Technology for Life

Dräger

The implementation of MDR at Dräger (2) - Clinical Evaluation

Robin Hüwel

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Agenda

Item 01

Introduction

Source: The Regulation Madness is Coming to an End - FreedomWorks

Item 02

Implementation of the MDR at Dräger – Clinical Evaluation

Source: The Future is Bright - Ingenu

Source: The Best Lessons We've Learned! - Event 360

Item 03

Lessons learned (so far) & current challenges

Item 04

Outlook & time for questions

01

Introduction

Who am I?
Short introduction of myself

Robin Hüwel | Clinical Affairs Manager

Work experience

Since Oct. 2017	Clinical Affairs Manager
Oct. 2015 – Sept. 2017	Jr. Clinical Affairs Manager
Aug 2012 – Sept. 2015	Dual Student

Education

Oct. 2018 – Jul. 2021	Master – Medical Biometry / Biostatistics
Oct. 2012 – Sep. 2015	Bachelor – Engineering / Medical Devices

Skills

Project management

Programming

Business / Data Intelligence

Interests

Cooperative board games

Running

Beer brewing

32 years old
Married
3 year´s old daughter
Living in Lübeck

Clinical Affairs at Dräger
Numbers, data & facts

>70% of the overall Clinical Evaluations are already compliant to the MDR requirements (as of Sept 2023)

I - IIb Is the range of device classes that are handled within the corresponding clinical evaluation within Dräger

Ten Is the number of Clinical Affairs Manager, that are responsible for the clinical evaluation and clinical studies within Dräger

77 Is the total number of separate clinical evaluations that are handled within Dräger, containing one or more medical devices and/or accessories (as of Sept 2023)

>6000 literature publications are included in total in the various clinical evaluation reports as relevant clinical data for the assessment

02

Implementation of the MDR at Dräger – Clinical Evaluation

The Medical Device Regulation
An adventurous journey … that continues

Photo from Dariusz Sankowski on Unsplash

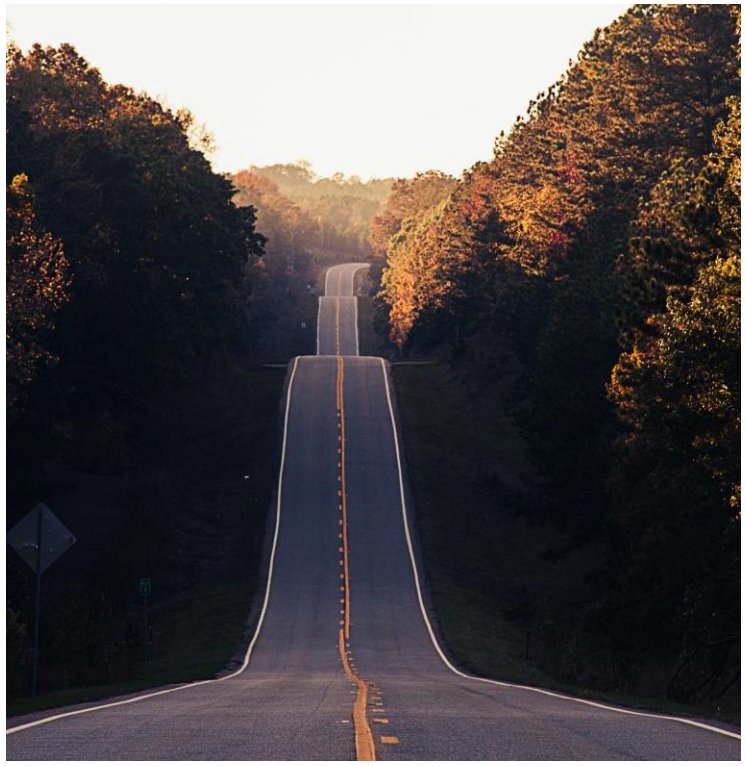


Photo from Matt Duncan on Unsplash

Photo from Jamie Street on Unsplash

Timeline
Early beginnings

Mai 2017 – Regulation (EU) 2017/745 (MDR) entered into force

2018 - Update of internal processes to be compliant with MDR e.g., Clinical Evaluation

