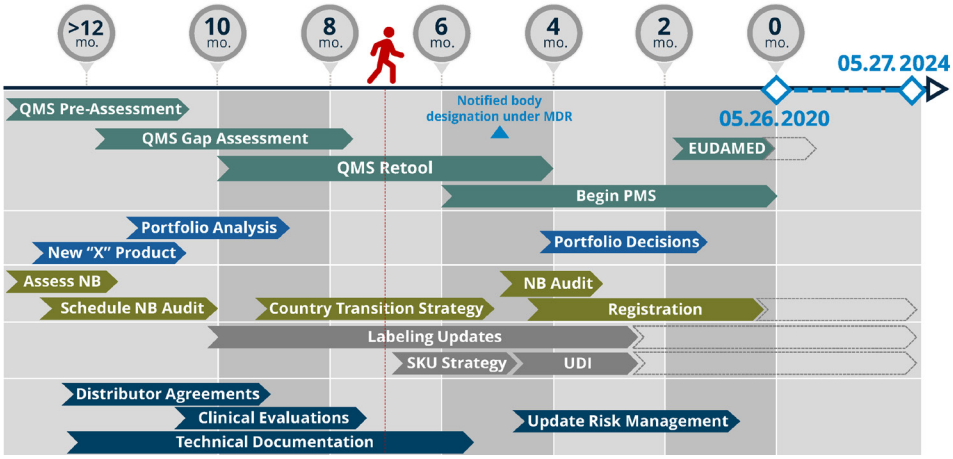
STEPS TO ACCELERATE SUCCESSFUL MDR COMPLIANCE

Medical device manufacturers have just over six months to be compliant with the new European Union Medical Device Regulation (EU MDR). Yet according to a recent survey from the Regulatory Affairs Professionals Society (RAPS), only 27% of medical industry leaders said they will be fully compliant by the May 26, 2020 deadline. If you are part of the 73% of companies that are behind, clearly, you're not alone. EU MDR compliance involves significant work, including product portfolio review and prioritization, product up-classifications, expanded clinical requirements, significant documentation, new labeling, and post-market surveillance. The significant effort involved, combined with ineffective program and transition change management approaches to structure, plan, and manage the work, is resulting in delays and business risks.

Based on our work in supporting organizations' EU MDR efforts and more than 30 years leading compliance projects with hundreds of medical device companies, the Quality and Regulatory team at Integrated Project Management Company, Inc. (IPM) has developed an approach to achieve on-time EU MDR compliance with lasting benefits. Following are steps you can take to accelerate successful compliance.



IF YOU ARE BEHIND SCHEDULE, YOU'RE NOT ALONE

CONFIRM YOUR CURRENT STATUS.

Collect workstream data from all teams inside and outside of the organization and determine the most current program status. A brainstorming or tracking tool can be a simple way to provide an organized list of activities. The goal is to objectively define where you are, what remains to be completed, and how to best use your resources to meet the compliance deadlines.

DEVELOP AN INTEGRATED MASTER PLAN.

Aggregate all the information, standardize terms and milestones, create a master tracker, and secure stakeholder alignment and buy-in. It is vital to have one source of truth that covers all the work and deliverable status and can serve as the roadmap to achieving compliance. You can use the master tracker to derive a master schedule that shows the critical path. You can also apply tools like Microsoft Power BI to clearly visualize the information by any tracked parameter and help optimize resource utilization.

UTILIZE EFFECTIVE PROGRAM MANAGEMENT.

An integrated plan needs a dedicated leader who will constantly monitor the status, drive progress, identify and mitigate risks, and find ways to remove impediments. A communication plan to effectively manage the flow of information among stakeholders and proactive organizational change management to promote sustained change should always be part of solid program management.

REVIEW PLAN AND ADJUST RESOURCES.

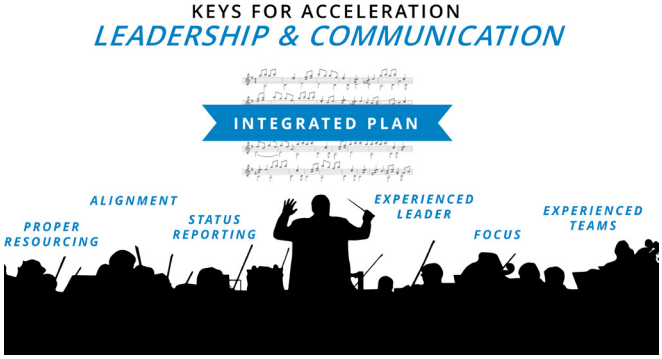
Analyze the integrated plan to confirm progress and assess resource needs. Leverage your experienced teams and knowledgeable resources (subject matter experts, project management support, quality, risk management, etc.) to deliver milestones on time. Since all team members have their day jobs as well, tough decisions may need to be made to prioritize tasks and free up resources.

REEVALUATE YOUR PRODUCT PORTFOLIO.

Prioritize product order based on recertification dates or the need to make product changes. If products have been reclassified, you will need more time to comply. Evaluate criteria such as ease of conversion, return on investment, market opportunities, external partners, and bandwidth to rationalize each product line. Some products may need to be delayed or even removed from the EU market if you can't achieve compliance, so ensure that the best decisions are being made for the business.

USE INVIGORATED PROCESSES TO ACCELERATE.

Think differently about solutions. The workload can be reduced through portfolio rationalization and rigorous risk management. Take advantage of experienced teams; as they learn, they can apply their knowledge to speed the process. Resources and advice are available outside the organization; consider investing in third-party solutions rather than inventing them.



Integrated Project Management Company, Inc. (IPM)

Integrated Project Management Company, Inc. (IPM) is a business consulting firm that advises on and executes critical initiatives. For more than 30 years, IPM has helped organizations solve complex problems and realize their strategies through program and project leadership. IPM has led thousands of projects for more than 150 biotech, pharmaceutical, and medical technology companies, as well as in the healthcare, consumer products, and industrial sectors. Headquartered in Chicago, IPM has regional offices in Boston, St. Louis, Los Angeles, San Francisco, Minneapolis, and Parsippany. IPM was a recipient of the 2018 Malcolm Baldrige National Quality Award. To learn more about IPM and its services, visit ipmcinc.com or call 630-789-8600.