Solution Overview

Cegeka Pharma & Life Sciences for Microsoft Dynamics 365

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OVERVIEW

Cegeka Pharma & Life Sciences for Dynamics 365 is an advanced solution built on Microsoft Dynamics 365 Finance & Supply Chain Management, designed specifically for the pharma & life sciences industry. With integrated capabilities for production efficiency, quality control, and supply chain management, it helps businesses reduce costs, mitigate risks, and accelerate innovation, all while maintaining compliance with FDA CFR 21 part 11 and part 211, EMA Annex 11, and other global standards.

KEY BENEFITS

- Optimize manufacturing operations

- Improve quality control and quality assurance

- Enhance lot and batch traceability

- Ensure continuous compliance with global regulatory standards
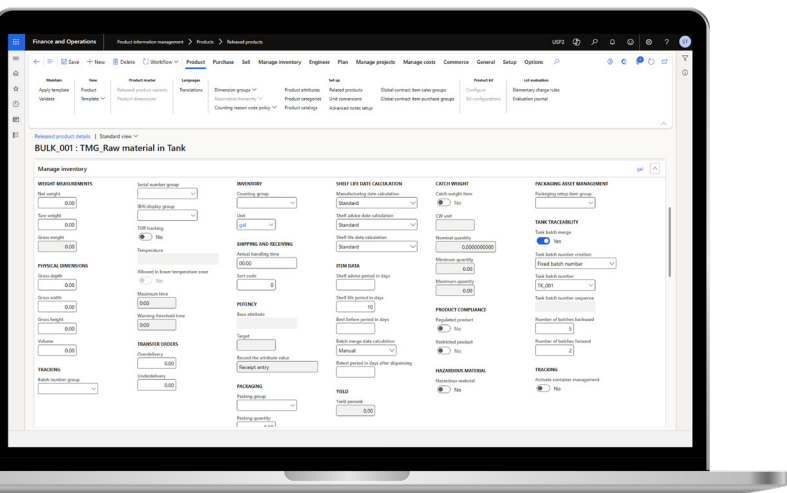
- Scale with a solution that grows with you

REGULATORY COMPLIANCE

Stay audit-ready with 21 CFR Part 11 compliant electronic signatures, approval workflows for GxP critical processes, and robust audit trails. Streamline Computerized System Validation (CSV) activities based on GAMP 5 recommendations.

REPORTS & DOCUMENTS

- Create electronic reports for production picking, dispensing, and sampling.

- Conduct annual product quality reviews (APQR) to analyze product quality based on all relevant documents.
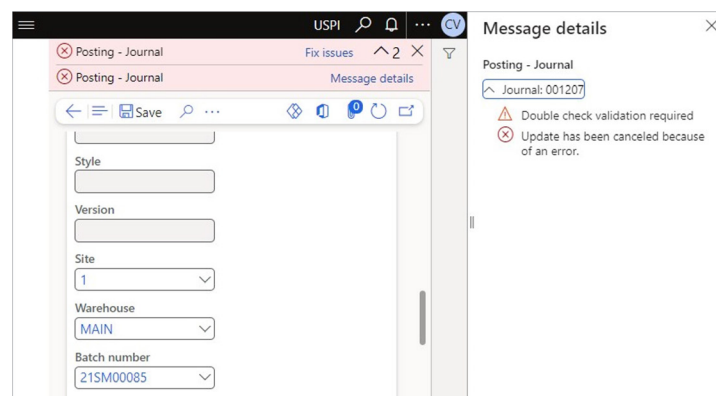

SECURITY PARAMETERS

- Set up and manage electronic signature security parameters, including maximum attempts before blocking, manual/automatic reset, and full audit trail capabilities.

- Configure mobile device security with password rules, blocking after failed attempts, and manual/automatic unblock.

- Ensure segregation of duties in journal entry and posting with double-checks and security role assignments.

APPROVAL WORKFLOWS

- Implement workflows for product creation and changes, ensuring multi-level review and approval.

- Set up multi-level workflows for quality inspection validation, enforcing review and approval steps.

- Approve and activate test groups, enabling version management.

