Pivoting to Assist with the COVID-19 Response? Key Things to Consider

ATS LIFE SCIENCES

COVID-19 continues to shake our world and challenge our perceptions of security and surety. No one is unscathed, from family to friends to communities, both social and business. But the resiliency of people and companies continues to be inspirational as they use whatever resources they have at their disposal in new and novel ways. If you have been pondering how to get involved and are interested in arming yourself with the necessary information to make the go/no go decision, here are a couple of things you should know about manufacturing in the life sciences market place.

Regulated Environment

Medical devices including masks, respirators, and ventilators, and medical diagnostics including swabs, test kits, and analyzers, are regulated by governmental authorities around the world. In this way, public safety is protected and the performance and benefit claims of approved products are guaranteed. But one of the consequences is that there are regulations and guidelines that must be complied with in order to manufacture – these are referred to as Current Good Manufacturing Practices or CGMP. If you have this experience, you are ahead of the game. If you don't, you need to partner with people and organizations that do.

Quality Management System

An integral part of being a compliant manufacturer is a Quality Management System. The existence of a QMS and the demonstration of due diligence are fundamental CGMP responsibilities. Organizations with formalized policies, processes, procedures and responsibilities for the planning and execution of production to meet quality requirements are well suited to be manufacturers of medical devices and diagnostics. Certification to the ISO 9001:2015 standard is a good start; ISO 13485:2016 is even better. If you are not familiar with either, buddy up with a manufacturer who is.

Production Capacity

With a sudden increase in demand for products, production operations can be severely strained. Sometimes this can be eased by sharing the burden with others, e.g. contract manufacturing. Another option is to consider the addition of lean cells or semi-automated manufacturing capability. Look for suppliers who have experience with CGMP equipment design, build and supply.

Manufacturing Equipment

Not everyone has spare manufacturing equipment or fallow assembly lines. But you may have an underutilized asset that can be repurposed or an equipment graveyard from which you can resurrect and salvage. If you have in-house, CGMP skilled technical staff, you are well-positioned to overhaul, upgrade, and configure 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.

Validation

An important last step before using your equipment to manufacture medical devices and diagnostics is validation. Make sure you thoroughly test and document the critical processes and equipment so that you have evidence that the equipment will repeatably and consistently produce the specified product.

Business Recovery

Make sure you are developing 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, and more. 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.

Business Continuity

Our businesses are vulnerable when we rely on a single production line or site or supplier. We are also vulnerable when our whole global supply comes from a single country. But the solution isn't necessarily creating a twin or twins in other locations. Once things have settled down, make sure to complete a review of your supply chain and determine what your risk tolerance is moving forward. Maybe you will need an entire repeat of a manufacturing system. Or maybe you will decide that only a portion of the system is critical and that is where you need redundancy. Another option might be to arrive at a partnership agreement with another company or contract manufacturer. Whatever your decision is, determine to be a good global citizen.

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?

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