MERIT SOLUTIONS | LIFE SCIENCES

We understand the quality and compliance requirements of Life Sciences organizations. Our solution, expertise, and industry-specific apps combine to support your growth and ensure efficiency. Here are specific examples of how Life Sciences manufacturers can benefit from our customer tailored workloads.
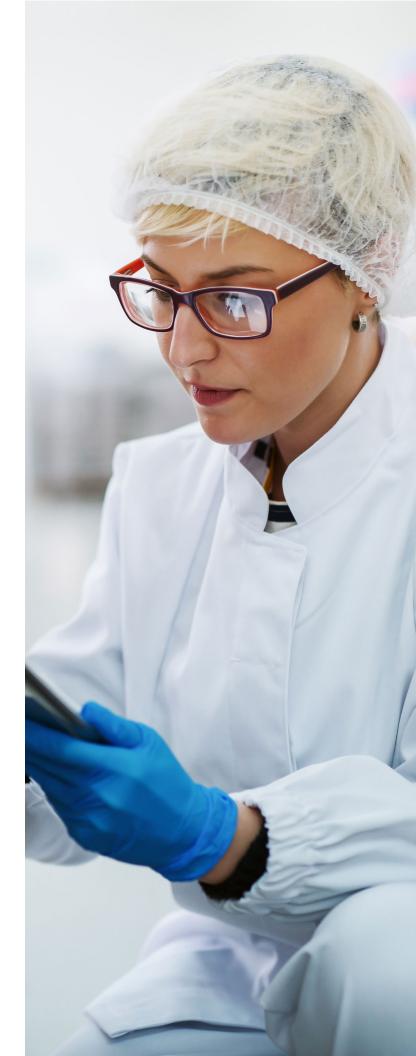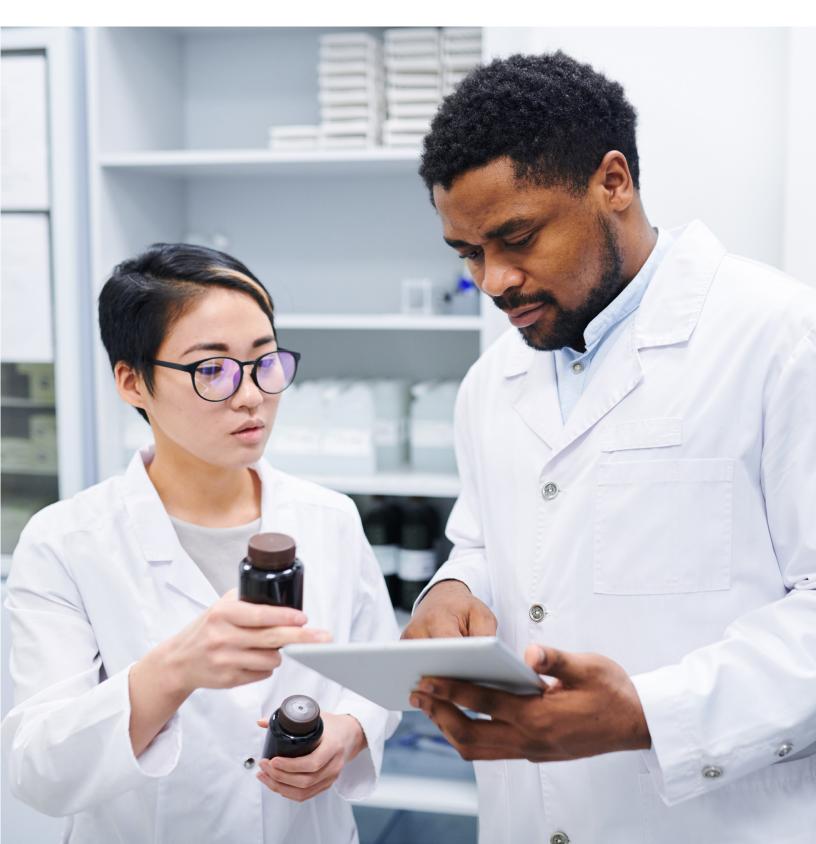
Production

• Handle unexpected volumes of success and growth through amodernized infrastructure and optimized business processes.

• Significantly shorten order production and delivery time.

• Implement a model driven planning engine for real-time insights into when to order or produce certain materials and shorten order cycle time.

• Deliver products on time with unprecedented accuracy.

• Digitally support tracking of material lot status to reduce human error and enforce software driven controls for material lot status changes and material movements.

• Digitally oversee batches that can be split into multiple lots or sub lots for downstream processing.

• Maximize the use of resources (machines, rooms, and people) for the best production schedule outcome and speed up scheduling decisions.

• Reduce the complexity of tracking various parameters related to specific business processes, as well as employees' training and certifications.

• Track the handling of raw materials throughout their preparation stage, capturing information about the process digitally and ensuring everything is auditable and done according to SOPs and specific batch requirements.

Compliance

• Enforce digital controls and ensure compliance for FDA significant processes. Meet Title 21 CFR Part 11, Part 211, and Part 820 requirements. Track all data changes related to those processes using data integrity controls. Enable authorized electronic signatures before changes can occur (preventative controls). Leverage an extensive framework that simplifies your process of meeting FHIR, HIPAA, and GxP requirements.

