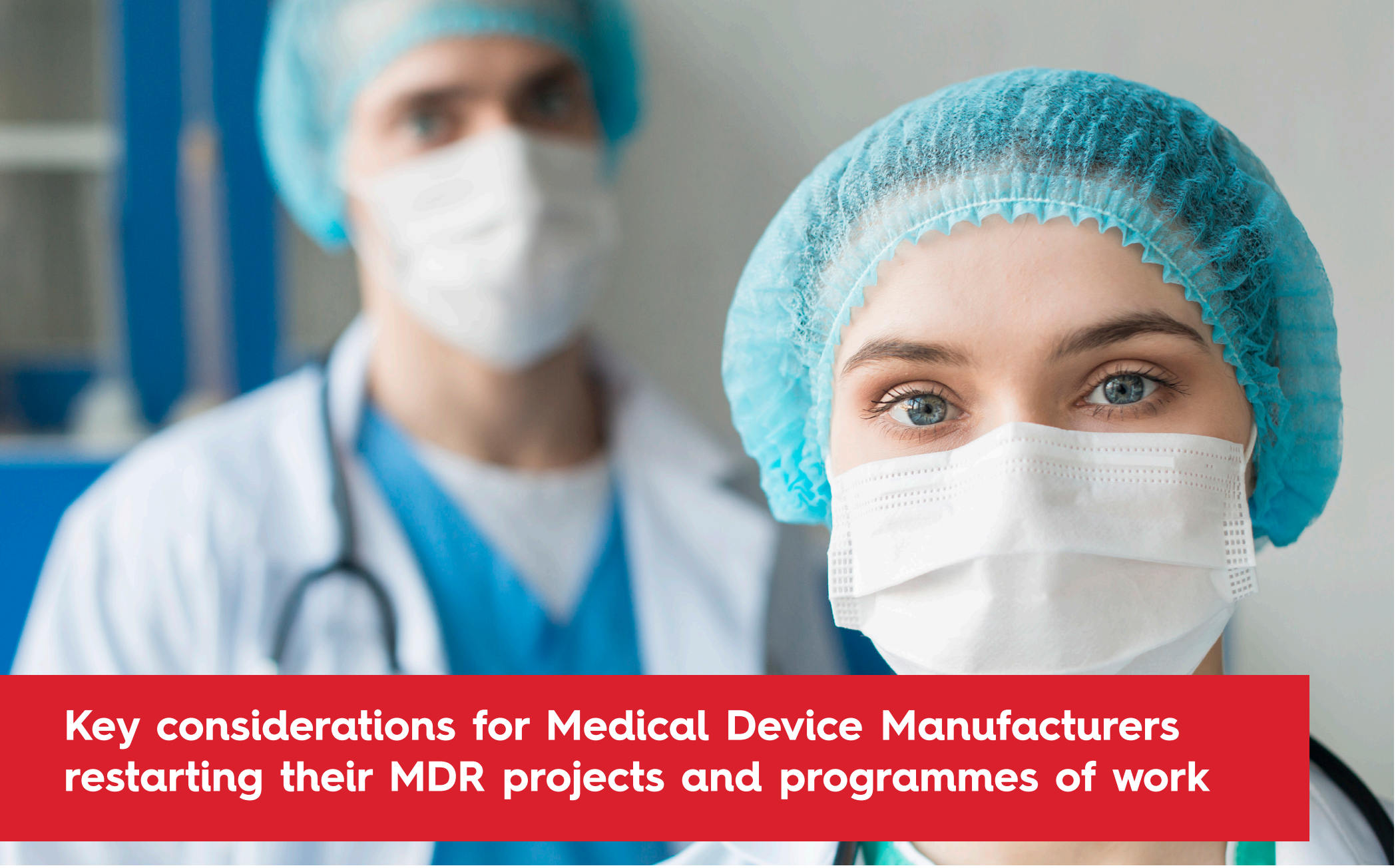

# Key considerations for Medical Device Manufacturers restarting their MDR projects and programmes of work

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***As the Government announce plans to move into a more relaxed phase of the COVID-19 lockdown, many organisations have started looking forward and addressing projects which have been on-hold for the past 5 months. Whilst some of these projects may be permanently cancelled, those which enable adherence to changes in legislation should be prioritised.***

It is clear we will not be returning to the ***'old normal',*** so medical device organisations who are restarting projects in preparation for the new May 2021 MDR deadline, will need to quickly adjust to the ***'new normal'.***

Restarting any digital or transformational project after a prolonged break is not easy. There are many considerations and the added complexity of COVID-19 has made this even more challenging:

## Remobilising employees

The biggest asset in most projects is human capital. The knowledge your teams have in terms of your processes, and maturity against the upcoming legislation, has to be unlocked and deployed. However the past 5 months has been challenging for many. You may have employees on furlough, employees who have experienced a change in circumstances which prevent a normal return to work, or organisational change which has meant a change in roles for others.