2017/2018 - MDR Project initiated Gap Assessment regarding the MDR and corresponding current processes

End 2018 - Creation of three pilot projects to validate the process adaptions

Gap assessment & process update
Early beginnings

Launch of a temporary MDR project with the aim of implementing the MDR requirements and making the company MDR compliant

This includes among other

- Gap assessment of requirements from MDR to existing processes and procedures
- Creation/adjustment of processes to implement new/higher requirements
- Cross-functional involvement from all key disciplines (e.g., RA, CA, RM, R&D, PMS, …)

Result for Clinical Evaluation:

- Adaptation / new revision of our process for clinical evaluation

Pilot projects
Early beginnings

Based on the gap assessment and the process adjustments, three pilot projects were called, whose documentation was the first to be fully converted to the MDR requirements

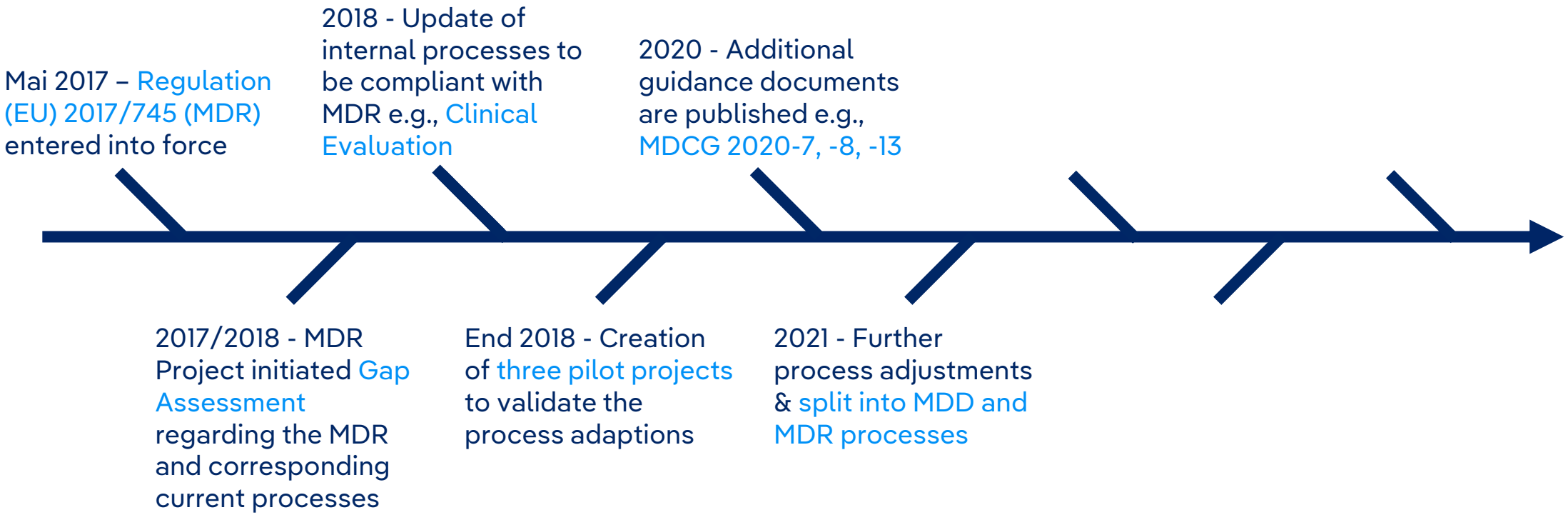
Pilot projects:

- Ventilator (Class IIb Product)
- Medical gas supply (Class IIa Product)
- Surgical lights (Class I Product)

Goal:

- Initial creation of a complete MDR documentation according to new processes
- Lesson Learned / Best-practice for further process adaptations and for follow-up projects
- Determination of processing times for the creation of the documentation for various products of different classes

