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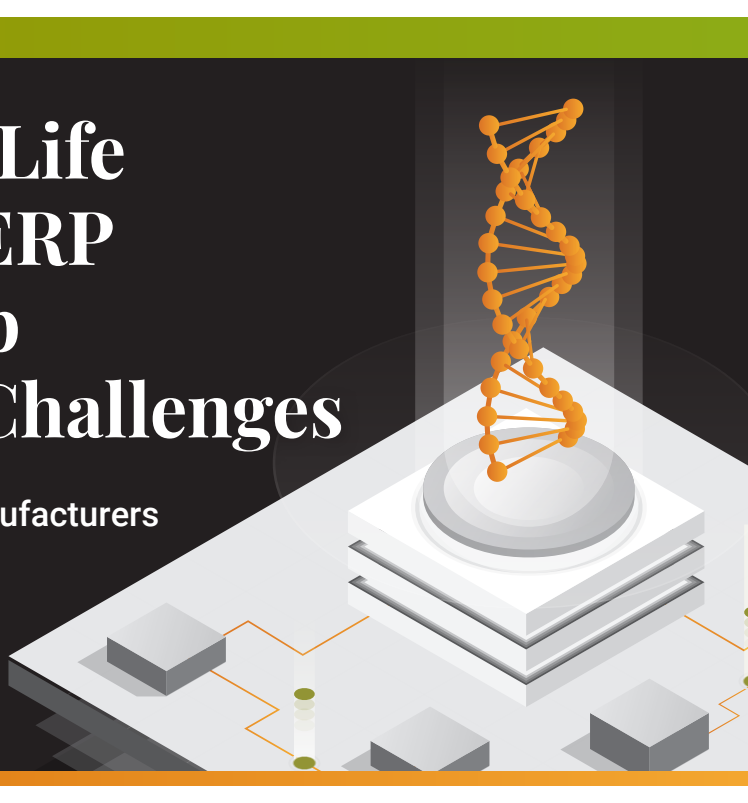
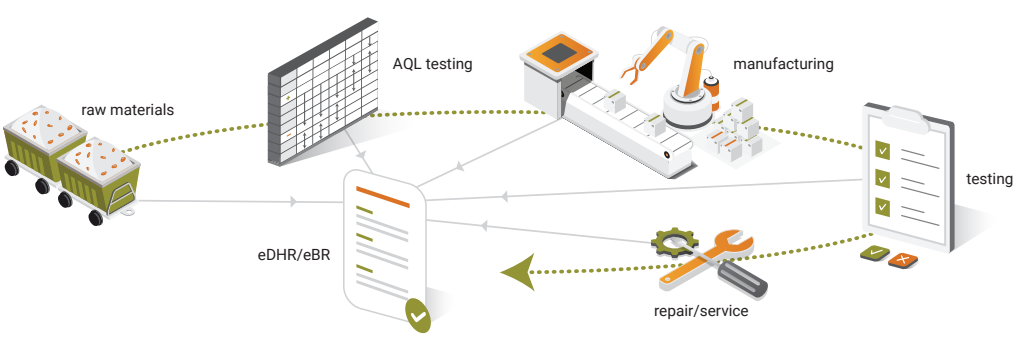
12 Ways A Life Sciences ERP Solves Top Industry Challenges

For Life Sciences Manufacturers



1 Meet FDA requirements with cradle-to-grave traceability and documentation.

Get a current electronic device history record (eDHR) or electronic batch record (eBR) for each product, using manufacturing data collection to capture information such as the material batch/serial numbers, equipment used, work instructions and revisions, pass/fail criteria and results, quantity released, acceptance records and primary identification label.

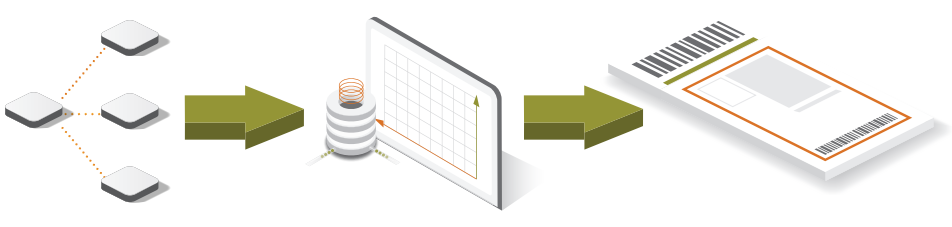


2 Manage rules and exceptions for the sale and distribution of your products.

Avoid fines and regulatory actions by managing the rules and exceptions regarding where your products can be sold. Capture and enforce limitations, restrict distribution to approved locations only, and add distribution confidence for sites where pre-market clinical trials have been approved.