MANUFACTURING

Enhance efficiency with real-time batch management, built-in mobile device capabilities, and seamless integration with weighing scales. Optimize material and resource planning with flexible recipe and routing combinations, ensuring precision and compliance at every step.
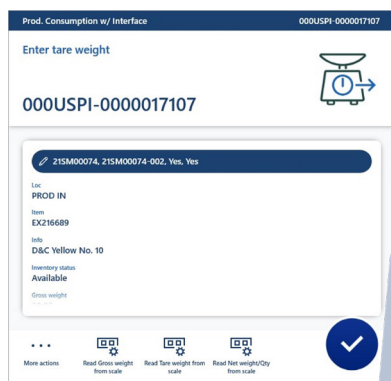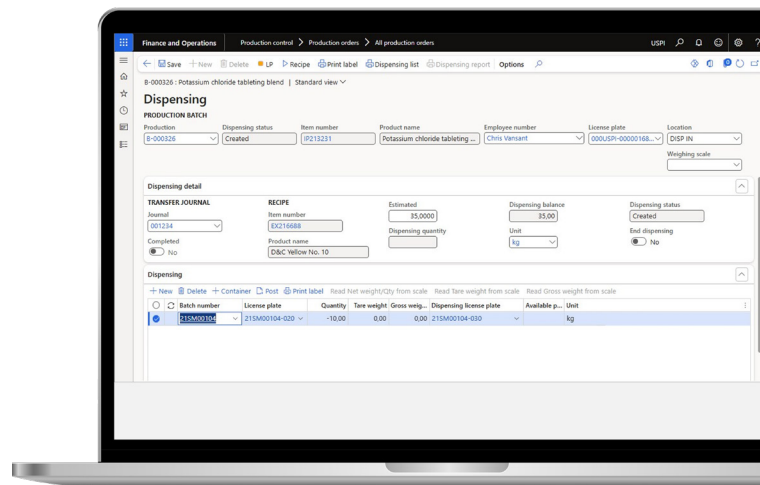

PRODUCTION RESTRICTIONS

- Handle reworking and reprocessing scenarios with varied restrictions according to GMP guidelines. For reprocess orders, only operations included in the active route can be selected.

- Ensure that an existing batch number cannot be reused in another batch order.

- Prevent non-qualified personnel from updating inventory dimensions on a batch order.

WEIGHING & DISPENSING

- Introduce guided and precise execution of weighing and dispensing operations in compliance with industry standards and regulatory requirements.

- Ensure all materials for production are correctly accounted for, preventing errors that may impact patient safety.

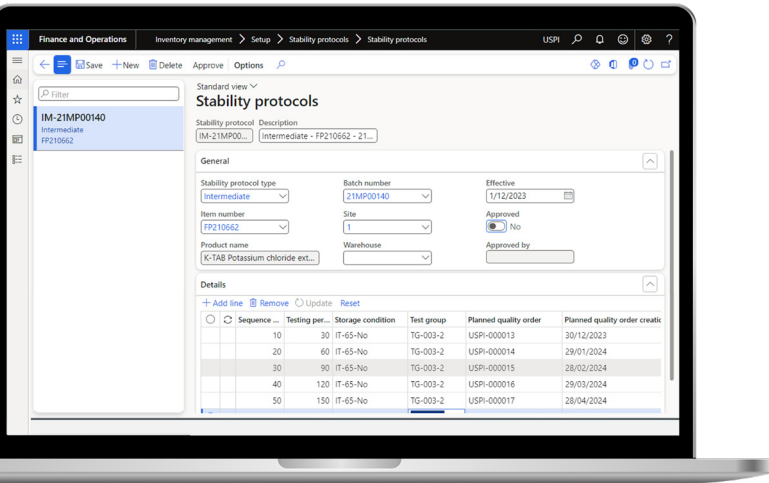- Control tolerance specifications for picking, weighing, dispensing, reconciliation, and material consumption.

INTERFACE WITH WEIGHING SCALES

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

QUALITY CONTROL

Cegeka Pharma & Life Sciences offers a Quality by Design approach that ensures quality is integrated into every stage of the production process.

