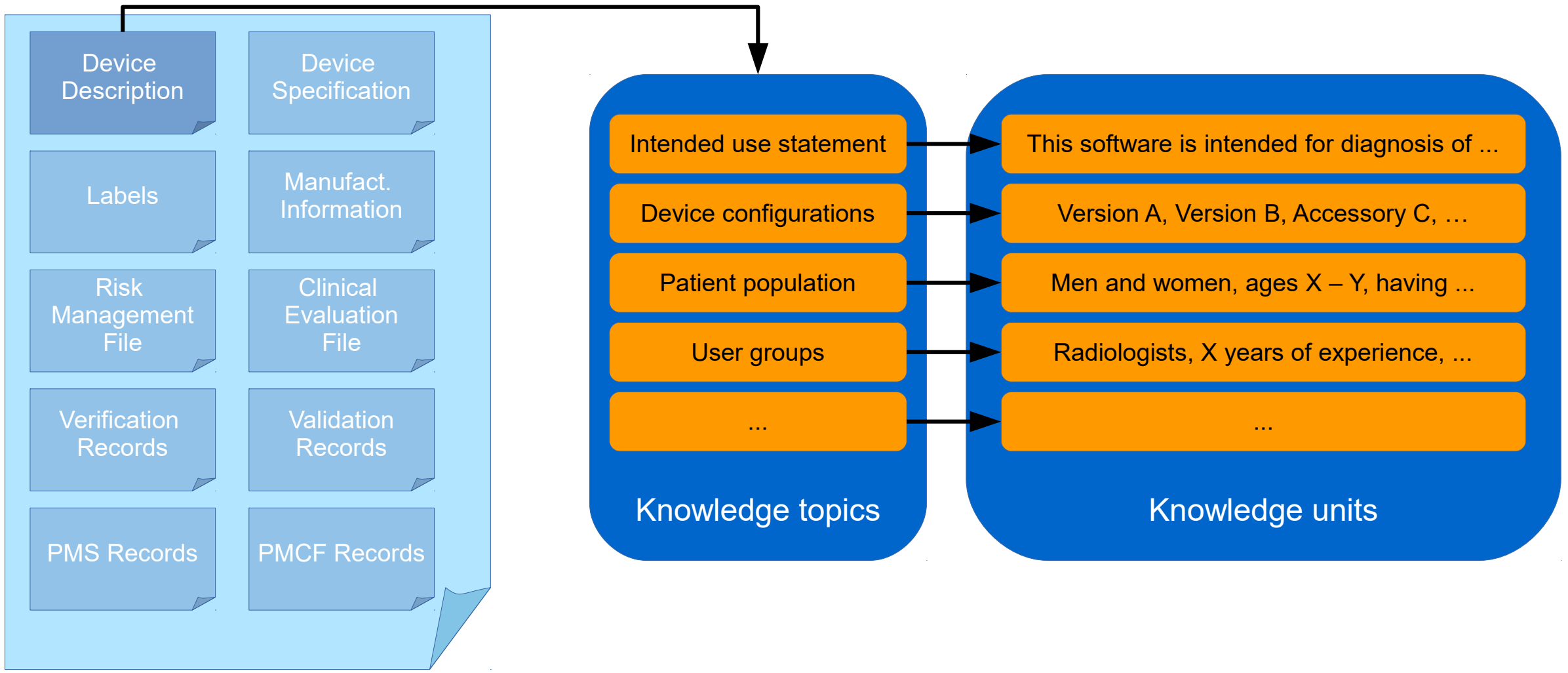
Technical Documentation



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Interrelations between challenges

		Challenges of MDR Compliance		
		Lack of Clarity	**Distribution of Accountability**	**Increase in Certification Costs**
Flaws of Technical Documentation	**Incompleteness of Content**	- Incorrect classification - Required procedures were not followed - crucial documents were not obtained - content of existing documents does not provide enough information.	- Splitting tasks between team members - Coordination between teams - Changes to business partners relations are costly	- Inaccuracies, contradictions or inconsistencies lead to additional invested time - Often flaws are discovered after the first audit - (Re-)Submission fees - Clinical examinations fees Corrections to documentation steal from product development time. Certification activities do not generate revenue for the company. Note: Notified Bodies charge variable fees depending on the product to be assessed.
	Inconsistency of Information	- new information does not contradict previous information		
	Impeded Traceability across Documents	- A new document can trigger a chain reaction requiring the replacement of previously valid papers. - Inability to effectively track changes	- Difficulty to replace or renew already processed files. - The amount of paper work increases and additional working hours are needed	

