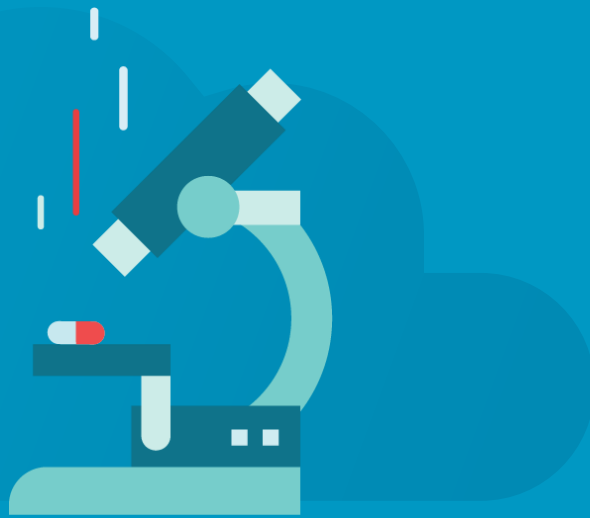


Become a connected PHARMA & LIFE SCIENCES company



Dynamics for Pharma & Life Sciences introduction

Challenges faced by organizations



Regulatory compliance

The challenges of compliance and validation in pharma and life science are becoming increasingly complex and demanding. Keep track of market authorization, sellable days per country, approved customers/ manufacturers ...



Effective collaboration

Cooperation and connection beyond company and country borders are increasing in pharma & life science. This requires flexible and easy-to-use collaboration tools.



Time to market

Combining scientific innovation with patient-centric business needs means that time to market – from front end to clinical trials – is often under pressure



Security

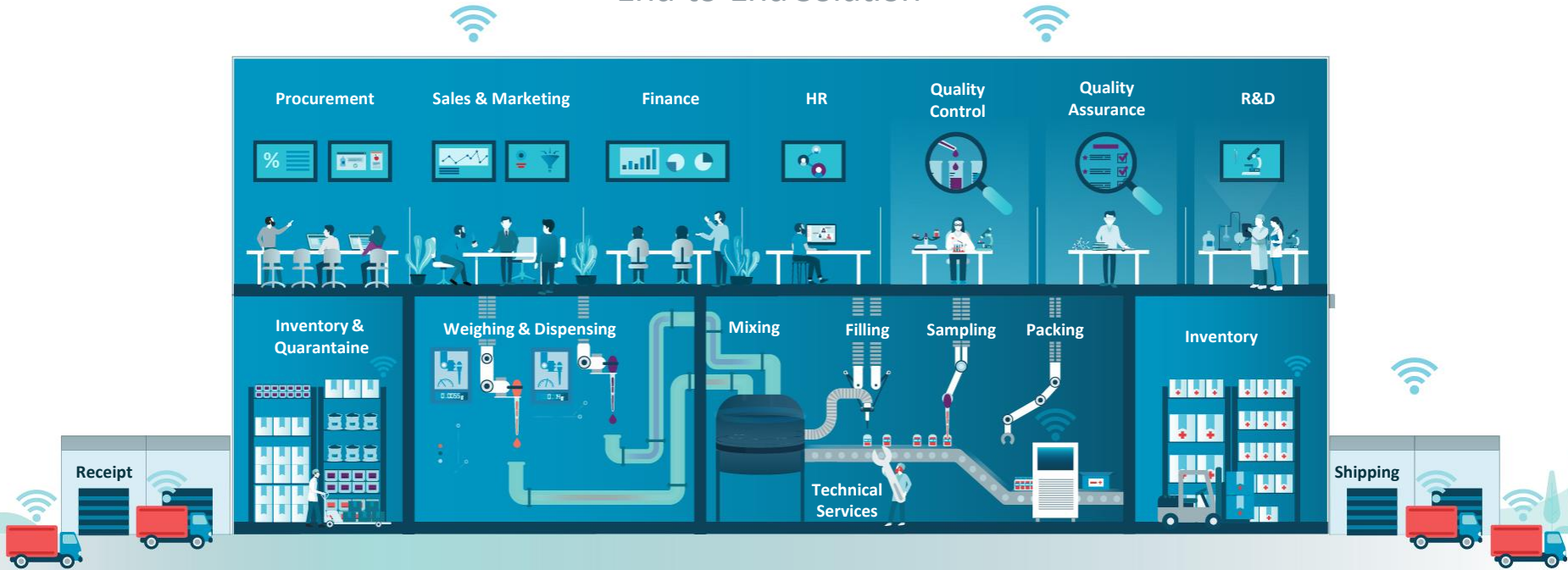
Security risks are rising along with the complexity of processes and systems. Your ERP must support optimal security, traceability and electronic signature towards customers.



*Dynamics for Pharma & Life Sciences helps you overcome challenges and become a **connected** company*

Dynamics for Pharma

End-to-End Solution



Dynamics for Pharma & Life Sciences

Overview of the Key Capabilities



	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

Regulatory
Compliance

Lot Traceability

Pharma
Manufacturing

Quality Management

Inventory & Material
Management

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.



OBJECTIVE

Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

Regulatory Compliance

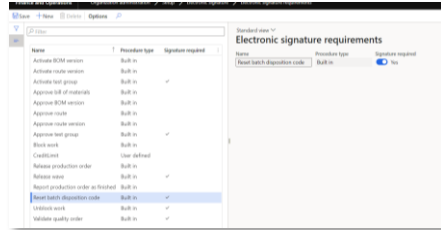
Lot Traceability

Pharma Manufacturing

Quality Management

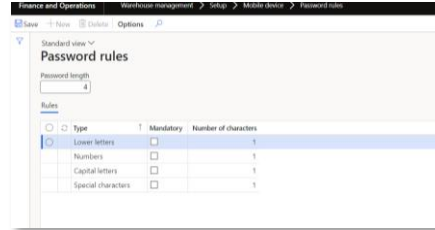
Inventory & Material Management

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



Solutions

Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

Regulatory Compliance

Lot Traceability

Pharma Manufacturing

Quality Management

Inventory & Material Management

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)



Solutions

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

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.



