Move forward now with a full solution for the Pharmaceutical Industry

AX for Pharma: a complete package that combines proven software with proven expertise from a trusted advisor

Solution Benefits

Meet business and industry needs with a single integrated solution
AX for Pharma combines Microsoft Dynamics AX with industry-specific solutions and capabilities such as Manufacturing Execution System, Advanced Quality Management and Enterprise Asset Management. Rich pharmaceutical expertise and best practices fuel successful system implementations and FDA validation.

Comply with GxP guidelines, 21 CFR Part 11, and EU Annex 11
Achieve full compliance with international guidelines and regulations. Drive consistent compliance by tracking GMP operations such as lot status, work order processing, batch releases, and quality control approvals.

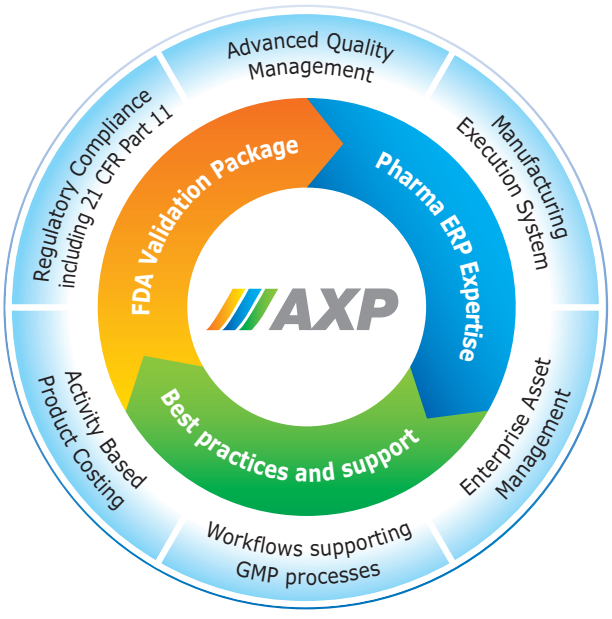
Implement Advanced Quality Management
Integrated quality assurance controls include non-conformances management, quarantine, quality orders, sampling plans, reduced/skip testing, acceptance criteria, certificates of analysis, and batch records. Activity-based product costing enables careful monitoring for both direct and indirect costs.

Promote best practices across your value chain
GxP-compliant development, manufacturing, inventory, and supply chain management support rework activities, co/by- products, contract manufacturing, in process quality, container/sub-lot management, skill management for manufacturing, and quality and project management.

Pharmaceutical companies face challenges that go well beyond standard enterprise resource planning (ERP)—complex operations, advanced project and quality management, compliance with stringent regulatory requirements—and much more. Too often, companies spend too much time and money struggling to build and customize a system that meets their needs and achieves FDA validation.

There is a solution. AX for Pharma is designed to meet the full range of needs for pharmaceutical companies, minimize customizations and implementation challenges, and give you expert, proven consulting and support from a trusted advisor. This complete package includes:

- AX for Pharma, built on Microsoft Dynamics AX. This industry-tailored, integrated ERP solution enables businesses to carefully monitor processes from research and development to sales, planning, purchasing, production, and quality management.
- The AX for Pharma validation package, including functional documentation and test protocols that support the validation process.
- Industry-specific expertise and best practices for delivering the ERP implementation that fits your business and achieves FDA validation.



AX for Pharma delivers a circle of excellence that lets you meet the full range of ERP and industry-specific needs with confidence.

AX for Pharma
The ERP solution for the Pharmaceutical Industry

Key Features

Inventory and Warehouse Management	• Item approval workflow includes automated, selective blocking for unapproved items. • Container/sub-lot management offers full batch and container traceability, including batch lifecycle and status changes, secured by electronic signature. • Inventory journals approval is secured by electronic signature. • Manage unit conversions by batch according to the actual batch assay and potency.
Sales	• Manage approved customer lists (ACL) by item, batch, and country. • Reserve batches that align with batch attributes and batch specifications defined by item and customer. • Secure Qualified Person approvals before shipment with electronic signatures.
Purchasing	• Generate approved vendor (AVL) and manufacturer (AML) lists, fully integrated with quality control for incoming goods. • Ensure consistency with a structured vendor/manufacturer qualification process.
Advanced Quality Management	• Quality order approval workflow provides users with a graphical interface, multiple levels of review, approval and escalation secured by electronic signature, and a conditional release process. • Robust integration connects stability studies and clinical and analytical services with project management. • Streamline sample management, reduce tests, and produce accurate sampling plans based on a statistical approach. • Generate Certificates of Analysis by item and by item/customer. • Test criteria based on mathematical calculations with multiple steps in compliance with US, EMA, Latin American and Japanese regulatory requirements.
Manufacturing Execution System	• Complete Dispensing and Filling module includes integration with scales with serial or RJ45 connections. • Assay management includes theoretical and actual batch assay, along with automatic recalculation/rescaling and reservation of components (active ingredients and excipients). Ensure continuous precision with scale management, calibration, and maintenance.
Production Control	• Manage reworking and reprocessing activities. • Generate production Batch Record. • Save time and reduce paper-based activities by managing master batch records within the system, automatically linked to the formula version.
GMP Plant Maintenance	• Manage preventive and corrective equipment maintenance with multi-level object control. • Preventive and ad-hoc work orders integrate with Materials Resource Planning and equipment availability. • Manage spare parts to ensure monitoring and optimization of costs, consumption and availability. • Full traceability of maintenance activities includes workflows and electronic signatures.
Activity-Based Product Costing	• Calculate full costs for items, including direct and indirect costs. • Capabilities include full alignment with sales and manufacturing forecasts, cost center budgets (quality, purchasing, indirect manufacturing, etc.), and product standard costs.
Compliance with 21 CFR Part 11 and EU Annex 11	• Electronic signature includes limited validity period and user lock-out if a certificate is repeatedly violated, as required by 21 CFR Part 11, Paragraphs 11.10, 11.200. • Use extensible, dynamic record-level security and permissions to define access rights and functions by user group, document status and other parameters.

CERTIFIED FOR Microsoft Dynamics AX 2012

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For more information please visit **www.axforpharma.com** or contact **info@axforpharma.com**