Pharma Software

Save time & effort and avoid risk

Werum PAS-X MES helps you to digitize your pharma and biotech production

100 % focused on pharma and biotech

You want to improve efficiency and compliance in your factory? We are the leading supplier of software solutions for pharma, biotech and cell & gene. The core of our offering is PAS-X – the market leading pharma MES software – combined with content and services out of the box.

ROI in 2-3 years
PAS-X helps pharmaceutical and biopharmaceutical manufacturers to increase efficiency, improve productivity, and meet regulatory requirements. On average, a return on investment is achieved within two to three years.

You worry, that your paper-based processes are too slow, error-prone and inefficient and might not comply with regulatory guidelines?
At Körber, we understand that you are dissatisfied with the traditional, paper-based way of your batch execution and documentation processes and need to produce more efficiently. You have to innovate while ensuring GMP-compliant manufacturing processes and the integrity of your data.

Introducing our PAS-X Manufacturing Execution System – enabling the digitization of your pharma and biotech production
PAS-X is run by the majority of the world's top 30 pharmaceutical and biopharmaceutical companies and by many regional and mid-sized enterprises around the globe. With PAS-X, we provide the leading MES product for pharmaceutical and biopharmaceutical manufacturing – enabling a fast implementation and providing complete out-of-the box functionality tailored to industry-specific needs.

In line with regulatory requirements
PAS-X meets all requirements set forth by the approving authorities for operating computer systems in regulated industries. This includes the EU GMP guidelines, the GMP Annex 11 for Computerized Systems Guidelines and the FDA guidelines 21 CFR Part 11 and 21 CFR Part 210/211.

Supporting data integrity
PAS-X supports data integrity requirements put forward by regulatory bodies such as the FDA, EMA, CFDA and WHO through:

- Best-practice business process harmonization per product and across sites
- Accurate data capturing and control strategy execution
- ALCOA implemented for raw data, meta data and true copies for data retention
- Secure data access and system-controlled data review

One community
The PAS-X users represent the largest pharma MES community worldwide.

1,000+ installations at large multinationals as well as regional and mid-sized enterprises
Among our references are many of the largest and most demanding pharmaceutical manufacturers worldwide who deployed PAS-X as their standard MES in large installations and cooperate with us on a strategic basis. The majority of the top 30 companies selected PAS-X to improve their production performance and compliance.

It is an important sign of our strength and capability that not only large multinationals are gaining the benefits of the PAS-X MES but that we have also implemented many successful solutions for leading regional and mid-sized enterprises in Europe, North and Latin America and Asia Pacific.

PAS-X is built together with our customers
The PAS-X users represent the largest pharma MES user community worldwide. Many of our customers are also members of the PAS-X User Forum “PAS-X For Us” (PFU). They actively participate in advancing the development of the PAS-X MES, thus ensuring that the PAS-X product is based on the best practices of the pharmaceutical and biopharmaceutical industries.

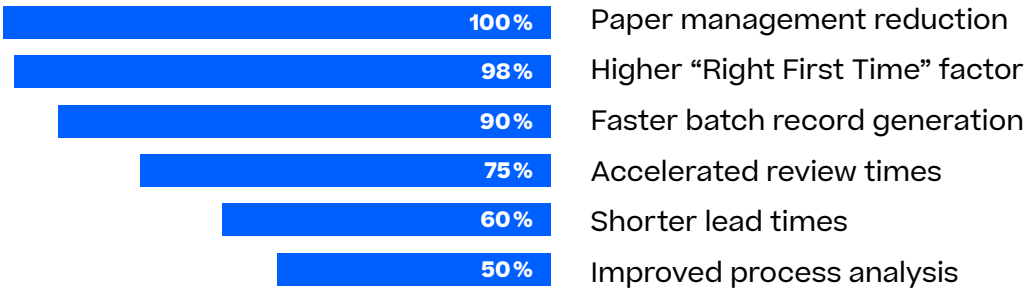
Join our PAS-X User Group Meetings
Our customers regularly come together at the annual PAS-X User Group Meetings in Europe and the USA. Join our next User Group Meeting and learn more about case studies, new product announcements and trends and visions of the manufacturing future presented by industry leaders. Benefit from this international networking event and meet top executives of the pharmaceutical and biopharmaceutical industries and establish valuable contacts.

PAS-X MES – the first step to your digital pharma factory

International network of excellence
We at Körber provide in our Business Area Pharma a unique combination of process know-how, software, and cutting-edge technology - offering holistic solutions for safe and efficient processes in the manufacturing, inspection, and packaging of pharmaceutical products from a single source.

