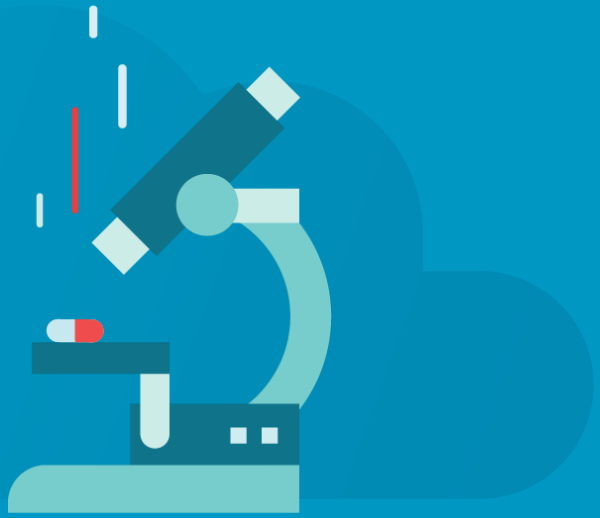
Become a connected PHARMA & LIFE SCIENCES company



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.

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

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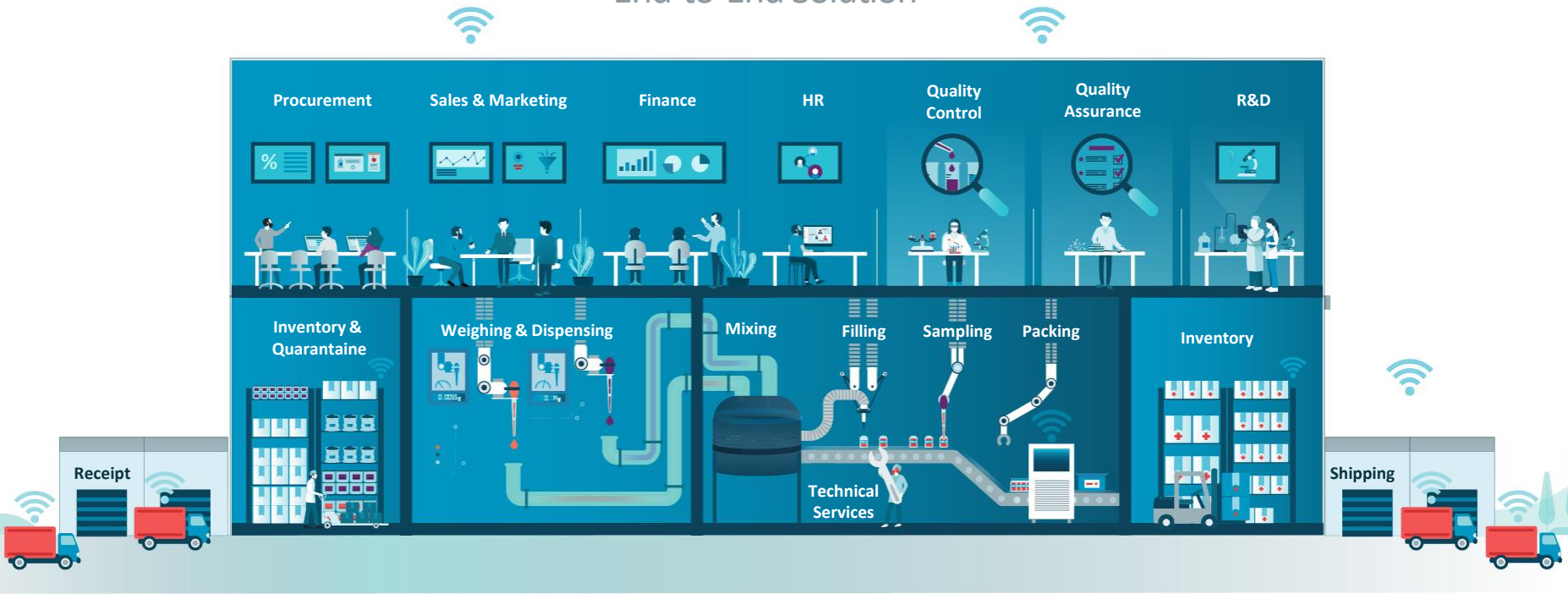
Dynamics for Pharma

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.

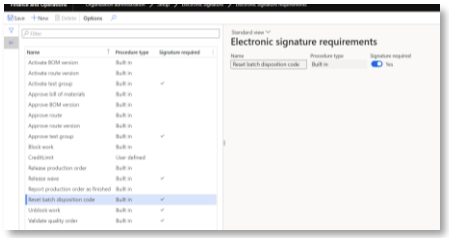
Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

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

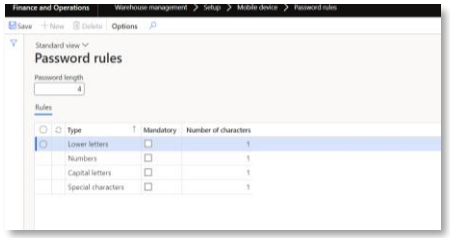
Solutions

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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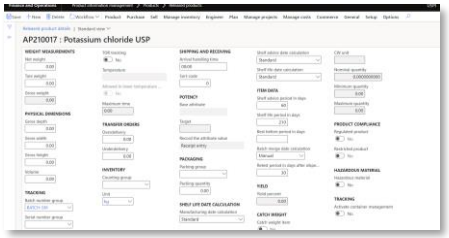
Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

