



ARMANINO'S LIFE SCIENCES INDUSTRIES FOR MICROSOFT DYNAMICS AX

Life Sciences for Dynamics AX



Quality, reporting, compliance and complex financials – we've got you covered. Get the most comprehensive Microsoft Dynamics ERP solution available for Life Sciences manufacturers within the Medical Device, Biotech, Pharmaceutical and Nutraceutical industry segments.

Microsoft Dynamics AX is one of the most robust ERP solutions available and is utilized by manufacturers worldwide. As a Microsoft Gold Certified Partner, Armanino brings comprehensive product knowledge and deep industry insight from over 15 years working alongside our customers, who include startups and extend to the most recognized names in Life Sciences.

Contact Armanino to discuss how we can help you with your Dynamics needs.

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Armanino's Life Sciences Industries for Microsoft Dynamics AX builds upon the Dynamics AX platform using industry-specific modules, prebuilt "best-practice" templates, configurations, and processes to deliver a holistic ERP solution. It reduces the reliance most life science companies have on ancillary and disparate systems to support quality, compliance and regulatory needs.

Armanino's solution delivers 95% of the functionality that most life science companies require from an ERP, right out of the gate. We enable companies to address critical needs while taking advantage of shorter implementation timelines and reduced costs.

Benefits of Armanino's Life Sciences Solution:

- Experience a shorter ERP implementation, resulting in faster ROI
- Adhere to FDA, country and government compliance requirements
- Achieve seamless supply chain integration with vendors, contract manufacturers and customers
- Manage complex revenue recognition management

- Meet quality management requirements
- Boost forecast accuracy
- Support discrete, lean, agile, process and mixed mode manufacturing model

Armanino's Life Sciences Industries for Microsoft Dynamics AX builds upon the robust functionality offered by Microsoft Dynamics AX and extends it to include a wealth of advanced capabilities around compliance, controls, quality, finance, complex supply chain management and more.

What Sets Armanino and Our Solution Apart?

Armanino is not just a Microsoft Dynamics AX implementer. We pride ourselves on being a true industry partner that works with you every step of the way to ensure that you are leveraging your ERP to address compliance, automation, and integration needs. Our deep life science expertise and investment into the Dynamics AX product has been recognized by Microsoft and we are proud to be designated as a *Microsoft Industry Program Partner for Life Sciences*.



Microsoft Dynamics
Manufacturing Partner

Feature Overview of Armanino's Life Sciences Industries for Microsoft Dynamics AX

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| Electronic Device History Record & Electronic Batch Record (eDHR/eBR) | <p>Achieve FDA required cradle-to-grave traceability. Using data from within the system—such as the manufacture date, quantity released, acceptance records and primary identification label. Armanino's Life Sciences Industries for Microsoft Dynamics AX compiles a current electronic device history record (EDHR) or electronic batch record (EBR) for each product.</p> |
| Limited Distribution Matrix | <p>Avoid fines and penalties by capturing limitations and restricting distribution to only approved locations.</p> |
| Unique Device Identification (UDI) | <p>Use data captured within this solution to generate UDI-compliant labels.</p> |
| Reports/Metrics | <p>Generate reports that provide actionable insights on manufacturing processes and vendor performance. This feedback creates an environment of continuous improvement and monitoring to help you pinpoint quality issues and trends early on and quickly adjust operations as needed.</p> |
| CAPA, NCR & Complaints | <p>Identify and respond swiftly to any current or potential product quality risks or customer complaints. Record failing events, complaints, launch a non-conformance report (NCR), trigger an investigation, or escalate your response and launch a corrective and preventive action (CAPA). The system documents your steps throughout, which simplifies regulatory compliance.</p> |
| Quality Sampling Tables | <p>Easily access embedded ANSI quality tables, set customized pass/fail rates and determine what actions to take when a failure occurs.</p> |
| Calibration | <p>Use integrated calibration and preventive maintenance tables to schedule inspections, maintenance, and document that the work has occurred. Receive notifications when an instrument is due for an inspection or servicing.</p> |
| Audit Management | <p>Manage your audit schedule to meet internal requirements and provide an audit trail for regulators. Define and trigger audits, record the results, and if need be, launch an NCR or CAPA.</p> |
| Electronic Signatures | <p>Generate 21CFR11, FDA-compliant electronic signatures for a wide range of functions, such as signing off on an inspection or creating a new bill of materials.</p> |

Inherent Life Sciences Functionality Built within Dynamics AX

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| Mixed Mode Manufacturing | Supports all three modes of manufacturing—process, discrete and lean—in one environment. |
| Multidimensional Inventory | Track and store inventory in multiple units of measure and identify the amount of active ingredient each unit contains. |
| Aggregate Spend Reporting | Comply with Sunshine Act and regulatory reporting requirements for payments, gifts, honoraria, and travel provided by your organization to healthcare professionals and organizations (HCP/O). |
| Drug Quality & Security Act (DQSA) Serialization Management | Meet the rigorous serialization standards required by the DQSA and comply with the evolving demands to provide e-pedigree and transaction documents as your product moves and as delivered. |
| Item Trace and Track | Maintain cradle-to-grave visibility and traceability to quickly and efficiently meet auditor demands and/or act on CAPAs/complaints or supplier quality issues. Tracing characteristics include forward/backward, by vendor, warehouse, site, date ranges and other product dimensions as well as UDI related field search information such as batch/lot or serial tracing. |
| Item Hold Capabilities | Various circumstances can arise which may necessitate the need to place a hold on items, orders, production, processes or even vendor activity until an initial investigation can be completed. In addition to these capabilities, companies can also establish blocking parameters in the areas of sales, production and transfers. |
| Quarantine | Maintain product segregation in cases such as pending inspection, or pending disposition based on inspection results. Features are available with the ability to direct inventory to specified quarantine locations upon product receipt and quality testing results. |