Based on own depiction

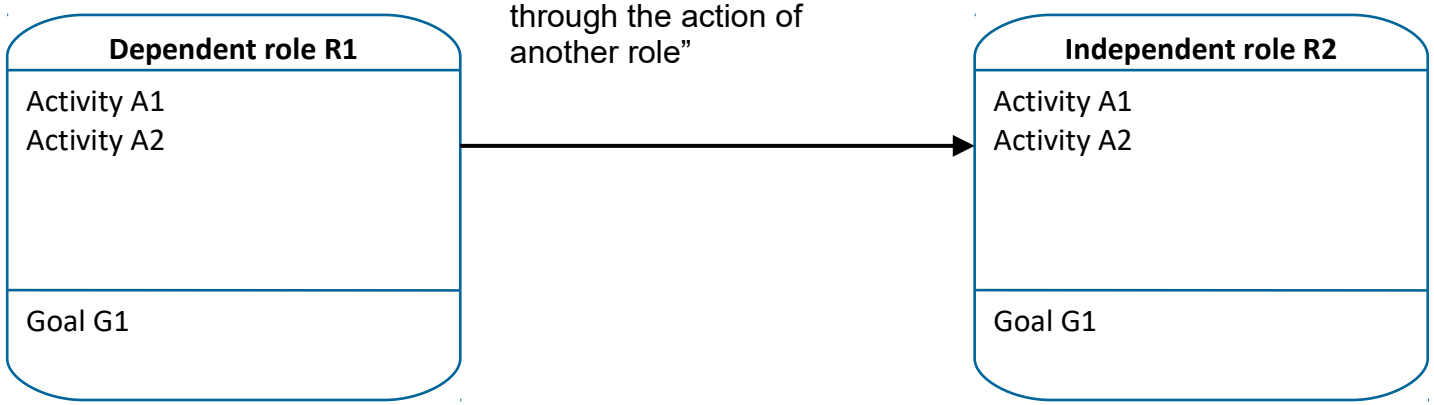
Dependency Network Diagram

Role R: “the encapsulation of a set of activities and goals [...]” represented by “individuals work groups, organizations […] sharing common activities and goals

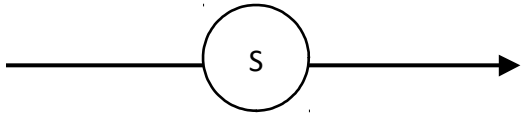
Activity An: “the means or procedure for the provisioning of material or informational resources necessary to achieve a goal”

Goal Gn: “a desirable or a suitable objective”

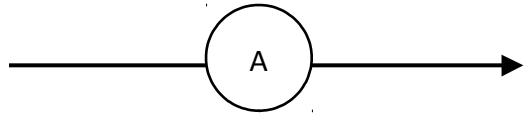
Dependency: “the need of one role to achieve a goal through the action of another role”



“The power of the dependency can be predominately ***symmetric*** (denoted as S) when “there are alternative sources available from which a needed activity or resource can be obtained.””



“The power of the dependency can be predominately ***asymmetric*** (denoted as A) when “it is difficult for the [dependent] role to find an easy replacement for the resource providing role, but not vice versa.””