OBJECTIVE

Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

Regulatory Compliance

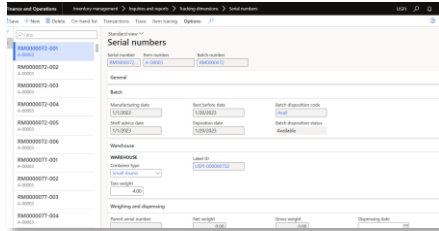
Lot Traceability

Pharma Manufacturing

Quality Management

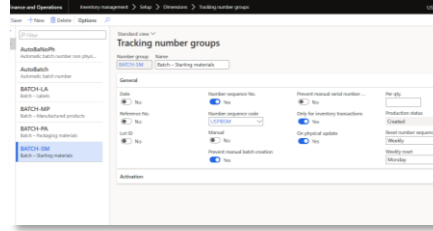
Inventory & Material Management

Container/Drum Management



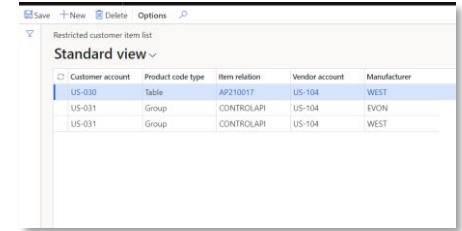
Uniquely identify each container/drum that is part of a specific lot, and maintain full traceability throughout the entire supply chain

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



Customer account	Product code type	Item relation	Vendor account	Manufacturer
US-030	Table	AP210017	US-104	WEST
US-031	Group	CONTROLAP1	US-104	EVON
US-031	Group	CONTROLAP1	US-104	WEST

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



Solutions

Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

Regulatory
Compliance

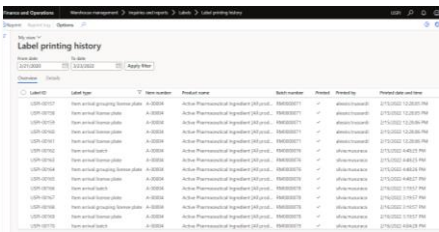
Lot Traceability

Pharma
Manufacturing

Quality Management

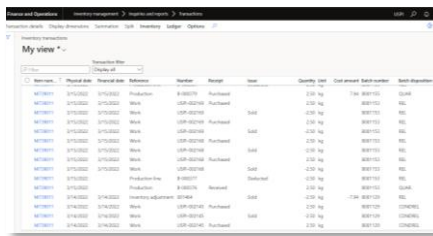
Inventory & Material
Management

Label Printing & Reprinting



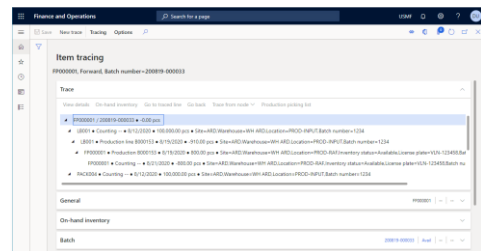
LabelID	Label type	Date	Quantity	Product name	Batch number	Product	Printing	Reprint date and time
100-001017	New label printing	2023-01-10	100	Actual Pharmaceutical Agent 200 (200)	100000001	Actual	Printed	2710:00:00 12:28:00 PM
100-001018	New label reprinting	2023-01-10	100	Actual Pharmaceutical Agent 200 (200)	100000001	Actual	Reprinted	2710:00:00 12:28:00 PM
100-001019	New label reprinting	2023-01-10	100	Actual Pharmaceutical Agent 200 (200)	100000001	Actual	Reprinted	2710:00:00 12:28:00 PM
100-001020	New label reprinting	2023-01-10	100	Actual Pharmaceutical Agent 200 (200)	100000001	Actual	Reprinted	2710:00:00 12:28:00 PM
100-001021	New label reprinting	2023-01-10	100	Actual Pharmaceutical Agent 200 (200)	100000001	Actual	Reprinted	2710:00:00 12:28:00 PM
100-001022	New label reprinting	2023-01-10	100	Actual Pharmaceutical Agent 200 (200)	100000001	Actual	Reprinted	2710:00:00 14:02:00 PM
100-001023	New label reprinting	2023-01-10	100	Actual Pharmaceutical Agent 200 (200)	100000001	Actual	Reprinted	2710:00:00 14:02:00 PM
100-001024	New label reprinting	2023-01-10	100	Actual Pharmaceutical Agent 200 (200)	100000001	Actual	Reprinted	2710:00:00 14:02:00 PM
100-001025	New label reprinting	2023-01-10	100	Actual Pharmaceutical Agent 200 (200)	100000001	Actual	Reprinted	2710:00:00 14:02:00 PM
100-001026	New label reprinting	2023-01-10	100	Actual Pharmaceutical Agent 200 (200)	100000001	Actual	Reprinted	2710:00:00 14:02:00 PM
100-001027	New label reprinting	2023-01-10	100	Actual Pharmaceutical Agent 200 (200)	100000001	Actual	Reprinted	2710:00:00 15:02:00 PM
100-001028	New label reprinting	2023-01-10	100	Actual Pharmaceutical Agent 200 (200)	100000001	Actual	Reprinted	2710:00:00 15:02:00 PM
100-001029	New label reprinting	2023-01-10	100	Actual Pharmaceutical Agent 200 (200)	100000001	Actual	Reprinted	2710:00:00 15:02:00 PM
100-001030	New label reprinting	2023-01-10	100	Actual Pharmaceutical Agent 200 (200)	100000001	Actual	Reprinted	2710:00:00 15:02:00 PM
100-001031	New label reprinting	2023-01-10	100	Actual Pharmaceutical Agent 200 (200)	100000001	Actual	Reprinted	2710:00:00 15:02:00 PM
100-001032	New label reprinting	2023-01-10	100	Actual Pharmaceutical Agent 200 (200)	100000001	Actual	Reprinted	2710:00:00 15:02:00 PM

Batch Disposition Traceability



Batch Number	Original Batch	Original Lot	Disposition	Quantity	Cost amount	Batch number	Batch expiration date
100000001	100000001	100000001	Production	100	100	100000001	2023-01-31
100000002	100000001	100000001	Material	100	100	100000002	2023-01-31
100000003	100000001	100000001	Material	100	100	100000003	2023-01-31
100000004	100000001	100000001	Material	100	100	100000004	2023-01-31
100000005	100000001	100000001	Material	100	100	100000005	2023-01-31
100000006	100000001	100000001	Material	100	100	100000006	2023-01-31
100000007	100000001	100000001	Material	100	100	100000007	2023-01-31
100000008	100000001	100000001	Material	100	100	100000008	2023-01-31
100000009	100000001	100000001	Material	100	100	100000009	2023-01-31
100000010	100000001	100000001	Material	100	100	100000010	2023-01-31
100000011	100000001	100000001	Material	100	100	100000011	2023-01-31
100000012	100000001	100000001	Material	100	100	100000012	2023-01-31
100000013	100000001	100000001	Material	100	100	100000013	2023-01-31
100000014	100000001	100000001	Material	100	100	100000014	2023-01-31
100000015	100000001	100000001	Material	100	100	100000015	2023-01-31
100000016	100000001	100000001	Material	100	100	100000016	2023-01-31
100000017	100000001	100000001	Material	100	100	100000017	2023-01-31
100000018	100000001	100000001	Material	100	100	100000018	2023-01-31
100000019	100000001	100000001	Material	100	100	100000019	2023-01-31
100000020	100000001	100000001	Material	100	100	100000020	2023-01-31
100000021	100000001	100000001	Material	100	100	100000021	2023-01-31
100000022	100000001	100000001	Material	100	100	100000022	2023-01-31
100000023	100000001	100000001	Material	100	100	100000023	2023-01-31
100000024	100000001	100000001	Material	100	100	100000024	2023-01-31
100000025	100000001	100000001	Material	100	100	100000025	2023-01-31
100000026	100000001	100000001	Material	100	100	100000026	2023-01-31
100000027	100000001	100000001	Material	100	100	100000027	2023-01-31
100000028	100000001	100000001	Material	100	100	100000028	2023-01-31
100000029	100000001	100000001	Material	100	100	100000029	2023-01-31
100000030	100000001	100000001	Material	100	100	100000030	2023-01-31

