



#### RESILIENT, AGILE AND TRANSPARENT SUPPLY CHAIN OPERATIONS

Designed for the Pharmaceutical and Life Sciences Industries

Comprehensive Support of All Supply Chain Management Processes

Digitalize your Supply Chain with a Single Integrated Solution

Optimized to Ensure Product Quality

Maintains Safety and Accuracy

Fully Compliant with Highly Regulated Industries



# **AX for Pharma 365** AXP365 Pharma Supply Chain Management™

Managing an efficient supply chain and an ever-growing number of supply chain partners is a major challenge Pharmaceutical and Life Sciences companies struggle to tackle in the highly regulated industry they belong to.

Easily track products with an end-to-end integrated solution that prevents inconsistent or duplicated data. AXP365 Pharma Supply Chain Management<sup>™</sup> has been specifically designed as a fully integrated solution with the purpose of serving the interests of pharmaceutical companies that care about increasing process efficiency.

The risk of endangering patients is eluded by an enterprise solution that increases operational responsiveness to changes and reduce human error deriving from manually entering data. Our solution complies with Good Automated Manufacturing Practice (GAMP) standards aiming to ensure the highest quality product and therefore the patient's safety.

With true end-to-end visibility into supply chain operations and utmost accuracy in terms of operational performance, transparency and reliability will be enhanced and conscious decision-making processes will increasingly be triggered.



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 Full Product Traceability and Control over Processes through a Supply Chain Management solution providing a comprehensive overview previously given by the coexistence of separate ERP, LIMS, and MES systems.



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#### RESILIENT, AGILE AND TRANSPARENT SUPPLY CHAIN OPERATIONS

Preconfigured Out-of-the-box Solution

GAMP Compliance Helps Increase Satisfaction for All of Your Customers

Full Control Over All Your Supply Chains with Transparent Ability to Track Every Unit in All Locations

Constantly Enriched with New and Dedicated Features

### **///AX for Pharma 365**<sup>™</sup> KEY BENEFITS

Ensure Trust in Increase trust in Product Quality for all the stakeholders **Product Quality** involved in the supply chain and reduce product waste through end-to-end visibility. Increase Trust between supply chain partners using a common platform on which they all have end-to-end visibility. **Conscious Decisions** Manage interoperable data points coming from the interaction of multiple supply chains along with being able to act as a key driver of conscious business decision-making processes. **Increase Your** By automating manual or paper-based processes, which besides being time-consuming practices, would **Process Efficiency** otherwise lead to committing mistakes. Guarantee the timely and accurate flow of information through a fluid system of transparency and real-time awareness.

Monitor and track sub batches and containers. Sample in all locations and isolate them if faulty or damaged.

Reduce the burden of audits and inspections with immutable record-keeping while simultaneously adhering to GAMP standards that improve your reputation and promote best practices on behalf of the patient's safety.

Full traceability, end-to-end sub batch management

**AXP365** 

**Strengthen Your** 

**Ensure Compliance** 

Ability to Track

Advanced Production Control, Advanced Warehouse Management, Weighing & Dispensing, Advanced Quality Management

Electronic signature fully compliant 21 CFR Part 11 Full Label Management, Integration with Warehouse Management, Integration with External Labeling Printing Systems

AX for Pharma 365<sup>™</sup>

### ///AX for Pharma 365"

### **FEATURES**

#### **Product Information Management**

- Configurable approval workflows for item creation.
- Configurable item number.
- Configurable batch number.

#### **Inventory Management**

- Enhanced batch attributes.
- Sub batch/container identification and tracking.
- Capability to isolate and block a specific sub batch/ container (e.g. if damaged).
- Use code and intended use code with configurable use matrix.
- Handling instructions by item.
- Handling instructions by transaction.
- Storage conditions by protocol.
- Storage conditions by item, batch and sub batch.
- Storage conditions mismatch report.
- Storage attributes.
- Storage attributes mismatch report.
- Restrictions and restriction types.

#### **Supply Chain**

- Approved vendor list with vendor qualification status.
- Approved manufacturer list.
- Approved customer list.

#### **Cleaning Management**

- Manage dispensing room availability and status.
- Configure cleaning rules based on frequency and material type.
- Enforce cleaning operations.

#### Compliance

- Electronic signature fully compliant 21 CFR Part 11.
- Enhanced database log/audit trail capabilities.
- Full lot genealogy.

#### Integration

- Full integration with AXP365 Advanced Quality Management<sup>™</sup> for Quality Control.
- Full integration with AXP365 Advanced Warehouse Management<sup>™</sup> to support warehouse processes.
- Full integration with AXP365 Weighing & Dispensing™.

#### Regulatory

- Advanced date calculation rules & controls.
- Shipment approval (QP release).
- Transfer order workflow (based on from-to country).
- Disposition code update by role (Different QP releases).
- Database log enhancements (trace electronic signature failure, database log advanced filters).
- Database log report (filters, reason codes and comments).
- Sunshine Act reportable (Finance).
- Sunshine Act report (Finance).
- Failed signature log.
- Failed signature report.

#### Material Identification

- End-to-end sub batch management.
- Material type.
- Material sub-type.
- Sub batch type.
- Use code.
- Components' verification.
- Enterprise labeling solution (e.g., material labels, sub batch labels, shipping labels).
- Advanced reporting tool and Power BI (e.g., Electronic Batch Record).

#### Storage and Distribution Features

- Study/Protocol management.
- Countries by protocol.
- Sites by protocol.
- Container configurations.
- Sub batch block/unblock.
- Batch-sub batch inheritance and independence.

#### **Return and Destruction**

- Destruction order (shipment of expired material or rejected material).
- Destruction date (batch and sub batch).
- Approval journal (destruction processes).

## Schedule a consultation with one of our pharmaceutical, biotech or medical devices subject matter experts to learn why AX for Pharma 365<sup>™</sup> remains unrivaled in optimizing operations for health and life sciences organizations.

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