NEW WAY TO MANAGE YOUR PRODUCTION:

MES & CHINA 2025 / INDUSTRY 4.0

Werum IT Solutions – the Leading MES Supplier for the Pharma & Biotech Industry

WERUM
KÖRBER SOLUTIONS

Agenda

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Today's Goal

- **China 2025 / Industry 4.0**
  - Understand why MES is Key
- **Integration and Data Flow**
  - Why it enables Right First Time

Pharma 4.0

Cyber Fred Workforce 4.0:

New Operator Challenges

Problem Statement: The Challenge of Implementing Integrated Automation Environments

■ Problem Statement out of Manufacturing Engineering & Automation:

1. "Our Manufacturing suites / machines are only partially networked and don't support horizontal & vertical integration…"

2. "Good and established PAT Sensors are available and proven. The feasibility of the technology is established and it needs the commercial manufacturing routine. The Operational GMP Manufacturing Control Strategies for Manufacturing Execution are not yet well implemented into the Manufacturing Execution Landscape (e.g. Equipment, IT Systems, Manufacturing Best Practices) Integration and Qualification of PAT methods / sensors in Manufacturing machines / networks and the related Data Management & Representation, Change Management, Knowledge Management & Data Integrity aspects are not implemented yet."
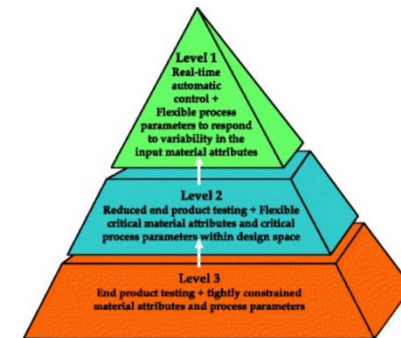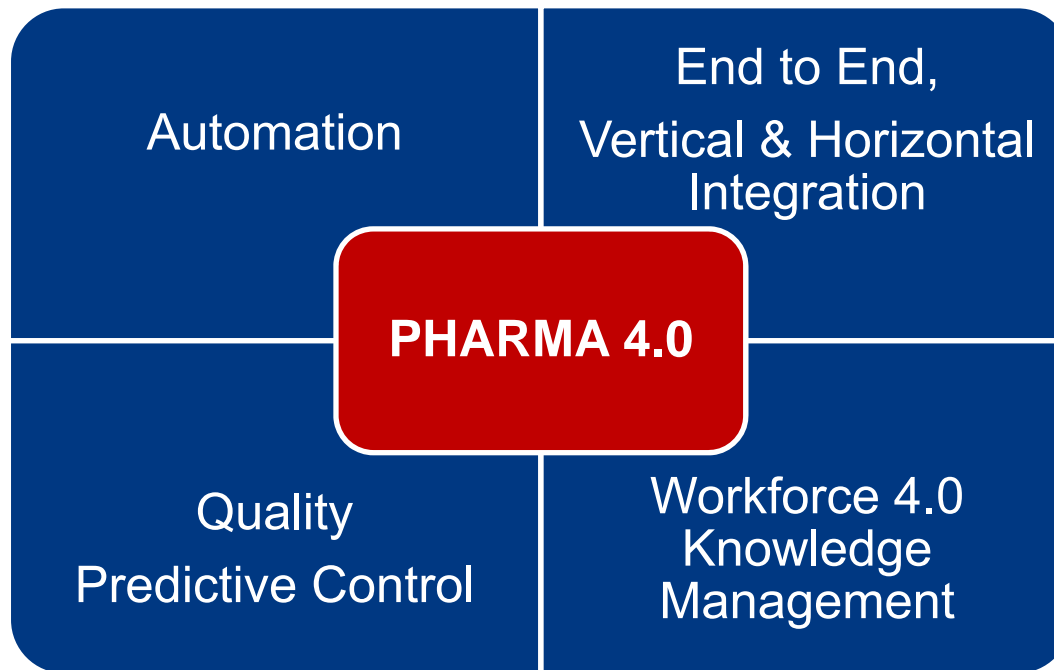
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Problem Statement: The Difficulty in Establishing a Robust & Flexible Control Strategy in Manufacturing

- The transfer from the development based Control Strategy to the Commercial Production by Tech Transfer and Scale up is missing Best Practice Methodology to create a flexible and robust Production Process with a well documented Lifecycle Management.

