AX for Pharma™

Move forward with a fully integrated solution for the Pharmaceutical industry

READY FOR Microsoft Dynamics 365 FOR FINANCE AND OPERATIONS

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

Pharmaceutical companies face challenges that go well beyond standard Enterprise Resource Planning (ERP), including complex operations, advanced project and quality management, and compliance with stringent regulatory requirements. Too often, companies spend excessive amounts of time and money struggling to build and customize a system that meets their needs while achieving FDA validation.

AX for Pharma is the solution. Our software is designed to meet the full range of needs for pharmaceutical companies, minimize customizations and implementation challenges, and provide proven expertise from a trusted advisor. The **complete package** includes:

- AX for Pharma, built on Microsoft Dynamics 365. This industry-tailored, integrated ERP solution enables to carefully monitor processes from research and development to sales, planning, purchasing, production, inventory & warehouse management, and quality management.
- The AX for Pharma validation toolkits. They include functional documentation and testing protocols that support and simplify the validation process.
- Industry-specific expertise and best practices.
- Proven software and expertise from a trusted advisor.

This is the **AX for Pharma Circle of Excellence**

KEY BENEFITS

Meet business and industry needs with a single solution

AX for Pharma combines Microsoft Dynamics 365 with industry-specific solutions such as: Manufacturing Execution System, Advanced Quality Management, Enterprise Asset Management.

Advanced Quality Management

Advanced Quality Management includes: quality orders, sampling plans, reduced testing, acceptance criteria, trending, certificates of analysis/conformance, stability studies, configurable approval workflows, and electronic signature.

Weighing and Dispensing

Weighing and Dispensing can provide the information to resolve issues like: weighing tolerances, operator training needs, material hazard warning messages, suggested container size and quantity, and weigh-scale calibration requirements.

GMP Plant Maintenance

GMP Plant Maintenance fully integrates with Microsoft Dynamics 365 and allows users to manage and track plant and equipment maintenance for machinery, scales, instruments and other critical assets.

Comply with GxP guidelines, 21 CFR Part 11 and EU Annex 11

Achieve full compliance with international regulations. Drive consistent compliance by tracking GMP operations such as lot status, work order processing, batch release, and quality control approvals.

Advanced Warehouse Management

The Advanced Warehouse Management module integrates with Microsoft Dynamics 365 to support the needs of highly-regulated logistic processes.

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.
- Manage Approved Warehouse List (AWL) by item, according to the required storage conditions of the product.
- Time and temperature tracking is enabled for perishable goods, verifying the maximum time out of approved storage areas.
- Advanced warehouse management functionality allows for the use of a mobile device to receive incoming batches and containers, transfer material across sites, execute inventory adjustments and inquire information related to the material in inventory.

Full traceability for batches, containers and serial numbers

- Container/sub-batch management offers full batch and container traceability, including batch lifecycle and status changes, secured by electronic signature.
- Serial number management includes inventory status of serial numbers, shelf life management and serial attributes for reservation.
- Batch label functionality to generate labels and log users, date and time of label generation.

Sales and Purchasing

- 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 with electronic signatures before shipment.
- 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.
- Monitor the maximum imported/exported quantity of controlled active substances in/out a selected country, as required by REACH regulations.

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, environmental control, and clinical and analytical services with project management and accounting.
- 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

- Weighing and Dispensing 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.

Compliance with 21 CFR Part 11 and EU Annex 11

- Electronic signature includes limited validity period and user lockout 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.

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