Additionally, our customers profit from our international network of excellent partners. We cooperate with leading software vendors like SAP, Oracle, and OSIsoft as well as with dedicated local endorsed service partners.

Benefits experienced by our customers using PAS-X MES



More than software: Best practices included!

Save time & effort and avoid risk.

With PAS-X, we provide a complete MES solution including software, comprehensive services and pre-configured content – for large multinational as well as regional and mid-sized enterprises.

Vaccines
Devices
Bio
Blood Plasma
Solids
Fine Chemicals
Consumer
Liquids
OTC
Pharma
Cell & Gene
Creams
Ointments

Product Life Cycle

Process Development → Clinical Trial Manufacturing → Launch → Commercial Manufacturing → Packaging Fill & Finish

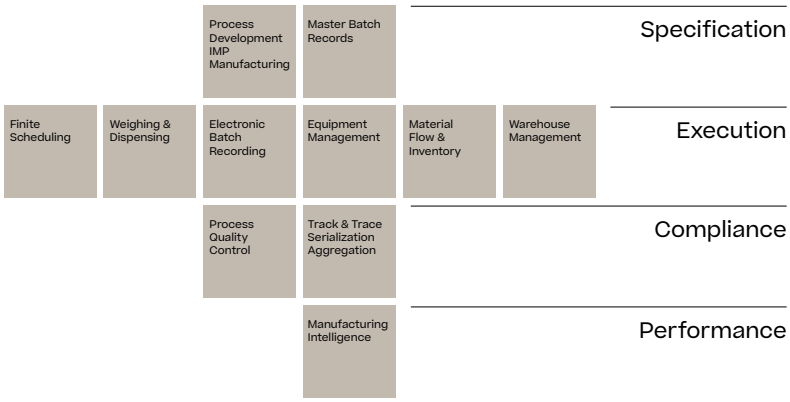
PAS-X covers all key life cycle stages in pharmaceutical and biopharmaceutical manufacturing comprising process development, commercial bulk manufacturing and packaging.

It supports all major types of pharmaceutical manufacturing, e.g. vaccines, biopharmaceuticals, solids, liquids and others.

Software

PAS-X is a functionally complete MES product enabling fast implementation. PAS-X provides out-of-the-box maximum standard functionality for all applications in the pharmaceutical and biopharmaceutical industries. The functional architecture of PAS-X closely follows the ANSI/ISA 95 standard.

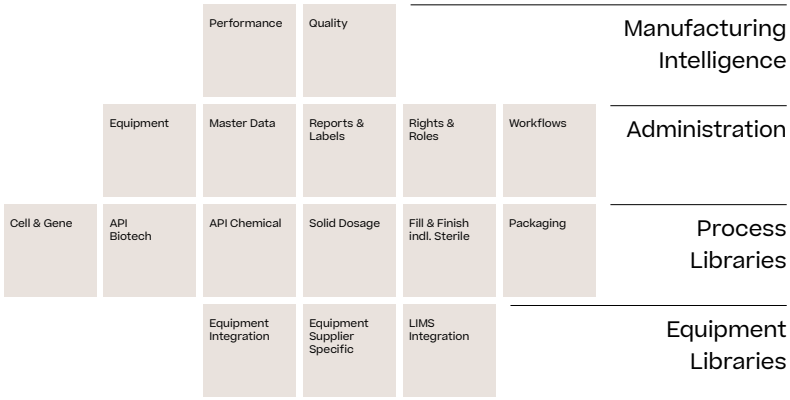
PAS-X Business Functions:
complete MES out of the box



Content

In addition to our software product, we provide pre-configured MES Content Packages supporting a jump-start to deploying PAS-X. Our GMP-compliant content packages are unique: They are based on the industry's best practices confirmed by our customers and they are influenced by the PFU, the largest pharma MES user community worldwide. Our industry-specific templates significantly save you time and effort. When configuring PAS-X, your production site no longer needs to start with an empty system.

