# Key considerations for Medical Device Manufacturers preparing for the long awaited EU MDR (2017/745) deadline

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***As we enter Spring 2021, the long awaited deadline for European Medical Device Regulation (2017/745) looms on the horizon. Against a backdrop of the global pandemic, medical device organisations still need to continue to put time and resource into ensuring compliance with this new regulation which is set to be launched in May 2021. However the response to COVID-19 which prompted the 1 year extension, has caused a challenging environment for medical device manufacturers to work in.***

It is clear we will not be returning to the ***'old normal'***, which has put a significant strain on medical device organisations working towards the May 2021 EU MDR deadline. Medical device organisations now have the added complexity of preparing for the May 2021 MDR deadline, whilst coming to terms with the ***'new normal'***, in regards to the future of work, and Brexit.

***At Sopra Steria we understand that handling ongoing disruption during any digital or transformational project is not easy. There are many considerations and the added difficulty of combatting COVID-19 accentuates this further:***

## Spend and Priorities

Over the past 12 months many medical device manufacturers have had to quickly reprioritise work to support the wider pandemic cause. A high demand for personnel protective equipment (PPE), and ensuring the flow of PPE supplies to protect key workers and patients became the top priority. The MDR extension was implemented to ensure healthcare facilities had the essential supply of devices during the critical phases of the response. Alongside this effort Medical Device Manufacturers also had to set aside extra budgets, time and personnel to make sure they were ready for the May 2021 deadline.

However in many organisations the extra year given to be ready and compliant wasn't an additional year spent on compliance readiness. Instead it was spent just making sure their organisation could meet unprecedented demand for specific products and in turn has taken budget, people and skills away from their compliance departments.

This means many Medical Device Manufacturing organisations are now faced with understanding and implementing a solution to MDR 2017/745 in shorter time scales and with less budget than they planned for. In some cases we are seeing some Medical Device Manufacturing organisations deploying short term quick fixes hoping that they will be able to recover and make up for lost time.

At Sopra Steria we believe a short term fix around MDR 2017/745 is probably going to do more harm than good to those organisations who adopt this approach. Our advice is clear; yes it may take you slightly longer than you anticipated but having a clear improvement roadmap linked to your organisations future desired state is the right way forward for MDR 2017/745 compliance. This means undertaking the right data discovery exercise, making sure the right people are available and partnering with technology experts so you meet your regulatory obligations. All of this starts with prioritising spend, resource and exploring the market of where suppliers can help you overcome the challenges your organisation is facing around this challenging legislation with an imminent deadline.

## Working Practices

As we continue down the ***'new normal'*** of working from home, all organisations have begun to realise some of the challenges employees face on a daily basis. Particularly those who were accustomed to working in an office, laboratory or manufacturing plant.

Repeated lockdowns are posing concerns for manufacturers who must balance the need for production with social distancing rules, resulting in staffing and shift pattern changes. Ultimately there are fewer people onsite which has an impact on the time taken to keep processes going. For regulators and medical device organisations the increasing likelihood of remote audits and adopting new processes to conform to them is an additional consideration.

For those employees who are coming back into the workplace, safeguarding may mean implementing measures such as temperature checks at the entrance of buildings and strict access control in line with regulations. Working with HR teams to ensure safeguarding of employee wellbeing is maintained is crucial to ensuring efficient employee productivity. Only by having the right staff available and ready to work will Medical Device Manufacturers be in a position to achieve compliance between now and the 26th May deadline. Failure to make staff available or not provide them with the right tools to undertake relevant checks and reports is highly likely to result in non-compliance by the given deadline date.

## Digital and Data

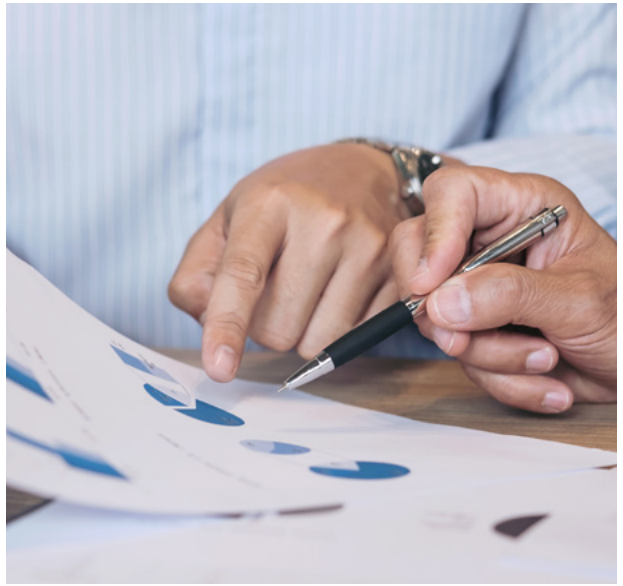
Efficiency of moving data throughout a supply chain has become extremely important due to Covid-19. Those with inefficient supply chain models in other industries are suffering. For example - are your supply chains and data management policies robust enough for when demand picks back up and hospitals start accepting patients back for operations?

There is general industry consensus that data-driven decision making and data availability must improve. **The fact sheet on MDR requirements for Publically available data is now live–**

*https://ec.europa.eu/health/sites/health/files/md_newregulations/docs/transparency_factsheet_en.pdf*

As a quick check, can you easily answer the questions or provide the data the form requires? Or is your organisation struggling to fulfil this basic data capture exercise?

> ***We are using remote collaborative tools more so than ever before. In the face of such growth, the reliability and resilience of your assets is paramount. Are employees getting the right training and tools to ensure they can work effectively, safely, securely, and at least to the same performance levels as pre-Covid?***



## Re-focusing employees

The knowledge your teams have in terms of your processes, and maturity against the upcoming legislation, has to be unlocked and deployed. However the disruption of the past year has placed greater emphasis on maintaining a people stream for MDR Projects. Whether as a result of organisational change or priority focus ensuring availability, training needs, and mechanisms for knowledge management are important aspects to refocusing your employees to the MDR challenge.

## Look for external help

Business and industry has demonstrated in response to Covid-19 that by collaborating together we can support the accomplishment of common goals. The model of ***'doing it yourself'*** is more strained than ever, and organisations should look to partner and collaborate with suppliers who can share the strain and challenge of meeting project deadlines, through providing appropriate skills, guidance, and tools. Innovative commercial models are available for you to take advantage of and to share this challenge with suppliers who are subject matter experts.

Customers and patients will be even more vigilant about health and safety. As Medical Device providers, there will be a greater focus that you continue to provide products and services which adhere to the most rigorous health and safety regulations, so consumer trust is not compromised.

***At Sopra Steria we believe Medical Device Manufacturers who are investing in technology and innovation to address their MDR projects and programmes of work now, will be in a better position than their competitors in addressing all this important upcoming industry regulation.***

# More Information

Our Medical Device Manufacturing team at Sopra Steria have real world expertise of guiding organisations through the MDR journey, equipping the business with an effective, data driven solution to facilitate regulatory compliance whilst reducing the reporting burden associated with this type of legislation.

**For more information on Sopra Steria compliance solutions for MDR 2017/745 please contact:**

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**We look forward to working with you.**

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