

CONTRACT MANUFACTURING

- ERP Built for the LIFE SCIENCES Industry

Navigator Business Solutions offers a unique solution for Contract Manufacturing Organizations (CMOs) combining a ready to validate cloud platform with years of Life Sciences Industry experience. The solution is built on the fully integrated SAP Business ByDesign Cloud ERP enhanced with additional specific functionalities that help CMOs optimize supply chain, comply with business and industry requirements, improve forecast accuracy, drive operational efficiency and improve delivery OTIF (on-time and in-full) while meeting Good Manufacturing Practices (GMP) including serialization regulatory requirements.

CHALLENGES FACED

Pharmaceutical Contract Manufacturing Organizations (CMOs) are at the center of today's life sciences global supply chain disruption; including a dramatic increase in demand, rapidly changing expectations from global drug manufacturing partners and increasing competition from start-ups looking to capture market share.

CMOs manage a complex and most often Global Supply Chain on a daily basis. This requires real-time visibility, going beyond price and availability to include the all important quality and regulatory aspects of materials.

CMOs face a constantly developing marketplace with evolving competition including an active mergers and acquisitions landscape. This means differentiation and innovation is more important than ever, to deliver to the customer's expectations. Today's environment, both medical and political, has amplified these points.

CMOs depend on validatable and robust, integrated solutions to achieve greater operational efficiency, to maximize capacity while providing the flexibility to support shorter production runs and scalability to meet demand spikes and future growth. CMOs continue to be pushed even harder to focus on quality, cost and delivery.

LOOKING INTO THE FUTURE

It is clear that Pharmaceutical organizations will continue to look to CMOs for more than basic manufacturing. Customers are moving more responsibility onto CMOs increasing the pressure to offer a wider array of services including R&D, warehousing and distribution.

As global competition increases pharmaceutical companies will expect ever increasing transparency into CMO operations with the ability to track beyond the number of units completed to include work-in-progress and quality.

The growing demand for agility and quality, mixed with the expanding market for more and unique pharmaceutical therapies, will expand the complexity of production and the attached supply chain, leading to a broader reliance on contract manufacturing in the future. In a continually expanding global marketplace with increasingly complex regulatory requirements CMOs will have the continuing need to make operational efficiency, flexibility and scalability their dominant focus.

ESSENTIALS FOR KEY DECISION MAKERS

COOs face the pressures to implement state-of-the-art processes and advanced technologies for digital transformation. These include IoT for production and warehouse operations, to improve regulatory compliance, quality and delivery. COOs need a comprehensive platform upon which to develop and deploy connected solutions and services, as well as improve the integration between IT/OT.

CEOs need to ensure their company is agile enough to execute rapidly on key decisions – this impacts every aspect of the organization; people, processes, practices, partners and solutions. The CEO will continually need to balance innovation with cost, risk and investment.

CIOs are at the heart of the required digital transformation and are required to move from old, unsustainable, insecure systems or their start up platforms, to best practice based solutions that will help their organization rapidly adopt changing business models and readily adapt to the turbulent external environment.

The VP of Supply Chain must become a more strategic partner to the business; moving from price-centricity to viewing and managing the complete supply chain, by improving visibility and applying best practices all while supporting the enterprises regulatory compliance.

The VP of Regulatory and Quality must be constantly aware of new industry regulatory and compliance requirements and have the tools to maintain and adapt a consistent Quality System to them.



HOW WILL NAVIGATOR HELP?

SAP has been a trusted solution partner to CMOs for decades. Navigator Business Solutions uses the SAP Business ByDesign platform to deliver an affordable, best practices based solution using its accelerated implementation methodology. This solution affords CMOs with access to SAP technology at a price they can afford and at a speed that enables CMOs to perform a digital transformation with minimal disruption.

The SAP Business ByDesign delivered by Navigator Business Solutions provides a comprehensive yet flexible solution for global manufacturers, supporting the unique needs of each manufacturer and offering excellent fit out of the box. Our SAP cloud-based, FDA- qualified environment reduces the effort required for software validation and 21 CFR Part 11 and Annex 11 compliance. It supports Track and Trace and comprehensive serialization to meet the DSCSA and Falsified Medicines Act to support ever-evolving compliance requirements.

The SAP Business ByDesign platform provides out of the box business processes that can be quickly and easily adapted to a CMO's unique needs using its comprehensive configurability, built in usability tools and ready to integrate open web services architecture.. The concept of "click not code" eliminates the needs to expensive and difficult to maintain (and validate) customizations. SAP's continuous innovation on their advanced cloud platform virtually future-proofs the application platform for CMOs.

SAP Business ByDesign is a Suite in a Box that provides the distinct planning and manufacturing needs of contract manufacturers – including demand and supply chain planning, shop floor visibility, warehousing and quality management.

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