Lot Traceability & Recall



Transaction	Quantity	Cost amount	Batch number	Batch expiration date
100000001	100	100	100000001	2023-01-31
100000002	100	100	100000002	2023-01-31
100000003	100	100	100000003	2023-01-31
100000004	100	100	100000004	2023-01-31
100000005	100	100	100000005	2023-01-31
100000006	100	100	100000006	2023-01-31
100000007	100	100	100000007	2023-01-31
100000008	100	100	100000008	2023-01-31
100000009	100	100	100000009	2023-01-31
100000010	100	100	100000010	2023-01-31
100000011	100	100	100000011	2023-01-31
100000012	100	100	100000012	2023-01-31
100000013	100	100	100000013	2023-01-31
100000014	100	100	100000014	2023-01-31
100000015	100	100	100000015	2023-01-31
100000016	100	100	100000016	2023-01-31
100000017	100	100	100000017	2023-01-31
100000018	100	100	100000018	2023-01-31
100000019	100	100	100000019	2023-01-31
100000020	100	100	100000020	2023-01-31
100000021	100	100	100000021	2023-01-31
100000022	100	100	100000022	2023-01-31
100000023	100	100	100000023	2023-01-31
100000024	100	100	100000024	2023-01-31
100000025	100	100	100000025	2023-01-31
100000026	100	100	100000026	2023-01-31
100000027	100	100	100000027	2023-01-31
100000028	100	100	100000028	2023-01-31
100000029	100	100	100000029	2023-01-31
100000030	100	100	100000030	2023-01-31



Solutions

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

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

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

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

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.



OBJECTIVE

Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

Regulatory Compliance

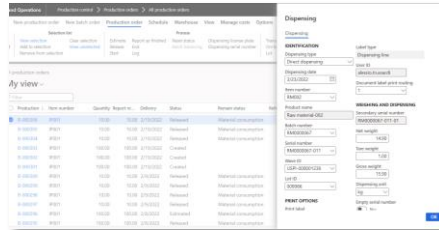
Lot Traceability

Pharma Manufacturing

Quality Management

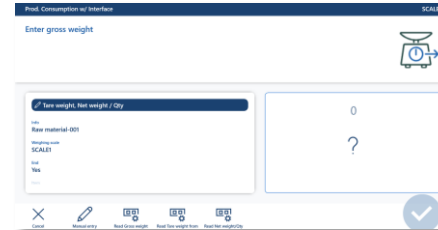
Inventory & Material Management

Weighing & Dispensing



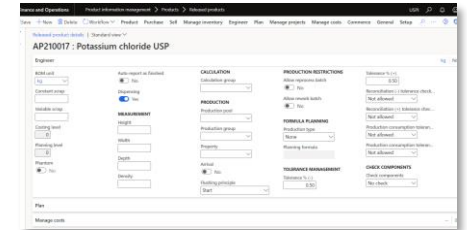
Introduce guided and precise execution of weighing & dispensing operations for production, in compliance with industry standards and regulatory requirements

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



Solutions

Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

Regulatory Compliance

Lot Traceability

Pharma Manufacturing

Quality Management

Inventory & Material Management



Solutions

Reconciliation

Raw material-001
Released qty: 70 kg
Reconciled qty: 10 kg
Discrepancy: -60 kg, Out of tolerance 79.80%

Back

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

Raw material-001

Material	Quantity	Unit	Status
Raw material-001	100.00	kg	Released
Raw material-001	100.00	kg	Released
Raw material-001	100.00	kg	Released
Raw material-001	100.00	kg	Released
Raw material-001	100.00	kg	Released
Raw material-001	100.00	kg	Released
Raw material-001	100.00	kg	Released
Raw material-001	100.00	kg	Released
Raw material-001	100.00	kg	Released
Raw material-001	100.00	kg	Released

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

REWORK BATCH # 000395, new record

Production	Quantity	Unit	Status
Raw material-001	100.00	kg	Released
Raw material-001	100.00	kg	Released
Raw material-001	100.00	kg	Released
Raw material-001	100.00	kg	Released
Raw material-001	100.00	kg	Released
Raw material-001	100.00	kg	Released
Raw material-001	100.00	kg	Released
Raw material-001	100.00	kg	Released
Raw material-001	100.00	kg	Released
Raw material-001	100.00	kg	Released

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

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

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

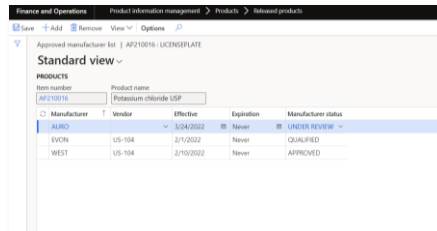
Lot Traceability

Pharma Manufacturing

Quality Management

Inventory & Material Management

Vendor & Manufacturer Qualification/Approval

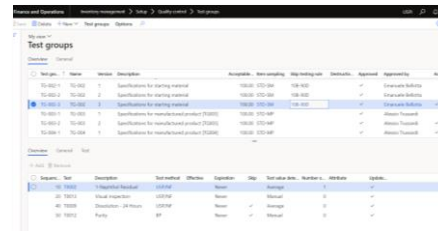


Standard view

Item number	Product name	Manufacturer	Vendor	Effective	Expiration	Manufacturer status
AP110106	Potassium chloride USP					
ALNO				3/24/2022	Never	UNDER REVIEW
EVON			US-104	2/1/2022	Never	QUALIFIED
WEST			US-104	2/15/2022	Never	APPROVED

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

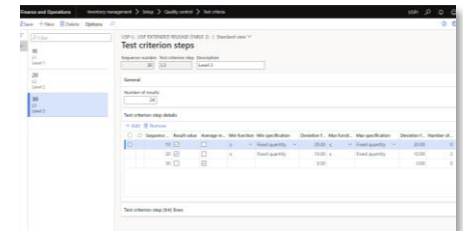
Specification Management



Test group	Description	Acceptance	Test method	Expiration	Approval	Approval	Action
10-001-1	Specifications for starting material	100.00-100.00	100.00-100.00				Generate table
10-001-2	Specifications for starting material	100.00-100.00	100.00-100.00				Generate table
10-001-3	Specifications for manufactured product (2000)	100.00-100.00	100.00-100.00				View test
10-001-4	Specifications for manufactured product (2000)	100.00-100.00	100.00-100.00				View test
10-001-5	Specifications for manufactured product (2000)	100.00-100.00	100.00-100.00				View test