Whatever the circumstances it is important to ensure you have a people plan or stream for your MDR projects which takes into account resourcing and availability, training needs for backfill, upskilling and cross training, and mechanisms for knowledge management.

## Working from home

As we continue down the 'new normal' of working from home, we have begun to realise some of the challenges employees will face on a daily basis. Sitting on a dining chair to eat a meal is fine but it quickly becomes uncomfortable when working at the dining table all day. From adequate seating arrangements, to appropriate technology, working with HR teams to ensure safeguarding of employee wellbeing is maintained is crucial to ensuring efficient employee productivity.

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.

***Appropriate hygiene and safety measures will need to be applied, which may extend to ensuring travel to work is as safe as possible.***

## Digital and Data

The sudden switch to remote working which has been adopted by most organisations has focussed the spotlight on the importance of data and digital as an enabler for success in the new normal economy.

Unifying silo'd data will become a clear competitive advantage. Data collaboration improves both speed and quality of insights. It is no longer good enough to just manage data. Value must be extracted across all business functions. This is of course relevant to Medical Device companies who must consider additional data sources to not only attain MDR legislation but also inform strategic and operational decisions.

Can your data operations scale and are they ready to ingest new sources? Many are still reliant on excel spreadsheets and manual processes – as we have discovered over the past 12 months.

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*

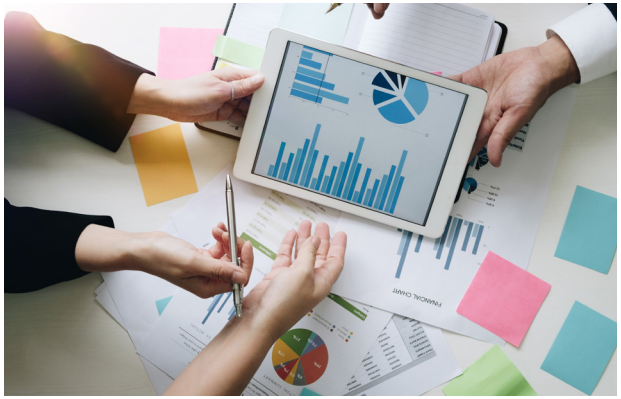
As a quick check, can you easily answer the questions or provide the data the form requires? Or is your organisation struggling to fulfil this basic data capture exercise?

> ***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?***

## Spend and Priorities

A short term decline in revenues has resulted in pressure on costs and investment for many Medical Device Manufacturing organisations.

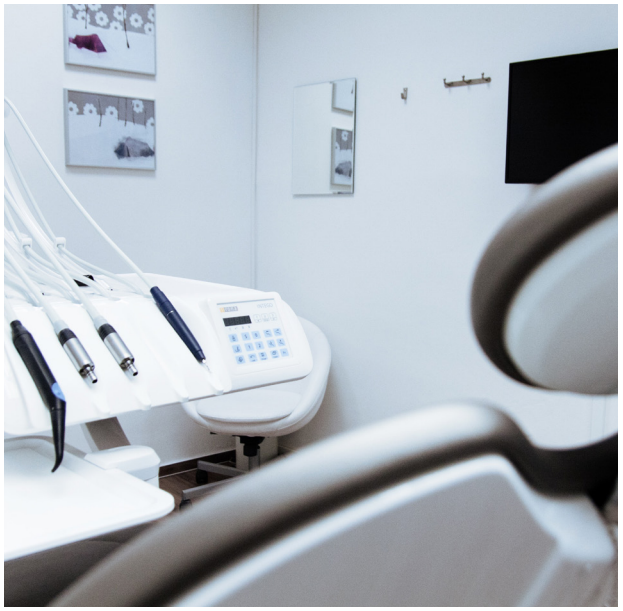
It is important to understand your current position vs your future desired state in the mix of your organisations new priorities and challenge appropriately. MDR legislation is not going away and failure to comply could cause significant reputational damage.