- Product independent Platform Knowledge is not well transferred into the Product Design Space.

- The impact of unknown process parameters and criticality, raw material attributes and impurities are normally not well addressed in the Product Control Strategy Lifecycle Management.

- "The transformation in the design and the execution of the Control Strategy has to follow a 'Data Integrity by Design' approach.
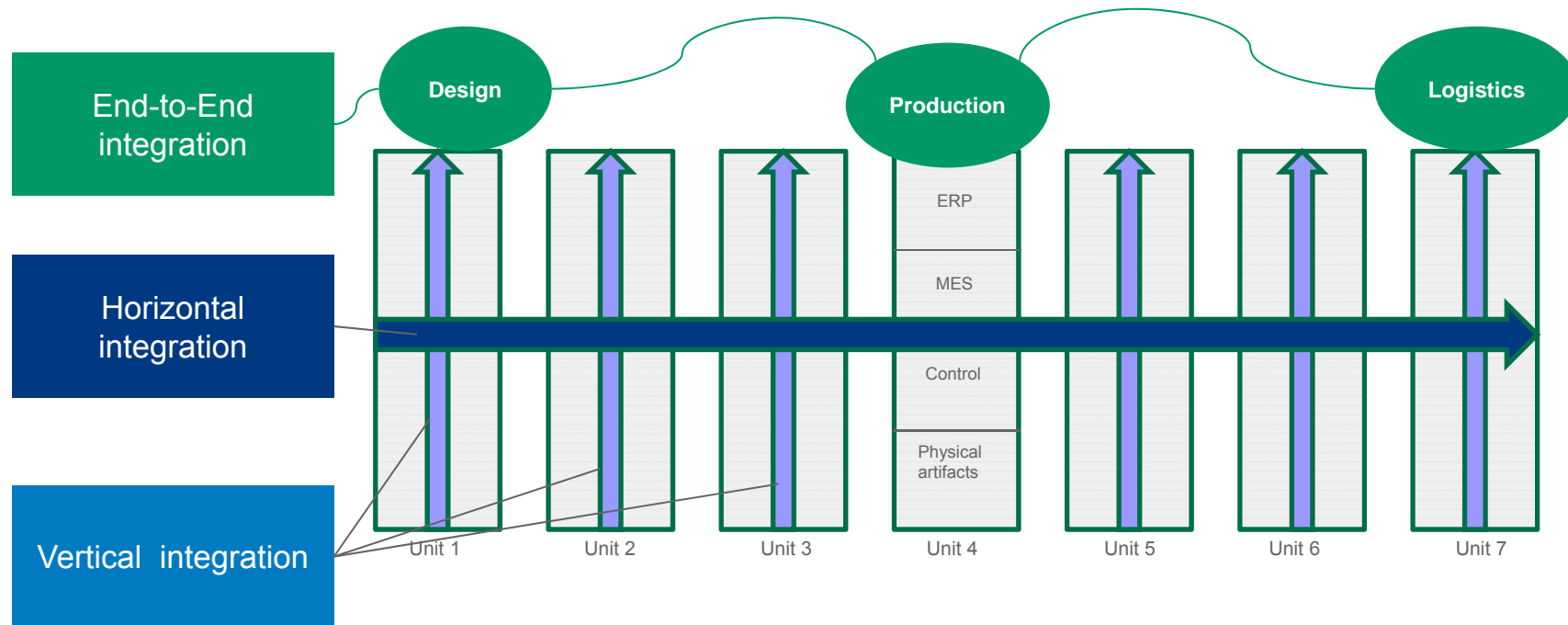
World Health Organization

