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FAST TRACK TO INNOVATION PROCUREMENT

MDR-PREP

DELFT UNIVERSITY OF TECHNOLOGY
(TU DELFT)

MDR-PREP

PITCH

MDR-prep, an innovative electronical QMS-tool for compliance to the Medical Device Regulation (MDR) of early-stage medical device development, providing of intuitive templates and guidance through Standard Operating Procedures (SOP). This guarantees MDR compliance of investigational medical device research and prevents incomplete dossiers and re-doing critical tests at a later stage saving time and assure proper use of funding.

ORGANISATION DESCRIPTION

Delft University of Technology (TUD), is a leading technical university located in The Netherlands, contributing to solving global challenges by educating socially responsible engineers, expanding the frontiers of the engineering sciences. TUD has a strong focus on research and education in the field of health technology, specialised in health technology, including Bioelectronics, Biomechanical Engineering, Imaging Physics, regenerative medicine, and medical robotics, including Master of Science programs in BioMedical Engineering and Technical Medicine. TUD collaborates with various research institutes, hospitals, and companies to develop innovative solutions to health-related problems e.g. the Medical Delta, a collaboration between TUD, Leiden University Medical Centre, and Erasmus MC and Convergence for Health & Technology, between Erasmus MC, EUR and TUD to cross-pollinate between ideas, procedures, instruments and products for which MDR requirements require alignment with legal obligations. This application supports one aspect of this: A MDR-tool for compliance and a dedicated Quality Management System (QMS).

CHALLENGE DESCRIPTION

According to the European Commission, 500,000 medical devices are available on the European market and about 10,000 new medical devices are added every year. In Europe, an average of 1% of GDP is spent on healthcare. Annual per capita expenditure on medical technologies in Europe is about €225 (average according to MedTech Europe) these numbers warrant a proactive approach to secure this part of the EU market.

The MDR is a European Union (EU) regulation becoming applicable on 31 December 2027 for higher risk devices and on 31 December 2028 for medium and lower risk devices. To comply with the MDR, medical device designers and engineers are to provide extensive documentation, quality control evidence, prior to clinical evidence demonstrating the safety and efficacy of their product as part of these requirements. These requirements are time-consuming, costly. Hence, dedicated information, guidance, documentation and an electronical QMS are required to streamline and control this process, ensuring legal compliance to foster medical innovation technology transfer and uptake. With Universities it starts with awareness of and assessing requirements of adherence to MDR-regulation.

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Firstly, to date a simple electronic tool to assess the need for compliance is not available and medical innovation projects are not properly judged and correctly prepared for the MDR-regulation. Secondly, the lack of experience with preparing for MDR-regulation is clear, as at universities new students may enter this field each semester, requiring continual support and training. Instruments developed within research institutes lack strong guidance and ease of use. An increasing number of health-related innovations mature into early clinical feasibility investigations, and standard research files are submitted for approval from METC (Medisch Ethische Toetsing Commissie). These investigational studies focus on clinical applicability of the medical device and should be conducted according to the Good Clinical Research Practice standard (GPRS) as defined in ISO 14155. Currently there is ample experience within research institutes what exactly should be communicated to the METC to obtain approval to test the innovation. By implementing a dedicated electronic MDR-regulation solution assures compliance to prevent obstacles at a later stage. Especially for research organisations the MDR-regulation has a significant impact, as this is where the idea, design and prototypes are being made and where the whole journey starts. MDR compliance is essential for medical products to make a chance for exploitation, commercialisation and market entry as all critical aspects regarding regulation, safety, and patient needs.

CHALLENGE MAIN OBJECTIVES

The development of a dedicated electronic tool for an QMS and increased awareness will de-risk investigational medical devices' lack of compliance to MDR-regulation. Most importantly it secures timely development into CE approved devices. It guarantees patient's and user's safety and allows for further clinical evaluation as preparation to CE marking, including registration of so-called off-label use. This connective and supportive route to marketing may contribute to innovation and cost health care savings. This dedicated electronic tool allows institutes to support its students, engineers and developers to operate within the MDR-regulations in a controllable manner, further improved by AI and Chat-GPT support.