TESTING

- Implement Periodic or Skip Testing based on company procedures or vendor qualifications.

- Configure tests with multi-level evaluation criteria (e.g. for USP dissolution or uniformity of dosage testing).

- Ensure compliance with best practices for rounding of test results based on pharmacopoeia(s) and/or product monographs

- Indicate alternative test values for internal purposes (warning/action limits).

STABILITY TESTING

- Assess drug quality over time under specific storage conditions.
- Automatically generate stability orders following predefined protocols.

ITEM SAMPLING

- Calculate sample quantities using mathematical algorithms for quality control.

- Provide an overview of samples with relevant information and distinguish between pooling and container samples.

- Ensure samples are not always blocked or destroyed, allowing for visual checks and uninterrupted processes.

PRODUCTIVITY ENHANCEMENT

- Copy test groups for updates, allowing version control and reducing manual efforts.

- Apply quality order line result copy across the production tree or across legal entities.

- Streamline test result entry with a user-friendly screen.

QUALITY ASSURANCE

Enforce product safety, process consistency, and regulatory compliance with built-in quality gates. Guarantee only fully approved batches are released, and secure final product certification—delivering consistent, audit-ready operations you can trust.
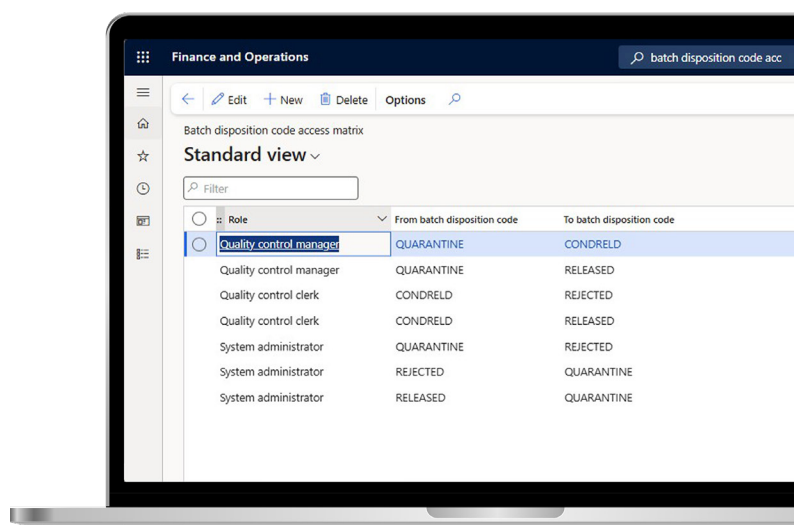

APPROVED SUPPLY & DEMAND

- Manage approved vendors and manufacturers with progressive control at the item level and mobile device integration.

- Oversee approved customers with progressive control at the item level and sales order checks.

- Enable restricted customer item lists, ensuring items to be consumed for production activities for certain customers or countries are purchased from specific vendors or vendor/manufacturer combinations.

BATCH AVAILABILITY MANAGEMENT

- Restrict and monitor batch disposition changes, ensuring changes are logged for traceability and only done by authorized users based on a defined matrix.

- Check component availability, preventing updates of a manufactured batch to a "Released" status if all ingredients are not available.

QP APPROVALS

- Enforce the approval of the shipment of batches with wave release and work unblocking.

- Track conditional batch release requests formally, allowing the batch status to be overruled without finishing the quality order.
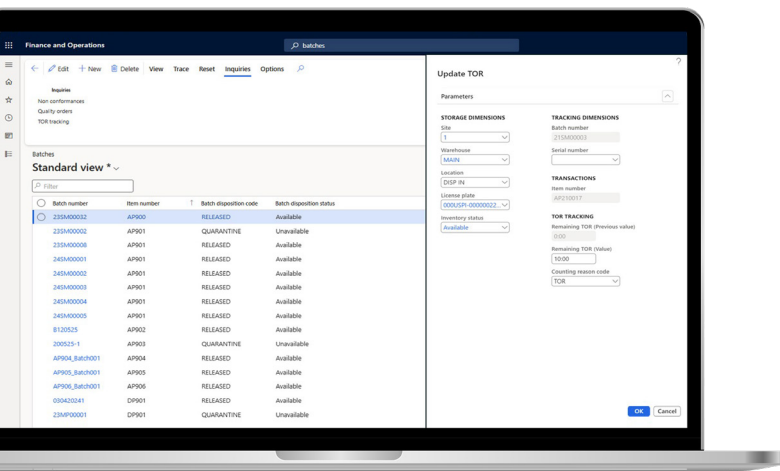
LOT TRACEABILITY