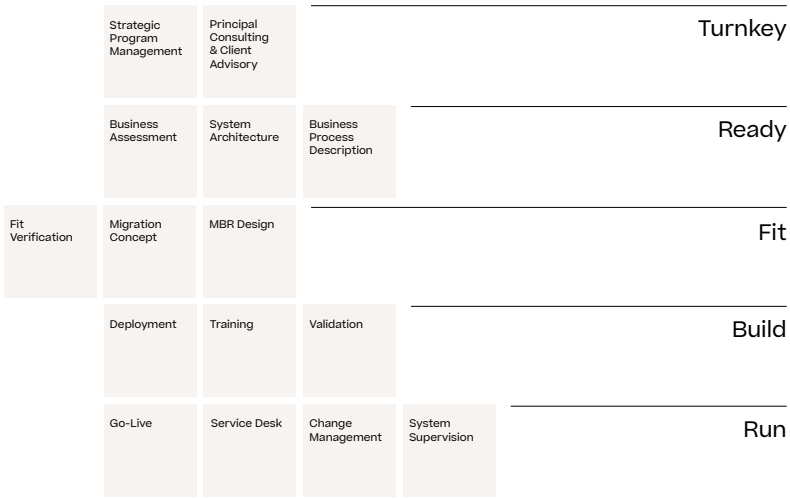
PAS-X Content Packages:
best practice industry templates save time



Services

With our comprehensive services we support you during all PAS-X implementation phases – we are recognized worldwide for our high level of responsiveness. The PAS-X service portfolio is based on the expectations of the PAS-X user community and on the best practices of the pharmaceutical and biopharmaceutical industries. You benefit from our outstanding pharmaceutical and biopharmaceutical MES expertise and highly specialized personnel avoiding resource gaps when implementing MES.

PAS-X Service Packages:
accelerated MES implementation



Software

The leading, most functional complete MES product

PAS-X provides complete functionality covering all your pharmaceutical and biopharmaceutical manufacturing processes.

MBR

Master Batch Records
PAS-X Master Batch Records allows you to easily set up and maintain libraries with standardized, reusable building blocks for MBR creation. An easy-to-use graphical design tool facilitates the MBR creation. PAS-X MBR simplifies workflows, shortening approval cycles and therefore drastically reducing associated documentation work. This function is also available as an entry-level solution, which enables manufacturers to start with a dedicated scope and scale up the system later on a step by step basis to a complete MES system.

EBR

Electronic Batch Recording
Efficient electronic batch documentation is one of the most important objectives in introducing an MES to the pharmaceutical and biopharmaceutical production. With PAS-X Electronic Batch Recording, all MBRs are electronically executed and the processes and results are documented in compliance with the applicable statutory provisions. PAS-X EBR ensures the error-free and guided execution of the entire production process and right-first-time manufacturing.

W&D

Weighing & Dispensing
The precise weighing and dispensing of input materials based on recipe specifications is the core of your pharmaceutical manufacturing processes. Accurate data collection within this first processing step is fundamental to batch tracking and documentation. In a reliable and easy-to-operate way, PAS-X Weighing & Dispensing guides the user through the weighing process and provides the necessary support for compliance with safety regulations and recipes. It supports manual as well as automated weighing and dispensing operations. Many customers start their electronic manufacturing projects with the W&D function and scale up according to their needs.

“PAS-X will expedite the record review process and reduce error traps for our production.”

Production Supervisor
AstraZeneca

MFI

Material Flow & Inventory
PAS-X Material Flow & Inventory secures the in-plant material flow throughout the entire pharmaceutical manufacturing process. It comprises sub-functions for manual and automatic transport control as well as in-plant administration of shop floor storage areas. PAS-X MFI ensures that the materials used in pharmaceutical production are uniquely identified on receipt by means of barcodes or transponders. Through its tracking function, PAS-X MFI supports uninterrupted tracking of the entire material flow and it provides details about material quantities, available batches, batch qualities, and storage locations.

EQM

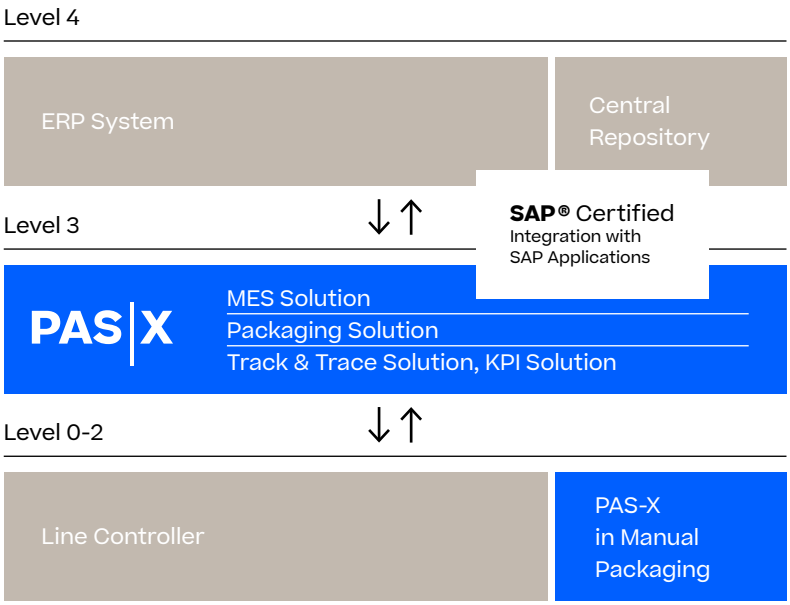
Equipment Management
PAS-X Equipment Management administers and monitors cleaning procedures and statuses for all types of production-related objects. This includes MBRs and particular rules for cleaning scales, work rooms, containers, production equipment, setup parts and toolkits. Even complex rules for sterilization can be managed and monitored. Electronic paperless equipment logbooks document status lists, cleaning rules and histories for individual container types.