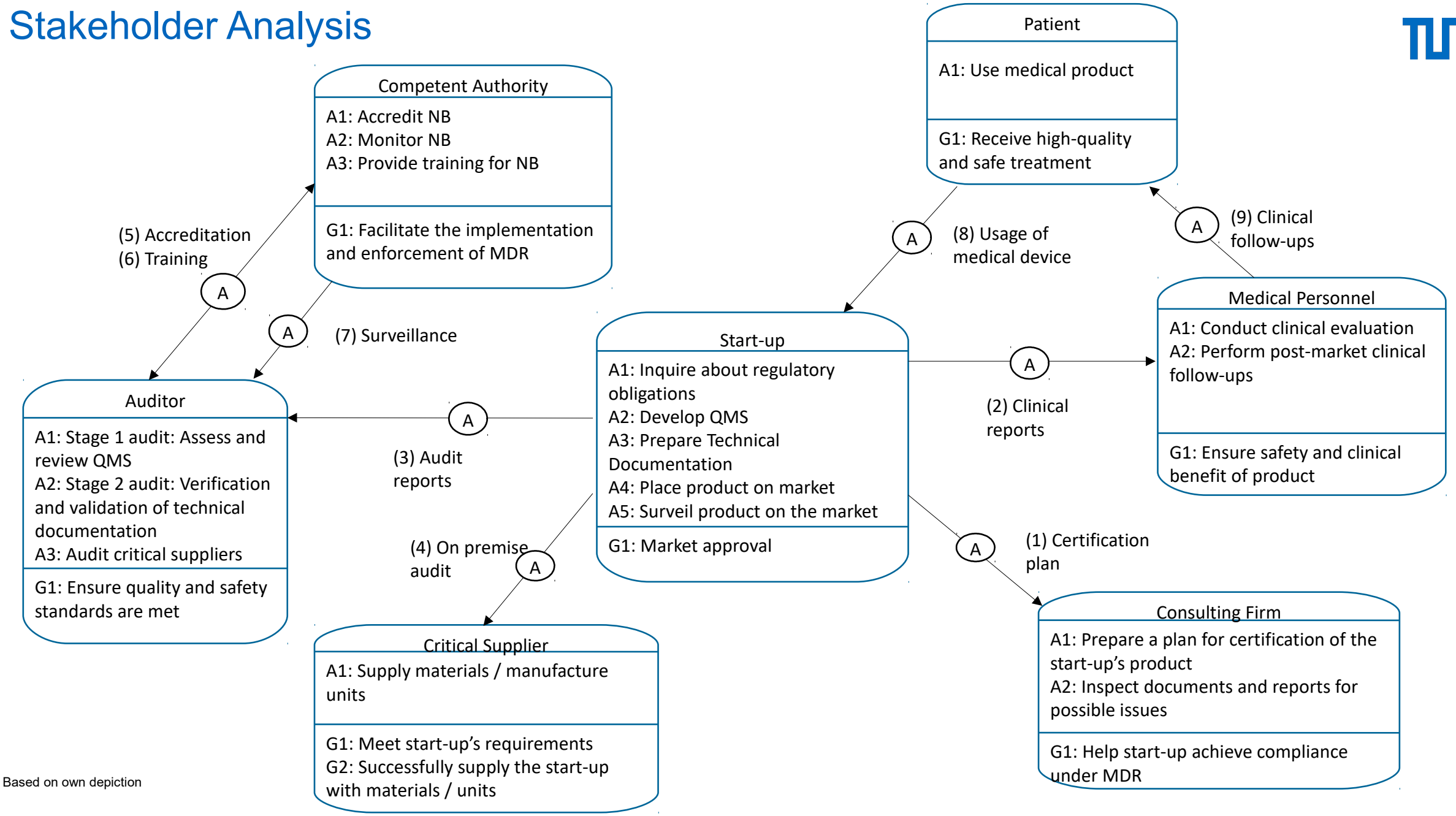


Sources:

Ulbrich, F., and Borman, M., "Revisiting Dependency Network Diagrams: A Conceptual Extension", AMCIS 2013 Proceedings, 2013, pp. 1-11.

D. Balta, V. Greger, P. Wolf, and H. Krcmar. “E-government Stakeholder Analysis and Management Based on Stakeholder Interactions and Resource Dependencies.” en. In: 2015 48th Hawaii International Conference on System Sciences.

