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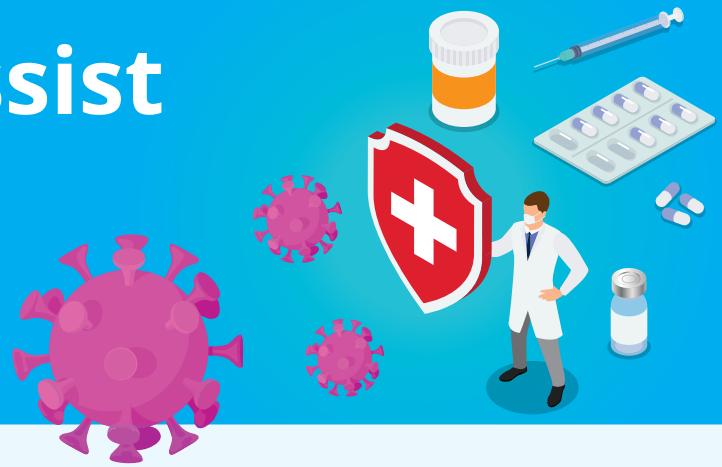
FAQ: Pivoting to Assist with the COVID-19 Response?



COVID-19 has left no one unscathed. As social creatures, these are challenging times. That being said, one of the most encouraging responses to COVID-19 has been the number of individuals and companies, large and small. We need to encourage this behaviour and leverage every opportunity but we need to do it wisely and deliberately. Here are a couple of things you should know about the field of life sciences manufacturing.

Can I manufacture necessary products like face masks? Face masks, respirators, and ventilators, nasal and throat swabs, test kits, and lab analyzers are regulated by governmental authorities around the world. Why? Public safety is paramount! The regulations and regulatory authorities are to ensure that the performance and benefit claims of regulated products are accurate and effective.

One of the consequences of a regulated environment is that there are regulations and guidelines that must be complied with in order to manufacture. If you have this experience, you are ahead of the game. If you don't, you need to seek guidance from people and organizations that do.

But I have ISO 9001:2015 certification. Isn't that enough? Not really. It's a good first step. ISO 13485:2016 is better. But the bottom line, although a strong quality management system is essential, there is more to manufacturing in a regulated market. You must comply with your region's CGMP requirements. If you are not familiar with these requirements, buddy up with a manufacturer who is.

My organization does medical device manufacturing but with this increase in demand for our products and social distancing constraints, my capacity is severely strained. What can I do?
Consider one of the following options:

- Identify a contract manufacturing partner with CGMP manufacturing experience.
- Add lean cells or semi-automated manufacturing capability which can be implemented in relatively short order. Look for suppliers who have experience with CGMP equipment design, build and supply.

I know we have some older equipment lying in our warehouse. How can I tell if it would be helpful to use? If you have in-house, CGMP skilled technical staff, have them look at the equipment for overhaul, upgrade, or re-purposing potential. You might also be able to reconfigure it for semi or fully automated workflows. But you can also consider partnering with others to fill those skill gaps and leverage their experience, expertise, and supply chains.

When the crisis passes, what should I do? There will be a point in time when you will want to return to normal operations. So make sure you have developed a plan to:

- Communicate with employees, suppliers, and customers.
- Address raw material and component supply.
- Clean and prepare production areas.
- Exercise equipment that has been fallow.

Don't assume that things will run smoothly when you turn the lights, air, and power on. Arm yourself with the resources you need to ramp-up efficiently and predictably.

Should I be doing something to prepare for future pandemics? Pandemics are only one kind of disaster. There are others like fire, political turmoil, etc. So you should definitely prepare a Business Continuity Plan. Consider things like:

- Supply chains – Are you relying on a single country or supplier?
- Production capacity – Are you relying on a single production line or site?

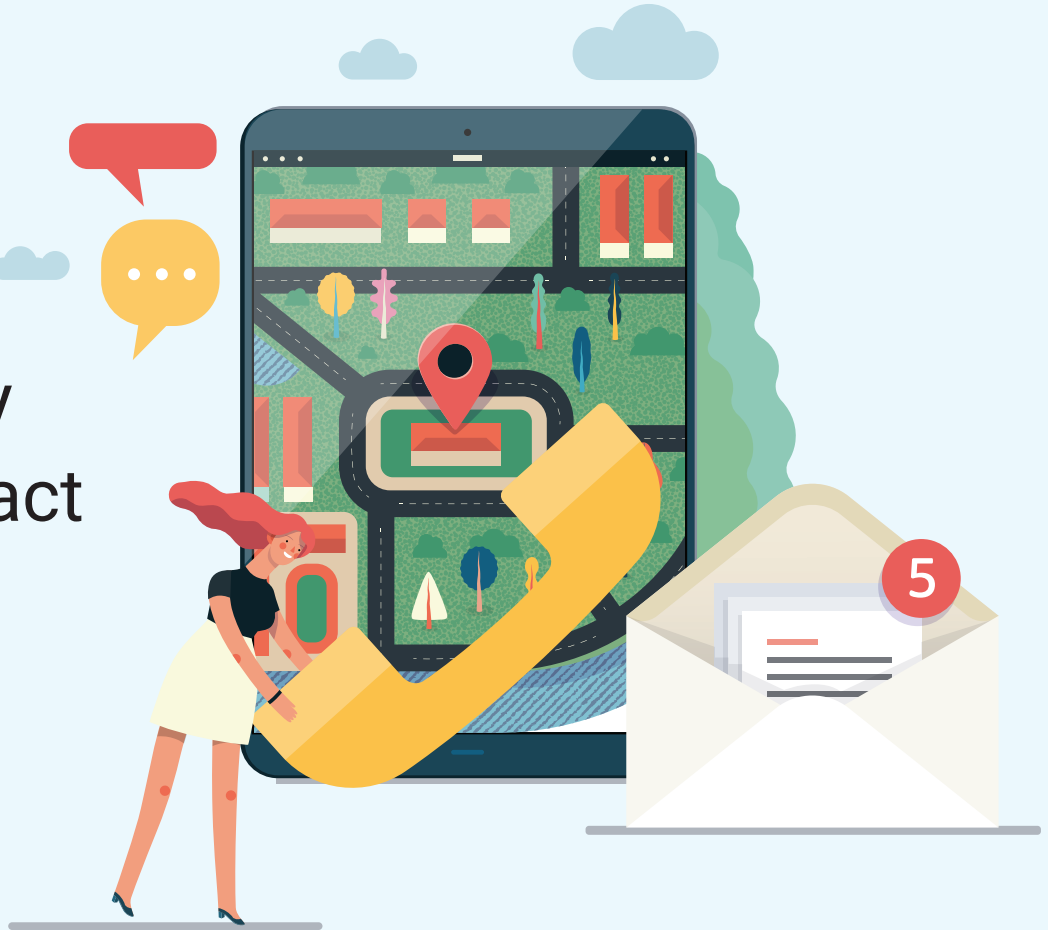
What can I do if I can't afford to implement full redundancy? You don't have to double up on everything. Begin with a review of your supply chain, your manufacturing capabilities, your products and demand forecast. Establish your risk tolerance and make adjustments accordingly. This will determine the need for complete or partial redundancy. Consider partnerships, contract manufacturers, and other models that would give you temporary or long term capacity options.

References

- Food and Drug Administration US (FDA) - www.fda.gov/medical-devices
- Canadian Health Protection Branch (HPB) - www.canada.ca/en/services/health/drug-health-products
- MHRA - www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
- European Commission - www.ema.europa.eu/en/human-medicines-regulatory-information

Questions?

For more information on any of these topics, please contact your ATS Automation Sales Representative.



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