



# **AX for Pharma 365™**

## Solutions Engineered for Biotech, Pharma, and Life Sciences

**Biotech, pharma, and life sciences** companies face numerous challenges, including the increasing complexity of clinical trials, rising supply costs, quality and validation expenses — while addressing stringent and changing regulatory responsibilities.

**Traditional enterprise resource planning (ERP)** systems often struggle to cope with the operational demands of biotech, pharma, and life sciences organizations. AX for Pharma 365™ (AXP365™) enables you to gain the competitive advantage of a digitally transformed operation in a single end-to-end ERP built on cloud technology, automated processes, and the modular design you need to scale.

**Gain competitive advantage** with the only complete industry solution suite based natively on the highly reliable and secure Microsoft Dynamics 365 ERP platform for clinical and commercial manufacturing. This combination can provide companies unparalleled potential for agile data-driven decision-making capabilities across their functional areas while increasing efficiencies.

**GMP compliant** — AXP365™ is designed to support your compliance with strict industry regulatory demands.

**Our commitment to excellence** and dedication to our clients is paramount for AX for Pharma 365™. This distinction is reflected in our industry training, our company's certifications like ISO 9001:2015, and our detailed project implementations.

*AX for Pharma 365™ goes beyond expectations by minimizing customizations and challenges — all while providing computer software assurance (CSA)*




**DESIGNED FOR THE PHARMACEUTICAL AND BIOTECH INDUSTRIES**

Single Solution Suite for Business and Industry

AXP365 Advanced Quality Management™

AXP365 Advanced Warehouse Management™

AXP365 Manufacturing Execution System™

AXP365 Weighing and Dispensing™

AXP365 Clinical Supplies™

Pharma Supply Chain Management

GxP FastTrack™ — Our Rapid Methodology of Accelerators and Best Practices

Follow GMP Guidelines Efficiently While Staying Compliant with Regulations Such as 21 CFR Part 11

Natively Integrated within Microsoft Dynamics 365



**AX for Pharma North America**  
100 S. Ashley Drive  
Suite 600  
Tampa, FL 33602  
United States

**AX for Pharma Europe**  
Centro Direzionale Milano Due  
Palazzo Bernini, 701-704  
20090 Segrate (Milan)  
Italy

info@AXforPharma.com  
www.AXforPharma.com  
Phone +1 813.358.3364

# AX for Pharma 365™

## KEY BENEFITS

### Meet Business and Industry with a Single Solution

AX for Pharma 365™ combines Microsoft Dynamics 365 with industry-specific solutions such as its AXP365 Manufacturing Execution System™, AXP365 Advanced Quality Management™, and Enterprise Asset Management.

### AXP365 Advanced Quality Management™

AXP365 Advanced Quality Management™ includes the tools needed to facilitate quality ordering, sampling plans, reduced testing, acceptance criteria, certificates of analysis/conformance, stability studies, configurable approval workflows, and electronic signature.

### AXP365 Weighing and Dispensing™

AXP365 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.

### Pharma Supply Chain

Pharma Supply Chain Management 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.

### Compliance with GxP Guidelines, 21 CFR Part 11, 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.

### AXP365 Advanced Warehouse Management™

The AXP365 Advanced Warehouse Management™ module integrates with Microsoft Dynamics 365 to support the needs of highly-regulated logistic processes.

## Scalability

## Flexibility

## Efficiency

*Delivering all you need within one comprehensive end-to-end solution that drives your success with unmatched tools.*

## GAIN ADVANTAGE FROM OUR FDA VALIDATION TOOLKIT

Functional Documentation

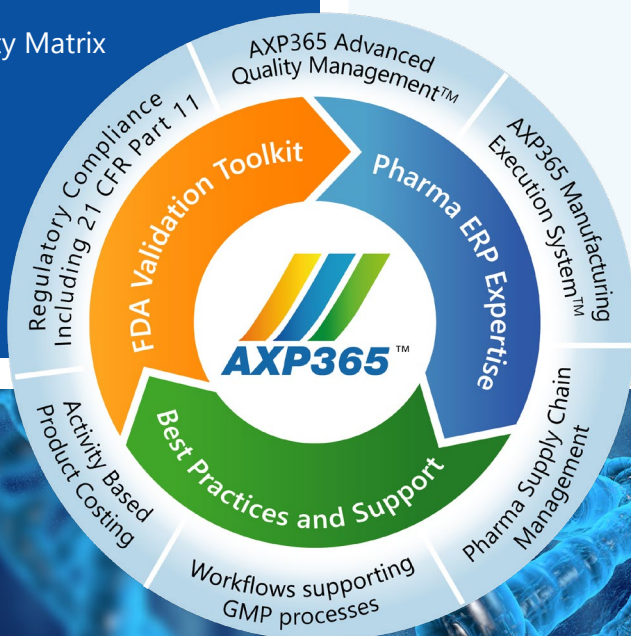
Testing Protocols

Risk Analysis and Mitigation

Design Qualification

Validation Project Planning

Traceability Matrix



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