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



Test criterion step	Description	Test method	Test quantity	Test quantity	Test quantity	Test quantity	Test quantity	Test quantity	Test quantity
10-001-1	Specifications for starting material	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00
10-001-2	Specifications for starting material	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00
10-001-3	Specifications for manufactured product (2000)	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00
10-001-4	Specifications for manufactured product (2000)	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00
10-001-5	Specifications for manufactured product (2000)	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00	100.00-100.00

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



Solutions

Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

Regulatory
Compliance

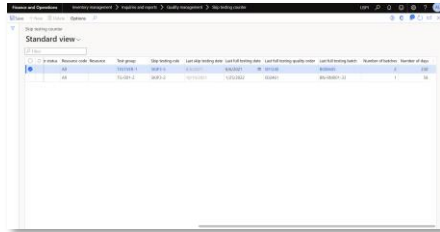
Lot Traceability

Pharma
Manufacturing

Quality Management

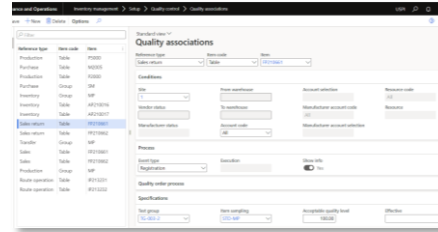
Inventory & Material
Management

Periodic/Skip Testing



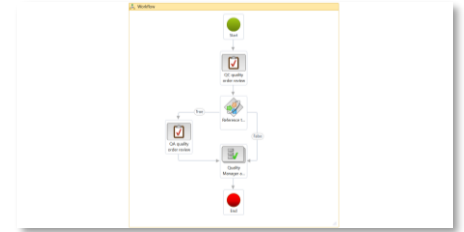
Implement Periodic Testing (PT) or Skip Testing (ST) based on company's written procedure, vendor qualification information or other available data

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



Solutions

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

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



OBJECTIVE

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

Item	Release	Number	Quantity	Unit	Batch number	Location	Temperature	Capacity	Current TOR
A-0000	3/17/2022 13:47 PM	Transfer	10000	kg	RM000001	0001	20.000101-01	10000	1000
A-0000	3/17/2022 4:00:00 PM	Transfer	10000	kg	RM000001	0002	20.000101-01	10000	1000
A-0000	3/17/2022 4:00:00 PM	Transfer	10000	kg	RM000001	0003	20.000101-01	10000	1000

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

Check values, then confirm

Item: Contoso Asia
Lot: 001588

Item: RM001 • Qty: 20.00 kg • Inventory status: Available • Batch number: RM0000008 • Serial number: RM0000008-001

Item: RM011
RM001 • Qty: 20.00 kg • Inventory status: Available • Batch number: RM0000008 • Serial number: RM0000008-002

Cancel Confirm

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

Advanced Production RAF

Check values, then confirm

Lot: 11

Intermediate product-001

QUAR: 10

Item: 9

Cancel Confirm

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

Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

Regulatory Compliance

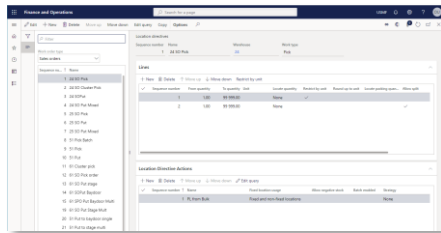
Lot Traceability

Pharma Manufacturing

Quality Management

Inventory & Material Management

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

A screenshot of a software interface showing a table of sampling data. The table has columns for Sample ID, Description, Sample type, Sampling time, Quality value, New number, Batch number, Serial number, Sampling date, Operator name, and Ownership.

Sample ID	Description	Sample type	Sampling time	Quality value	New number	Batch number	Serial number	Sampling date	Operator name	Ownership
PH01-000001-001	Control	Raw	2017-11-11 10:00:00	100.0000	1001	PH01-000001	PH01-000001-001	10/11/2017	ABE	ABE
PH01-000001-002	Control	Raw	2017-11-11 10:00:00	100.0000	1002	PH01-000001	PH01-000001-002	10/11/2017	ABE	ABE
PH01-000001-003	Control	Raw	2017-11-11 10:00:00	100.0000	1003	PH01-000001	PH01-000001-003	10/11/2017	ABE	ABE
PH01-000001-004	Control	Raw	2017-11-11 10:00:00	100.0000	1004	PH01-000001	PH01-000001-004	10/11/2017	ABE	ABE
PH01-000001-005	Control	Raw	2017-11-11 10:00:00	100.0000	1005	PH01-000001	PH01-000001-005	10/11/2017	ABE	ABE
PH01-000001-006	Control	Raw	2017-11-11 10:00:00	100.0000	1006	PH01-000001	PH01-000001-006	10/11/2017	ABE	ABE
PH01-000001-007	Control	Raw	2017-11-11 10:00:00	100.0000	1007	PH01-000001	PH01-000001-007	10/11/2017	ABE	ABE
PH01-000001-008	Control	Raw	2017-11-11 10:00:00	100.0000	1008	PH01-000001	PH01-000001-008	10/11/2017	ABE	ABE
PH01-000001-009	Control	Raw	2017-11-11 10:00:00	100.0000	1009	PH01-000001	PH01-000001-009	10/11/2017	ABE	ABE
PH01-000001-010	Control	Raw	2017-11-11 10:00:00	100.0000	1010	PH01-000001	PH01-000001-010	10/11/2017	ABE	ABE

