Integrated manufacturing with Körber's software solutions

Strategic partnership to boost Novo Nordisk's digital push



It is a special bond that connects Novo Nordisk with Körber. The first PAS-X MES go-live at a key site in Hillerød, Denmark in 2008 laid the foundation for a longstanding and successful strategic partnership. Körber supports the digital ambitions of the global healthcare leader and acts as trusted MES core program partner, ecosystem provider, and rollout service partner.

Global MES core program partner

The market-leading manufacturing execution system Werum PAS-X MES from Körber has evolved into Novo Nordisk's standard MES system. Today, over 25 PAS-X MES systems are in operation, with more than 10 more planned for implementation within the next 5 years. These systems support over 450 production lines and serve more than 10,000+ users worldwide.

"PAS-X MES is vital in our global production network, supporting our instant batch release and future capacity investment programs, while enabling guided, integrated manufacturing execution in clinical, commercial, and device production," says Bahast Bakir, Head of MES Programme at Novo Nordisk.

Novo Nordisk follows a core approach, globally managed by their MES Center of Excellence (CoE): the template is based on the current PAS-X MES





version, serves as the standard solution for all plants worldwide and is centrally maintained, validated, and rolled out. The benefits: reduced site variations and efforts for maintenance and implementation.

Instant batch release to save time and effort

Novo Nordisk's instant batch release program aims to expedite batch releases within minutes, leveraging review by exception, which only shows critical parameters and exceptions. Thus, quality assurance (QA) was able to reduce review times by 3 hours per batch. With 750 batches per year in a typical plant, this corresponds to 1.4 FTE/year (full-time employees), freeing up valuable working hours for additional tasks.

· Paper reduction:

Savings of 1 ton of paper/year, archival space, and time

· Error correction reduction:

50% reduction of batch error correction in QA, 20% reduction in batch record corrections

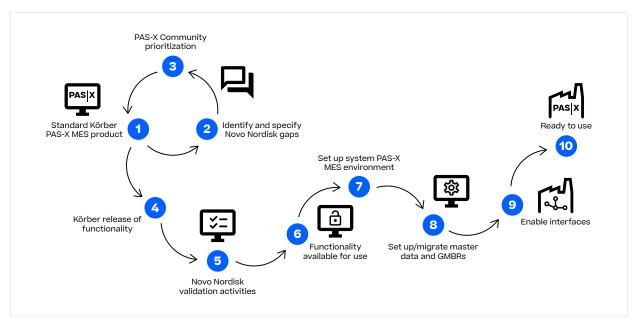
· Scrap reduction:

Savings of 1.5 million pen fills and 12.6 tons of waste

· Inventory reduction due to faster release

PAS-X MES goes cloud

By migrating to the cloud, future updates will be even easier to carry out. The NextGen PAS-X MES serves as a standardized solution without customizations, allowing Novo Nordisk to leverage Körber's continuous evolution stream to bring new functionality into production. Körber's Global Program Management & Strategic Advisory ensures best practice organizational setup and governance framework for the NextGen cloud program.



From development to digital shop floor application

Software co-development

To advance the development of PAS-X MES and incorporate new features, Novo Nordisk is dedicated to the PAS-X Community, a group of PAS-X users who work together to exchange product requirements, best practices and ideas to drive innovation. Gaps between the standard Körber PAS-X MES product and

specific processes are identified and prioritized by the PAS-X Community for release with the next PAS-X MES version. Novo Nordisk then validates the new functionality before it is rolled out to their production facilities.





PAS-X MES history at Novo Nordisk

Novo Nordisk's MES journey started in 2008 with the first PAS-X MES go-live in Hillerød, Denmark at a facility dedicated to the assembly and packaging of insulin pens. This successful standalone pilot grew into the company's largest ever IT initiative PS@SAP, a long-term project to install a globally standardized ERP/MES solution on the basis of SAP and PAS-X MES across a total of 12 sites for the production of diabetes finished products throughout Europe, Asia, North and South America.



"PAS-X MES has allowed us to replace our legacy MES system and a range of manual processes."

Bahast Bakir Head of MES Programme, Novo Nordisk

"The objective was to reduce time to market, shorten production lead times, and cut production costs. Additionally, there was a focus on introducing crossplant standardization and improvements in production processes, optimizing procedures for quality assurance, and ensuring transparency across all sites," says Novo Nordisk's Bahast Bakir. "PAS-X MES has allowed us to replace our legacy MES system, which was no longer meeting the company's needs, as well as a range of manual processes."

In 2022, Line Optimizer – Connect and PAS-X Scheduler were added to the Novo Nordisk target manufacturing IT architecture. 2022 also marks the start of the NextGen MES program. As part of this, the healthcare company will go in the cloud and replace their current core system, based on PAS-X MES 3.1.8, with the latest PAS-X MES 3.3 version out-of-the-box in the coming years.