Timeline
Mid-term



Additional guidance
Mid-term

About clinical evaluation, the following guidances are particularly noteworthy

- MDCG 2020-5 (April 2020) - Clinical Evaluation - Equivalence
- MDCG 2020-6 (April 2020) - Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC
- MDCG 2020-7 (April 2020) - Post-market clinical follow-up (PMCF) Plan
- MDCG 2020-8 (April 2020) - Post-market clinical follow-up (PMCF) Evaluation Report
- MDCG 2020-13 (July 2020) - Clinical evaluation assessment report template

Key message

- Clearer guidances on specific topic like equivalence and requirements for the PMCF Plan and Report documents
- Good understanding, what will be expected from the Notified Bodies (NB) in the future, especially due to the MDCG 2020-13 as the “Checklist” for the Clinical Evaluation Assessment
- Still some lack information/hints about the “how” to fulfill the requirements, e.g., use the same wording as the MDR text and does not provide additional information

Process adjustments – MDD and MDR process
Mid-term

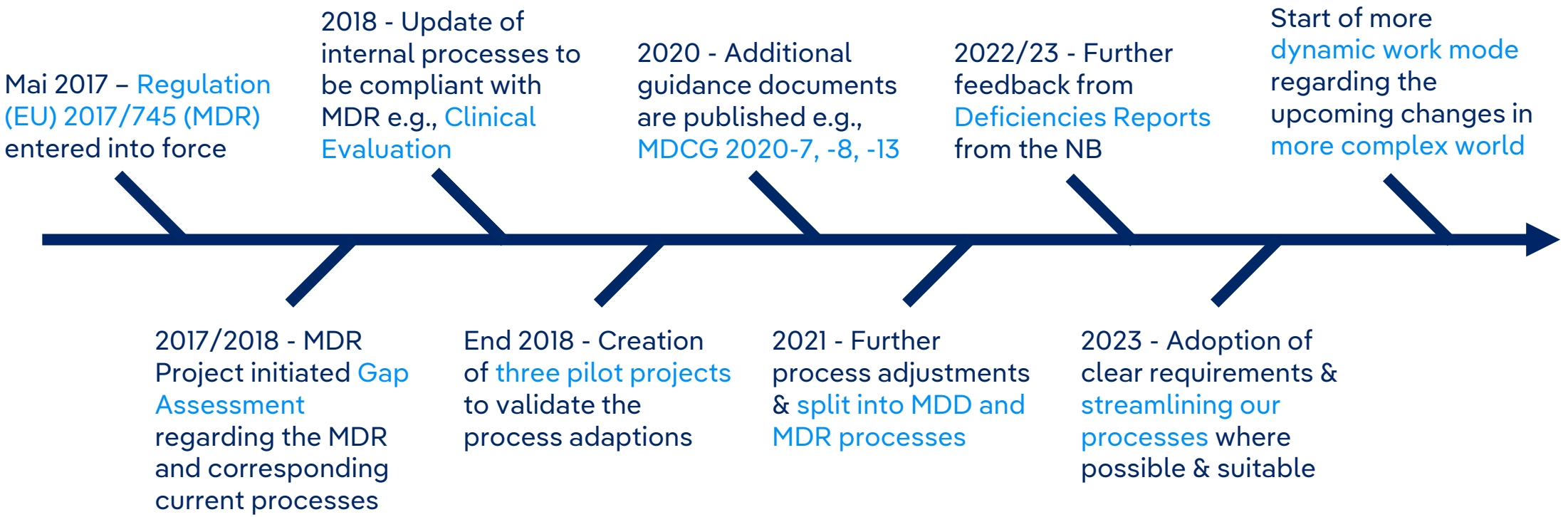
Due to new guidance document and the decision that not the complete product portfolio should continue under MDR, consequently the Clinical Evaluation process was split:

- IN 4250 - Clinical Evaluation
- IN 4251 - Clinical Evaluation (MDD)

Key reasons for the separation were:

- Valid process for clinical evaluation of products remaining under MDD until phase out
- Reference to different requirements e.g., Essential Requirements vs. General Safety and Performance Requirements
- Continuous improvement/updates for IN4250 (MDR) required, stable environment for IN4251 (MDD)

Timeline
Current situation



Deficiency Report(s)
Current situation

As part of Clinical Evaluation Assessments or Technical Documentation Review, we also regularly receive feedback from our Notified Body in the form of Deficiency Reports (DR)