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

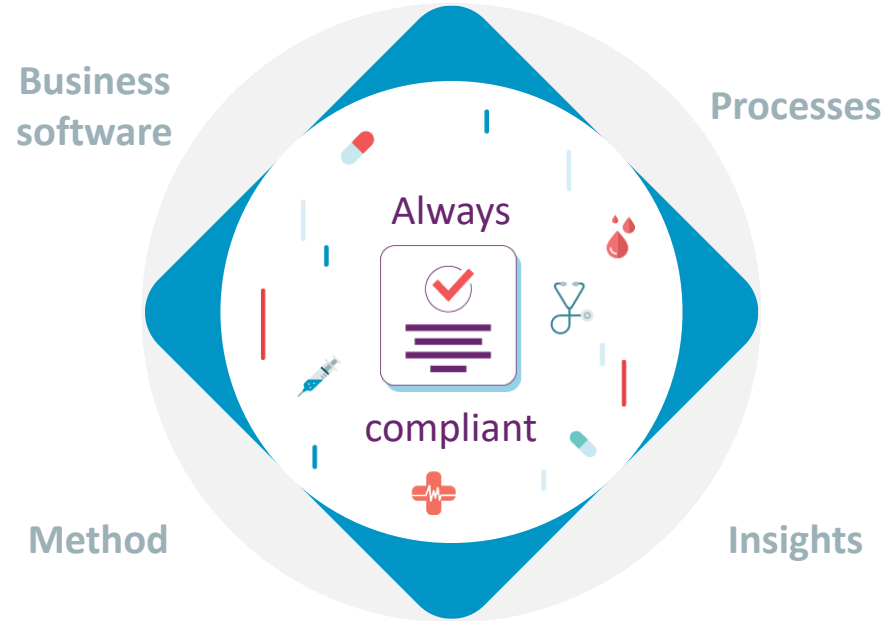


Solutions

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

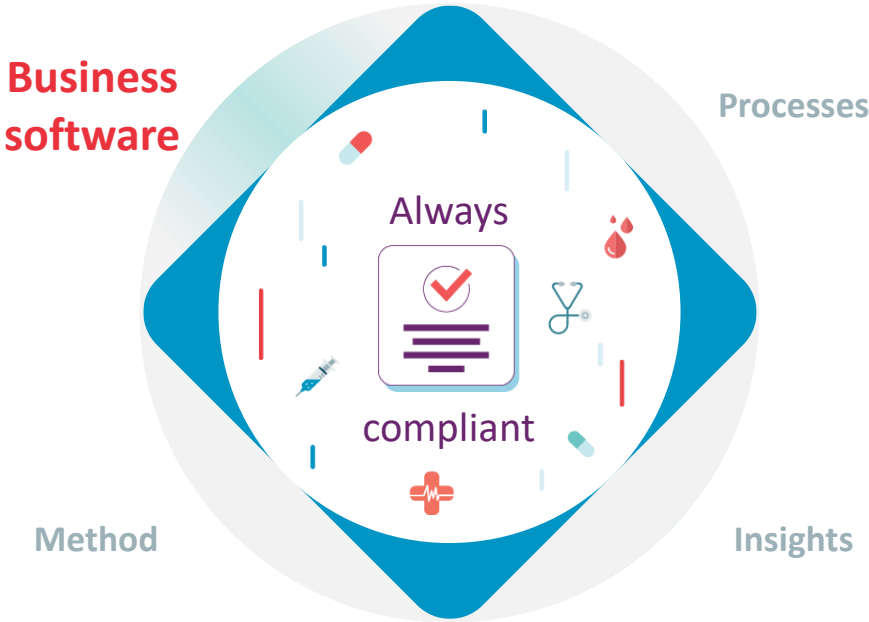
Dynamics for Pharma & Life Sciences

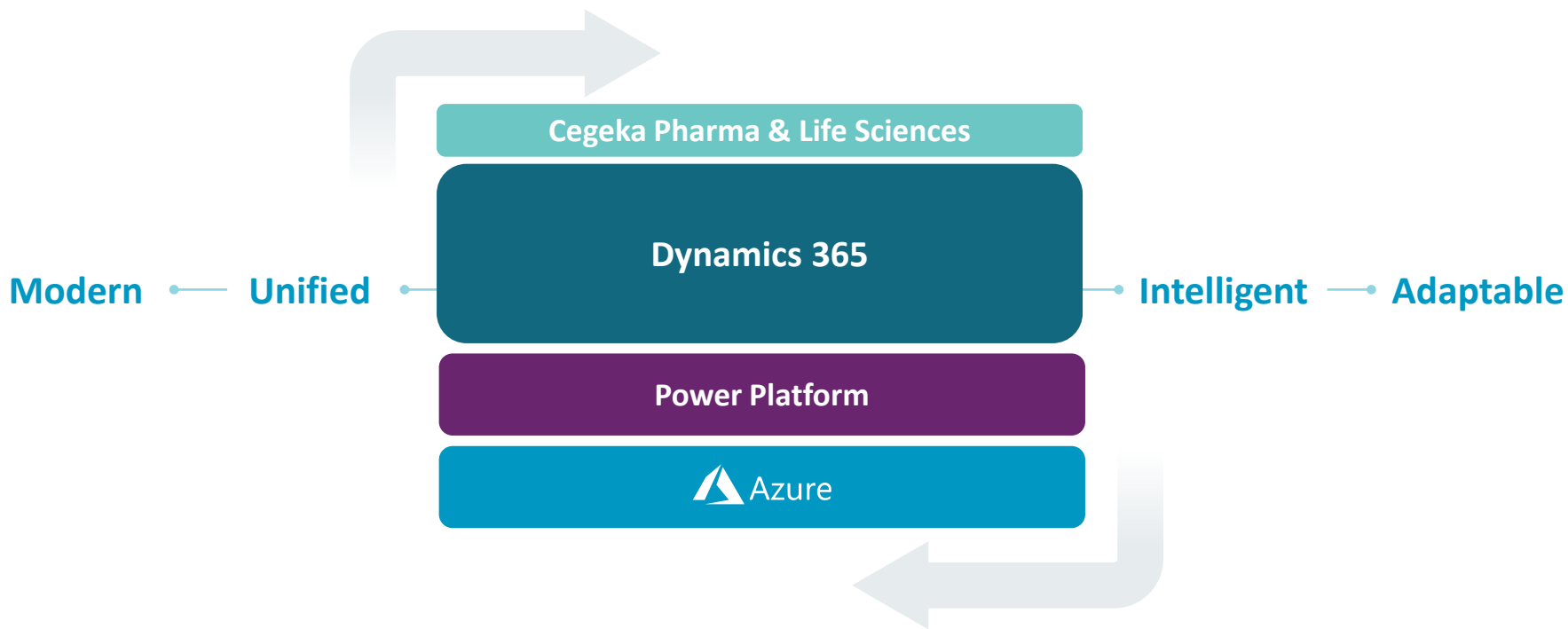
Building business continuity through intelligent, unified systems



Dynamics for Pharma & Life Sciences

Building business continuity through intelligent, unified systems



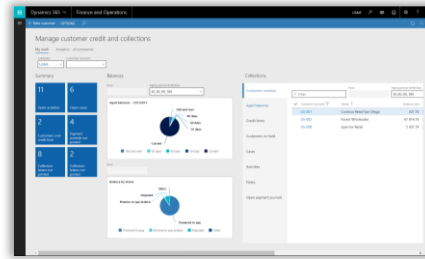


Modern

Cegeka Pharma & Life Sciences

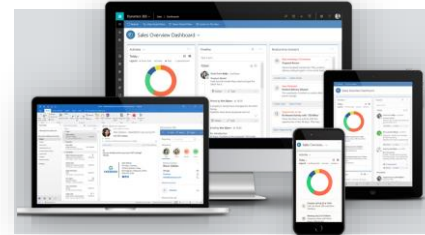
Dynamics 365

Power Platform



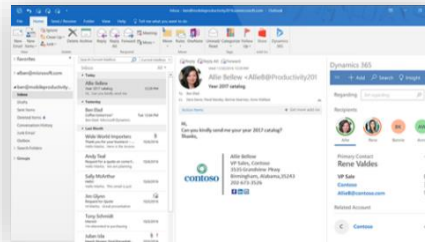
User friendly boosting adoption

The interface is intended to guide the user to those processes that need attention (manage by exception). It offers a modern user experience and enables faster adoption.