Source: **Ian Thrussell**, "DI Expectations and Guidance", WHO Prequalification Team (ISPE EU Conference, March 2016)
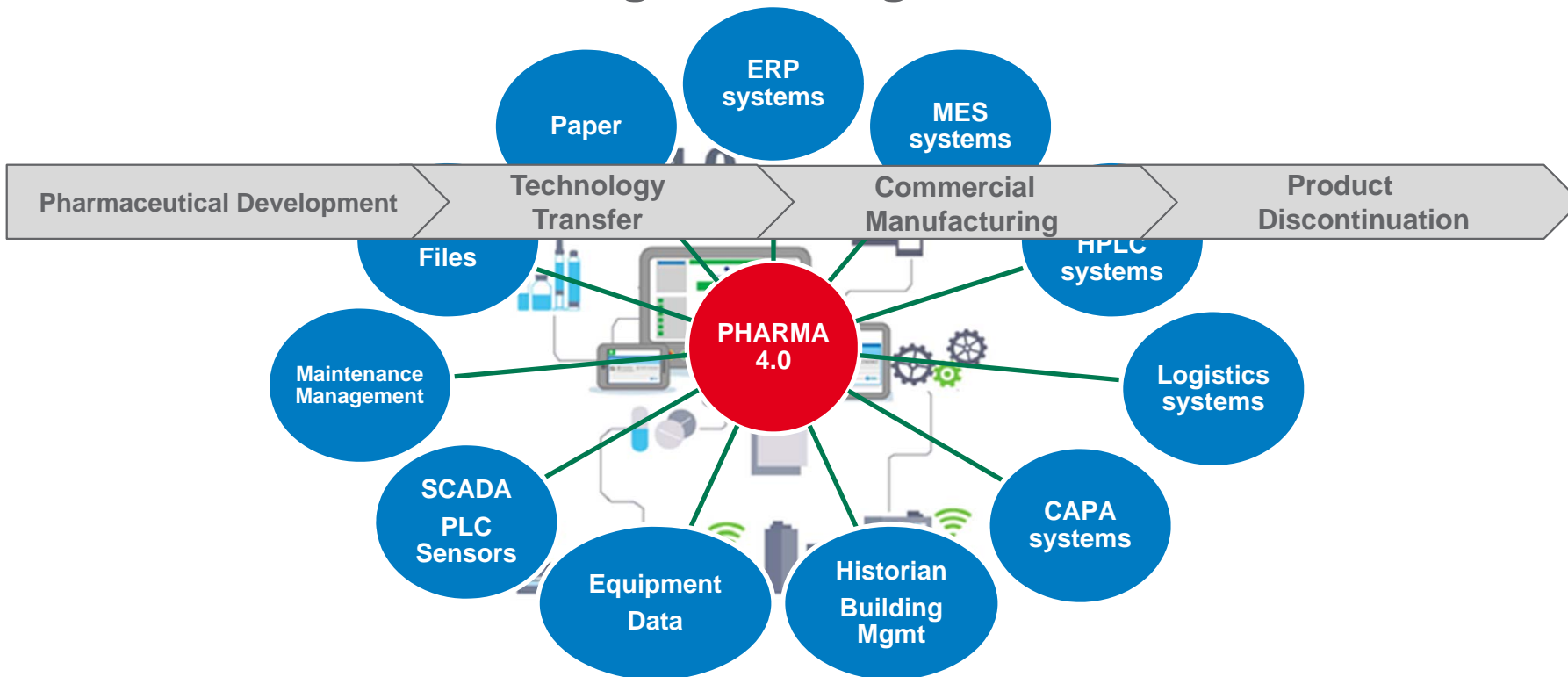
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Key Areas of PHARMA 4.0

Automation	End to End, Vertical & Horizontal Integration
PHARMA 4.0	
Quality Predictive Control	Workforce 4.0 Knowledge Management

Level 1
Real-time automatic control + Flexible process parameters to respond to variability in the input material attributes

Level 2
Reduced end product testing + Flexible critical material attributes and critical process parameters within design space

Level 3
End product testing + tightly constrained material attributes and process parameters

Control strategy implementation options

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Automation Industry 4.0: Applying Industry 4.0 to Pharma

Industry 4.0
Reference Model
Smart Factory
IIoT

Pharma GxP
Requirements
ICH
Pharma Quality System,
Control Strategy

PHARMA 4.0
Holistic Manufacturing Control Strategy

End to End Integration: Challenge & Opportunity

Vertical & Horizontal Integration: Big Data

Pharmaceutical Development → Technology Transfer → Commercial Manufacturing → Product Discontinuation