Learnings from the previous Deficiency Report(s)

- NB reviewers essentially orientate themselves on MDCG 2020-13 when reviewing/questioning the clinical evaluation topic
- Partial variation in the depth of content queries of the actual clinical evaluation; dependent on the background/experience of the individual reviewer & the device under evaluation
- Different approaches (depending on product class, product category) lead to answering the reviewers' queries and thus to resolving the deficiencies

Streamline process – Dynamic work mode
Current situation

Due to recent feedback from reviewers from the Notified Body, we have decided to streamline our clinical evaluation process

Assumptions:

- Include requirements that are always/mainly requested quickly in the process or templates
- Dynamically (case-by-case) confirm/document requirements that have been requested by single requests

Aim:

- Process allows for sufficient flexibility, while maintaining high quality and regulatory requirements

Result:

- A further adjustment, to the current valid process revision of the IN4250.

03

Lessons Learned (so far) & Current challenges

Lessons Learned

Higher need for coordination across various departments required e.g.,

- Interaction between Risk Management - Clinical Evaluation on topics such as e.g., Benefit-Risk Ratio, Clinical Risks
- Interaction between Post-Market Surveillance - Clinical Evaluation on topics such as e.g., Complaints, Trends, Literature

Management / maintenance of two processes requires essential resources

- New dynamic work mode and streamlined process allows more flexibility
- Outlook: In the future again only one process for the topic "Clinical Evaluation" that maps MDD and MDR requirements equally but can be flexibly adapted for the underlying product and applicable regulation

Capture feedback from reviewers as one possible interpretation

- Include same/similar feedback on identical items as improvement in process update and future documentation

Allow for longer processing times on both sides (manufacturer / NB)

- More extensive documentation, its review, as well as answering queries require more resources on all sides

Current challenges

Increasing requirements for clinical evaluations/clinical evidence (worldwide)

- In addition to MDR requirements, more and more countries are requiring evidence based on clinical data summarized as part of a "clinical evaluation“

Room for interpretation of MDR & current guidance documents - different understanding

- Partly different and still evolving understanding/expectation of how to fulfill certain requirements

Increasing complexity due to more documentation/data being incorporated into the clinical evaluation

- Higher dependencies within the overall technical documentation <-> clinical evaluation
- Higher volume of non-clinical and clinical data to be analyzed and evaluated

04

Outlook & Time for questions

Outlook (1)
New guidances

MEDDEV 2.7/1 – Revision 5 – MDR Update by MDCG

- The MEDDEV 2.7/1 - Rev. 4 is still considered the central guidance document for the topic of clinical evaluation
- A MEDDEV 2.7/1 - Rev.5 updated to MDR requirements will, at best, close some questions left open by MDR itself and the MDCG Guidance documents, thus giving manufacturers and notified bodies more certainty
- An update is planned for 2024

ISO/AWI 18969 - Clinical evaluation of medical devices

- The technical committee ISO/TC 194 - Biological and clinical evaluation of medical devices - is currently working on the first standard for clinical evaluation of medical devices
- A corresponding standard could harmonize the requirements for clinical evaluation across the borders of individual regulatory systems
- A draft is expected by the end of 2024 and publication by the end of 2025

Outlook (2)
New technologies

Digitization, including machine learning / AI, is now finding a wide range of applications. A few perspectives on how these also provide potentially in the creation of Clinical Evaluations:

Content Automation for technical documentation and STED, including Clinical Evaluation

- Several basis information (intended purpose, general device description, device specification, …) shall be aligned over the technical documentation and are reused in several documents

Pre-selection/Refinement of adequate search terms

- Based on Intended Purpose, Device Specification and already used literature, adequate search terms for the updated literature search can be identified or refined

Pre-selection of possible suitable published literature

- Literature hits can be pre-sorted/selected based on their relevance for the device under evaluation

Benefit:

All these potential solutions free up resources that can be used for other clinical evaluation activities, e.g., clinical data assessment, PMCF strategy development, etc.

Time for questions

Thank you

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