Available Anywhere Anytime

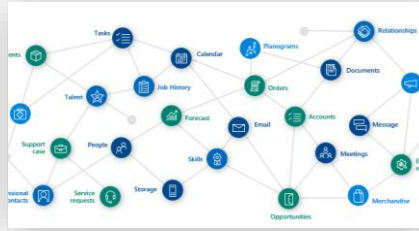
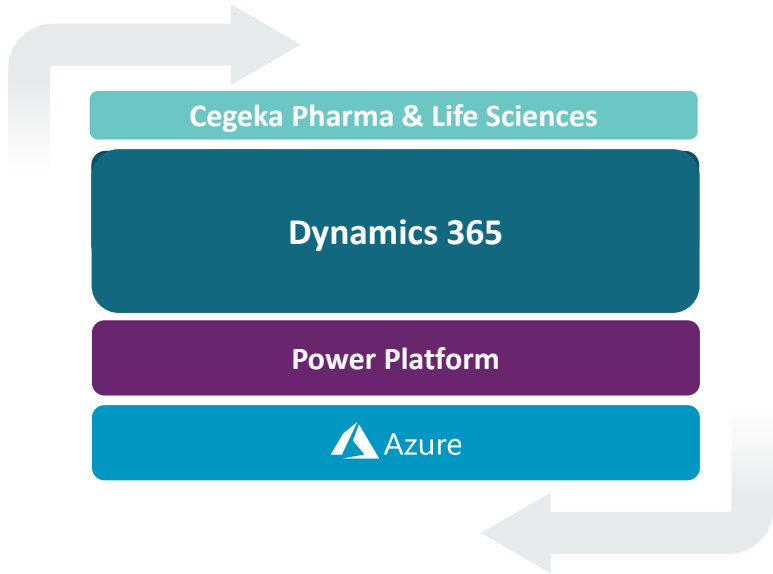
The user interface is web based and enriched with specific apps making the solution anywhere available, on any device and any time. Fully secure thanks to the underlying Microsoft Azure cloud.



Higher Productivity

Dynamics 365 is deeply integrated with Microsoft Office apps such as Excel or Outlook. This offers users additional capabilities and improves their productivity.

Unified



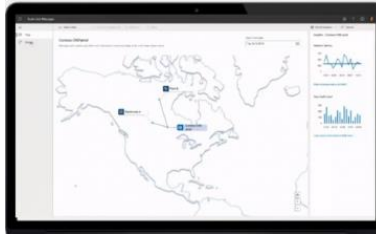
Unified Data Model

Get rid of data silos. Dynamics 365 brings all data into one unified data model. This allows your organization to work together cross department or cross countries.



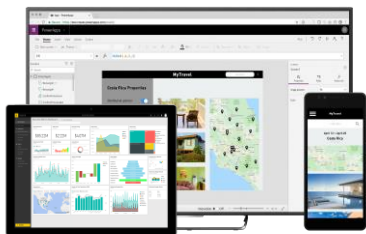
Integrated

Dynamics 365 and the underpinning Azure cloud platform offer extensive integration service to connect Dynamics internally and externally



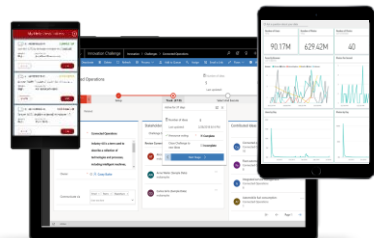
Business Security

Dynamics 365 ensures data integrity and privacy within your organization; the underlying Azure Cloud-platform offers data backups and allows you to stay in line with regulations.



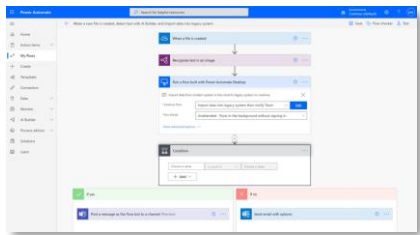
Scalability – grow with you

Within the Dynamics 365 platform you can easily add additional workloads, countries and/or users allow you to grow with your business.



Extend & Automate

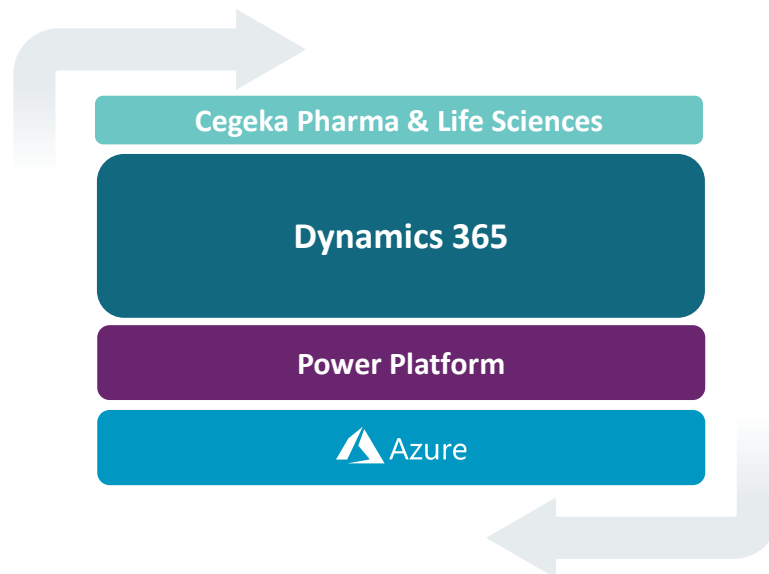
Thanks to the Power Platform, the Microsoft low code solution embedded in Dynamics 365, you can easily extend the capabilities and automate processes between different applications.



Flexible - Ownership

You can take ownership and modify, processes and workflows without the need for external partners to adapt to changed business circumstances and grab new opportunities.

Adaptable

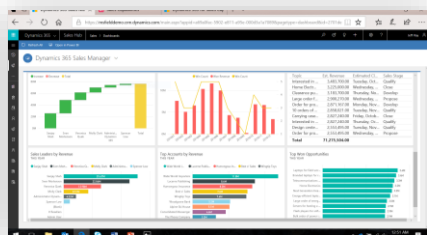


Cegeka Pharma & Life Sciences

Dynamics 365

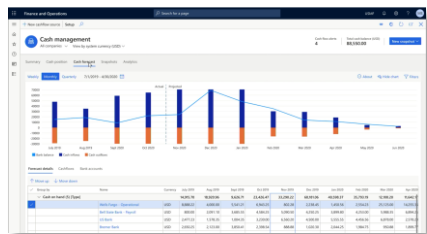
Power Platform

Azure



Business Intelligence

Power BI dashboards are embedded in Dynamics 365 offering advanced insights. Drill down to details without switching apps and allowing users to take better decisions.



