AX for Pharma™

Advance your Quality Management processes with one full-featured solution

Advanced Quality Management for Microsoft Dynamics AX: a natively integrated platform that supports quality across your business.

For pharmaceutical companies, best-of-breed quality management is centered in laboratory processes, but impacts all areas of your business - planning, manufacturing, project management production scheduling, and more. Companies invest significant time, resources and money implementing add-on solutions to ensure product excellence, cost control and compliance with stringent regulations.

What if you could address those challenges at a fraction of the cost you expect, with effortless integration across your total operations system? Advanced Quality Management delivers a complete platform that works as a native part of Microsoft Dynamics AX and helps you drive results built on productivity and compliance:

- The built-in connection of information and processes ensures accurate monitoring of the value vs. cost of quality, real time communication and visibility across departments.
- Quality processes comply with GxP guidelines and regulatory requirements, in particular 21 CFR Part 11 and EU Annex 11, simplifying Computer System Validation.

WHAT'S NEW IN AX FOR PHARMA

- ✔ New release for **Microsoft Dynamics AX 2012 R3 CU9** since August 2015.
- ✔ Many **new features** including: Quality inquiries, Trend for quality results and Test group versioning …
- ✔ **Upcoming release** of Stability Studies.

The Advanced Quality Management Platform

Sample Management

- Sample login
- Statistical sampling plans linked to supplier qualification
- Barcode labels
- Retest/retain samples
- In-process samples

Results Entry

- Multi-level tests based on mathematical functions
- Reduced testing/skip testing
- Results validation vs. internal and customer specifications
- Test sheet management

Batch Approval

- Configurable graphical workflow engine
- Analytical review and quality assurance (QA) approval with electronic signatures
- Conditional release
- Batch management

Project Management

- Quality activities integrated with project management and accounting
- Stability studies and analytical services
- Value of Quality/Cost of Quality

Work Assignment

- Skill management for quality, production, projects, maintenance
- Production scheduling including quality control

AX for Pharma™
The ERP solution for the Pharmaceutical Industry

Key Features

Sample Management	✔ Issue sample requests based on sampling plans with a statistical approach, taking into account the vendor qualification status, batches received, and time intervals. ✔ Support a full chain of custody with sample receipt and storage. ✔ Advanced item sampling capabilities to define the number and quantity of f batches / containers to be sampled. ✔ Generate barcode sample labels. ✔ Manage retest and retain samples.
Test specs. and Results entry	✔ Create, modify and approve analytical specifications, reducing paper-based approvals and documentation ✔ Utilize different types of tests and results - including options, numeric, and multi-level test criteria - and perform results entry, calculations and validation within the same solution. Test criteria consist of multiple steps requiring mathematical functions and support the different tests included in the US and European Pharmacopoeia. ✔ Reduced testing / skip testing streamline and optimize inspections following a risk-based approach. ✔ Validate test results against company and customer specifications to increase customer satisfaction, compliance with country regulations and productivity. ✔ Generate Test Sheets that include testing procedures, methods and batch information. ✔ Copy Test Results from intermediate to finished products and across sites with a multi-level bill of materials.
Batch Approval and Release	✔ A graphical workflow engine provides configurable processes for analytical approval, QA approval, and batch release by site, product type and other options. Workflows are integrated with electronic signatures and the daily work list that each employee accesses when entering the system. ✔ Increase flexibility and reduce lead time for operations with a conditional release process for raw materials and intermediates. ✔ Ensure full lot traceability and chain of custody with batch management from receipt to release. ✔ Plan quality control activities by defining quality lead time times for incoming materials and manufactured products.
Project Management	✔ Easily track costs and revenues: quality activities related to manufacturing and internal/external services are fully integrated with project management and project accounting. ✔ Manage stability studies and analytical services.
Skill Management and Work Scheduling	✔ Apply skill management to quality, production, project and plant maintenance activities, enforcing compliance with GxP guidelines and regulatory requirements. ✔ Track and maintain employee certifications, training records and skills within the system. ✔ Production scheduling includes time needed for lab activities and quality inspections.
Compliance with 21 CFR Part 11 and EU Annex 11	✔ Electronic signature certificate includes limited validity period and user lock-out if a certificate is repeatedly violated, as required by 21 CFR Part 11 (11.10, 11.200). ✔ Secure batch review and approval processes with electronic signatures. ✔ Apply audit trail and/or electronic signature requirements to GxP-critical fields and tables.
Supplier Qualification	✔ Reduce costs and accelerate time-to-benefit with native integration across all AX for Pharma modules, including the Manufacturing Execution System for dispensing and assay management, GMP Plant Maintenance for instruments calibration, Activity-Based Product Costing, and all Pharmaceutical Operations.
Certificate of Analysis and Quality Reports	✔ New out of the box layouts for Certificates of Analysis for internal use or customers, including sales and shipping information. ✔ Generate Product Specifications reports based on active test groups and quality associations. ✔ Product Review and Quality Review inquiries to support data analysis for Annual Product Reviews.

CERTIFIED FOR Microsoft Dynamics AX 2012

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