Comprehensive ecosystem provider

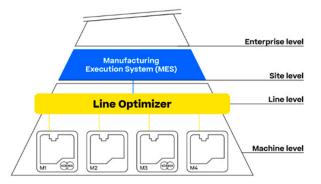
As an international technology group, Körber orchestrates a complete ecosystem that offers Novo Nordisk significant added value compared to standalone solutions. The healthcare company uses inspection machines, packaging machines, and handling units from Körber and benefits from supply chain and SAP EWM integrations (Extended Warehouse Management). In addition to PAS-X MES, the target IT architecture is supplemented by Körber's Line Optimizer – Connect and PAS-X Scheduler.

Seamless L2 integration: Line Optimizer – Connect

Currently, over 50 production lines are connected to PAS-X MES through Line Optimizer – Connect, with an additional 100 expected to follow within the next five years.

Line Optimizer – Connect provides Novo Nordisk with a standardized and vendor-independent interface layer to different pieces of equipment and production lines such as filling and packaging. It translates the message-based communication from PAS-X MES to the tag-based communication of equipment, providing the opportunity to configure and control machines or entire production lines via a single centralized solution.

"By using PAS-X MES with Line Optimizer – Connect, we have achieved a 50% reduction in maintenance efforts between MES and machine interface. Furthermore, by adopting a configuration-only approach instead of code-based implementation, we successfully decreased the implementation times from the typical 15-20 days per interface to just 4 days – a reduction of 77% on average," says Bjarne Jensen, Pharma IT Project Manager at Novo Nordisk.

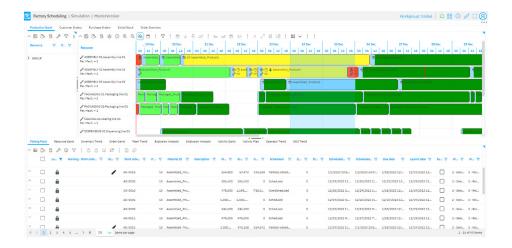


Streamlined production sequences: PAS-X Scheduler

PAS-X Scheduler is rolled out along with PAS-X MES wherever applicable. Today, it is in operation at seven sites spanning all three lines of business: biopharm and rare disease (BRD), oral finished products (OFP), and injectable finished products (IFP). PAS-X Scheduler was chosen over other scheduling solutions due, in part, to the unique integration features between PAS-X Scheduler and PAS-X MES.

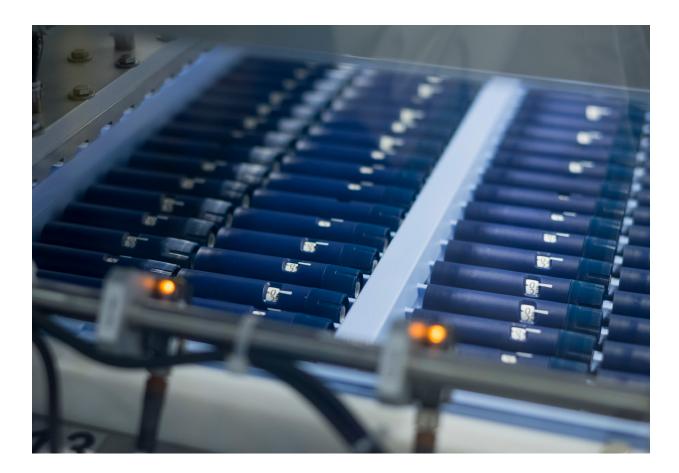
PAS-X Scheduler – powered by sedApta – is an off-the-shelf yet flexible, no-code solution. In a simple and intuitive way, it allows Novo Nordisk's shopfloor planners to generate optimized production plans and sequences integrated with PAS-X MES, both in terms of lead-time for fulfilling orders and production costs, with configurable heuristics. It automates the scheduling of production orders with precise timing and has the capability to address business criticalities by minimizing setups and allocating orders.

Bjarne Jensen: "Utilizing the automated planning capabilities of PAS-X Scheduler, we achieved a substantial improvement in Overall Equipment Effectiveness. Our machines operate more efficiently, leading to a significant increase in overall output. Additionally, the implementation of PAS-X Scheduler has enabled us to cut our replanning time by 50%."









Global rollout service partner

Körber is the preferred PAS-X rollout service partner for Novo Nordisk. The technology group operates eight consulting hubs globally, ensuring staffing and deployment scaling aligned with Novo Nordisk's requirements around the world. For site rollouts, Körber provides comprehensive global deployment services and a dedicated infrastructure.

The rollout teams at Novo Nordisk benefit from best-in-class training – training strategy and content are developed in close collaboration with the customer – ensuring fast and cost-efficient deployments. These deployments are fully integrated into Global Program Management to maintain close alignment and enhance central deliverables. Strategic advisory consulting services contribute to consistent program governance and overall strategy.