Intelligent processes

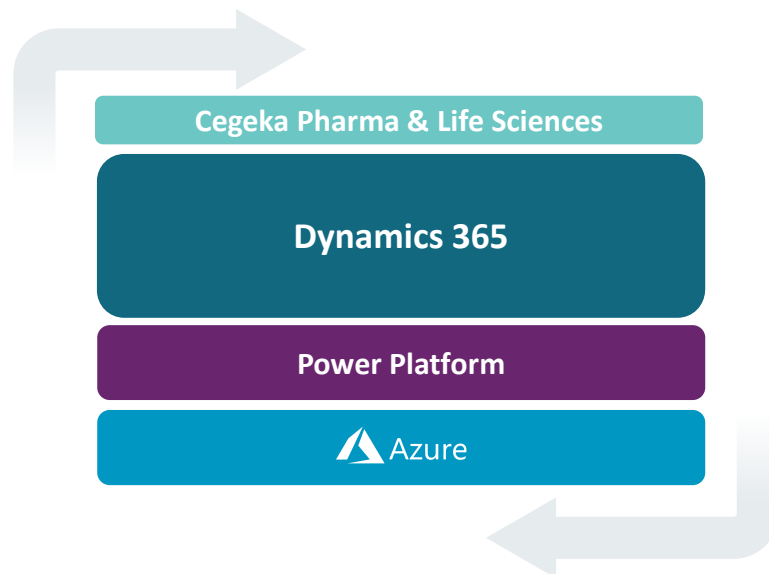
Offering AI-powered capabilities such as customer payment predictions or intelligent budget proposals. Making innovative technologies easily availability to improve your efficiency.



Advanced guidance

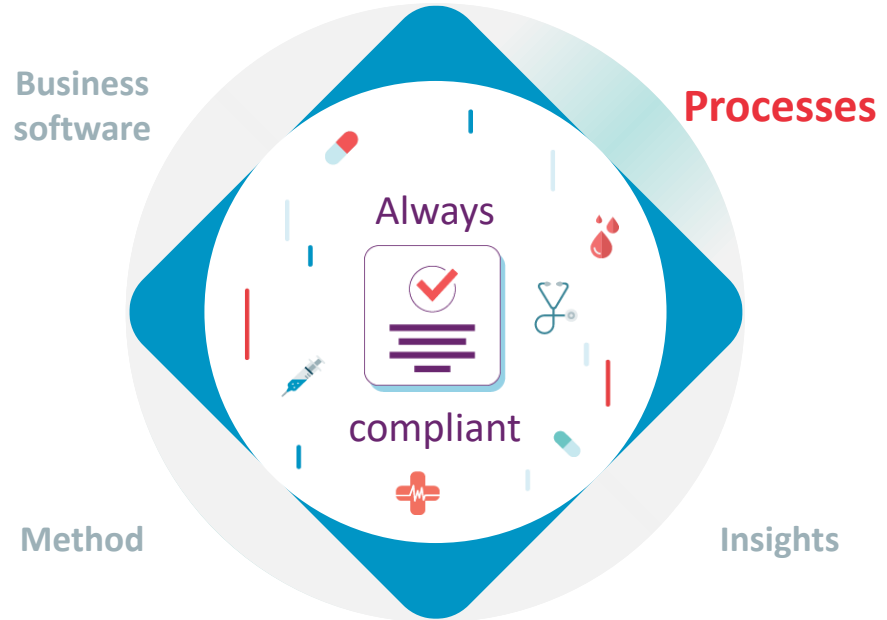
With Mixed Reality capabilities in Dynamics 365, you can give your employees the expert guidance wherever they are.

Intelligent



Dynamics for Pharma & Life Sciences

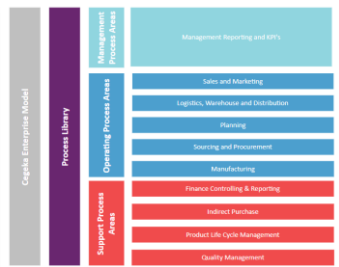
Building business continuity through intelligent, unified systems



Processes

Dynamics for Pharma & Life Sciences offers pharma industry specific processes

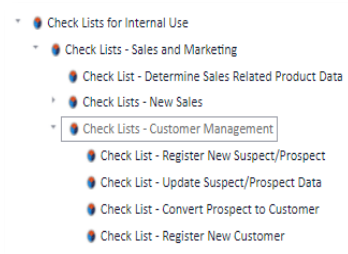
Processes



- 495 Best Practice Processes
- Pharma Industry Specific Processes

Industry Accelerator

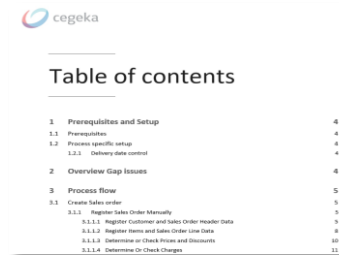
Checklist



- Questions per process
- Collecting a comprehensive set of requirements

Quality Assurance

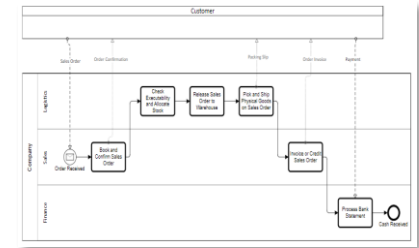
Descriptions



- Starting point for work instructions
- Starting point for As Build documentation

Fully Documented

End-2-end



- Cross department value streams
- Helicopter view

End-2-end Optimization

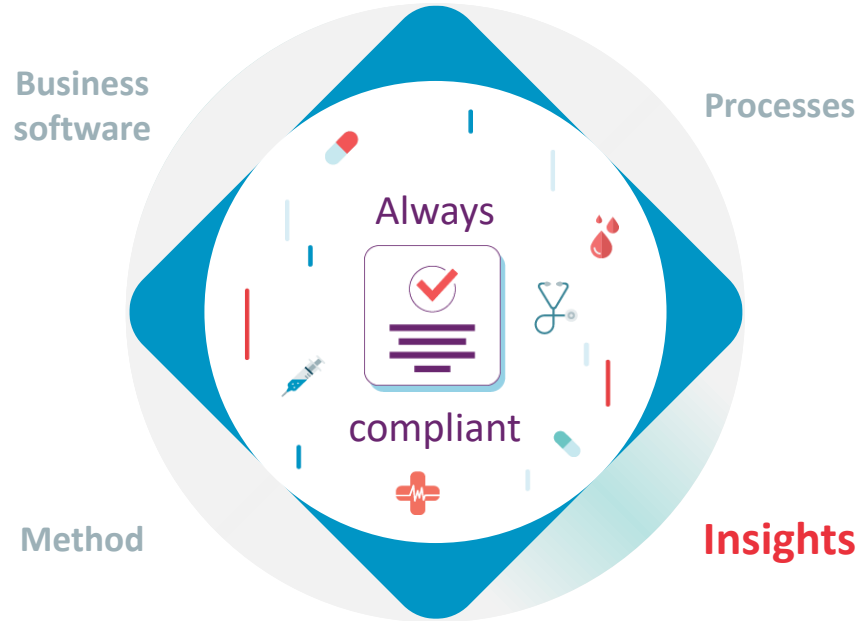
Processes

GxP assessment for Pharma & Life Sciences processes

Process Area	GxP-Critical Processes per Process Area	Total Processes per Process Area
Finance Controlling & Reporting	2	162
Logistics, Warehouse and Distribution	108	136
Manufacturing	22	26
Planning	7	25
Product Life Cycle Management	15	15
Quality Management	9	9
Sales and Marketing	17	77
Sourcing and Procurement	24	45
TOTAL	204	495

