Become a connected PHARMA & LIFE SCIENCES company

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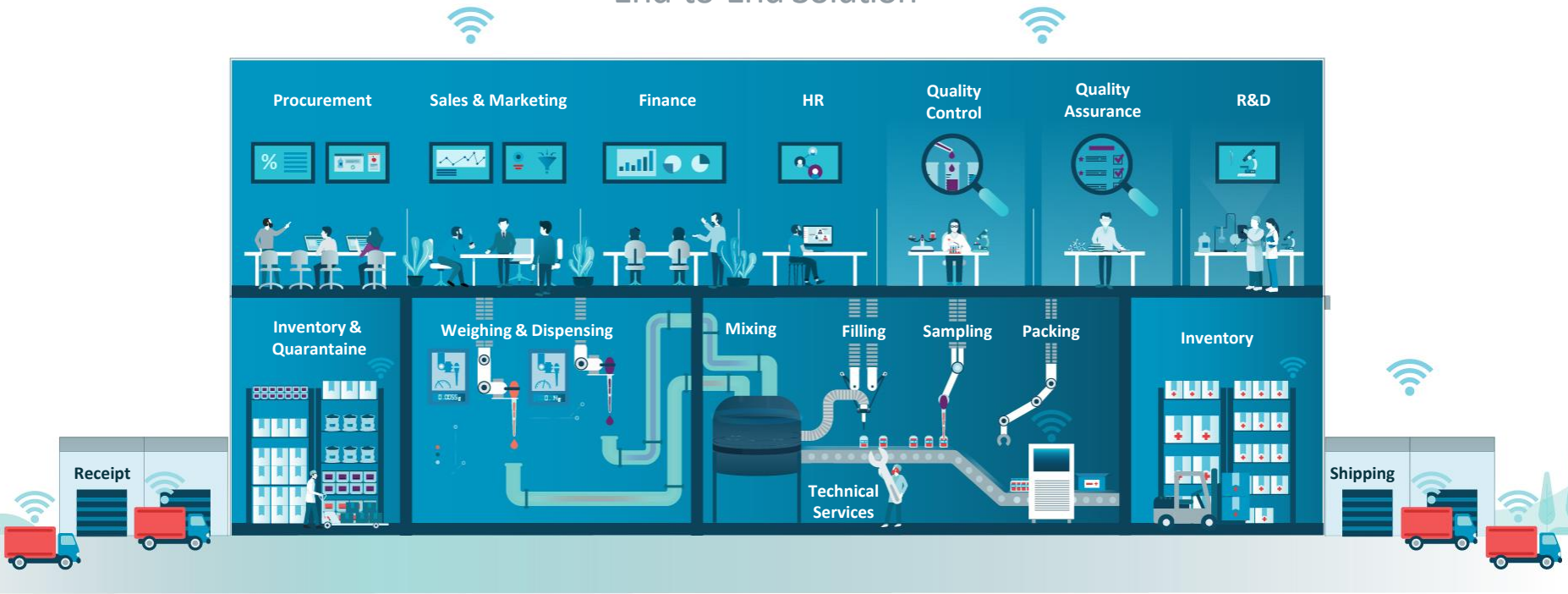
Dynamics for Pharma & Life Sciences introduction

Dynamics for Pharma

End-to-End Solution



Dynamics for Pharma & Life Sciences

Overview of the Key Capabilities

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	Regulatory Compliance	Lot Traceability	Pharma Manufacturing	Quality Management	Inventory & Material Management
Microsoft Dynamics for PHARMA	21 CFR Part 11 Compliant Electronic Signature	Container/Drum/Sub-Batch Management	Weighing & Dispensing	Vendor & Manufacturer Qualification/Approval	Temperature Monitoring
	Mobile Device Security	Advanced Product and Batch Numbering	Interface with Weighing Scales for W&D, Consumption and RAF	Advanced Specification/ Test Group Management	Sampling
	Product Creation and Modification Approval Workflows	Approved Customer/ Vendor/Manufacturer List	Tolerance Management	Statistical Test Criteria	RF Scanning & Barcoding
	Advanced Shelf Life Date Calculation Rules	Label Printing and Reprinting	Reconciliation of Production Components	Periodic/Skip Testing	Picking & Put Away Strategies
	Restrictions on Batch Disposition Changes	Batch Disposition Traceability	Advanced Production Consumption in Mobile Device	Quality Orders for Transfer & Sales Return	Advanced Purchase Receipt in Mobile Device
	QP Shipment Approval	Forward/Backward Traceability & Recall Management	Rework & Reprocess Management	Quality Order Approval Workflow	Advanced Production RAF in Mobile Device

