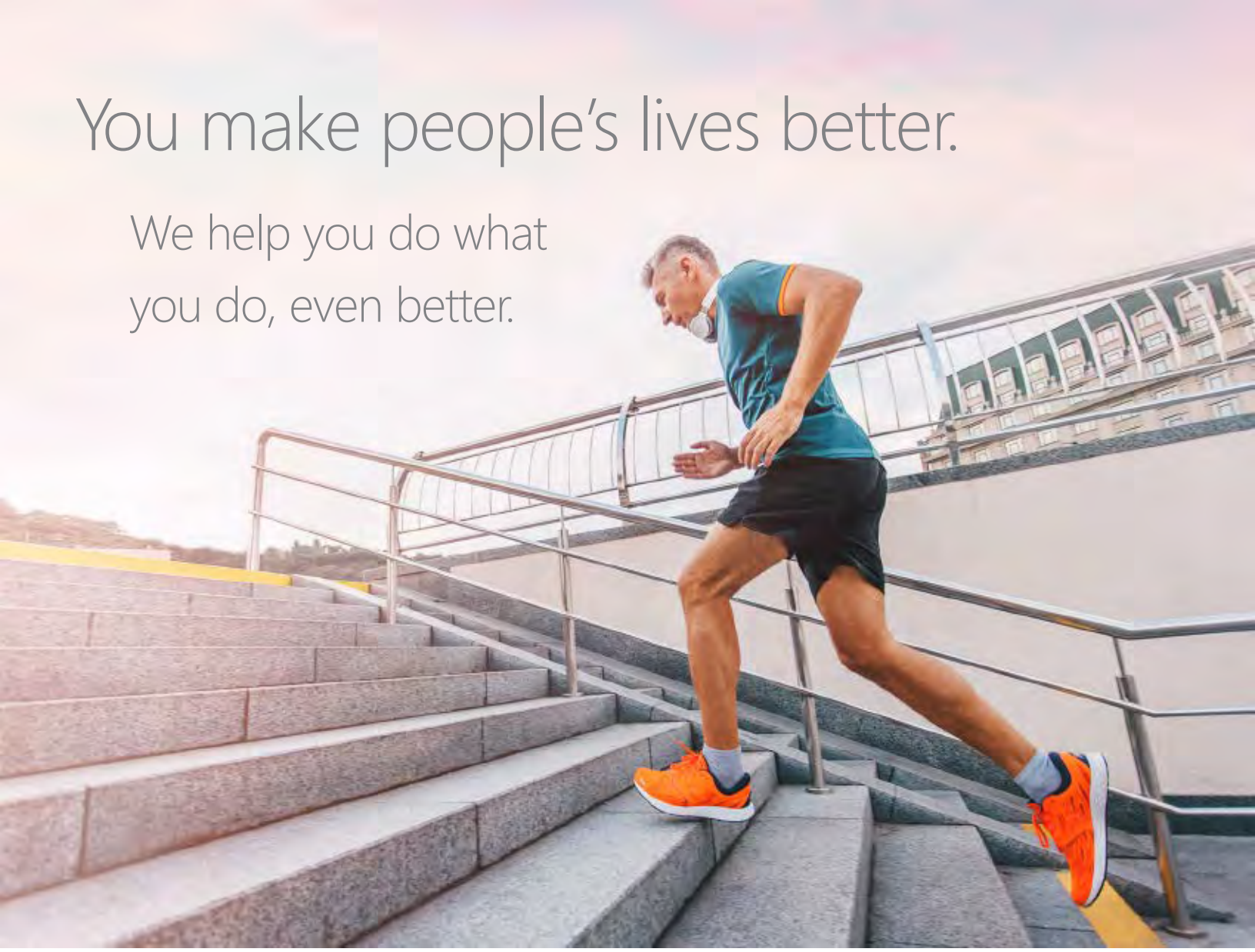
MERIT SOLUTIONS

Merit for Life Science

You make people's lives better.

We help you do what you do, even better.



More than any other industry, pharma, biotech and medical device organizations need an ERP system that is specifically built for the needs of life science manufacturers. The good news is, there's no need to compromise. As you navigate an ever-growing maze of stringent regulations, you can be confident that your ERP system has you covered – from demand forecasting and capacity planning to incidents, NCRs and CAPAs, from track and trace and electronic batch reporting to integrated labeling, shipping and tracking, and more.