Dynamics for Pharma & Life Sciences

Building business continuity through intelligent, unified systems

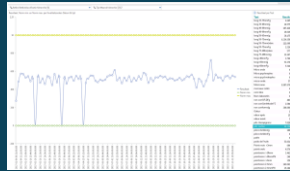


Business Insights

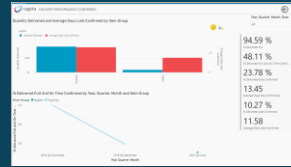
Dynamics for Pharma & Life Sciences offers out of the box insights and dashboards



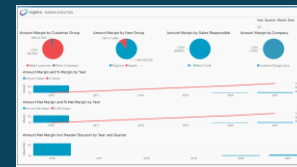
Production Efficiency



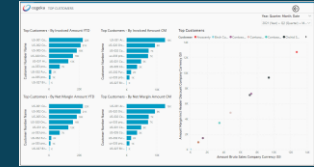
Quality results



Delivery Performance



Margin Evolution



Top Customers



Contract Fulfilment



Costing Details



Stock Expiry



Margin Analysis



Customer Payments



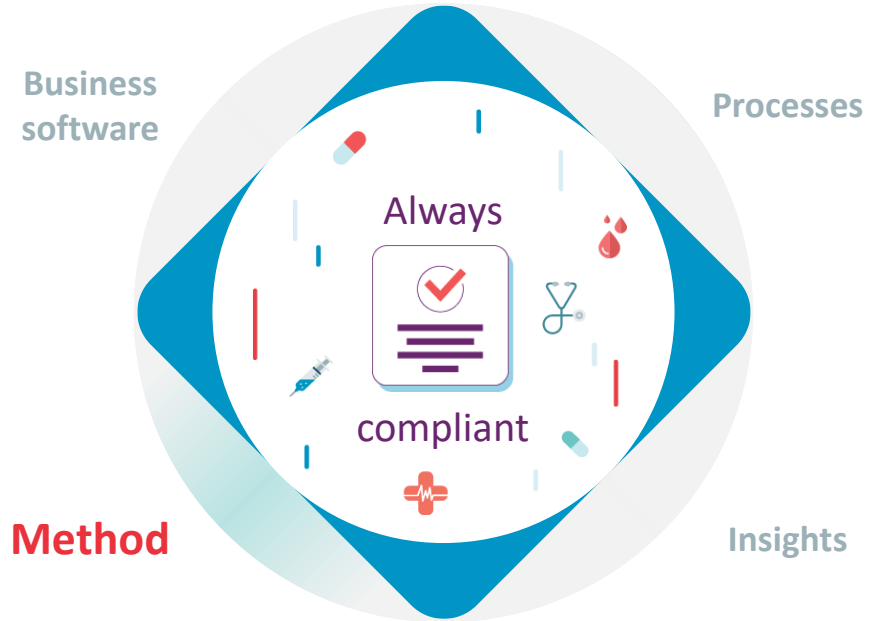
Get insights out of your data

with more than **+75** dashboards for your industry



Dynamics for Pharma & Life Sciences

Building business continuity through intelligent, unified systems



Proven Methodology

Dynamics for Pharma & Life Sciences is implemented using a proven methodology



Fully Documented

- Templates
- Instructions

**Transparent &
Predictable**



Supporting Tools

- Collaboration tools
- Documentation & Reporting

**Collaborative &
In Control**



Academy & Guidance

- Trainings
- Coaching

**Professional &
Proven**

Proven Methodology

Solution and approach validated by independent software validation companies



Solution



Methodology



The **Cegeka Dynamics Pharma & Life Sciences solution** is, from a regulatory perspective, fit and documented for intended use in the Pharma and Medical device industry

System validation is embedded in every phase of our project methodology and fully aligned with the required validation deliverables according to GAMP 5 recommendations



Software validation partner: [Epista Life Science](#)



Dynamics 365 complies with Good Clinical, Distribution, Laboratory, and Manufacturing Practices (GxP): [Microsoft GxP documentation](#)

ICH Guidance Q8, Q9 and Q10

Pharma EU: EudraLex Volume 4: Annex 11 Information Technology, Annex 15 Qualification, and validation

Medical Device EU: MDR 2017/745 Appendix 1, chapter 1 part 17.

OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE

MONITORING Number 17 - Application of GLP Principles to Computerized Systems

US: 21 CFR Part 11: Electronic Records and Electronic Signatures

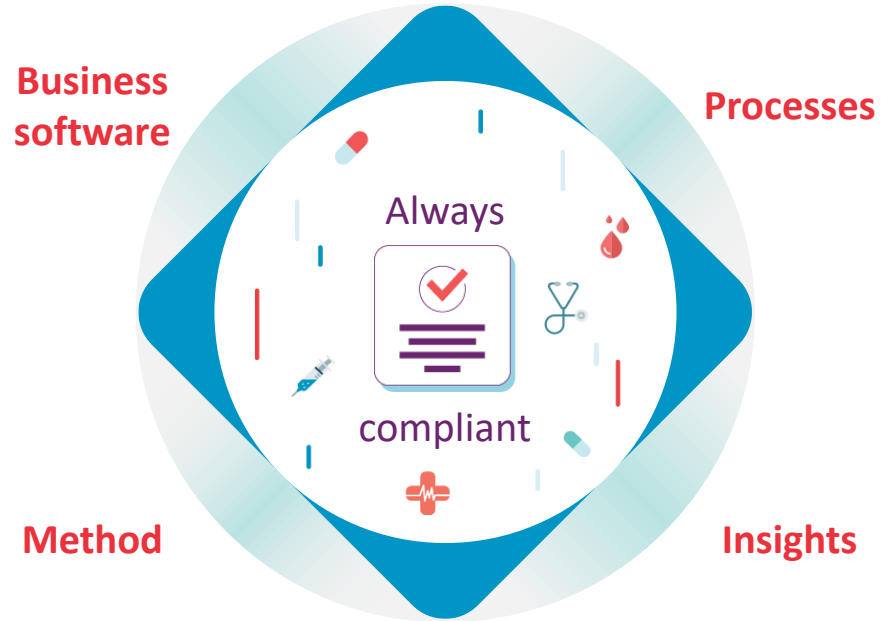
GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems

ISO/IEC 12207 - Systems and software engineering

ISO/IEC 90003 Software engineering — guidelines for the application of ISO9001:2015 to computer software

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