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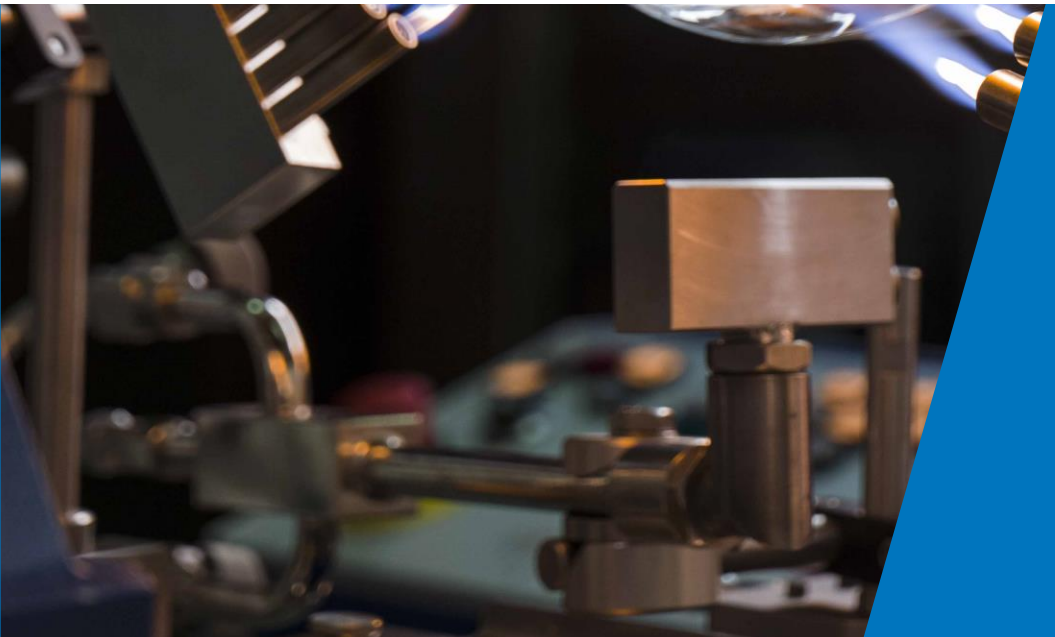
Medical Device Regulation (MDR) -update-



Martina Pieper
Senior Marketing Manager

Strasbourg, September 2022

Dunlee's best practice tips

Planning phase:

- **Prioritize** project on high management level, allocate budget and obtain management support for human resources
- Establish a **Governance** program to gain visibility, including establishing a project leader and filling other positions
- Schedule monthly / quarterly meetings with different levels of leadership and management to **report the status** of KPIs and ask for help if needed
- Get together a **core team comprising all those needed to make the project a success** (Project Management, R&D, Quality & Regulatory, Clinical, Risk Management, Marketing, Operations Quality) and establish weekly meetings to track progress

Dunlee's best practice tips

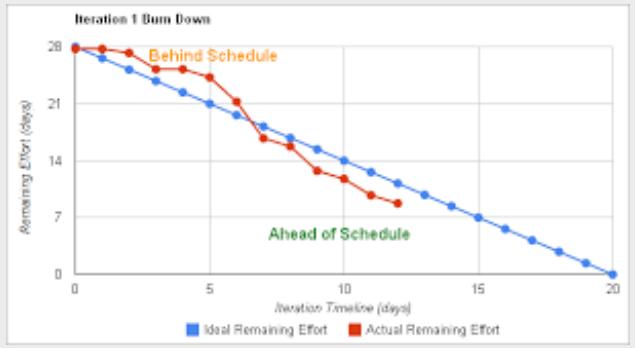
Analysis phase:

- **Analyze** product portfolio and strategically **identify** products that should be discontinued to reduce effort
- Conduct a **gap assessment** of your QMS + Technical Documentation (TD) with regards to MDR
- Close the identified gaps and **track execution** in the core team

Dunlee's best practice tips

Implementation phase:

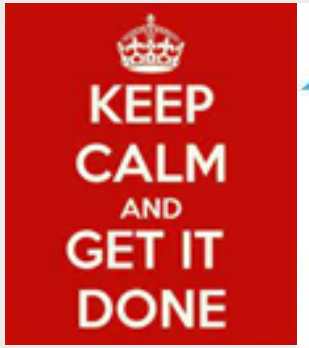
- Establish a stable reporting mechanism of closed identified gaps (**burn down chart**) and set goals for completion per phase



- **Sample first, I**f you have multiple products / technical files, focus on one and complete that TD first, then let your Notified Body (NB) review it

Dunlee's best practice tips

Implementation phase:



- Ask your Notified Body for capacities 3-6 months before you will send your documents

- After all the questions and answers rounds with NB is completed for the first sample TD and all NB gaps are closed, use the **lessons learned** to finalize the remaining TD's subsequently (from our experience this will reduce re-work by ~30%).

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