Merit for Life Science advances the finance and operations (ERP) capabilities of Microsoft Dynamics 365* to deliver an industry-tailored solution that meets the rigorous requirements of pharma, biotech, medical device, and other regulated industries, with advanced planning, quality, procurement, materials management, production, and compliance functionality.

With Merit for Life Science, regulated manufacturers can drive increased process efficiencies, ready for and support rapid growth, and drive valuation while maintaining FDA CFR 21 part 11 and part 211, EMA Annex 11, and other country-specific regulatory compliance.

With our experienced implementation and consulting team, you gain an ERP partner who understands the complex operational, manufacturing, and compliance challenges organizations in regulated industries face.

**Merit Solutions also has a suite of applications for Dynamics 365 Business Central. For more information, visit meritsolutions.com/merit-business-central.*

Streamline operations to ramp growth and sustain profitability

Competing in the biotech, pharma, and medical device world means you have to be ready to handle volume before it hits. There is no time to be held back by spreadsheets and manual processes.

With Merit for Life Science, you've got the tools you need to increase manufacturing productivity, reduce time-to-market, and plan for and manage growth. You'll be on pace to ride the momentum from start-up to commercial success – and do so in a way that makes good fiscal sense.

FINANCE

- Evaluate and implement appropriate funding models to reduce R&D expense burden via licensing arrangements or other partnerships to ensure tax efficiencies.
- Make informed decisions about business development transactions.
- Establish financial reporting standards for acquired entities or to prepare for acquisition
- Transform your operations from disconnected silos to collaborative departments.
- Improve your decision-making process with reliable, auditable accounting practices.

PRODUCTION

- Electronically manage everything from materials evaluation and potency to equipment calibration and device/batch history records, across multiple modes of manufacturing.
- 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.
- Implement a model-driven planning engine for real-time insights about when to order or produce certain materials and shorten order cycle time.
- Digitally support tracking of material lot status to reduce human error and enforce software-driven controls for material lot status changes and material movements.
- Split batches into multiple lots or sub lots to improve and manage downstream processing.
- Use real-time data to maximize resources for the best production schedule outcome.
- Reduce the complexity of tracking various parameters related to specific business processes, as well as employees' training and certifications.
- Deliver products on time with unprecedented accuracy.

DIGITAL 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.
- 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.