PHARMA 4.0

ERP systems
MES systems
Paper
HPLC systems
Files
Logistics systems
Maintenance Management
CAPA systems
SCADA PLC Sensors
Equipment Data
Historian Building Mgmt

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Interdisciplinary Collaboration to Create the Manufacturing Control Strategy
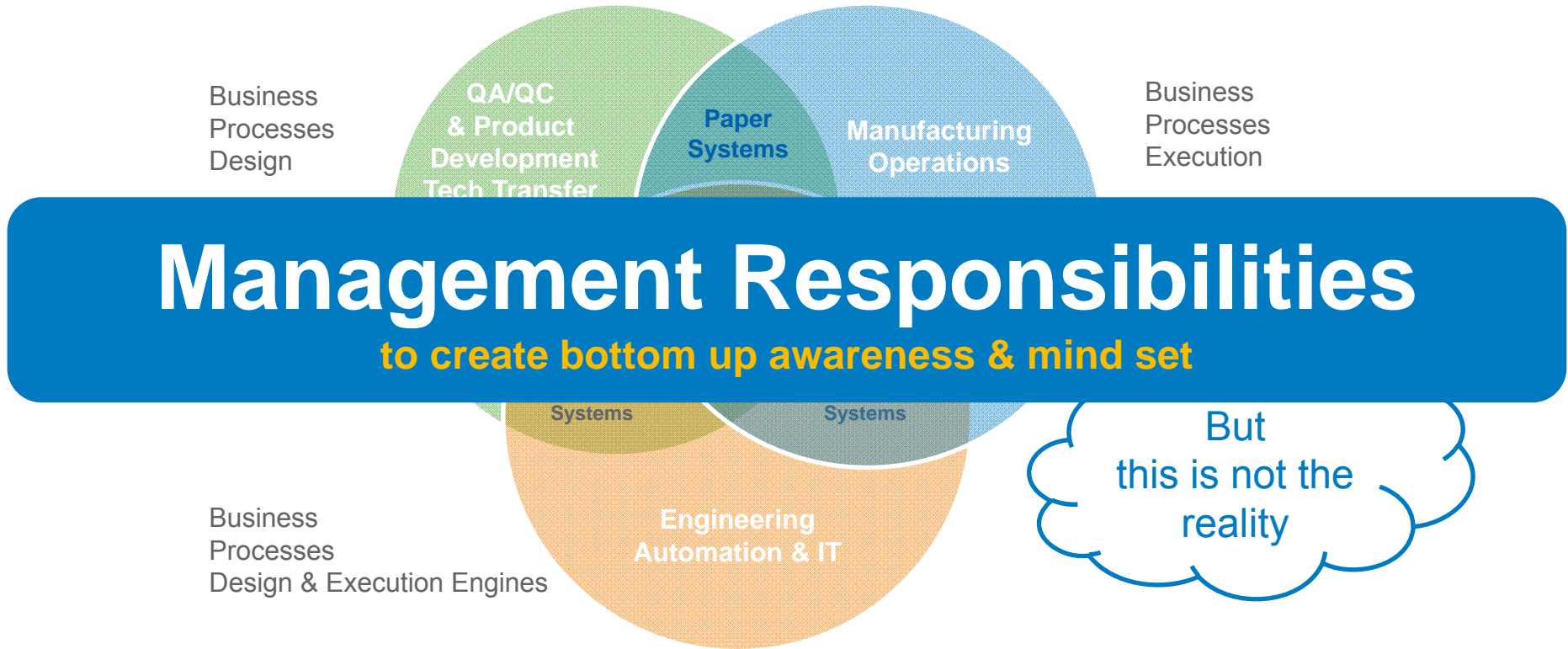
Business
Processes
Design

QA/QC & Product Development Tech Transfer

Paper Systems

Manufacturing Operations

Business
Processes
Execution

Management Responsibilities
to create bottom up awareness & mind set

Systems

Systems

But this is not the reality

Business
Processes
Design & Execution Engines

Engineering Automation & IT

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Agenda

1   New Industry Focus Area: China 2025 / Industry 4.0

2   MES: Focus on enabling Pharma 4.0

3   Werum IT Solutions: Company Profile

Industry 4.0 – Digitization of the manufacturing sector

Connectivity & Use of Data

"Industry 4.0 is based on the availability of all relevant information in real-time via networking all instances contributing to added value and the ability to determine the optimum added value stream from the data at any time. The linking of people, objects and systems generate dynamic, real-time optimized and self-organizing, cross-company value-added networks which can be essentially enhanced according to criteria like costs, availability and consumption of resources."