Microsoft Dynamics	Planning & Manufacturing Execution	Inventory & Warehouse Management	Transport Management	Product Information Management
	Project Management & Accounting	Expense Management	Procurement and Sourcing	Asset Management
	Marketing Management	Financial Management & Budgeting	Sales Management	Human Resource Management

Business Intelligence	**Collaboration & Portals**	**Workflow Management**	**Integrations**

Key Drivers

What our customers are looking for in a Pharma & Life Sciences Solution

OBJECTIVE

Comply with Regulatory Requirements

- Achieve and maintain compliance with GxP regulations and guidelines from international agencies and organizations (EMA, FDA, WHO, ICH, etc.).
- Produce and store accurate and consistent data, maintain a transparent and tamper-proof electronic audit trail for electronic records.
- Streamline Computer System Validation (CSV) activities in compliance with GAMP5 risk-based approach for GxP computerized systems, 21 CFR Part 11, 21 CFR Part 820 and EudraLex Volume 4 Annex 11 and Annex 15.

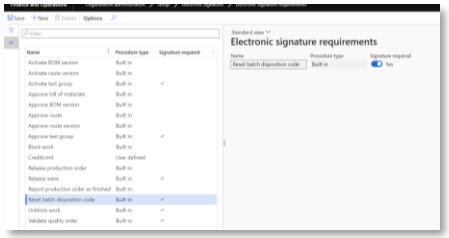
Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

Regulatory Compliance | Lot Traceability | Pharma Manufacturing | Quality Management | Inventory & Material Management

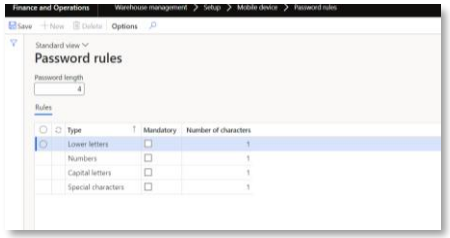
Solutions

Electronic Signature



Enforce electronic signature requirements for GxP critical processes (approval of BOM's, approval of quality specifications, batch disposition changes, QP shipment approval, etc.)

Mobile Device Security



Provide secure and traceable access to the mobile devices used by warehouse & production operators on the floor

Product Approval Workflows

Set up multi-level configurable workflows for the creation and modification of released products, thus entrusting the corporate functions to populate the fields of their competence and tracking their approval

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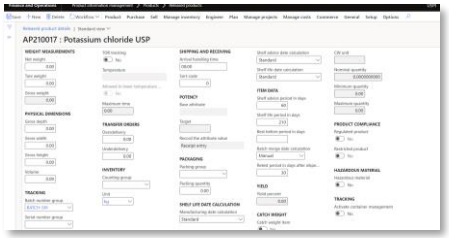
Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

Regulatory Compliance | Lot Traceability | Pharma Manufacturing | Quality Management | Inventory & Material Management

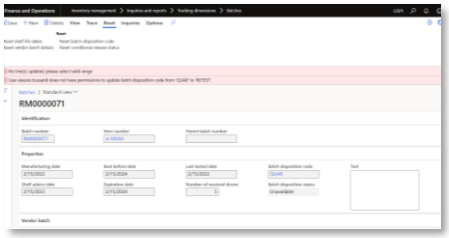
Solutions

Shelf Life Dates



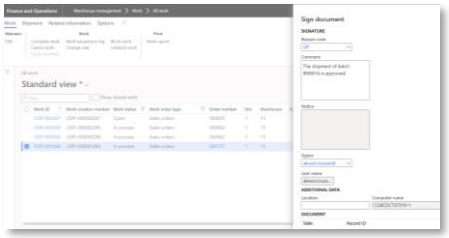
Automate shelf life date assignment (production date, expiry date, retest date, etc.) based on product and manufacturing process

Batch Disposition



Segregate specific batch disposition changes to selected combinations of security roles

QP Shipment Approval



Prevent the shipment of specific material unless approved and signed off by an authorized user (QP)

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Key Drivers

What our customers are looking for in a Pharma & Life Sciences Solution

OBJECTIVE

Maintain Full Lot Traceability

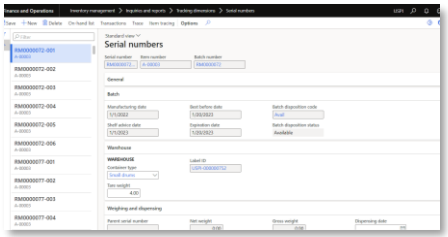
- Improve the traceability of items throughout the entire supply chain with lot tracking and container/drum management.
- Monitor the lifecycle of each lot/batch of material from vendor receipt of raw materials through delivery of manufactured products to the customer.
- Promptly react to defective products and hazards to reduce customer chargebacks and avoid industry fines, as well as implement continuous improvement processes.

Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

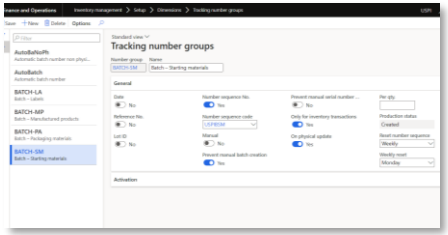
Solutions

Container/Drum Management



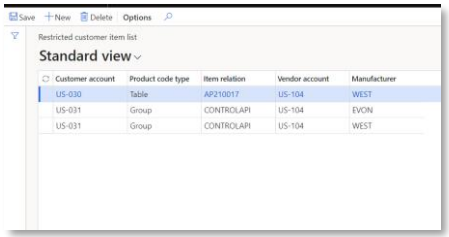
Uniquely identify each container/drum that is part of a specific lot, and maintain full traceability throughout the entire supply chain

Product & Lot Numbering



Automatically generate product & lot numbers based on configurable rules, thus providing flexibility to meet the company-specific requirements

Approved Customer/Vendor/Manufacturer



Enforce approval on the supply chain from the customer back to the supplier of the starting material and original manufacturer

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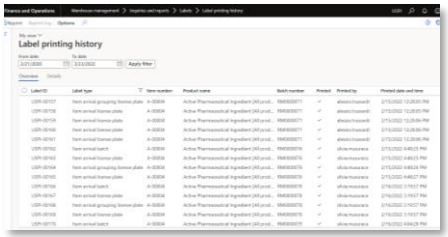
Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

Regulatory Compliance | **Lot Traceability** | Pharma Manufacturing | Quality Management | Inventory & Material Management

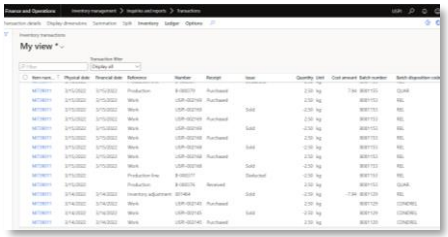
Solutions

Label Printing & Reprinting



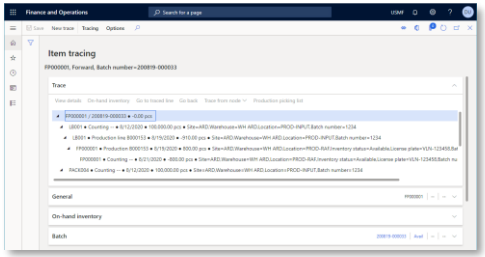
Meet legal requirements for the labels set by federal law and specific regulations by tracking printing and reprinting activities for any type of label

Batch Disposition Traceability



Capture the disposition status of the material in any transaction to analyze the evolution of the quality status of a particular batch and easily inspect the history

Lot Traceability & Recall



Get a complete end-to-end view on the process flow of every single lot and the involved customers, suppliers, locations, production orders, quality orders… allowing appropriate and immediate actions in case of a recall

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Key Drivers

What our customers are looking for in a Pharma & Life Sciences Solution

OBJECTIVE

Operate Agile Factories

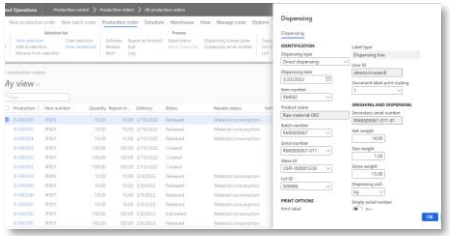
- Improve production efficiency and reduce downtime.
- Optimally plan and combine upstream & downstream manufacturing, packaging, MSAT and contract manufacturing processes
- Support production and raw material consumption in line with changing customer-specific requirements.

Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

Solutions

Weighing & Dispensing

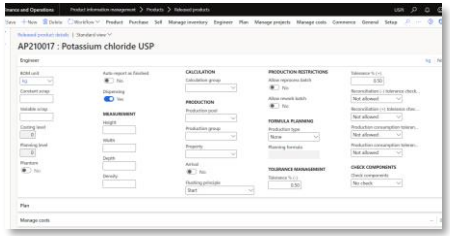


Introduce guided and precise execution of weighing & dispensing operations for production, in compliance with industry standards and regulatory requirements

Interface with Weighing Scales

Implement real-time communication between weighing scales in the production room and the ERP system in order to automatically collect weight measurements directly from the scale

Tolerance Management



Control tolerance specifications for picking, weighing & dispensing, reconciliation and material consumption

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Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

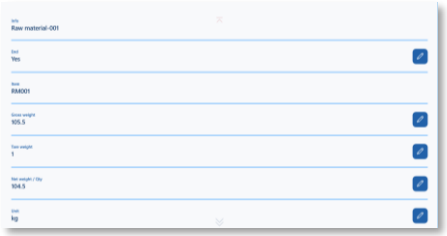
Regulatory Compliance | Lot Traceability | **Pharma Manufacturing** | Quality Management | Inventory & Material Management

Solutions

Reconciliation

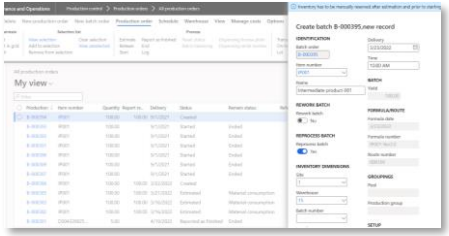
Ensure all materials to be consumed for the production process of manufactured products are correctly accounted for, and no errors occur that may impact patient safety

Production Consumption



Process material consumption with the mobile device ensuring any deviation from the standard formulation is small enough to have no impact on quality

Rework & Reprocess



Handle reworking and reprocessing scenarios with a different level of restrictions according to GMP guidelines

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Key Drivers

What our customers are looking for in a Pharma & Life Sciences Solution

OBJECTIVE

Quality by design

- Improve production standards and manufacture high-quality products
- Increase customers' confidence in the safety and effectiveness of medications
- Accommodate regular quality control tests, result tracking and implementation of corrective actions without the need for a separate Laboratory Information Management System (LIMS)

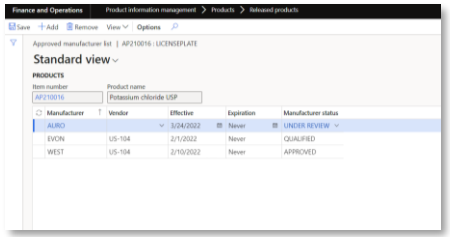
Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

Regulatory Compliance | Lot Traceability | Pharma Manufacturing | **Quality Management** | Inventory & Material Management

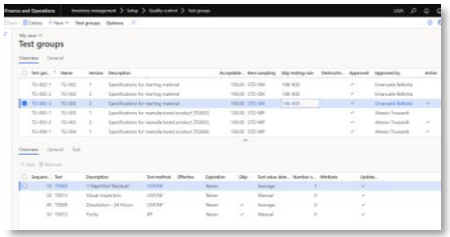
Solutions

Vendor & Manufacturer Qualification/Approval



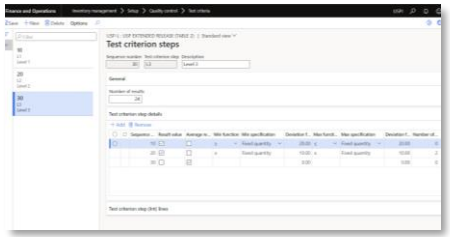
Perform selection, qualification, approval and maintenance of suppliers of starting materials, and drive quality control activities based on the qualification/approval status

Specification Management



Maintain authorized and dated specifications for all materials and track periodic revisions to comply with new editions of national pharmacopoeias or other official compendia

Statistical Test Criteria



Configure tests that require the definition of multi-level evaluation criteria (dissolution, uniformity of dosage, etc.)

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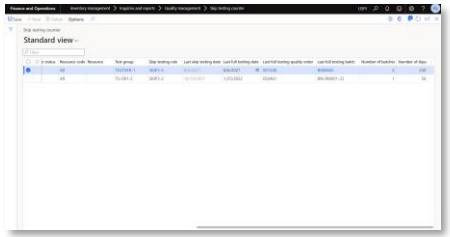
Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

Regulatory Compliance | Lot Traceability | Pharma Manufacturing | **Quality Management** | Inventory & Material Management