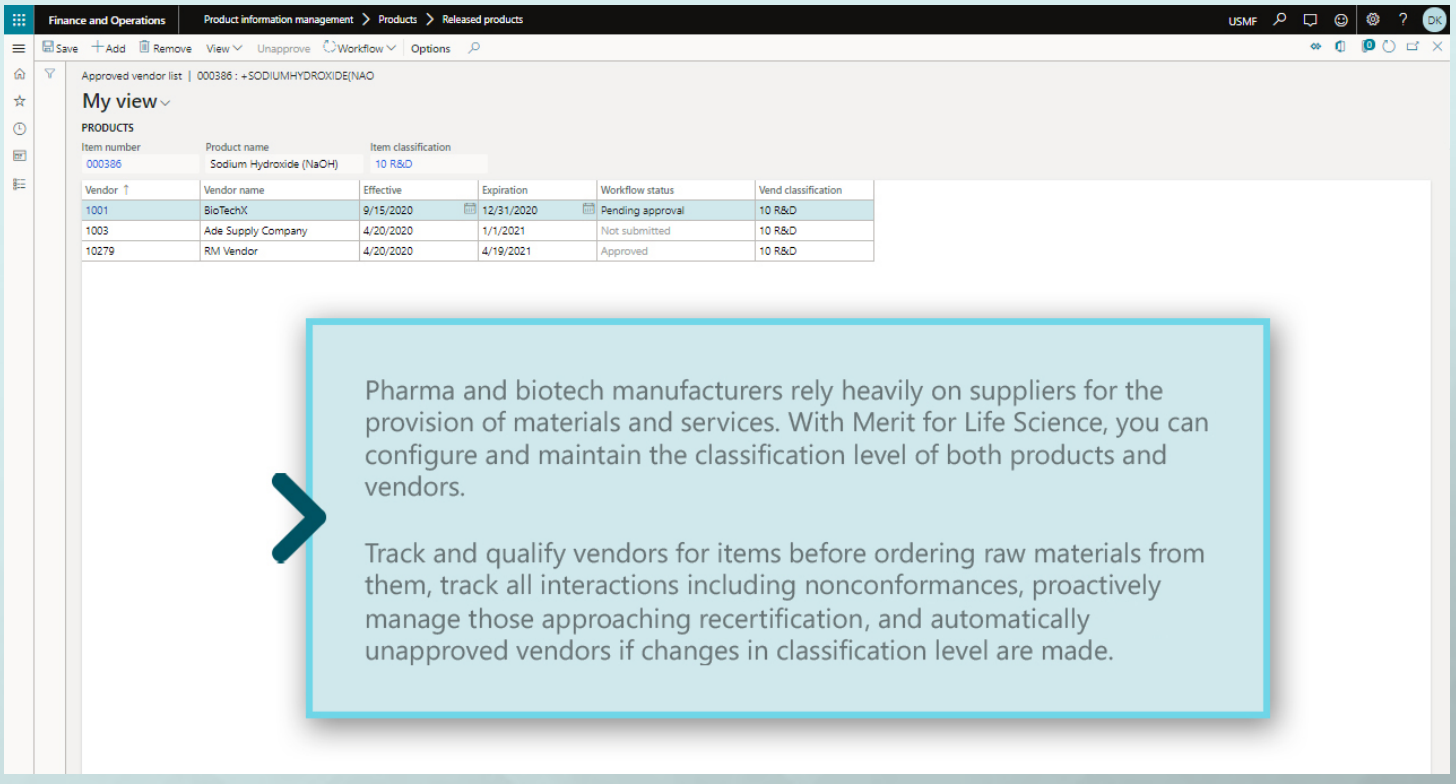
Gain End-to-End Supply Chain Excellence

Nothing magnifies internal and external issues like an unexpected disruption in the supply chain. For regulated manufacturers, the speed with which you can remedy those interruptions can be life-changing.

With Merit for Life Science, you can pinpoint the trouble spots and put the right checks and balances in place to prevent them. By monitoring the rules that matter, you'll have confidence that you're working with qualified suppliers, managing resources with precision, and accurately and consistently producing product.

PROCUREMENT

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



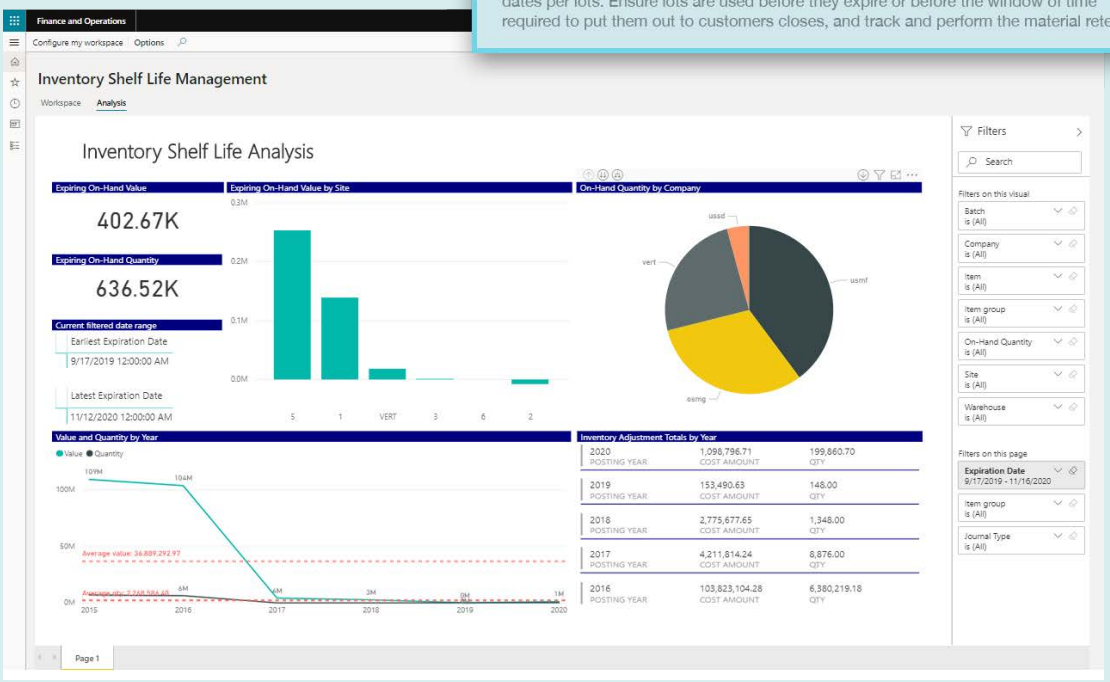
MATERIAL MANAGEMENT AND CONTROL

- 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.