SOLUTION FUNCTIONAL REQUIREMENTS

The Solver will develop in SharePoint an innovative dedicated electronic tool, MDR-prep, for early-stage development of medical devices to comply with the requirements of the MDR. We apply stratified MDR requirements according to TRL: 1) TRL 1-3 exempted from MDR regulations as non-medical devices (Article 4.2.3); 2) TRL 4-6 performed according to Article 82 definition of the MDR (knowledge institutes); 3) TRL 7-9 excluded as it relates to Article 62 of the MDR.

The solution to this challenge requires the following mandatory elements as under MDR Article 82 captured by a electronic database comprising templates provided by the Challengers:

Medical Device classification tool, limited from Class 1 to Class 2b,
QMS process validation,

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procurement records (Bill of Material),
risk assessment,
systematic development decision records,
validated test records

- proof of using calibrated equipment and
- proof of listed qualified personnel

as part of the IT QMS-Tool to be built by the Solver.

A decision tree will guide the user to what classification their medical device belongs to, and to what MDR requirements are relevant. Medical Class classification will be the first guidance into the built-in obligations as an integral part of the IT QMS-Tool. This newly developed IT QMS-Tool will be assessed by ultimately the METC approval of various submitted IMDD's. These IMDD records encompass the MDR obligations on QMS, development records and safety tests. It is mandatory to select different Medical Device classes and an increasing complexity to thoroughly test and release the IT QMS-Tool. Therefore, it includes products related to Class 1, introduced to the outer skin less than 24 hours, as well as Class 2b requiring sterility but also medical devices having software components.

As this new solution is not aiming to be yet another fully QMS system, compliant to a full CE dossier, but instead is dedicated to early-stage development. The IT QMS-Tool is limited up to but not beyond the level of the obligations under MDR Article 82.

This means for instance that an electronic QMS flowchart built by the Solver is sufficient, supported by linked templates for Standard Operating Procedures (SOP's) for procurement, risk assessment, development decisions and steps, production and testing by the Challengers. Guidance is provided by electronically linking all GSPR requirements through an exhaustive checklist for relevant ISO standards. In order to facilitate the novice user, these requirements are intrinsically linked to the QMS flowchart and are explained and supported by training programs.

All mandatory input by risk assessment experts on technology, material and medical topics are registered and require electronic signing as part of a final release system, ready to submit to an METC for approval of testing in a medical environment under MDR Article 82.

SOP's include electronical registered references to the use of calibrated machines during development and production of the investigational devices. Traceability is implemented by a Bill of Material, listing all components of the final medical product, including procurement Material Safety Data Sheet, without its electronic authorisation any product release is impossible.

Desired objectives are, beyond a dedicated and extensive IT QMS-tool, the use of and implementation of AI and Chat-GPT to generate dedicated forms as device records that are more suitable to the huge variety of requirements as listed by the intrinsic complexity of the design in conjunction with the GSPR requirements. This results in more to the point records

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and enhances the quality of the QMS in total and allows the involved institutes to adhere to the MDR-regulations in most of their medical device cases.

Compulsory functional requirements

The compulsory functional requirements are listed below as these elements are mandatory as under MDR up to but not beyond Article 82:

- Medical Device classification tool, limited from Class 1 to Class 2b,
- QMS process validation,
- procurement records (Bill of Material),
- risk assessment,
- systematic development decision records,
- validated test records
    - proof of using calibrated equipment and
    - proof of listed qualified personnel

as part of the IT QMS-Tool to be built by the Solver.

Desirable functional requirements

Desired objectives are the use of and implementation of AI and Chat-GPT to generate dedicated forms as device records that are more suitable to the huge variety of requirements as warranted by the intrinsic complexity of the design in conjunction with the GSPR requirements. This results in more to the point and better guiding templates of records which enhances the quality of the QMS in total and allows the involved institutes to adhere to the MDR-regulations in most of their medical device cases. This is best implemented when sufficient data sets are becoming available to feed the AI and Chat-GPT, which is anticipated to be feasible after sufficient implementation and use in the field.

PILOT SCOPE

This MDR-prep consortium comprises of TUD software developers, experts and relevant Solvers from outside the consortium.

