

Enterprise Systems Assessment for Medical Imaging and Diagnostics Business

This client is a U.S.-based manufacturing organization that designs and manufactures equipment for production of hyperpolarized xenon or helium gas. When used in conjunction with MRI, these gases offer a fundamentally new and non-invasive functional imaging platform. Current investigational uses include identifying early diagnoses of respiratory diseases as well as monitoring progression and therapeutic response.

In 2021, the organization was looking for early Q4 FDA approval of their first product. As part of this process, they partnered with Clarkston to help them assess and define their enterprise system roadmap to support their expected commercial launch and growth plans. This included a review of their sales and operations plans over the next 2-3 years, their current systems and processes, and their organizational structure. In addition, the effort included helping to define a pharmacovigilance and call center outsourcing model that would still enable the client's quality group to effectively manage adverse events.

Life Sciences Case Study

PROJECT OVERVIEW



INDUSTRY:



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PRODUCTS AND SERVICES :



Designs and manufactures a combination drug/device product for use in diagnostic processes

PRIMARY OBJECTIVES:

- Detailed business processes based on business requirements and industry best practices needed to support pre- and post-commercialization
- Defined organizational structure and areas of responsibility to align with pending commercial launch and business growth strategy
- Developed an enterprise system roadmap to meet the organization's needs and priorities with regards to expected approval and launch

RESOLUTION:

- Defined current and future business processes to support commercialization
- Identified quality and regulatory components and touchpoints, including pharmacovigilance and product release, to resolve/avoid compliance issues
- Analyzed timing of systems and capabilities based on value proposition and criticality to launch
- Prepared a working roadmap with a focus on standing up critical systems and capabilities necessary for commercialization in addition to a long-term approach to support growth
- Provided a budgeting tool that reflects spend by quarter based on real-time roadmap timeline adjustments

KEY BENEFITS:

- Reached alignment on key processes and organizational structure to support new areas of responsibility required for commercialization
- Provided approach to spread organizational and budgetary impact while balancing near-term requirements with long-term plans for scaling
- Established a timeline with key business milestones, dependencies, and the supporting technology that will be needed for scale

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IT Consulting

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