MI

Manufacturing Intelligence
PAS-X Manufacturing Intelligence helps you to enhance the shop floor performance of your manufacturing processes. For instance, PAS-X KPI supports operators, supervisors and production site managers to constantly monitor operational performance data from the shop floor. This function is also available as a lean standalone software solution for fast and easy implementation. With PAS-X Data Access you get curated data from your PAS-X MES that can be consumed and visualized without detailed PAS-X knowledge. It provides full access to all data captured during electronic batch recording, material flow control or equipment management. Data from external systems like LIMS, ERP and Historian is also available.

T&T

Track & Trace Serialization Aggregation
PAS-X Track & Trace enables you to comply with anti-counterfeiting requirements for medical drugs. It provides serialization and aggregation out-of-the-box functionality for packaging processes and integrates the ERP and the Global Repository with the shop floor packaging equipment and line controllers (vendor-independent). PAS-X T&T is also available as a standalone solution or as part of the packaging solution seamlessly integrated into packaging EBR.



FISC

Finite Scheduling
PAS-X Finite Scheduling is covering the whole production planning process and offers a tight integration of scheduled activities with the actual as-is status of the production within PAS-X. The integrated solution delivers detailed scheduling of your production processes and resources with finite capacity, the optimization of production sequences, multi-scenario analyses, and the management of materials and teams.

WMS

Warehouse Management
PAS-X Warehouse Management supports production-related warehouse logistics. The system components can be configured as required and form the basis for implementing warehouse management systems, control systems and picking systems.

PQC

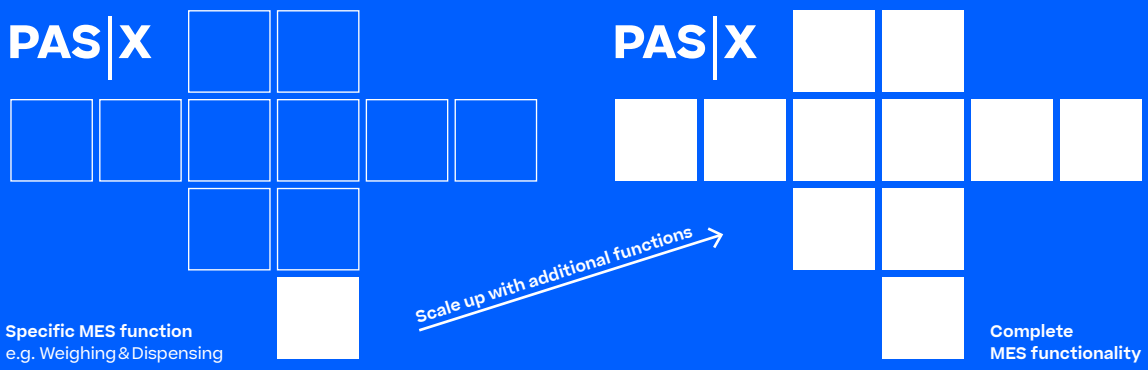
Process Quality Control
PAS-X PQC ensures continuous monitoring of the production quality. It captures events and deviations enabling you to drastically reduce batch review and release times. In order to achieve the best possible quality and to take preventive measures, PAS-X PQC supports process-analytical on-line, in-line, and at-line quality control. The function allows the implementation of Process Analytical Technology (PAT) as well as Review by Exception and state-of-the-art Quality by Design (QbD) concepts.

“Werum’s PAS-X MES shows great promise to help improve quality in a number of areas. These include operator sign off within batch records, release without exception and improved deviation tracking.”

David Smith, Head of Innovation and Engineering
Hitachi Chemical Advanced Therapeutics Solutions, LLC

Easy to start: start small and scale up later

Our entry-level solutions allow you to gradually implement different parts of our MES solution – an appealing option especially for regional and mid-sized pharmaceutical and biopharmaceutical enterprises.