Prof. Dr. Dr. h.c. Detlef Zühlke, PAS-X User Group Meeting 2014: From Smart Technologies to Smart Factories

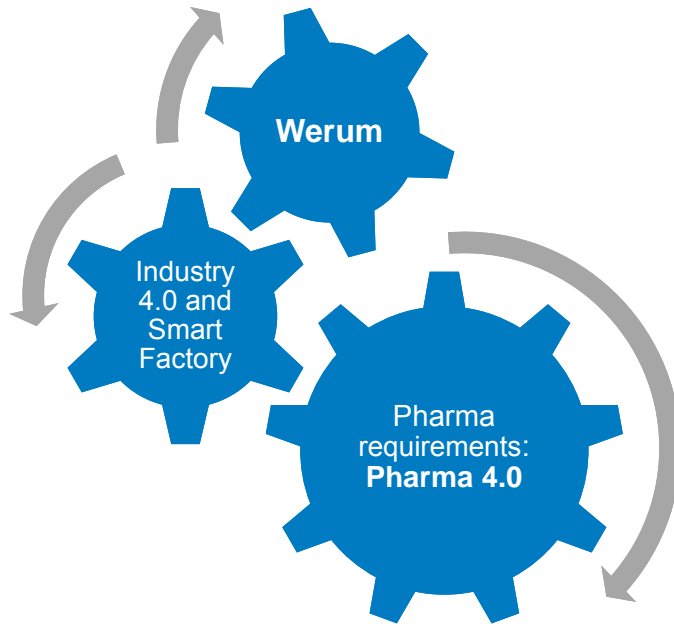**WERUM**
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4.0
PHARMA

DIGITIZATION:
PHARMA. SIMPLY CONNECTED.

- Thinking ahead the intelligent pharma production
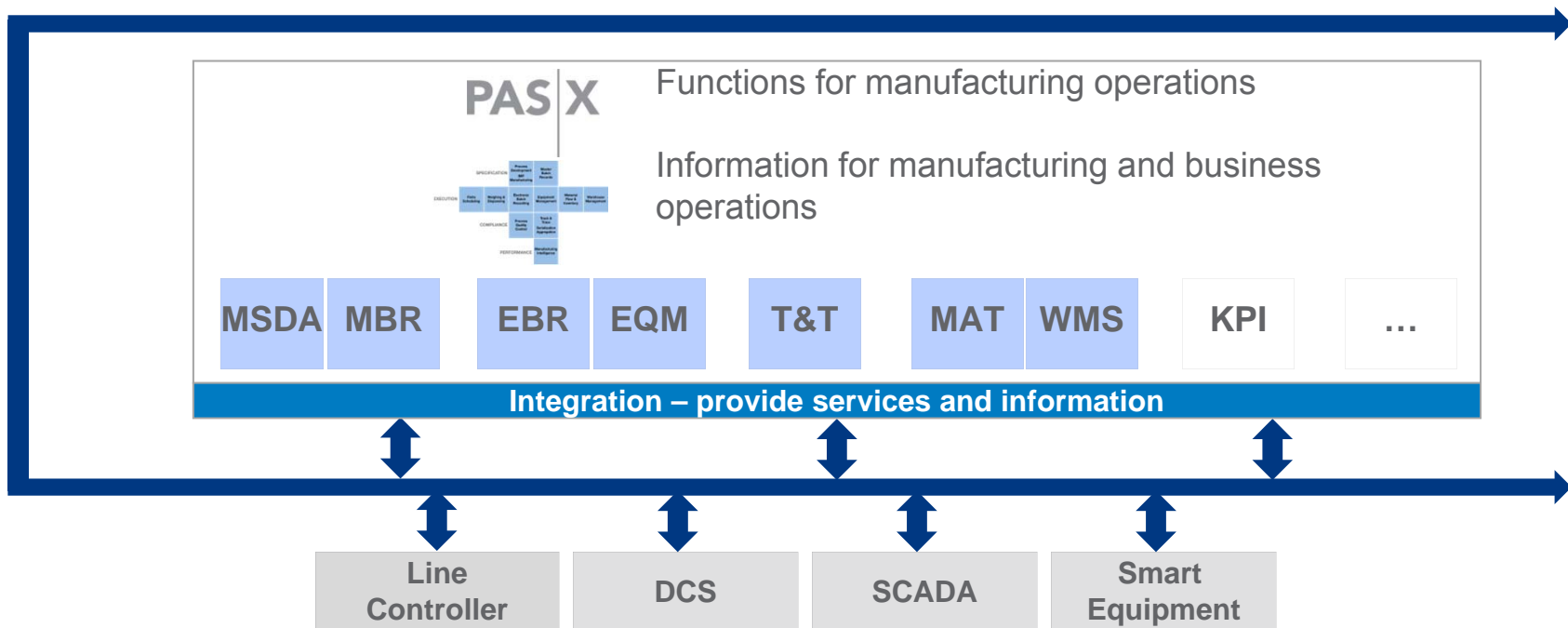- Efficiency meets flexibility
- Performance meets individualization

