A chance to get it right

Making sure you are ready for the EU Medical Device Regulation (MDR)

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The European Commission has announced its intention to postpone the implementation of the upcoming Medical Device Regulation (MDR) following the Coronavirus outbreak.

The postponement allows Medical Device Manufacturers to concentrate on the global effort against the Covid-19 pandemic, whilst offering a welcome respite to those organisations who are struggling with the demands of the regulation.

The MDR (2017 / 745) legislation was due to come into force on 26th May this year, however the European Commission has proposed postponement by one year, enabling Medical Device Manufacturers to focus efforts on fighting the global pandemic, whilst keeping critical healthcare systems running.

It is evident that implementation of the MDR requirements amongst Medical Device Manufacturers is a challenging undertaking. Recent research by a leading Health Tech in February 2020 showed that only a few companies were ready for the regulation, with many still using paper and excel spreadsheets for clinical data collection. Medical Device Manufacturers are faced with increased costs and resourcing to pull together the programmes which will deliver compliance against the regulation, in some cases up to 5% of turnover.

Don’t underestimate the challenges

From our experience of navigating the journey to MDR compliance, the scale of effort required can easily be underestimated, as can the pressure it places on internal teams and work.

> At Sopra Steria we strongly recommend maintaining a degree of continuity on your MDR programmes over the next year.

Be prepared, ensuring your people, processes, and technology choices are aligned to achieving a positive outcome on the new 2021 date. Specifically we would suggest over the coming 6 months you should consider the items below, allowing for any remediation measures to be put in place in a timely manner.

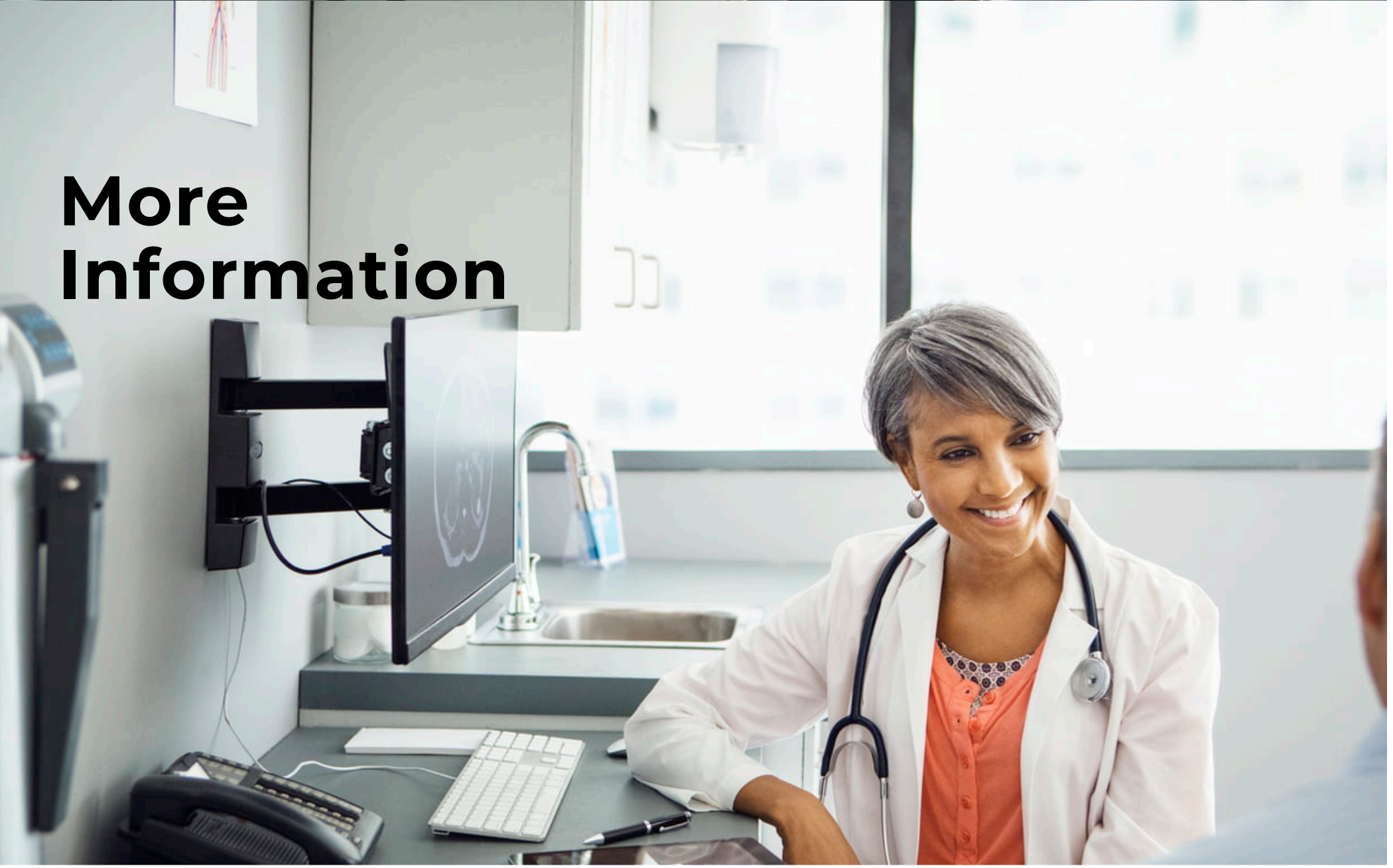
- **Reassess your Solution:** Is your level of investment into MDR compliance likely to bring satisfactory results in a years’ time? In doing so consider the challenge of collating product data from dispersed and silo’d sources, and having the ability to present this in an easily digestible and searchable platform, offering meaningful analysis which will ultimately save you time and cost in meeting the ongoing requirements of legislation.

- **Look at external support and partnering options -** Medical Device Manufacturers are utilising a significant proportion of their employee base in bringing their procedures up to standard. There are some credible technology providers in the market who can advise and accelerate your path to compliance. Manufacturers should ensure that they have the right partners to support them through the process. Small and Medium-sized manufacturers are unlikely to have the capacity to dedicate much of their workforce and should consider options for external support.

- **Reassess whether your Operating Model is ‘Fit for the Future’:** Get clarity on the new requirements. The regulation in terms of Post-Market Surveillance, Quality Management Systems, Notified Bodies and clinical data capture systems is complex, so speak to experts who can guide you. As well as preparing all data in advance of the new deadline, speak to your notified bodies for advice.

For now the priority must be a collective focus to fight the Covid-19 virus, putting patient safety first and keeping healthcare systems running through these unprecedented times. However by using the extension effectively, the benefits of successful MDR implementations will ensure we as an industry are better prepared for future threats.

More Information



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In the forthcoming weeks Sopra Steria's Medical Device Manufacturing experts will be creating a number of articles for IT, Data and Compliance professionals in this marketplace. 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 burden of effort upon the business whom can focus their true product expertise upon the explanatory evidence which has led to product remediation changes undertaken during the past regulatory cycle.

For more information on Sopra Steria compliance solutions for MDR please contact:

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Thank you for reading

Medical Device Regulation (MDR)