Scalable entry-level solutions
The entry-level solutions focus on specific business processes and their functionality covers a dedicated scope of related tasks. Later, you can expand your entry-level solution by adding new business functions to a functionally complete PAS-X MES. Each acquired module builds on and complements the previous modules. This approach provides you with just the functionality you require and ensures a maximum security of your investment.

Entry-level solutions:

- **Weighing & Dispensing**
- **Master Batch Records**
- **Packaging**
- **Track & Trace**
- **KPI/OEE**

Best-practice content for fast MES deployments

Our pre-configured PAS-X Content Packages allow a jump-start to deploying PAS-X MES. Based on the industry best practice and the knowledge of our consultants, they reflect the requirements of the PAS-X users.

Industry-specific templates
Using PAS-X Content Packages, projects have an excellent starting point to quickly create the final parameterization of your PAS-X MES system.

Manufacturing Intelligence

PAS-X as a batch recording system collects data from various sources into the batch record. The “**PAS-X Performance**” and “**PAS-X Quality**” Content Packages offer pre-configured evaluation templates for different areas such as performance data and quality data along with the associated consulting services and a state-of-the-art tools for data evaluation. The evaluation templates comprise dashboards, production monitoring and process optimization to make this data available, easily accessible and convenient to visualize. This will enable visibility in manufacturing. Typical production questions such as trends for yield, exceptions, deviations and review times (time to market) are answered in a smooth way.

Administration

The “**PAS-X Equipment**” Content Package delivers a best practice guideline of how to design and document equipment status diagrams. It shows the dependencies and functionalities of the different states, activities and their respective semantics. Additionally, the package contains ready-to-use best practice status diagrams e.g. for cleaning, assembly, sterilization, reusables etc.

The “**PAS-X Master Data**” Content Package details relevant master data for PAS-X required to use the MES system. The step-by-step parameterization guideline explains details regarding the master data and takes into account the sequence of creating master data and highlighting dependencies between them. Once all chapters of the content package were considered, a functional PAS-X system becomes available that can be used to create MBRs, execute orders and produce materials.

Fast MES setup
The content packages can be used to prepare PAS-X systems for different industry segments.

The „**PAS-X Reports & Labels**“ Content Package offers pre-configured reports (MBR reports, batch reports, etc.) and labels along with the associated comprehensive consulting services. The package comprises GMP-compliant templates for reports and labels which are specifically tailored to manufacturing technologies such as solid dosage and biopharmaceutical API production.

The “**PAS-X Rights & Roles**” Content Package supports the parameterization of PAS-X user rights based on global, GMP-compliant profiles and specific roles such as Operator, Supervisor and QA/QM personnel. It considerably simplifies the configuration and maintenance of the highly flexible user rights capability of PAS-X. System administrators can save up to 95 % of the time usually required for the initial configuration and testing of rights.

The “**PAS-X Workflows**” Content Package delivers workflows for reviewing and releasing, e.g. MBRs and BRRs. The packages are preconfigured based on industry best practices and can be adapted in a flexible fashion. System administrators are enabled to manage PAS-X workflows in a self-dependent manner.

Process Libraries

The “**PAS-X Process Libraries**” Content Packages accelerate the development of MBRs and help to assure high quality MBR design based on the industry best practices and considering data integrity, lean BRRs and process harmonization. MBR designers can save up to 80 % of the time usually required for initial MBR creation. The packages provide templates with MBR design elements to create MBRs for specific pharma and biotech processes such as granulation, IPC testing or reconciliation. They are available for all major manufacturing technologies, such as **cell and gene therapy, API biotech, solid dosage and packaging.**

Equipment Libraries

The “**PAS-X Equipment Integration**” Content Package offers best practice guidelines on how to integrate equipment with PAS-X. Additionally, the package contains ready-to-use best practice state machines and MBR design elements for equipment integration. MBR designers can save up to 80 % of the time usually required for initial MBR creation considering equipment integration.

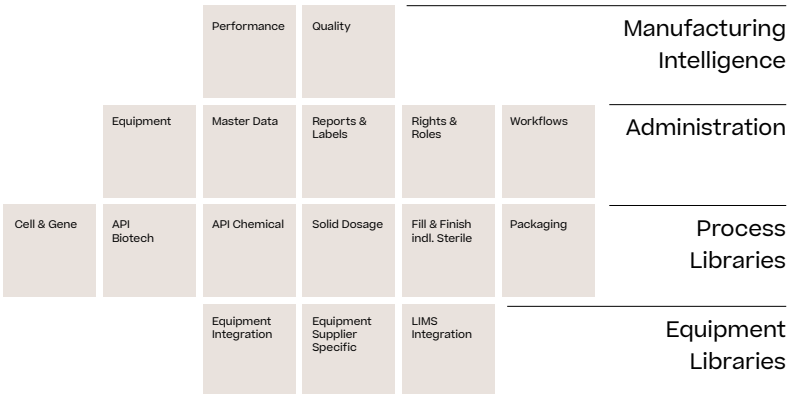
The “**PAS-X Equipment Supplier Specific**” Content Packages accelerate the creation of MBRs and help to assure high quality MBR design. They contain templates with MBR design elements to create MBRs for the integration of specific pharmaceutical and biopharmaceutical equipment such as granulators, tablet presses or packaging lines.