3 Meet FDA regulations and generate UDI-compliant labels.

Simplify and support unique device identification (UDI) requirements by eliminating the need to populate external systems with UDI data to generate compliant labels. Easily maintain UDI records by creating a single source of truth, and support FDA labeling requirements via a built-in UDI table that facilitates transmission to the GUDID database.

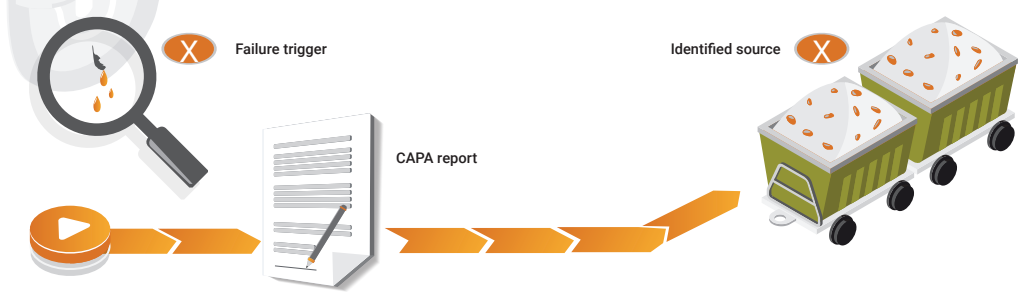


4 Get quality reports and business intelligence (BI) that provides actionable insights.

Gain visibility into your operations with industry-specific reports and BI dashboards that track critical manufacturing and vendor performance KPIs. Using this information, you can foster an environment of continuous improvement and monitoring, enabling you to quickly adjust operations when issues or opportunities arise.

5 Identify, record and quickly respond to risks, failures and complaints, via a configurable workflow.

Launch non-conformance reports (NCRs) and trigger investigations. For severe problems, based on your business risk categories, you can initiate a corrective and preventive action (CAPA). The system documents your steps throughout, simplifying regulatory compliance.

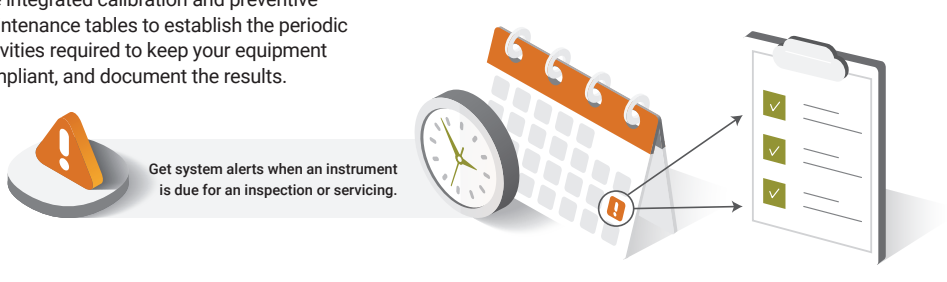


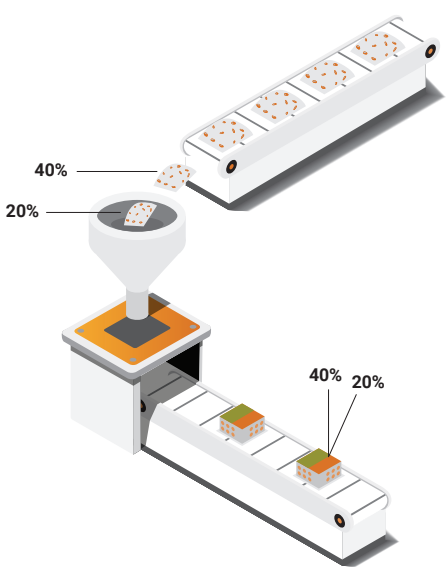
6 Easily access industry standard sampling tables.

Using various industry standard sampling tables, such as ANSI, ISO and NIST, you have the functionality to apply sampling techniques to standard inspections, first article and skip lot plans. Flexibility is built in, enabling you to easily set customized pass/fail rates and dictate the actions to take if a failure occurs.

7 Keep equipment compliant with automated system alerts.

Use integrated calibration and preventive maintenance tables to establish the periodic activities required to keep your equipment compliant, and document the results.

