

## AX for Life Sciences

# Thrive with industry-specific ERP that balances speed, quality, and compliance

**AX for Life Sciences: One integrated, affordable package that meets the full range of your company's needs.**

### Solution Benefits

#### Accessible, Real-Time Information

AX for Life Sciences enables your company to provide a complete trail of critical data, including details for specific materials and suppliers, process execution, operator training, quality test results, and more. Real-time, accurate, and accessible data is available to all users at any time. It provides a "single version of the truth" and audit trails for complete evidence and history.

#### Integrated Industry ERP Solution

Connect data across all functions, enabling 100 percent accuracy and consistency. Built on top of Microsoft Dynamics AX, our industry ERP solution integrates Manufacturing, Quality Management, Supply Chain Management, Plant Maintenance, Activity-Based Product Costing and Document Management.

#### Integrated Quality Management and Supplier Management

Enable your company to meet specific requirements for verification of the effectiveness of corrective and preventive actions (CAPA). Drive compliance with additional ISO 9001 requirements for inspection, traceability, documentation, and validation of processes.

#### Production Tracking and Visibility

Ensure precise batch and sub-batch tracking and traceability, both upstream and downstream, from production to shipment. Integrated traceability features allow manufacturers to quickly pinpoint and isolate problems with precision, and quarantine any problem products immediately.

For healthy Life Sciences companies, success depends on accelerating time to market and reducing costs - without compromising innovation, product quality and safety, and stringent local regulatory requirements. AX for Life Science offers a flexible, scalable solution that supports all these business and industry imperatives - from product development and manufacturing to maintenance and customer service.

AX for Life Sciences supports manufacturers by seamlessly integrating all transactions in manufacturing, inventory, warehousing, order management and customer service. Rich industry-specific capabilities are ideal for capturing data, enforcing best practices, validating manufacturing processes, and ensuring adherence to product specifications. The solution also provides rapid access to that information in the precise format and detail required by regulating bodies, including 21 CFR Part 820 and Part 11.

A modular design lets you choose and enhance capabilities at your own pace. Proven, structured implementation methodology aligns with specialized requirements for Life Sciences. Industry-specific expertise and best practices for delivering the ERP implementation help ensure computer system validation.



## Key Features

<b>Inventory and Warehouse Management</b>	<ul style="list-style-type: none"> <li>• Item approval workflow includes automated blocking of unapproved items.</li> <li>• Batch and sub-batch management ensure full batch traceability, including batch lifecycle and status changes secured by electronic signature.</li> <li>• Secure Inventory journals approval with electronic signatures.</li> <li>• Save time and improve accuracy for inbound/outbound processes with barcode identification.</li> </ul>
<b>Sales and Distribution</b>	<ul style="list-style-type: none"> <li>• Approved customer list (ACL) by item, batch, and country.</li> <li>• Batch reservation aligns precisely with batch attributes and batch specifications defined by item and customer.</li> </ul>
<b>Purchasing</b>	<ul style="list-style-type: none"> <li>• Approved vendor (AVL) and manufacturer (AML) lists are fully integrated with quality control for incoming goods.</li> <li>• Ensure consistency and quality control with structured vendor/manufacturer qualification process</li> <li>• Monitor supply chain relationships for quality, efficiency, and optimal pricing and costs with supplier performance reports.</li> <li>• Work proactively to remediate and prevent issues and errors with built-in CAPA management.</li> </ul>
<b>Advanced Quality Management</b>	<ul style="list-style-type: none"> <li>• Streamline quality order approval workflow with a graphical interface, multiple levels of review, approval and escalation secured by electronic signature, and a conditional release process.</li> <li>• Meet stringent requirements for incoming/receiving and in-process inspections with electronic signatures for materials, quality dispositions complaint tracking, and non-conformance reporting.</li> </ul>
<b>Production Control</b>	<ul style="list-style-type: none"> <li>• Reduce errors and manual data entry with Batch Records</li> <li>• Maintain a complete audit trail of manufacturing processes.</li> </ul>
<b>Enterprise Asset Management</b>	<ul style="list-style-type: none"> <li>• Master complex equipment maintenance with multi-level object control.</li> <li>• Preventive and ad-hoc work orders integrate with Materials Resource Planning.</li> <li>• Monitor and optimize costs, consumption, and availability with spare parts management and documentation.</li> <li>• Full traceability of maintenance activities includes workflows and electronic signatures.</li> <li>• Protect investments with warranty management and service tracking.</li> </ul>
<b>Activity-Based Product Costing</b>	<ul style="list-style-type: none"> <li>• Calculation of full costs for items includes direct and indirect costs.</li> <li>• Accelerate and simplify item cost calculation by using S&amp;OP, forecasts and budgets to generate standard costs for products, including costs like purchasing, quality and indirect manufacturing costs.</li> <li>• Analyze all costs related to performing quality processes.</li> </ul>
<b>Compliance with 21 CFR Part 820 and 21 CFR Part 11</b>	<ul style="list-style-type: none"> <li>• Electronic signature certificate includes limited validity period and user lock-out if a certificate is repeatedly violated, as required by 21 CFR Part 820 and 21 CFR Part 11.</li> <li>• Gain flexibility to work with complex, changing requirements with extensible, dynamic record-level security and permissions to define access rights, functions for a user group, document status, and other parameters.</li> </ul>