The “**PAS-X LIMS Integration**” Content Package provides several best practice MBR workflows for the integration of data exchange between LIMS or similar systems and PAS-X EBR. These workflows are provided as library templates which use preconfigured, ready-to-use message schemes as basis for the communication.

Why PAS-X Content

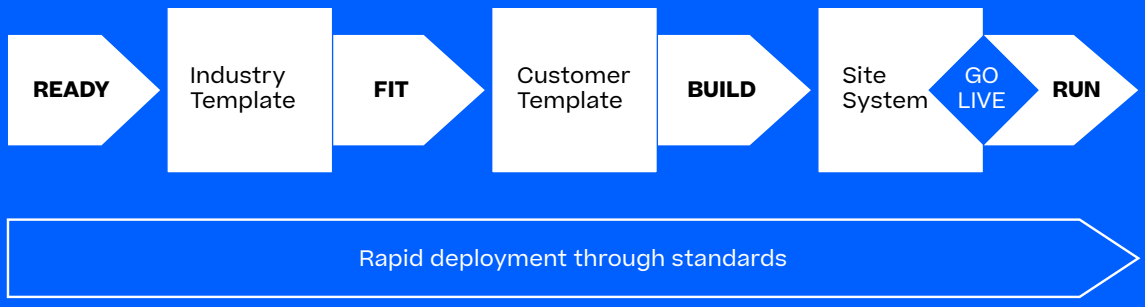
- **Easy and fast setup of PAS-X MES**
- **Industry best practice based configuration**
- **GMP compliance**
- **Specified content for pharmaceutical and biopharmaceutical manufacturing**
- **Accelerated MBR creation**
- **Process harmonization**

PAS-X Content Packages
Best practice industry templates to save you time.



Speed up deployment!

Our unique implementation methodology allows a fast MES implementation at pharmaceutical and biopharmaceutical production sites.



Ready

Prior to the start of an MES project – in the Ready Phase – we offer consulting services to ensure process understanding and the organizational readiness of your site.

Fit

In the Fit Phase, the customer-specific business processes are mapped to the PAS-X software product. The PAS-X system is configured and parameterized according to the business processes and production recipes.

Build

In the Build Phase, the system is configured or enhanced, for example with interfaces, and it is implemented and qualified at your plant.

Run

Once the system is operational, we support you in the Run Phase with our qualified service desk team and with maintenance agreements that ensure the protection of your investment with an upgrade guarantee.

Lean MBRs
We offer MBR development services and process consultation to design, create and verify high-quality MBRs for you.

High-quality MBRs with “Design as a Service”
With our unique “Design as a Service” offering we provide a complete solution for the cost-effective creation of lean, high-quality and streamlined MBRs. The packages comprise pre-configured industry-specific content based on best practices, ready-to-use concepts and guidelines for the efficient creation and optimization of MBRs and profound, first-hand PAS-X knowledge directly from the MES supplier. The resulting MBRs are lean, efficient and optimized to meet your requirements in regard to “Review by Exception”.

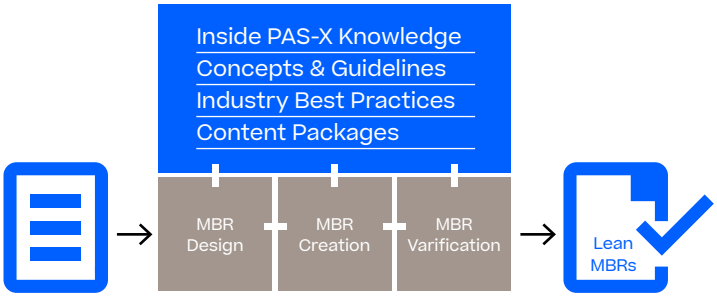
Ensuring the success of your MES project

- **“Design as a service” MBR development**
- **Local PAS-X training courses**
- **Highly qualified consultants**
- **Qualified service desk 24/7**
- **Self-Service Portal**

Pharma software academy: well-trained and qualified PAS-X users
Only well-trained personnel ensures the success of your PAS-X MES project – we deliver the relevant out-of-the-box PAS-X training tracks. Our PAS-X training courses are composed of standardized modules that can be selected and organized flexibly to cover all PAS-X functionalities. We will be happy to hold your PAS-X training courses locally at your plant and on your date of preference. Apart from this, we regularly offer training courses at our modern premises in our headquarters in Lüneburg, Germany, or at one of our international locations.