## 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.

Although lockdown restrictions are now easing, 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 take the time to re-start their MDR projects and programmes of work now, will be in a better position than their competitors when the legislation comes into force in May 2021.***

By re-starting MDR programmes of work now, Medical Device Manufacturers can make sure they are capturing the right data, putting in place the right processes and make sure they have access to the skills their organisation needs to be compliant.

# 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 please contact:**

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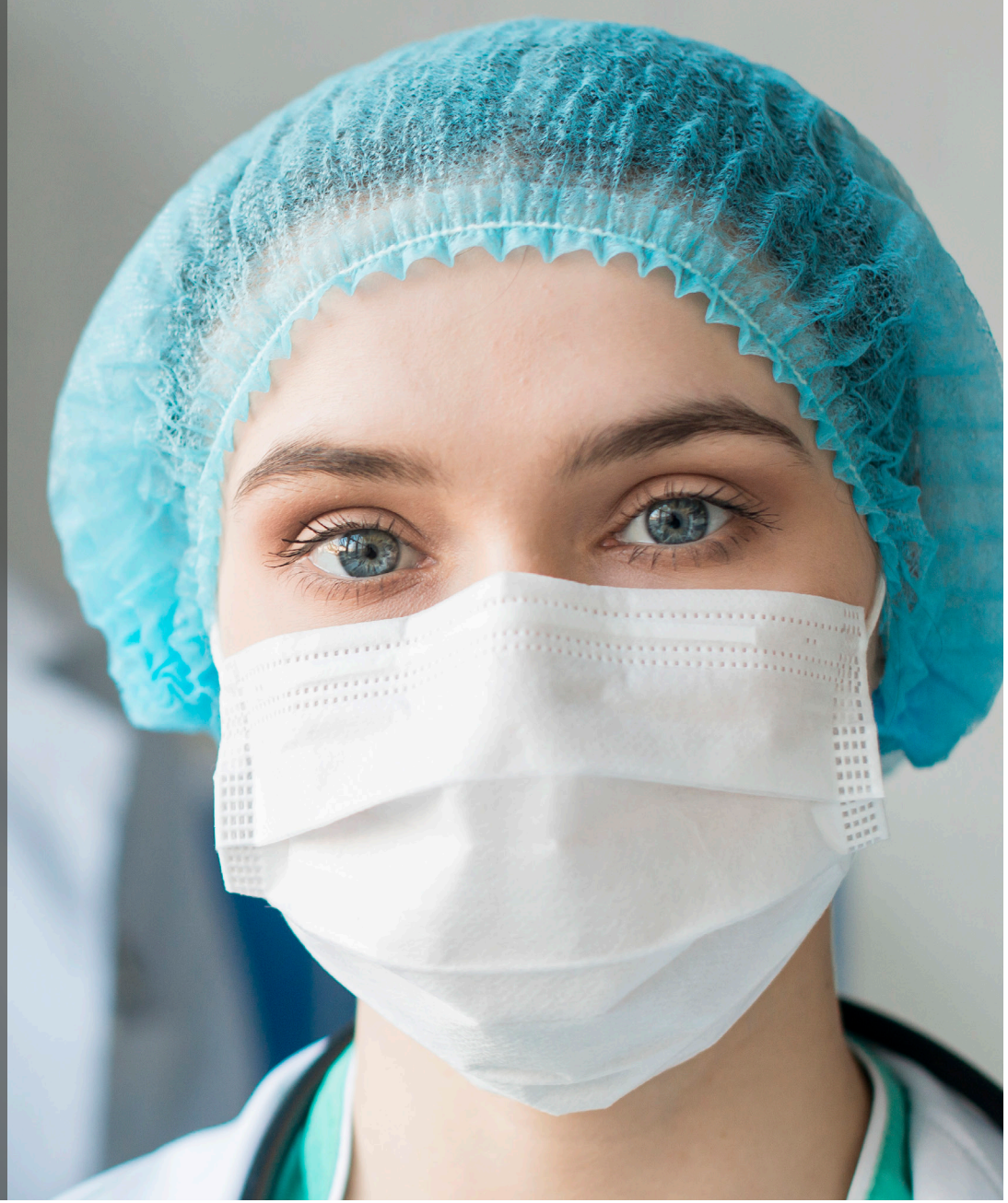
**We look forward to working with you.**



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