

The Path to a Resilient Supply Chain

Life science companies are transforming distribution methods with next gen business applications

Security of Supply in Dynamic Times

Supply chains in the life sciences are complex. They must comply with strict legal regulations, coordinate the activities of many parties globally and operate efficiently under enormous cost pressure. Therefore, it is important to ensure that they function smoothly even when unexpected events occur.

Whether the pharmaceutical industry, biotech companies or the production of medical technology — reliable supply chains are the backbone of the life sciences. However, the Covid pandemic has brutally revealed what can happen if companies keep their supply chains too lean. Among other things, there have been supply shortages in vaccines, protective equipment and generic medicines, which highlighted each country's dependence on other parts of the world.

In particular, products with complex production processes and special storage conditions pose major challenges for all involved. Many life sciences companies already state that their systems lack transparency, control and standardization, or that they do not have an end-to-end picture of these processes. In the future, it will be crucial for the life sciences industry to be able to manage complex supply chains in order to ensure security of supply and quality standards.

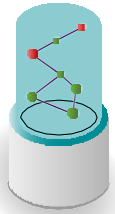
Find out on the following pages how life sciences companies can successfully master this new era of uncertainty.



Challenges in Supply Chain Management

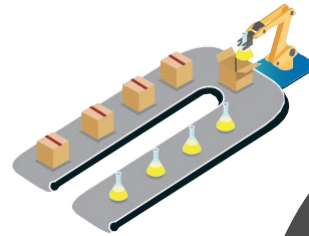
Development

- All data from the R&D phase (especially clinical studies) must be integrated.
- Formulations must be available in one place — across all product phases.



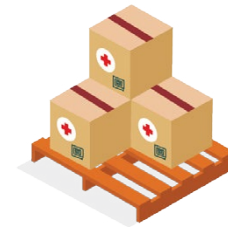
Production

- Manufacturing is becoming more demand-oriented.
- Contract manufacturing is gaining importance.



(Contract) / Packaging Orders

- Integration of CxO into the supply chain is necessary.
- All refrigerated chains must be maintained.



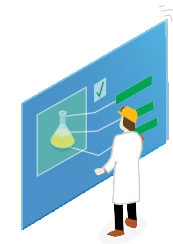
Transportation

- Temperature management is gaining importance.
- Transport will be more differentiated (generic medicines by sea, special drugs by air freight).



Raw Material Storage

- Inventories are being increased to withstand bottlenecks.
- Storage in accordance with prescribed conditions must be observed.



Quality Management

- Quality parameters must be able to be checked completely throughout the entire supply chain.
- Complex regulatory requirements must be met.



Customer Management

- Accurate adjustments to forecasts must be made in the event of short-term sales fluctuations.

Strengthening Supply Chains with next gen business applications

Transparency and a new culture of collaboration are key factors in meeting the challenges in the life sciences sector. To succeed in this transformation, organizations need a powerful digital foundation.

Enterprise resource planning (ERP) systems are the backbone of every production but in the pharmaceutical, biotech and medical device industries, most vendors' software is reaching its limits. In order to manage the increasing complexity of clinical trials, keep delivery costs in mind and meet stringent regulatory requirements, life science stakeholders need a solution that is tailored to the needs of their industry.

AX for Pharma 365™ combines Microsoft Dynamics 365 with industry-specific solutions. It is a powerful end-to-end solution designed specifically for life

sciences companies. This cloud-based ERP solution automates many manual processes that are slow, inefficient and prone to errors but are still a part of everyday life in many companies in the industry.

60% of supply chain executives (pharma/biopharma/medical device) struggle to get real-time inventory and visibility from external manufacturing partners.

One Platform, Numerous Advantages

Processes formerly managed via separate ERP, laboratory information (LIMS) and manufacturing execution systems (MES) systems can now be centralized in AX for Pharma 365™. This prevents inconsistent or duplicated data and this new transparency also improves product quality. The use of a system specially developed for the industry facilitates the planning of capacities along the entire

supply and production chain. This speeds up the product life-cycle and enables flexible adaptation to requirements.

Comply with Regulations

AX for Pharma 365™ complies with GAMP (Good Automated Manufacturing Practice) standards, which aim to produce products of the highest quality and thus ensure the safety of patients. This makes it fully compatible with all regulatory requirements of the life sciences sector. An optional module for clinical studies is available for research and development.

Ready for Use Immediately and Up to Date with the Latest Trends

AX for Pharma 365™ enables native integration with Microsoft Dynamics 365 Finance and Operations. Simplified computer system validation makes it easy to get up and running. Regular updates and enhancements ensure that the solution keeps pace with the needs of the industry. A specific life sciences validation service and automated testing for cloud-based ERP implementations are also available.



Case Study

A **Global Player** in Immune and Cell Therapy Makes Its Supply Chains Transparent

Challenge

The company is one of the leading providers of immune and cell therapy. It develops its products at several locations around the world. However, the reliable supply of materials for the production of the drugs was a constant challenge. Warehouse management, traceability, and the billing workflow were also error-prone, time-consuming and costly.

Solution

AX for Pharma 365™ has established an integrated ERP system for supply chain management. The company can now manage its inventory and warehouse in real time (including container management, storage conditions, security information, and integration with handheld devices). The production, quality management and finance functions also use the system to smoothly run their own processes and to collaborate with each other more effectively. The solution is now in use at all the company's locations and is used by around 500 users every day.

Functions in Detail

AX for Pharma 365™ provides a wide range of industry-specific services integrated with the D365 standard. These include software as a service, testing as a service and validation as a service.