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

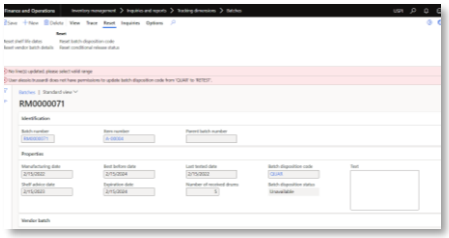
Solutions

Shelf Life Dates



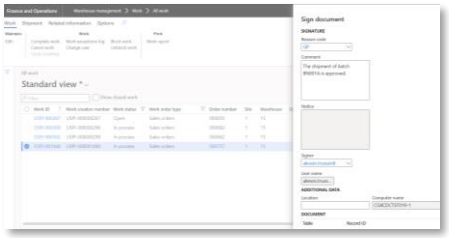
Automate shelf life date assignment (production date, expiry date, retest date, etc.) based on product and manufacturing process

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

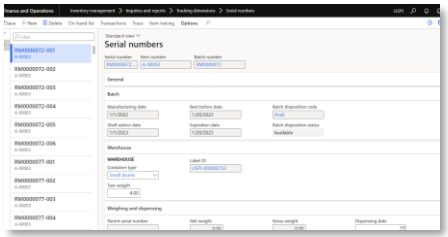
- Improve the traceability of items throughout the entire supply chain with lot tracking and container/drum management.
- Monitor the lifecycle of each lot/batch of material from vendor receipt of raw materials through delivery of manufactured products to the customer.
- Promptly react to defective products 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

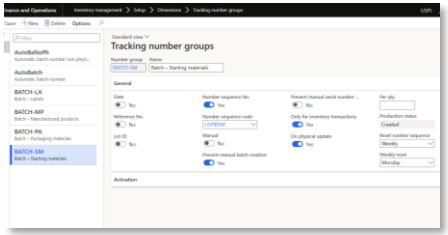
Solutions

Container/Drum Management



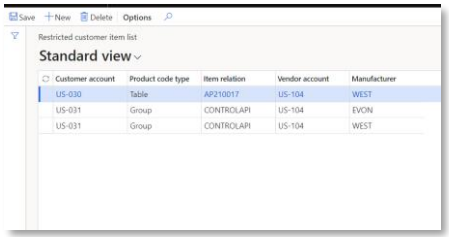
Uniquely identify each container/drum that is part of a specific lot, and maintain full traceability throughout the entire supply chain

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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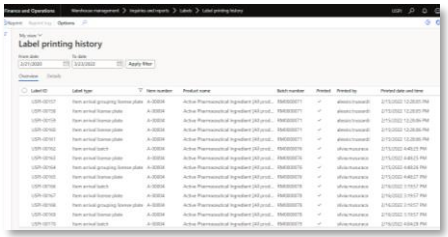
Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

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

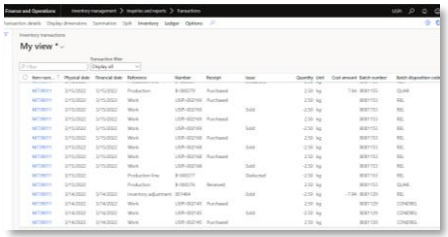
Solutions

Label Printing & Reprinting



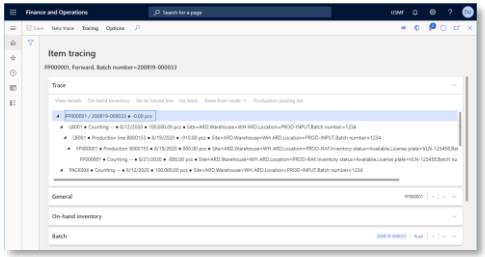
Meet legal requirements for the labels set by federal law and specific regulations by tracking printing and reprinting activities for any type of label

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

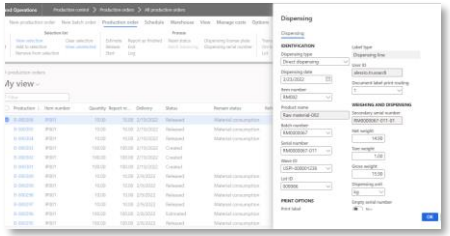
- Improve production efficiency and reduce downtime.
- Optimally plan and combine upstream & downstream manufacturing, packaging, MSAT and contract manufacturing processes
- Support production and raw material consumption in line with changing customer-specific requirements.

Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

Solutions

Weighing & Dispensing

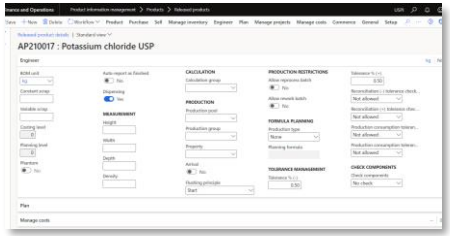


Introduce guided and precise execution of weighing & dispensing operations for production, in compliance with industry standards and regulatory requirements

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

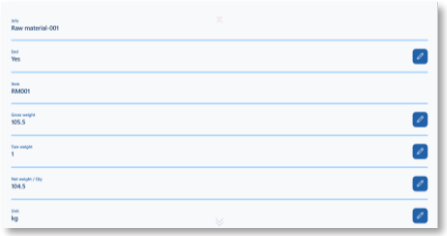
Regulatory Compliance | Lot Traceability | **Pharma Manufacturing** | Quality Management | Inventory & Material Management

