propharma

CASE STUDY

EU MDR PMO & Project Delivery

challenge

- Medical Devices client had the right-level of internal talent, but was overloaded with daily work and EU MDR (2017/745) expectations
- Our Project Management team drove the PMO and partnered with the client to successfully deliver the EU MDR project ahead of the newly updated 2021 deadline

solution

- Conducted planning session(s) to define program approach, workstreams, definition of done, scope, and timing
- Designed/rolled-out Program Mgmt structure
- Built value proposition to educate on importance of regulation, key messages, and potential impacts (e.g., revenue, process, organizational)
- Developed/executed ongoing governance strategy (Steering Committee, Core, and Extended Teams)
- Drove project workstreams and developed content with the clients; escalated/resolved issues and risks
- Defined/rolled-out ongoing communications strategy

results

- Created and launched EU MDR PMO and governance structure
- Completed and communicated EU MDR value proposition to key senior leadership stakeholders (e.g., Manufacturing, Manufacturing QA, R&D QA, PV, Clinical Development)
- Completed QMS, PMS, and Clinical Documentation Creation and Updates
- Completed all product remediation activities (e.g., labeling, IFUs, create MDR Tech File)
- Completed supporting white papers and EU MDR interpretation documentation, including legal reviews
- Finalizing owners for new roles and responsibilities (e.g., PRRC)

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.

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