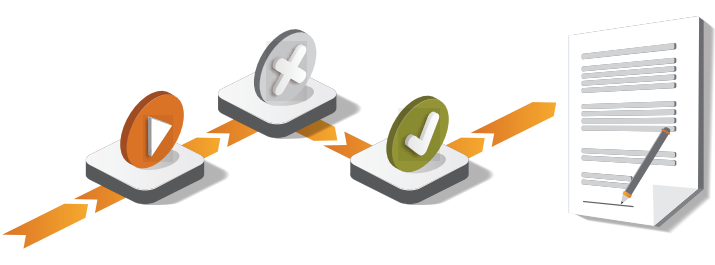




8 Track and store inventory in multiple units of measure.

Ingredient purity varies, so you need to calculate and manage the potency of the components used in each batch in order to keep formulation consistent. Track and store inventory in multiple units of measure and identify the amount of active ingredient each unit contains.

9 Manage your audit schedule and provide an audit trail for regulators.



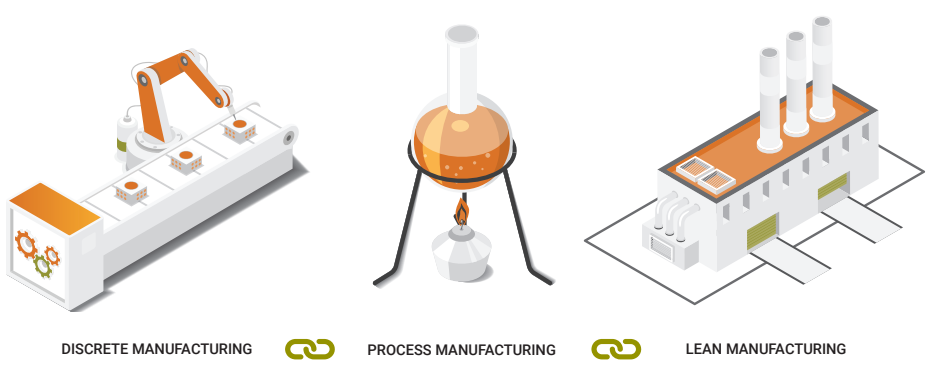
Generate scheduled internal audits, record results and if needed, generate associated NCRs or CAPAs.

10 Generate FDA-compliant electronic signatures.

Per 21 CFR Part 11, generate FDA-compliant electronic signatures for a wide range of functions, such as signing off on an inspection or creating a new bill of materials.

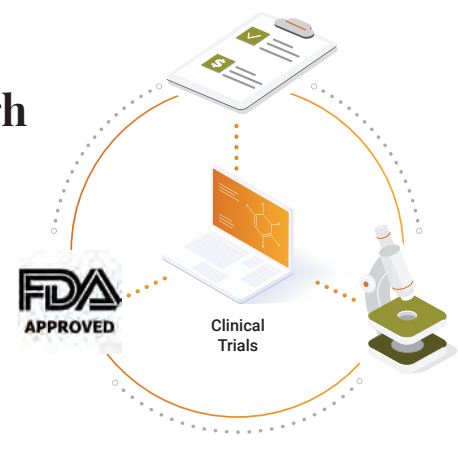
11 Support mixed mode manufacturing in a single environment.

Life sciences companies often use several modes of manufacturing. If your ERP system can only handle one of these, you may have to work outside the system for the others or limit yourself to one manufacturing type. An industry-specific solution can support all three manufacturing modes—process, discrete and lean—in one environment and within a single product structure.



12 Track and manage multiple items through the R&D process.

Track and manage expenses, activities, milestones and regulatory requirements as projects move through the clinical trial process and undergo post-approval research and monitoring.



ABOUT ARMANINO

Armanino's Life Sciences Solution delivers the robust enterprise resource planning (ERP) capabilities of Dynamics 365, plus extended functionality to help medical device, biotech, pharmaceutical and nutraceutical manufacturers overcome critical regulatory, quality and business challenges.

Armanino is a Gold Certified Microsoft Dynamics 365 Business Applications Partner with a reputation for developing innovative solutions for life sciences companies. Based on our experience working with leading life sciences firms, we've developed core functionalities that address critical industry needs. Let us bring our strategic insight, Dynamics 365 expertise and industry knowledge to your next project. At Armanino, we deliver the tools you need to focus on your customers and grow.

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