Stakeholder Analysis



Based on own depiction

Framework to Approach MDR Certification

The framework should streamline the certification process by:

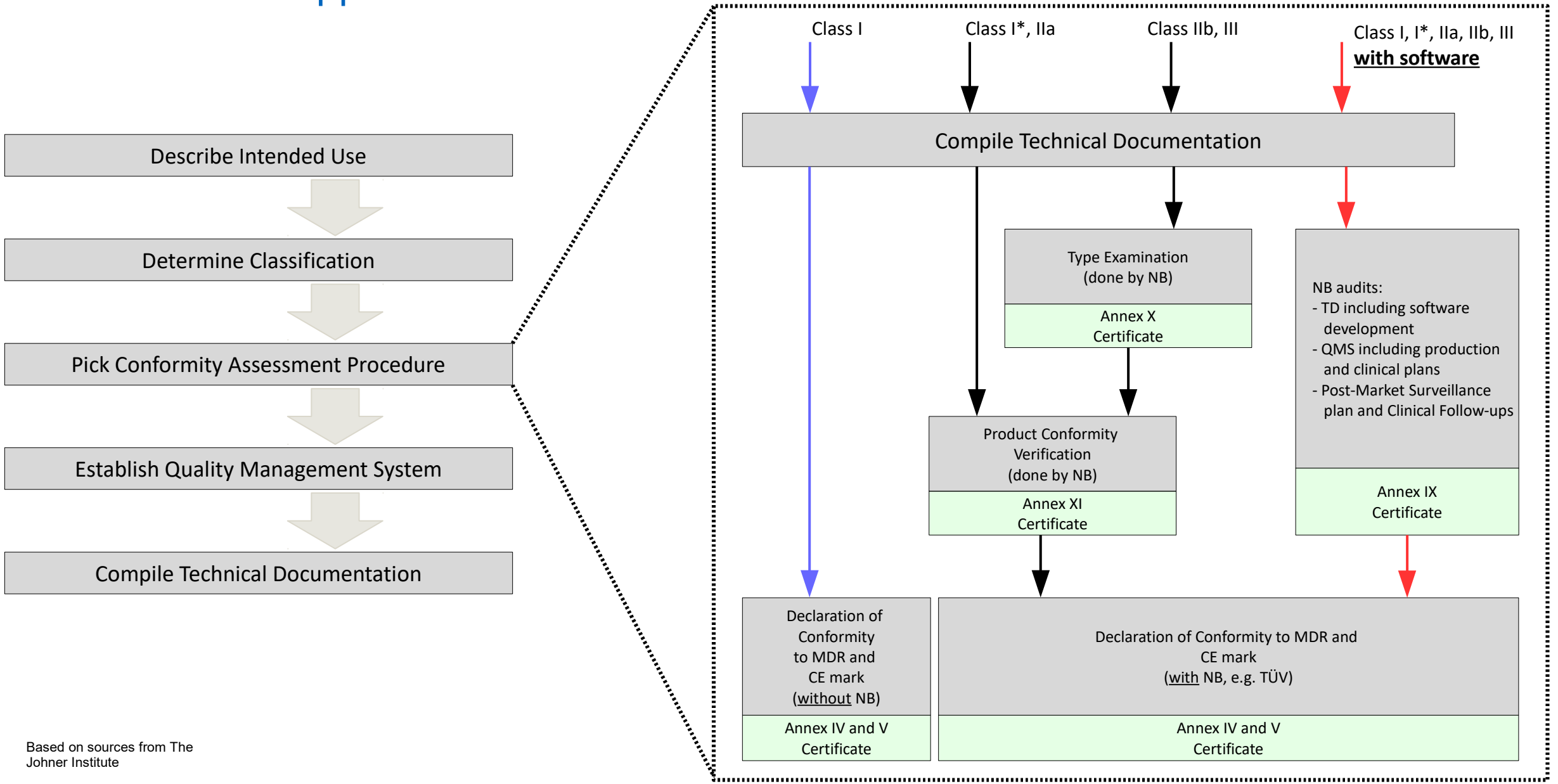
- linking challenges and roles in the certification process to enable solutions
- describing risk ownership
- mapping different procedures towards regulatory compliance

Interrelations between roles

Challenges of MDR Compliance	Stakeholders in the certification process				
	Start-up	Critical Supplier	Consulting Firm	Medical Personnel	Notified Body
Lack of Clarity	✓	✓	✓		
Distribution of Accountability	✓	✓	✓		
Increase in Certification Costs	✓				
Challenges of Compiling Technical Documentation					
Completeness of Content	✓		✓	✓	✓
Consistency of Documentation	✓		✓	✓	✓
Traceability across Documents	✓		✓	✓	✓