Materials Management

• Control assets tied up in raw materials, intermediate product, and finished goods product inventory with expiration dates per lots. Ensure lots are used before they expire or before the window of time required to put them out to customers closes.

• Reset material lots expiration dates after retesting for stability and other attributes. Use a digital platform to identify those material lots and retest within the available times.

• Recall trace any product at any time, quickly and completely, from the customer finished good all the way back to all raw materials used and every step in between.

• Control material labels, with the ability to audit printed labels. Automate label printing and have the system pull relevant information onto labels in a controlled manner.

• Prevent cross-contamination of materials while enabling accurate costing of materials based on actual dispenses units. Ensure accurate and consistent weighing of all material types.
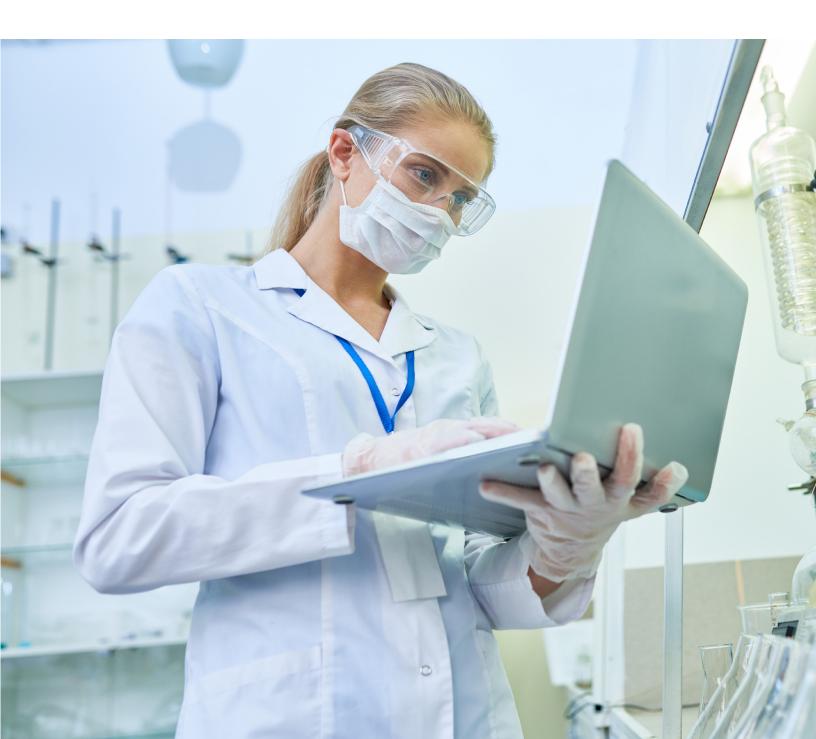
Quality Management

• Have our solution prompt for QC tests where needed, track the status sent out to QC, and manage against the expected timelines while waiting.

• Manage various quality test points throughout the materials and production process. Manage those quality test points, either by having the system perform that task, or by managing the queue of tests that have to go to QC and back while production is held up.

• Ensure sampling rules associated with specific items are followed automatically. Use industry standards such as ANSI to know when to increase or reduce sampling based on actual history of pass/fail rates of items.

• Keep comprehensive and auditable records of every reported incident. Ensure investigations can be performed across multiple people, facilities and geographies, knowing everything can be tracked and audited.

• Oversee the status of reported incidents from a centralized workspace and manage them to completion effortlessly.

• Store and manage SOPs, track their effective period and revision updates.

• Remove the need for applying electronic signatures to certain process steps by performing processes digitally instead of manually using controlled system events.

• Perform quality tests in the system, setting up tolerances for acceptance for specific items. Use the ability to retest if you get a marginal failure result the first time.

Procurement

• Audit and qualify vendors for items before ordering raw materials from them. Track all interactions with vendors including vendor nonconformances that could put them out of vendor qualification. Digitally enforce ordering from qualified vendors only.

• Proactively manage what qualified suppliers are coming up for recertification audit. Perform and track audits without disrupting the process of ordering required raw materials from vendors when needed.

• Test incoming vendor raw materials according to various test protocols related to risk and industry accepted sampling protocols.

Digital Customer Experience

• Digitalize your customers' interactions with your organization, ensuring everything is done in a secure and FDA compliant manner.

• Automate processes such as managing technical materials, specifications, sign offs and various other steps during the 'customer readiness' or 'batch readiness' phase. Reduce cycle times and work processes between the time an order is placed and the time the production batch for that order can be processed.

Digital Team Experience

• Enable your team to work with the best and latest digitally enabled apps optimizing the management of processes across your organization. Do away with time consuming manual tasks and enable your employees to become more productive and joyful.

• Transform some of your critical business process information into data which the system can use to recognize patterns, make better decisions and become even more efficient.

A Solution for Today and the Future

The tremendous potential of the Life Sciences industries requires organizations to be ready for major growth at a moment's notice.

Merit Solutions for Life Sciences exists to support the ambitions of those looking to improve the lives of others and prepare themselves for even greater future challenges.

It does so by providing customers with the necessary expertise and technology on their path forward, as well as by simplifying and reorganizing business processes for greater efficiency.

The success of our partners has the ability to extend the frontiers of knowledge in Life Sciences. It is our job to create a future-proof tool capable of helping them achieve it more swiftly and methodically.

For more information, please visit www.meritsolutions.com