Solutions

Reconciliation

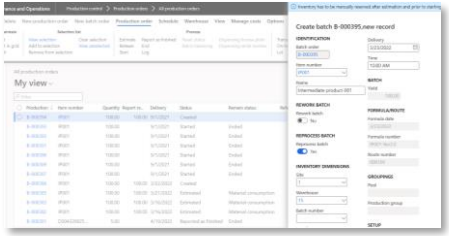
Ensure all materials to be consumed for the production process of manufactured products are correctly accounted for, and no errors occur that may impact patient safety

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)

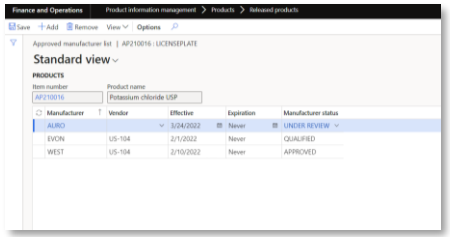
Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

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

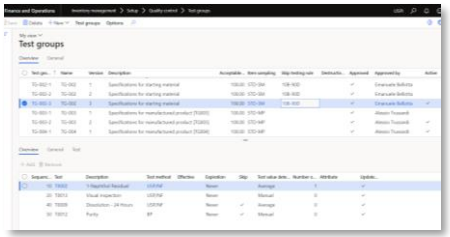
Solutions

Vendor & Manufacturer Qualification/Approval



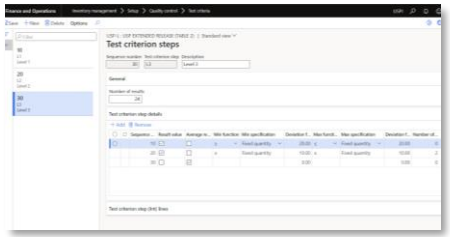
Perform selection, qualification, approval and maintenance of suppliers of starting materials, and drive quality control activities based on the qualification/approval status

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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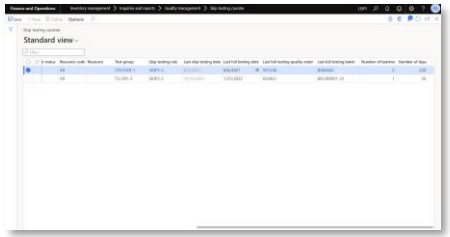
Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

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

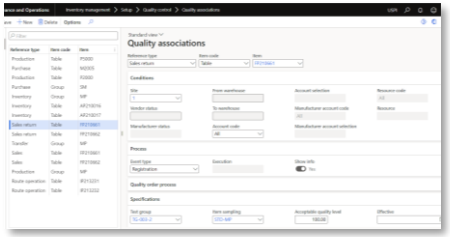
Solutions

Periodic/Skip Testing



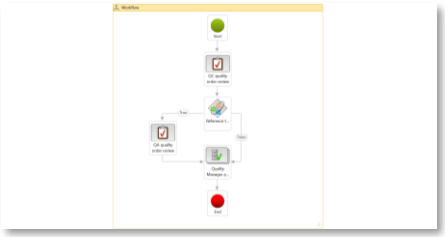
Implement Periodic Testing (PT) or Skip Testing (ST) based on company's written procedure, vendor qualification information or other available data

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

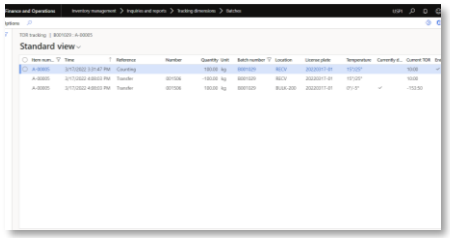
Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

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

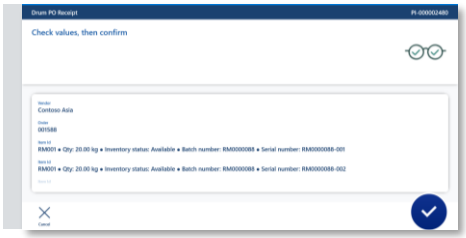
Solutions

Temperature Monitoring



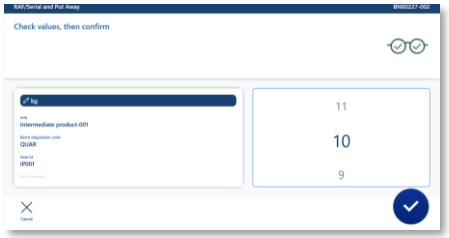
Track the time spent by controlled items out of refrigerated zones (TOR/TOS) and compare it to the medicine's allowable excursion time

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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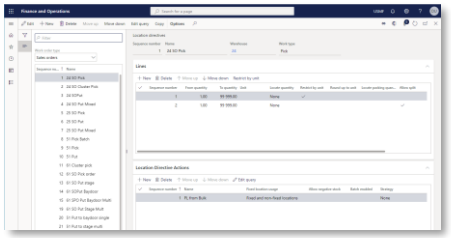
Key Drivers