In-depth experts on QMS and QA/QR related expertise have access to sets of documentation on processes, SOP's and templates supported by the TUD IT-department and requires Solvers capable of developing an electronical IT-QMS-Tool in a SharePoint environment.

Participation by several institutes ("observer challengers") interested in the solution, provide users feedback during development and IMDD submissions test cases.

The MDR-prep consortium and Solvers co-create a first test IT QMS-Tool within 6 months and tests against MDR requirements by actual users within 10 months. Training for awareness and support for users to prepare for METC approval is also provided for by the user experts. The language shall be English, most common for medical devices.

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Type and number of targeted end-users

End-user type	Role	Number
Research universities	*They provide IMDD cases, first users for testing and training*	*5*
Hospitals	*They provide IMDD cases, METC approval and clinical test environment*	*3*
Institutes for applied research	*They provide IMDD cases, first users for testing and training*	*1*
Consortia on medical device development	*They provide IMDD cases, first users for testing and training*	*2*
Solvers on software development	*They provide the basis for the electronical QMS database including authorisation and checks*	*(3 to be sought)*

Language

It is believed that for most the English language is leading especially for medical oriented institutes, the notified bodies such as Tüv and DEKRA as well as the METC. As this is the case no additional translation is required during the Pilot phase.

Other aspects

Based on the previous engagement with the parties listed in Table 1 it is believed that all requirements are met to secure timely development and sufficient implementation and checks of a functional IT QMS-Tool set up, as to be proven by the generated IMDD dossiers and released after of METC approval for a variety of medical products having increased MDR complexity. The desired AI and Chat-GPT may be part of the deliverables providing sufficient data sets and additional funding is realized. For future applications in other national languages translations are required which are not yet part of the deliverables.

PILOT SET-UP CONDITIONS

Ethical, legal or regulatory

In the pilot phase the solver will interact with TU Delft IT-department to get access to SharePoint and also with researcher(s) with specific existing MDR-relevant pilot projects (TU Delft and/or extern). We might start with mock-projects to set up the structure and then test it with real-live cases projects. To assure data confidentiality of real-live cases, we will set up an NDA with the use-case owner and the solver. In this case NDA is related to the confidentiality of the data and not to the IPR of the IT tool.

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In the interaction between TU Delft parties and the solver and/or external stakeholder TUD will adhere to its own internal rules. For example, within TU Delft there are internal rules for storage and management of data and software including storage solutions, organisation and documentation, processing and exchange as well as working with confidential data which will be done directly with the ICT Privacy Team (GDPR compliant) and with the TU Delft Human Research Ethics Committee, if required during the process.

The pilot and the efforts requested for co-creation are limited to the IT QMS-Tool itself. The test phase, by submitting relevant IT QMS-Tool generated IMDD dossiers, remains a confidential process, governed by the submitting institute. Comments on the submitted IMDD dossiers by the METC are to be shared anonymously only to allow for adaptation of the IT QMS-Tool.

The tool, MDR-prep, will comply with the requirements of the MDR, up to the level of Article 82 definition of the MDR.

The MDR mandatory elements up to but not beyond MDR Article 82 are validated by both end-users and as well as ultimately by submission of an IMDD based on the (partial) input of the IT QMS-Tool. The IMDD seeks informed consent by the patient for the use of the medical device from the submitted IMDD. Without an approved informed consent protocol and documents no IMDD approval by the METC (**Ethical Committee**) is obtained.

This newly developed IT QMS-Tool itself is assessed by successful METC approval of the submitted IMDD's. These IMDD records encompass all the MDR obligations on QMS, development records and safety tests. It is mandatory to select different Medical Device classes and increasing complexity to thoroughly test and release the IT QMS-Tool.

Guidance to these MDR requirements is intrinsically linked to the QMS flowchart and are explained and supported by training programs, which form part of the release process as well.

All mandatory input by risk assessment experts on technology, material and medical topics are registered and require signing as part of a final release system, i.e., released to be part of an IMDD record ready to submit to an METC for approval of testing in a medical environment under MDR Article 82.

Technological

The system will be based on the SharePoint built into TU Delft IT operating system. Solver will get access to the system based on internal TU Delft rules, to develop the IT-tool (MDR-prep system structure). The solution is hosted at TU Delft servers. Due to wide-spread use of SharePoint systems within the academic (and beyond) sector, the solution is transferable and compatible with all FAIR and GDPR requirements.