In addition to the rollout services, Körber globally supports Novo Nordisk with Computer Systems Validation (CSV), the design, harmonization and validation of MBRs/generic MBRs and the creation of playbooks to facilitate onboarding.

Continuing the combined strategy for success

The digitalization of the entire product lifecycle has become essential for pharmaceutical and biotech manufacturers in addressing industry challenges. These challenges include technology transfer, product quality and data integrity, as well as managing costs and ensuring the affordability and accessibility of drugs. To stay competitive, pharmaceutical companies are seeking global, standardized and integrated IT solutions that facilitate digital transformation.

It was a similar situation for Novo Nordisk. The starting point for Novo Nordisk's digital journey was the quest for a globally standardized manufacturing IT solution without customizations to replace their legacy systems. The primary goal was to enhance production efficiency by minimizing time to market, production lead times, and overall production costs. Furthermore, there was a need to harmonize processes, including manufacturing recipes, across their numerous plants worldwide. Lastly, Novo Nordisk wanted to ensure that future PAS-X MES upgrades could be executed quicker and easier.





"Since the first rollout in Denmark, PAS-X MES became the standard MES at Novo Nordisk. The subsequent successful PAS-X MES installations have confirmed the product's ability to standardize and optimize manufacturing processes across sites, ensuring cost-efficient production and consistent batch quality," says Bahast Bakir, Head of MES Programme at Novo Nordisk.

The core approach made it possible to reduce site variations and maintenance efforts while introducing streamlined processes through the integrated SAP

ERP/PAS-X MES solution. The implementation of EBR ensures guided manufacturing execution and significantly reduces lead times. By using PAS-X MES in the cloud, deployments and upgrades will become even easier and faster.

Looking ahead, Novo Nordisk and Körber will embark on further PAS-X software rollouts, reinforcing their combined strategy for success.

At a glance







Challenges

- Globally standardize manufacturing IT solutions without customizations
- Reduce time to market, production lead times, and production costs
- Harmonize processes across sites
- Enable easier and faster PAS-X MES upgrades

Solutions

- · Werum PAS-X MES
- · Werum PAS-X Scheduler
- · Line Optimizer Connect
- · Global rollout services

Customer benefits

- Faster lead times through EBR and instant batch release
- 3 hours/batch review time reduction
- 50% batch error correction reduction
- 1.5 million pen fills scrap reduction
- 1 ton of paper/year reduction
- Reduced site variations in manufacturing IT through core template
- Efficient processes through standardized SAP ERP/PAS-X MES solution
- · Reduced efforts for maintenance
- Fast and cost-efficient deployments
- Easier upgrades through cloud deployment and continuous evolution stream





About Novo Nordisk

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. The company's purpose is to drive change to defeat serious chronic diseases, built upon its heritage in diabetes. It does so by pioneering scientific breakthroughs, expanding access to its medicines, and working to prevent and ultimately cure disease. Novo Nordisk employs about 59,000 people in 80 countries and markets its products in around 170 countries.

Further resources

 Website: www.novonordisk.com

· Use case:

Novo Nordisk leads cloud-native manufacturing with NextGen PAS-X MES from Körber

· Video:

Agile PAS-X MES deployments – Harmonization across 30+ PAS-X installations in Novo Nordisk

About Körber

We are Körber – an international technology group with more than 12,000 employees at over 100 locations worldwide and a common goal: We turn entrepreneurial thinking into customer success and shape the technological change. In the Business Areas Digital, Pharma, Supply Chain, and Technologies, we offer products, solutions and services that inspire. We act fast to customer needs, we execute ideas seamlessly, and with our innovations we create added value for our customers. In doing so, we are increasingly building on ecosystems that solve the challenges of today and tomorrow. Körber AG is the holding company of the Körber Group.

At Business Area Pharma, we deliver the difference along the entire pharmaceutical value chain by offering a unique portfolio of integrated solutions. With our software solutions we help drug manufacturers to digitize their pharmaceutical, biotech and cell & gene therapy production. The Werum PAS-X MES Suite is recognized as the world's leading Manufacturing Execution System for pharma, biotech and cell & gene. Our Werum PAS-X Savvy Suite accelerates product commercialization with data analytics and Al solutions and uncovers hidden business value.

Delivering the difference in pharma

As your personal partner and expert for the pharmaceutical industry, we support you with industry-leading consulting services – from needs analysis to project implementation:

- Access to industry-leading experts with extensive experience in the pharmaceutical, biotechnology and medical device sectors
- $\boldsymbol{\cdot}$ Development of a solution tailored to your company size and needs
- Keep pace with the times and benefit from important trends in Pharma 4.0
- · Realize your potential and get support from over 2,500 pharma experts in 100 locations worldwide

Industry sector
Biotech