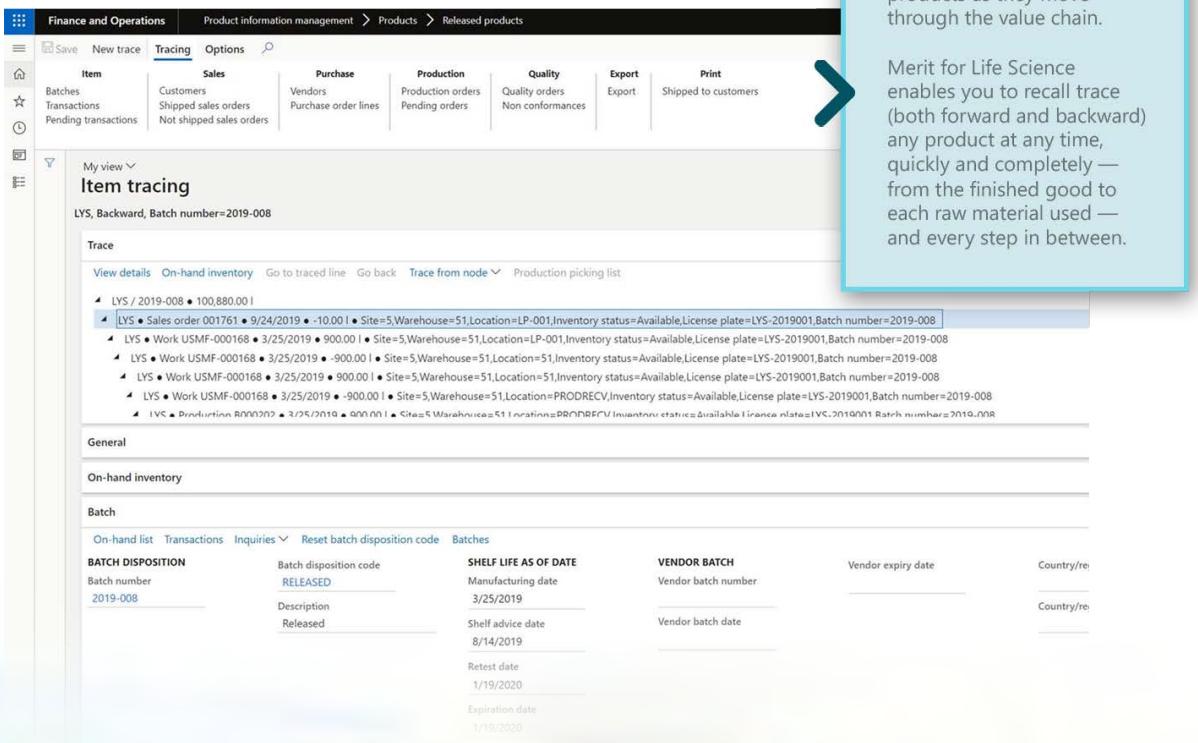
- Reset material lots expiration dates after retesting for stability and other attributes. Use a digital platform to identify those material lots and retest within the available times.

Merit for Life Science helps you better manage inventory shelf life, an ongoing challenge for pharmaceutical manufacturers.

With embedded PowerBI, you can proactively manage inventory, 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, and track and perform the material retest.



- 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 dispensing units. Ensure accurate and consistent weighing of all material types.



Track and trace is critical to ensure the integrity of products as they move through the value chain.

Merit for Life Science enables you to recall trace (both forward and backward) any product at any time, quickly and completely — from the finished good to each raw material used — and every step in between.