Overview of the Dynamics for Pharma & Life Sciences Solution

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

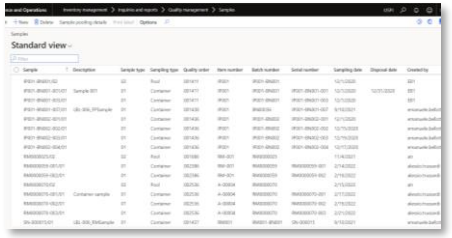
Solutions

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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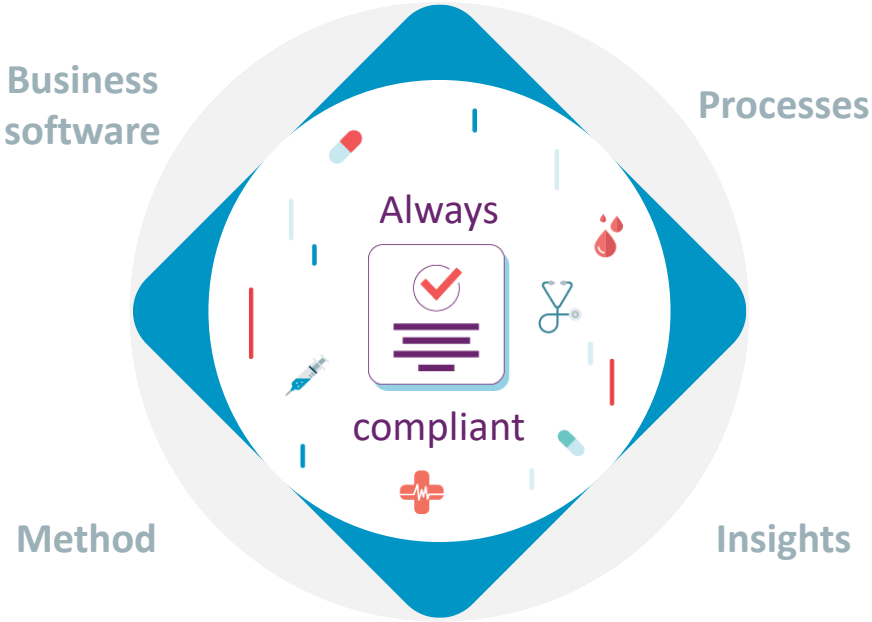
Dynamics for Pharma & Life Sciences

Building business continuity through intelligent, unified systems



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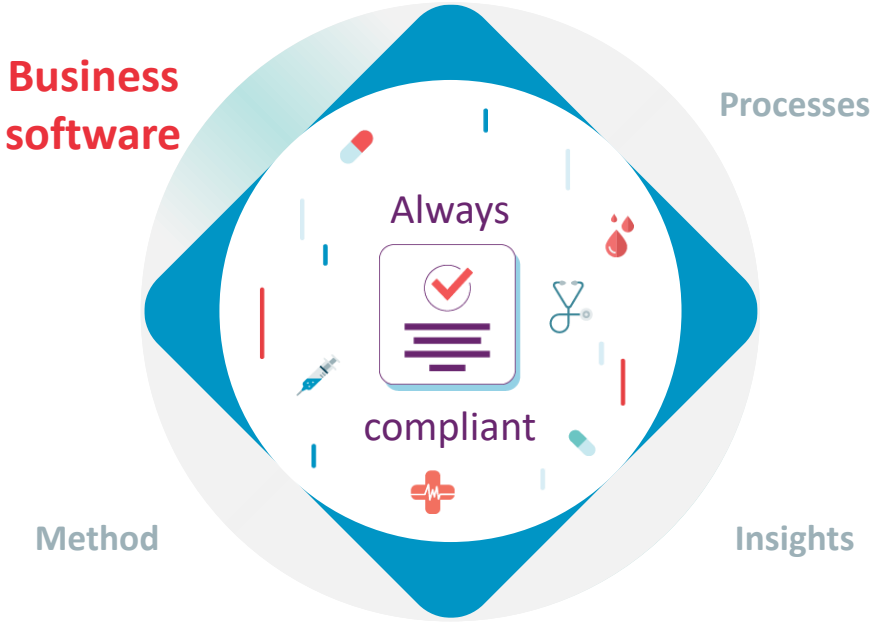
Dynamics for Pharma & Life Sciences