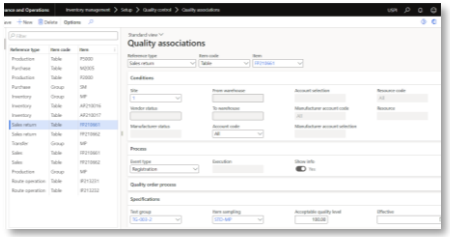
Solutions

Periodic/Skip Testing



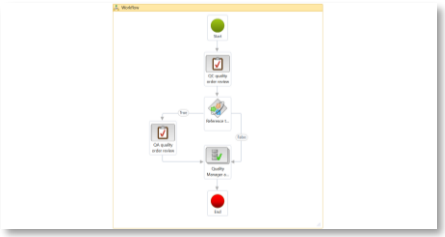
Implement Periodic Testing (PT) or Skip Testing (ST) based on company's written procedure, vendor qualification information or other available data

Quality Orders for Transfer & Sales Return



Automatically trigger quality inspections upon warehouse transfers and material return from customers

Quality Order Approval Workflow



Set up multi-level configurable workflows for the validation of quality inspections, thus enforcing several steps of review and approval

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Key Drivers

What our customers are looking for in a Pharma & Life Sciences Solution

Regulatory Compliance | Lot Traceability | Pharma Manufacturing | Quality Management | **Inventory & Material Management**

OBJECTIVE

Streamline Pharmaceutical Supply Chain

- Establish material requirements for production, control material usage and set specific goals for procurement and replenishment
- Simplify the supply chain workflow with built-in scanning capabilities of mobile devices and scanners
- Optimize sampling activities to consistently and rapidly monitor materials and interim products during production, thus accelerating product release

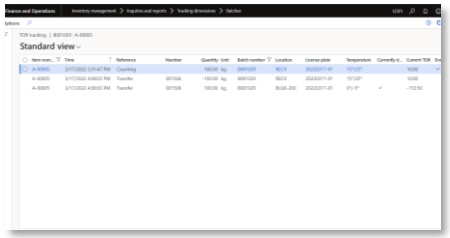
Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

Regulatory Compliance | Lot Traceability | Pharma Manufacturing | Quality Management | **Inventory & Material Management**

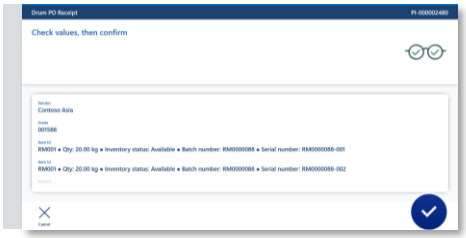
Solutions

Temperature Monitoring



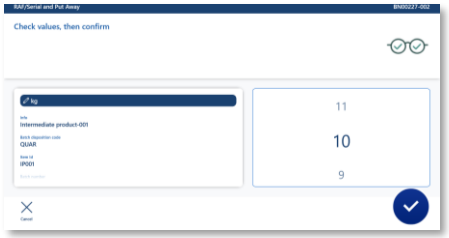
Track the time spent by controlled items out of refrigerated zones (TOR/TOS) and compare it to the medicine's allowable excursion time

Advanced Purchase Receipt



Handle the inbound process of lot and container/drum receipt into the warehouse using mobile devices

Advanced Production RAF



Create lots and containers/drums of manufactured product, print identification labels, and report as finished the actual quantity using mobile devices

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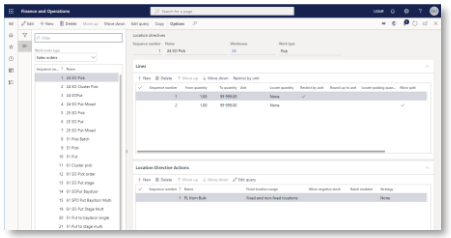
Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

Regulatory Compliance | Lot Traceability | Pharma Manufacturing | Quality Management | **Inventory & Material Management**

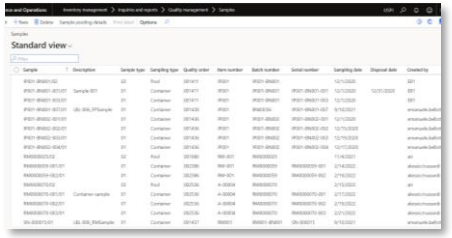
Solutions

Picking & Put Away Strategies



Optimize time and movements by adopting the best picking and put away strategies taking contamination and storage conditions into account

Sampling



Conduct sampling activities and track information related to samples for batch release testing, in-process control, special controls, stability studies or other purposes

RF Scanning & Barcoding

Improve productivity with built-in mobile warehouse capabilities

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*Dynamics for Pharma & Life Sciences combines **business software** with industry best practice **processes**, **insights** and a proven **methodology** to successfully implement*

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