Deliver innovative, effective, and safe products

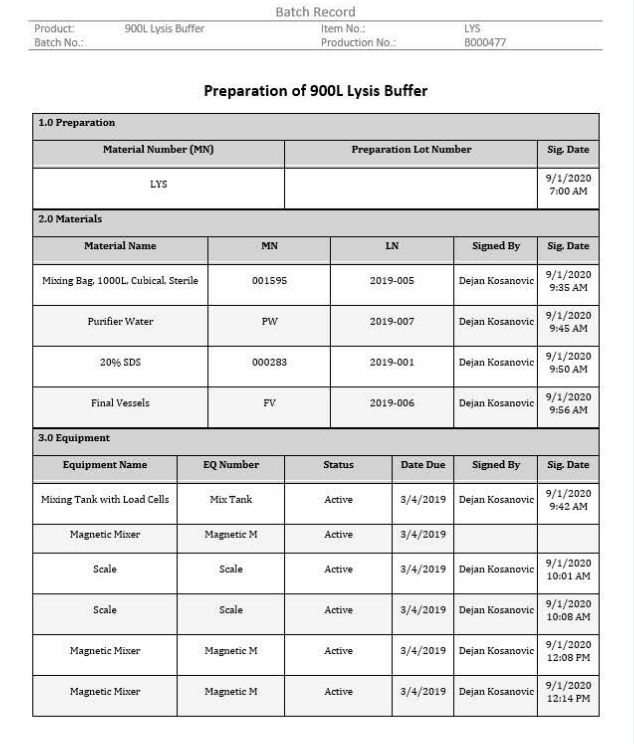
Measuring compliance is critical, but in manufacturing, compliance alone is not enough. You must also continuously improve the quality of your operations and your products. With Merit for Life Science, you gain a comprehensive platform to establish and maintain a culture of quality while also supporting regulatory compliance.

You'll manage end-to-end quality test points with granularity and meet the rigorous requirements of your industry with digital traceability. And, if you're preparing for M&A activity, having both critical practices built into your operational system will make your company an attractive target.

REGULATORY COMPLIANCE

- Leverage an extensible digital framework that simplifies your process of meeting FHIR, HIPAA, and GxP requirements, as well as ensures 21 CFR Parts 11, 210, 211 and 820 compliance.
- Provide functionality to address: planning, compliance, quality, shelf life and retest, CAPA, controlled labels, electronic batch record / electronic device history record, audit management, weighing and dispensing, and instrument calibration.
- Guided compliance-related tasks such as procurement, dispensing, retesting, materials management, and others saves resources.

The Electronic Batch Report process simplifies and automates the creation of a document that includes all details in a single report. This eliminates the need for users to run multiple reports and manually assemble the summary.



Batch Record

Product: 900L Lysis Buffer | Item No.: LYS
Batch No.: | Production No.: B000477

Preparation of 900L Lysis Buffer

1.0 Preparation

Material Number (MN)	Preparation Lot Number	Sig. Date
LYS		9/1/2020 7:00 AM

2.0 Materials

Material Name	MN	LN	Signed By	Sig. Date
Mixing Bag, 1000L, Cubical, Sterile	001595	2019-005	Dejan Kosanovic	9/1/2020 9:35 AM
Purifier Water	PW	2019-007	Dejan Kosanovic	9/1/2020 9:45 AM
20% SDS	000283	2019-001	Dejan Kosanovic	9/1/2020 9:50 AM
Final Vessels	FV	2019-006	Dejan Kosanovic	9/1/2020 9:56 AM