Building business continuity through intelligent, unified systems



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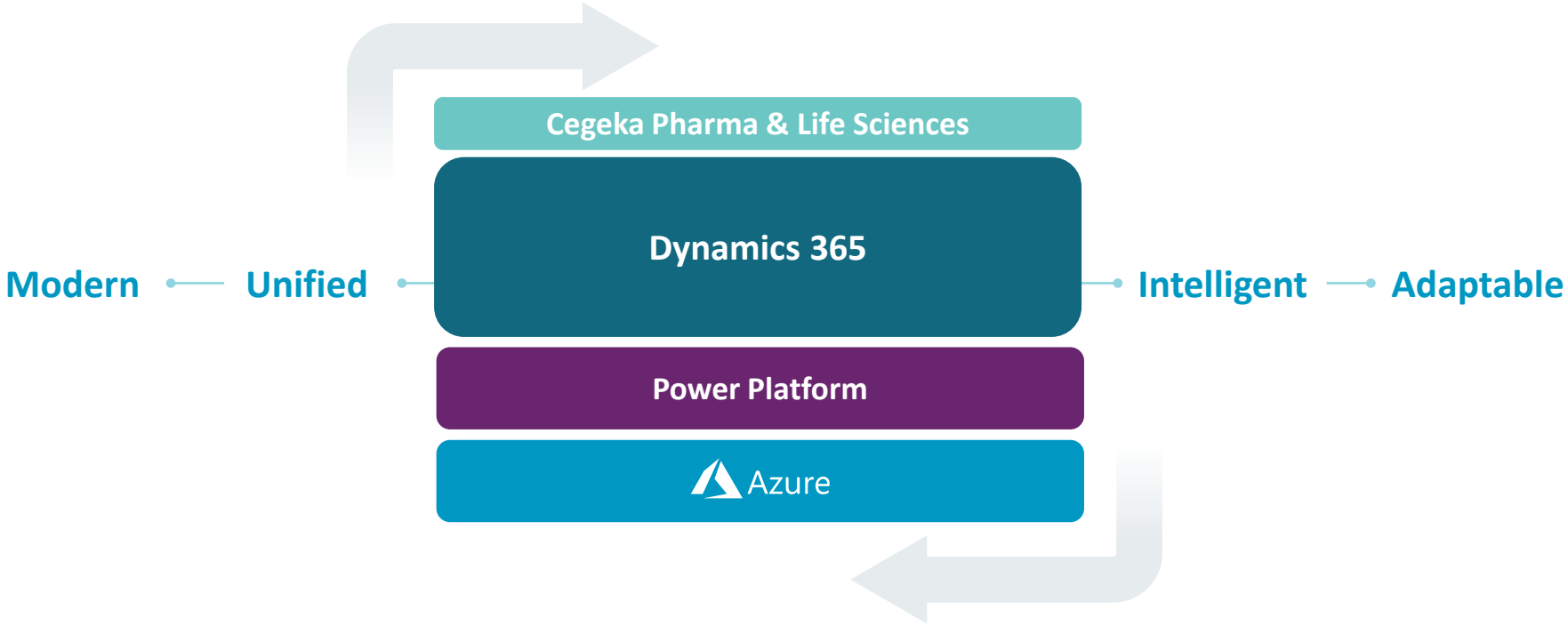
Cegeka Pharma & Life Sciences
Dynamics 365
Power Platform
Azure
Modern
Unified
Intelligent
Adaptable

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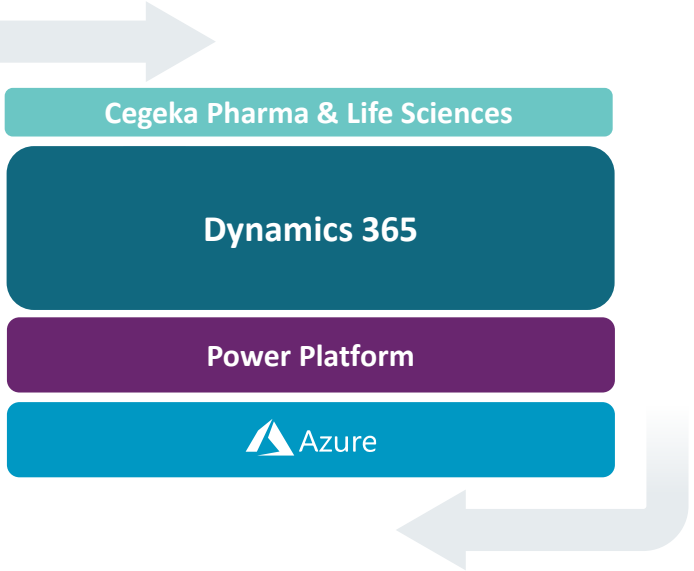
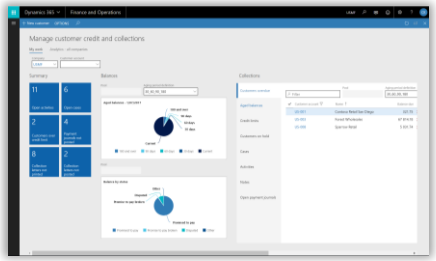
Modern



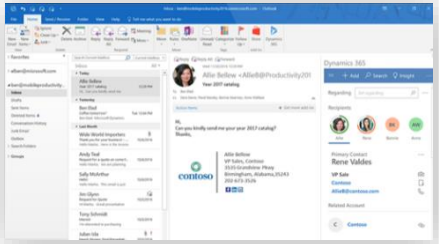


User friendly boosting adoption

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.

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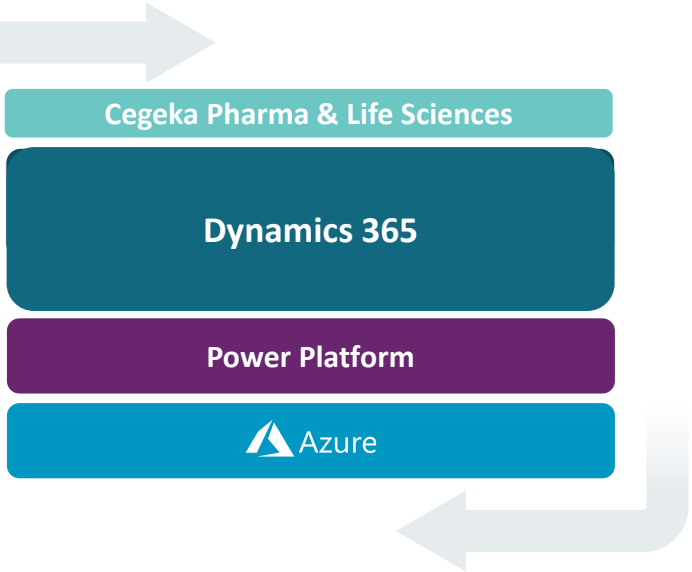
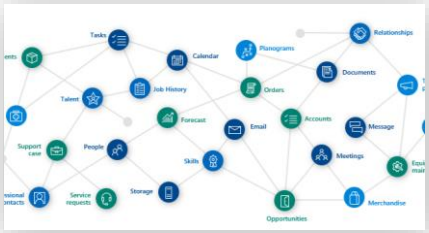
Unified