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The IT QMS-Tool is a stand-alone system that does not require nor relies on sensitive patient data sharing from the end user's system. The upload of the product and development data is performed on a local server dedicated for the IT QMS-Tool only. The resulting QMS documents are stored per dedicated medical product files having a unique folder name and are stored separately in the end-user's environment of choice to which internal safety standards apply and can be pasted in the end user's IMDD submission freely but only after a final release on completeness of the QMS documents and processes.

Data access

The systems and servers needed for running the pilot will be hosted by the Challenger (TU Delft), with Solver(s) having access to it based on TU Delft rules. The system will be compatible with stakeholders if using SharePoint platform (all observers).

Other

Not applicable

EXPECTED IMPACTS AND KPIS

Pilot KPIs:

- development and release of the Beta version of the IT QMS tool (M6)
- testing the tool with 3-10 (mook) use cases (M10)

Long-term KPIs (M36)

- testing X real cases (MX)
- implementation of MDR-prep at "observer" institutions (n=at least 3, MX)
- raising awareness among student and engineers (n=X, M36)

Increasing awareness via the IT QMS-Tool within the knowledge institutes and for students, engineers and developers will **reduce development time by 1 up to 2 years avoiding redoing essential documenting and tests**. Guaranteeing compliance with the industry's standards under the MDR-regulation will lead to **improved technology transfer** resulting earlier product market launch by up to 2 years and increases. The current conversion rate of 29% from start-up to scale-up by 25% towards 55% as such allowing for better patient care at lower costs. Implementing the dedicated IT QMS-Tool allows for an increased thorough METC assessment due to recognizable Investigational Medical Device Dossiers (IMDD) formats and clear indication of meeting essential requirements and thus **secure patient's and users' safety**, which may reduce the Ethical Committee workload by at least 20%. Applying the MDR-Tool, especially the templates for design and testing according to the ISO standards, avoids late-stage redoing development or testing under MDR-regulation and avoids thwarting CE submission and market launch for up to 25% of the products.

The development of a dedicated tool for and QMS in combination with increased awareness will de-risk investigational medical devices' lack of compliance to MDR-regulation.

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Furthermore, it supports timely development into CE approved devices by start-up's or the (larger) industries. It guarantees patient's and user's safety and allows for further clinical evaluation as preparation to CE marking, including registration of so-called off-label use. This connective and supportive route to marketing may contribute to innovation and cost health care savings. Having a dedicated tool will allow knowledge institutes to support its students, engineers and developers to operate within the MDR-regulations in a controllable manner.

BUSINESS OPPORTUNITY

Market size

Scalability of the solution is realistic at national and European level. Early developers of the medical technology are: **i) universities and public research centres; ii) hospitals; iii) start-ups and incubators.**

At organisational level:

- User numbers in excess of 20 cases per year.

At national level:

- With 14 research universities and 6 research institutes and 88 both public and private hospitals as well as over 1,000 health tech start-ups in The Netherlands it amounts to over 3,160 individual users.
- Representing estimated revenues of € 1-5k per year per user amounts to € 3.1 to 15.8 Mio per year.

At European level:

It is estimated that the numbers from the Netherlands market size can be multiplied by 16 to arrive at European market estimation resulting in:

- User numbers in excess of 50,560.
- Representing estimated revenues of € 1-5k per year per user amounts to € 50.4 to 252.8 Mio per year.

Increasing conversion rate from 29% to 55% by using IT QMS-Tool amounts to an increase of the European GDP with 0.25%.

Adoption plans

TUD as a large university with a turnover of around €1 billion p/a and more than 28.000 students, large well equipped labs for research and education, significant procurement power is a must have. A dedicated, centralized procurement system, as part of the Corporate Affairs Finance unit ensures all purchases are following relevant regulations and laws. Part of the process is to ensure the university obtains the best value for money. The developed IT QMS-Tool is a need to have tool to follow the new MDR and at a pay per use of a proven tool to facilitate, guide and train the continual influx of users (students) is very much

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supported by TUD and shall be used and scaled up within the relevant departments of the TUD.

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