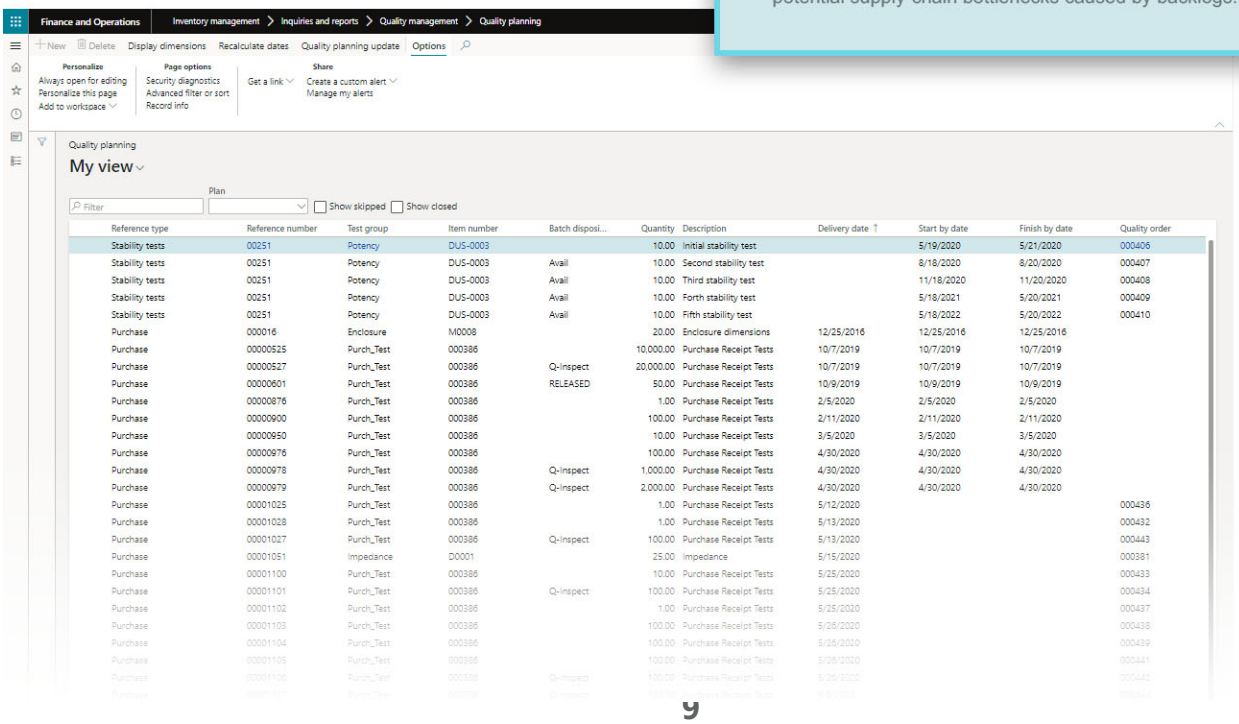
3.0 Equipment

Equipment Name	EQ Number	Status	Date Due	Signed By	Sig. Date
Mixing Tank with Load Cells	Mix Tank	Active	3/4/2019	Dejan Kosanovic	9/1/2020 9:42 AM
Magnetic Mixer	Magnetic M	Active	3/4/2019		
Scale	Scale	Active	3/4/2019	Dejan Kosanovic	9/1/2020 10:01 AM
Scale	Scale	Active	3/4/2019	Dejan Kosanovic	9/1/2020 10:08 AM
Magnetic Mixer	Magnetic M	Active	3/4/2019	Dejan Kosanovic	9/1/2020 12:08 PM
Magnetic Mixer	Magnetic M	Active	3/4/2019	Dejan Kosanovic	9/1/2020 12:14 PM

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 drive sampling plans and different test plans for skip lot, qualification, re-qualification, retest and stability testing protocols.
- Oversee the status of reported incidents from a centralized workspace and manage them to completion effortlessly.
- 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.
- Operationalize your standard operating procedures detailing what's required when dealing with a non-conformance (NCR) and corrective action preventive action (CAPA.)
- Leverage automation to assign expiration dates to material batches and drive a proactive retest process (for inventory approaching expiration) to support a compliant process of re-certifying and extending expiration dates to avoid costly material loss.
- 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.

Merit for Life Science extends standard master planning functions to create a full projection of future-dated anticipated Quality Orders. This provides key information for users responsible for planning or scheduling quality testing resources and for anticipating potential supply-chain bottlenecks caused by backlogs.



A Solution for Today and Tomorrow

In today's fast-paced business landscape, automation and advanced cloud technologies are transforming how organizations operate. At Merit Solutions, we empower regulated industries to reach new levels of efficiency, reliability, and agility, helping them overcome challenges and move into new frontiers of innovation.

Our tailored solutions—Merit for Life Science, Merit for Regulated Industries, and Merit for Business Central—are designed to equip ambitious organizations with the tools to thrive in the face of change. Whether in pharma, biotech, medical devices, food & beverage, or another regulated sector, we support your commitment to delivering safe, effective products with solutions that streamline your operations, enhance compliance, and scale with your vision.

At Merit Solutions, we see this as our purpose-driven mission. To learn more about how our solutions can help drive efficiency, compliance, and innovation in your organization, visit www.meritsolutions.com.

MERIT SOLUTIONS