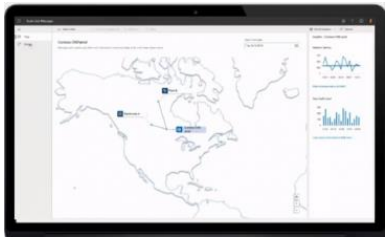


Unified Data Model

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.

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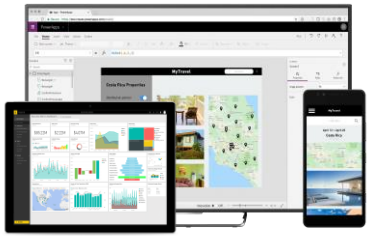
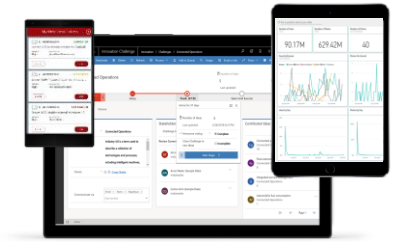
Adaptable



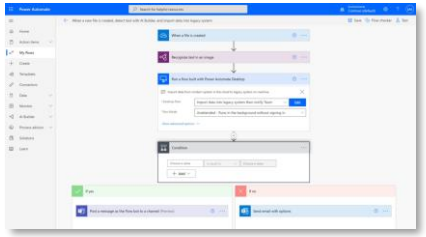
Scalability – grow with you

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



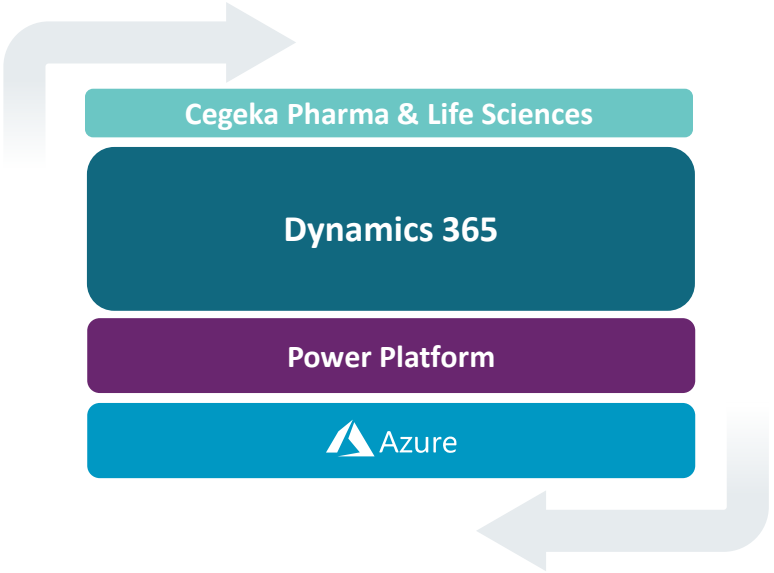
Extend & Automate

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.



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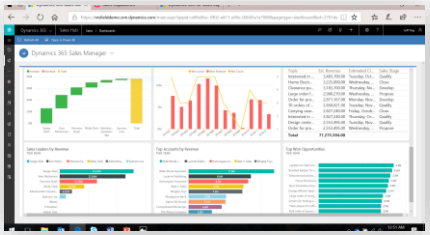
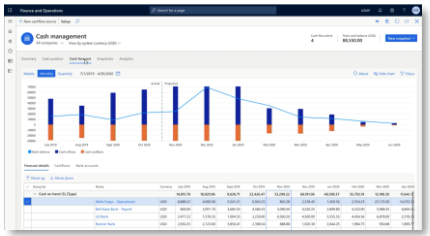
Intelligent



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.

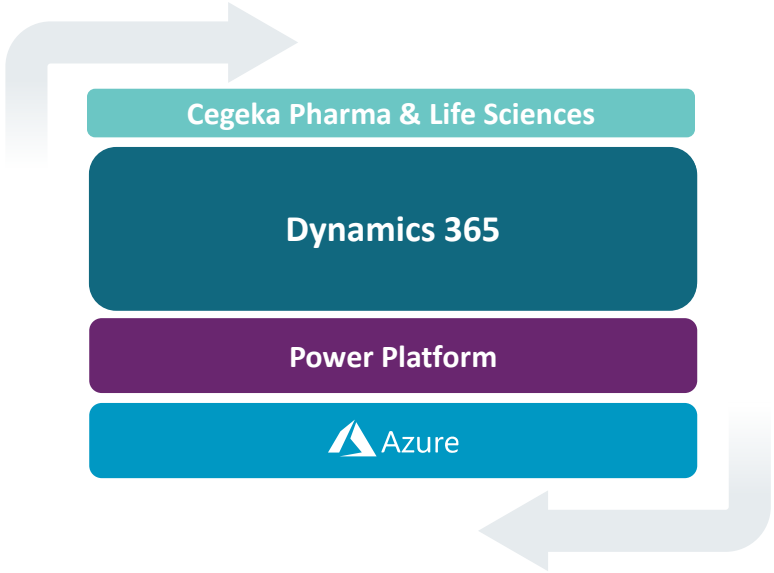


Intelligent processes

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.