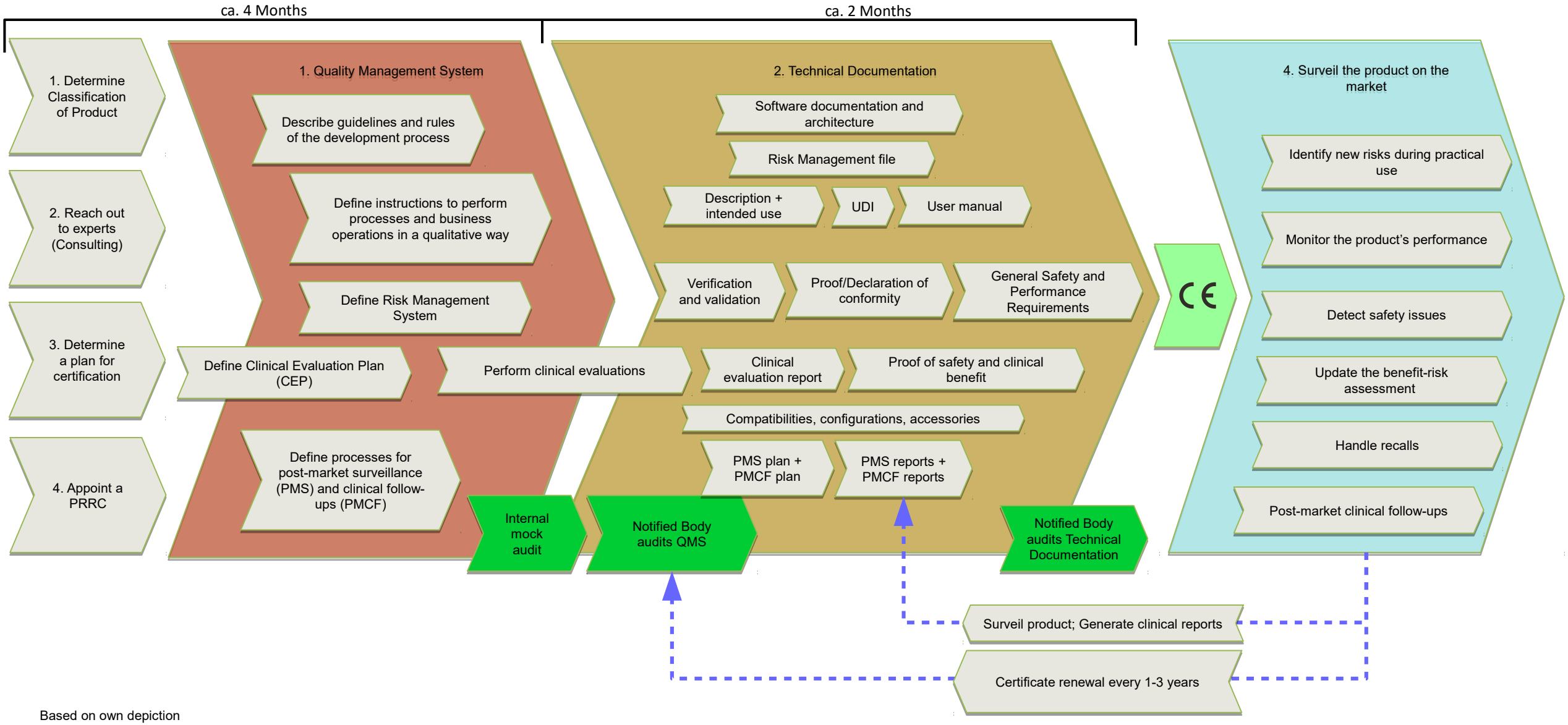
Based on own depiction

Framework to Approach MDR Certification



Based on sources from The Johner Institute

Timeline of MDR Certification



Based on own depiction

Conclusion

Limitations

- Scope limited to start-ups
- MDR has been effective for ca. 1 year
- Some of the available literature is only estimating predictions based on a draft version of the regulatory requirements

Future Work

- Financial development of SMEs
- Comparison of the challenges between large and small companies, as access to resources is different
- Long-term decline in innovation