Consulting: Our experts take care solely about your industry
To ensure the most effective management of your PAS-X MES implementation project, we offer a comprehensive set of consulting services and a dedicated team of consultants with the skill and expertise to design and create MBRs for various industries. Our consultants are in personal and direct contact to our PAS-X product development teams and well-trained in operating PAS-X MES. They are excellent experts for all major pharmaceutical manufacturing technologies like solid production, packaging, biopharmaceutical and chemical API production. With this wide set of skills, our consultants are able to advise our customers in using PAS-X MES functionality and creating MBRs to support their business processes in the best possible way.

Cost-effective creation of high-quality MBRs

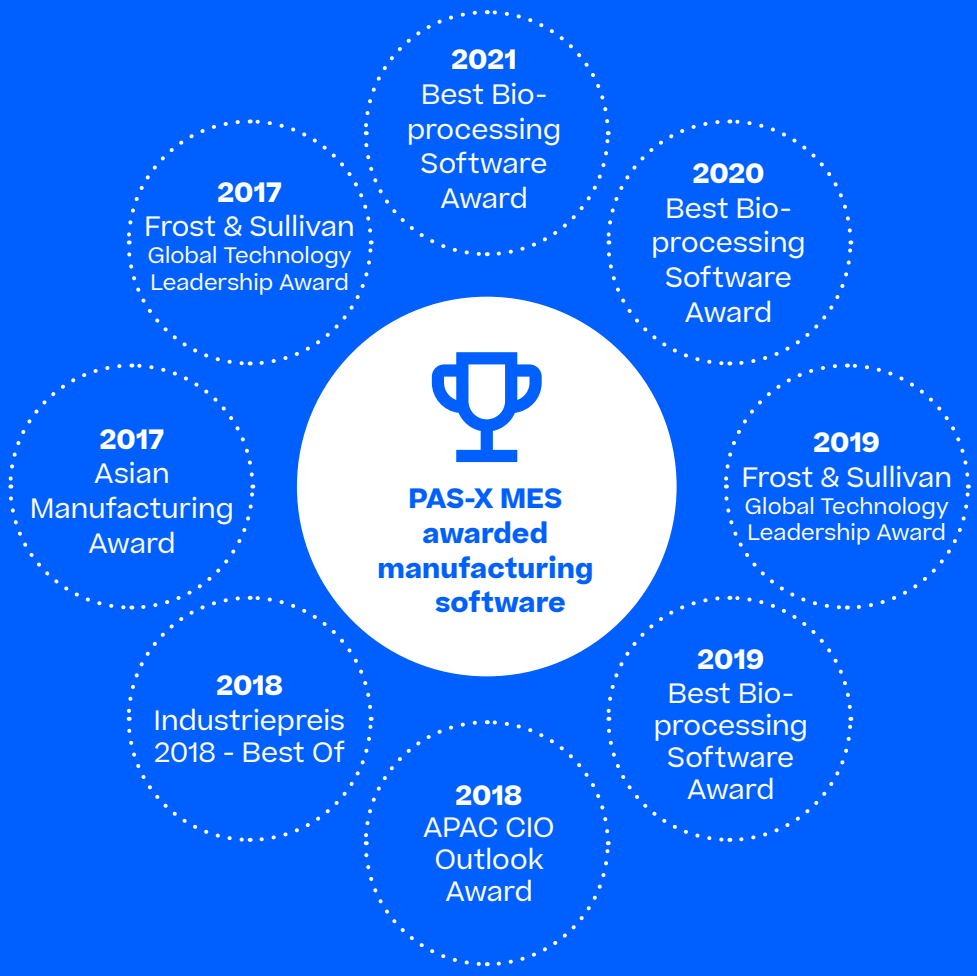


Design as a service –
more than MBR Factory

MBR Factory

Self-Service Portal & excellent local support and services
As a customer you get access to our digital Self-Service Portal with know-how databases, FAQs, current product information and other helpful services. If you prefer personal support you benefit from our worldwide 24/7/365 support team with short solution times. Our team members are highly qualified experts with long-time experience. Local support during operation at your site is guaranteed by our subsidiaries and endorsed service partners. Our partners are obliged to fulfill all the requirements of the PAS-X service partner program.