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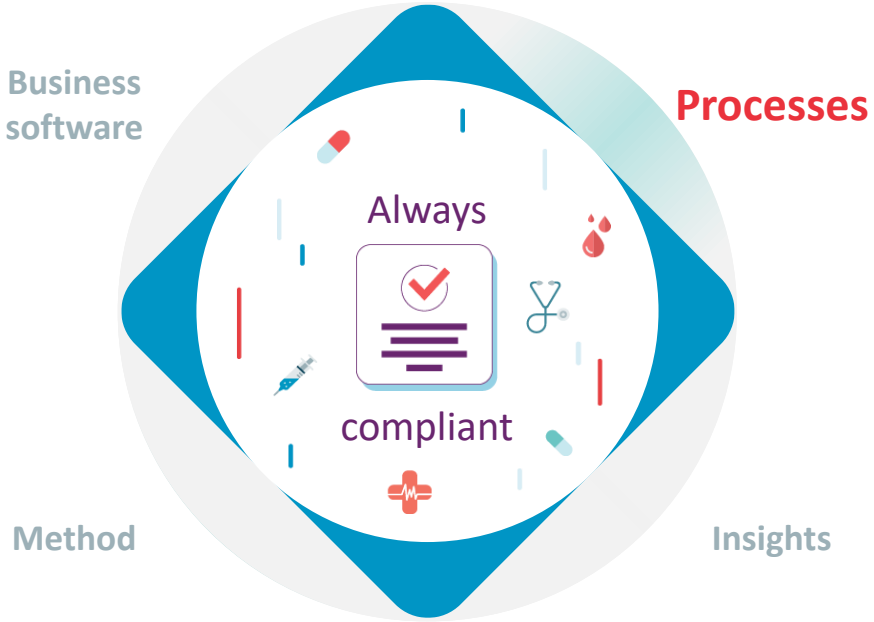
Dynamics for Pharma & Life Sciences

Building business continuity through intelligent, unified systems



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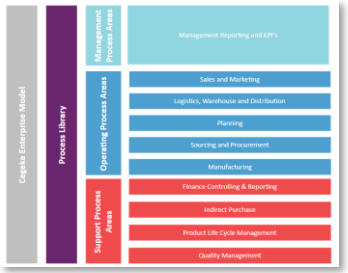
Processes

Dynamics for Pharma & Life Sciences offers pharma industry specific processes

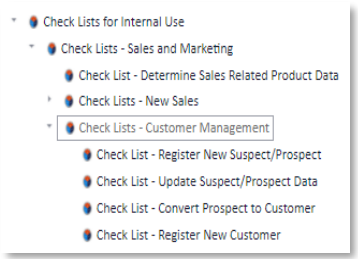
Processes



- 495 Best Practice Processes
- Pharma Industry Specific Processes

Industry Accelerator

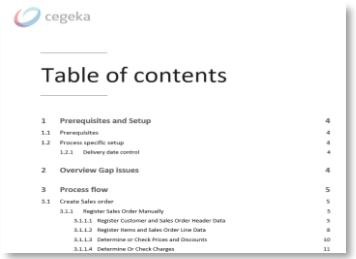
Checklist



- Questions per process
- Collecting a comprehensive set of requirements

Quality Assurance

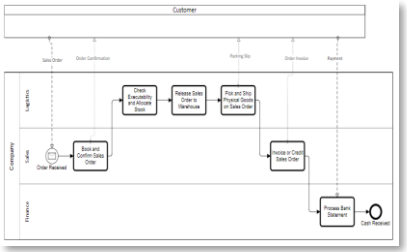
Descriptions



- 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

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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

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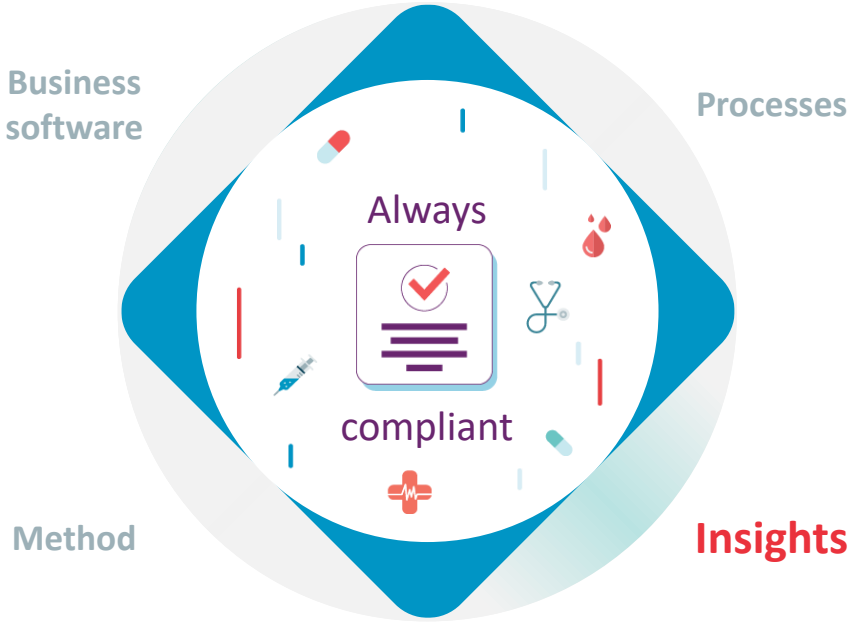
Dynamics for Pharma & Life Sciences