Gain full visibility of every batch with automated lot and serial tracking, real-time disposition status, and shelf-life management. Simplify recalls and ensure end-to-end traceability to meet the strictest industry regulations.

SHELF-LIFE DATES

- Ensure accurate shelf-life management, meeting regulatory requirements.

- Automate shelf-life date calculations, including production date, expiry date, and retest date, based on the product and manufacturing process.

TEMPERATURE/TIME OUT OF REFRIGERATION (TOR) MONITORING

- Track time spent by controlled items outside refrigerated zones, comparing it to the allowable excursion time.

- Allow manual updates to TOR information.

- Calculate remaining TOR for production items using TOR data from consumed ingredients.
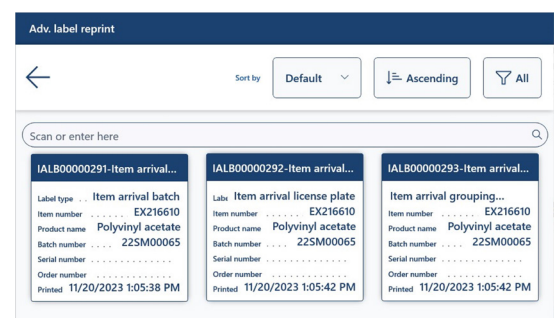

TRACKING COMPONENTS

- Map sub-batches (containers/drums/boxes/etc.) with serial number tracking dimension, providing full traceability of the individual unit across the full supply chain.

- Prevent manual creation of batch, serial, or product numbers by ensuring automatic generation during specific processes.

- Monitor batch disposition status in real-time, registering it on every transaction to maintain control over batch availability.

LABEL MANAGEMENT

- Print labels for sampling, dispensing, and item arrival journals.

- Reprint any existing label with logging of reprint actions.

ACCELERATE VALUE REALIZATION

Cegeka Pharma & Life Sciences for Dynamics 365 combines a continuously compliant business software based upon industry best practice processes, insights and a verified methodology.

INDUSTRY-BUILT FRAMEWORK

Leverage a comprehensive industry library with thoroughly documented business processes, built on real-world experience and best practices. Combined with pre-configured templates for key processes, this approach helps reduce customizations, streamline implementation, and accelerate user adoption—getting you up and running with confidence.

Faster implementation with an industry- specific framework	**Minimal customizations** for reduced complexity and cost	**Accelerated adoption** with standardized best practices

PROVEN METHODOLOGY

Cegeka follows a proven and thoroughly documented project methodology, designed to increase project success rates, reduce risks, and ensure a smooth, predictable deployment.

Let's get in touch!

Cegeka Pharma & Life Sciences for Dynamics 365 delivers the expertise and agility needed for the pharmaceutical and life sciences industries. Contact us today to discover more.

✉ Contact us

www.cegeka.com

Cegeka is a leading ICT solutions provider, supporting businesses in their digital transformation journey. Recognized for excellence, we hold all Microsoft Solution Partner Designations, are a member of the Microsoft Inner Circle, and were named Microsoft Partner of the Year for Western Europe in 2023 and Belgium in 2024.Cegeka has a global presence with offices in the Benelux, Germany, Austria, Romania, Moldova, Italy, Sweden, Greece, Denmark, France, the United Kingdom, the United States, Colombia, and India. With a workforce of over 10,000 employees, the company achieved a consolidated revenue of €1.03 billion in 2023. Founded in 1992, we remain a family-owned company headquartered in Hasselt, Belgium.

Microsoft Dynamics 365 is only sold by authorized Microsoft resellers like Cegeka. For more information, visit www.cegeka.com or send an email to CBS.info@cegeka.com.