Product Information

- Approval workflows
- Configurable item and batch number

Inventory

- Extended batch attributes
- Identification and tracking of sub-batches or containers
- Possibility of isolating and blocking certain sub-batches/certain containers (e.g. in the event of damage)
- Usage code and planned usage code with configurable usage matrix
- Instructions for handling items and transactions
- Storage conditions according to protocol, item, batch or sub-batch
- Report on storage condition discrepancies
- Restrictions and types of restrictions

Storage Attributes

- Report on non-conforming storage attributes
- Restrictions and types of restrictions

Supply Chain

- Defined transfers and sub-orders for CRO, CMO, CPO, CDO and third parties
- List of approved suppliers with status of their qualification
- List of certified producers and customers

Cleaning Management

- View the availability and status of the dosing range
- Cleaning rules based on frequency of use and material type
- Perform cleaning procedures

Compliance

- Electronic signatures and records (per 21 CFR Part 11)
- Audit paths
- Complete traceability of batches

Material Identification

- End-to-end management of sub-batches
- Material type and sub-type
- Sub-batch type
- Usage code
- Verification of components
- Identification for companies (e.g. labels for material, sub-batches, shipping, etc.)
- Advanced reporting tools and Power BI (e.g. electronic batch log)

Legal Regulations

- Expanded possibilities for calculating and checking expiration dates
- Transport approval (QP approval)
- Order workflow for transports (based on from-to country)
- Update disposition code by role (different QP versions)
- Database log extensions (tracking electronic signature errors, advanced filters in the database log)
- Database log reports (filters, reason codes, and comments)
- Sunshine Act reportable / Report (finances)
- Log and report for failed signatures

Storage and Distribution Functions

- Administration of trials/protocols
- Countries by protocol
- Locations by protocol
- Container configurations
- Lock/unlock sub-batches
- Discount and independence of batches and sub-batches

Return and Destruction

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

A New Era of Collaboration Begins

Microsoft Dynamics 365 makes supply chains more resilient in the life sciences and improves collaboration with suppliers and sub-contractors.

High Product Quality



Improve collaboration among all stakeholders in your supply chain through end-to-end visibility, thus improving the quality of your products.

Sound Decision-Making



Bring multiple supply chain records together on a single platform, creating a common basis for well-founded business decisions.

Efficient Processes



Automate manual or paper-based processes that are not only time-consuming but also error-prone, and enable a smooth, real-time flow of information.

Better Tracking



Monitor and track sub-batches, containers and samples at all locations and isolate these if defects or damage are found.

Greater Compliance



Reduce the amount of work required for audits or inspections by keeping all the necessary information in digital form. At the same time, GMP standards are met in accordance with 21 CFR Part 11 and EU Annex 11.



Case Study

A Specialist in DNA Therapy Optimizes Its Delivery, Production and Quality Control

Challenge

The company is active in the fields of medical technology and biotechnology. It specializes in the rapid introduction of precision DNA therapeutics administered with state-of-the-art medical devices. The group also applies this know-how to the development of other innovative gene therapies, working in conjunction with national government initiatives. It needed a powerful ERP solution to optimally orchestrate the interplay of its demanding and networked activities.

Solution

The new ERP system based on AX for Pharma 365™ ensures efficient interaction of all product lines. Around 50 users benefit from greater transparency and efficiency in supply chain management, inventory and warehouse management, production, and quality management at the company's central plant.

What **Makes Avanade** Unique

Avanade is one of the world's leading implementation partners for Microsoft. With a variety of services, we help companies get the most out of their investment.

For more than 20 years, we have been supporting the digital transformation of organizations by developing and implementing business solutions based on Microsoft. We have commended many times for these solutions, including by [Forrester](#) and [IDC](#).

Our services cover a wide range of industries and a broad portfolio. With strategy and consultation, we ensure that digitization projects are planned profitably from the outset. As an end-to-end provider, we are able to seamlessly connect a company's systems. We also provide training and managed services to help organizations keep their business processes running smoothly.

As a global networked company, we are able to implement digitalization projects on a large scale and at various locations. Within a short space of time, we also created the digital basis for the [production of ventilators](#) when people worldwide needed them the most and we continue to demonstrate our expertise in a number of life sciences digitization projects for our clients.

Microsoft
Partner



2022 Partner of the Year Winner
Global System Integrator (GSI) award
Dynamics 365 Customer Service & Field Service Award
Dynamics 365 Customer Insights Award
Manufacturing & Supply Chain Award
Austria
Denmark
Poland
Singapore
Spain
Sweden

- 17 Microsoft Partner of the Year awards
- 90% of the life sciences companies in the Fortune 500 are our customers
- Over 60,000 certifications in Microsoft technology
- More than 1500 successful Dynamics 365 projects
- More than 1000 life sciences and healthcare professionals worldwide
- Joint venture between Microsoft and Accenture

Next Steps

Let us start with an analysis of your specific challenges. [Contact us](#) for an initial discussion, a demo or an interactive workshop. We look forward to hearing from you.

Want to see yourself? We would be happy to present AX for Pharma 365™ and our services to you in a free demo workshop.

DEMO

Would you like to have the condition of your supply chains assessed by an external party?

Our life sciences experts will analyze your situation and work with your team to develop a potential optimization scenario.

SMART SERVICE CHECK



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About Avanade

Avanade is the leading provider of innovative digital, cloud and advisory services, industry solutions and design-led experiences across the Microsoft ecosystem. Every day, our 56,000 professionals in 26 countries make a genuine human impact for our clients, their employees and their customers. Avanade was founded in 2000 by Accenture LLP and Microsoft Corporation. Learn more at www.avanade.com.

About AX for Pharma 365™

AX for Pharma 365™ is designed to meet the needs of life sciences companies. The software offers biotechnology and pharmaceutical companies and medical device manufacturers the opportunity to optimize their workflows based on Microsoft Dynamics 365.

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