Building business continuity through intelligent, unified systems



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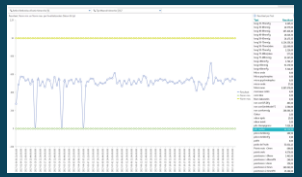
Business Insights

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

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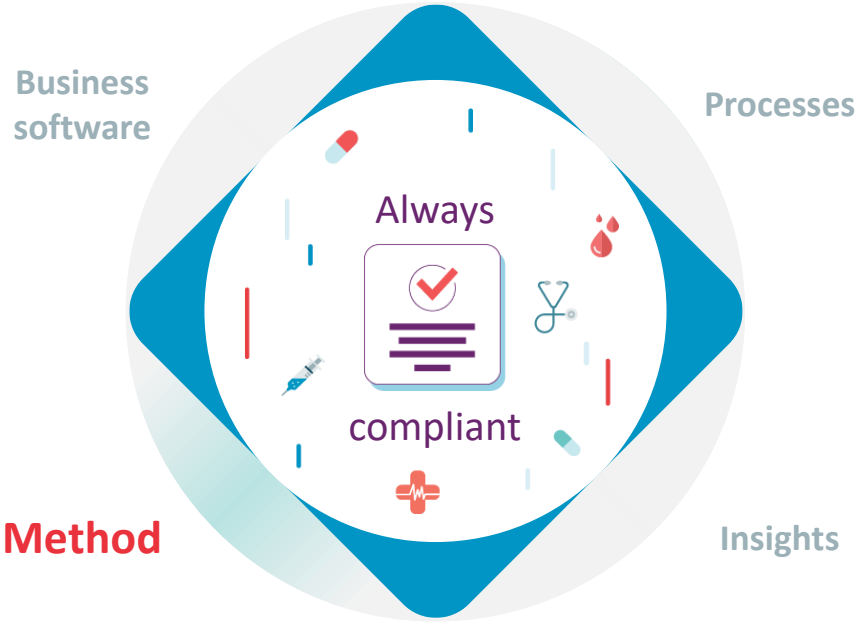
Dynamics for Pharma & Life Sciences

Building business continuity through intelligent, unified systems



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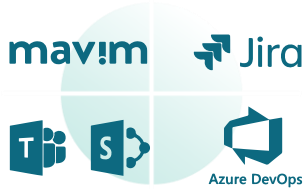
Proven Methodology

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

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Proven Methodology

Solution and approach validated by independent software validation companies

Solution

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

Software validation partner: Epista Life Science

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

Methodology

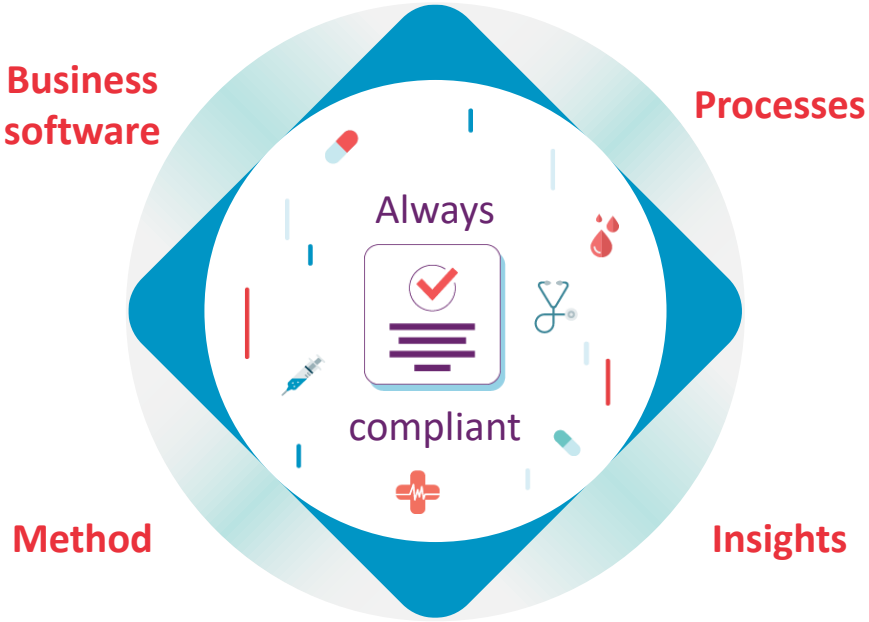
System validation is embedded in every phase of our project methodology and fully aligned with the required validation deliverables according to GAMP 5 recommendations

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 IS09001:2015 to computer software

Dynamics for Pharma & Life Sciences

Building business continuity through intelligent, unified systems



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