Good reasons to decide for PAS-X



PAS-X speeds up **time-to-market**

PAS-X enables **digitization**

PAS-X boosts **efficiency**

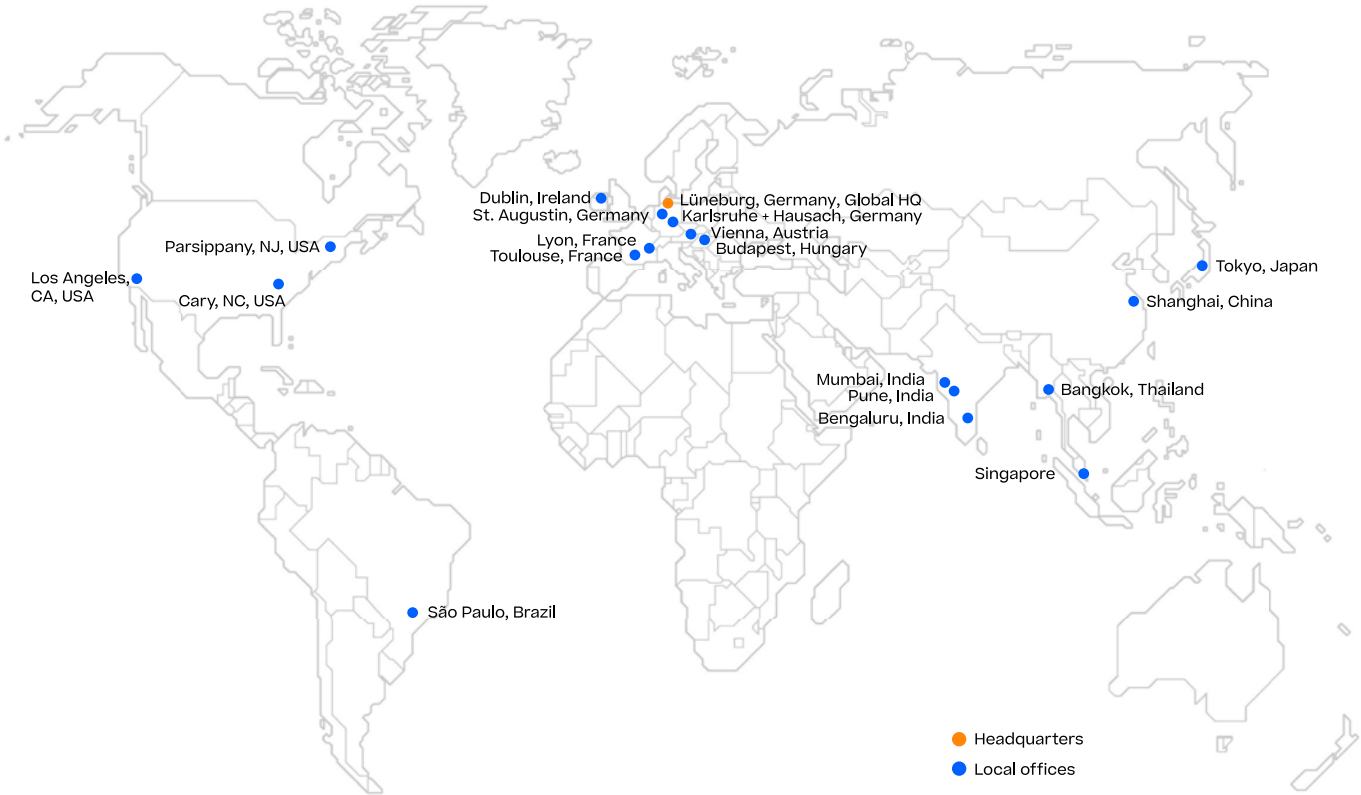
PAS-X improves **quality**

PAS-X safeguards **compliance**

save time **save effort** **avoid risk**

We always have you covered – everywhere

With local offices around the world our pharma software experts support you wherever your business is located.



Delivering the difference in pharma

We are Körber – an international technology group with about 10,000 employees, more than 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, Tissue and Tobacco, we offer products, solutions and services that inspire.

At the Körber Business Area Pharma we are delivering the difference along the pharma value chain with our unique portfolio of integrated solutions. With our software solutions we help drug manufacturers to digitize their pharmaceutical, biotech and cell & gene factories. 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 Intelligence Suite accelerates product commercialization with data analytics and AI solutions and uncovers hidden business value.

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