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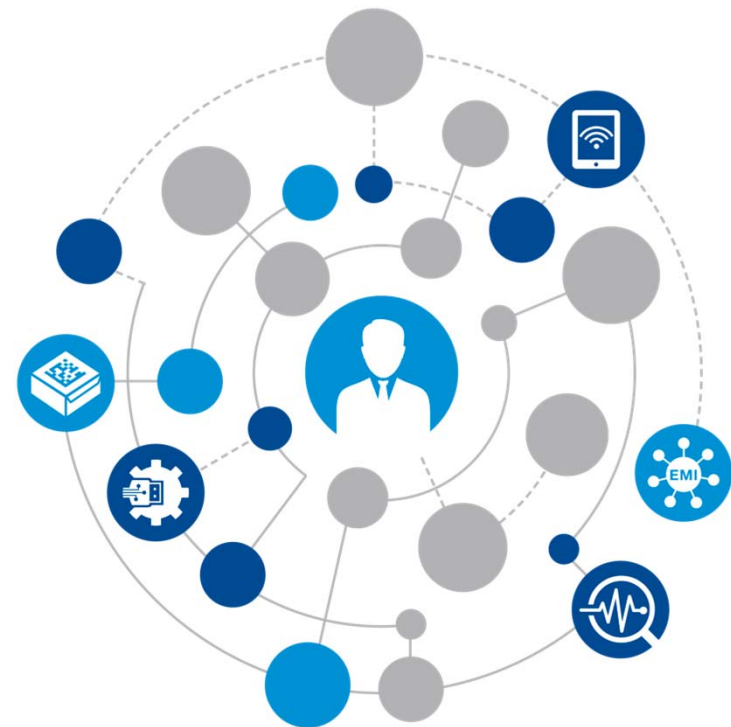
Werum: from Industry 4.0 to Pharma 4.0

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4.0
PHARMA

Werum

Industry 4.0 and Smart Factory

Pharma requirements: **Pharma 4.0**

- Customers
- Partners
- Committees
- Innovators

PHARMA 4.0

Holistic Manufacturing Control Strategy — Plug&Produce

Focused on Product/Quality System with strong relation to ICH

Focused on system/equipment integration with strong relation to NAMUR

ISPE

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DIGITIZATION: PHARMA. SIMPLY CONNECTED.

Smart Packaging:
Enabling a new level of personalized medicine and product safety

Smart Devices:
The right information at the right time and place

Condition Monitoring & Predictive Analytics:
Reducing downtimes and optimizing the deployment of personnel and recourses

Plug & Produce: Laying the basis for IIoT functionalities
by integration using standardized interfaces to reduce complexity of integration

Enterprise Manufacturing Intelligence (EMI):
For improved product quality (process stability) and productivity (process efficiency)

SMART PACKAGING – CONSUMER INFORMATION

The package as an information carrier opens up new information and service options for patients and users of pharmaceutical products.

Use cases:

- Digital patient information leaflets

- Audio patient information leaflets

- Digital tamper-proof protection

- Better product protection Health management

- Intake reminder

- Automatic repeat order

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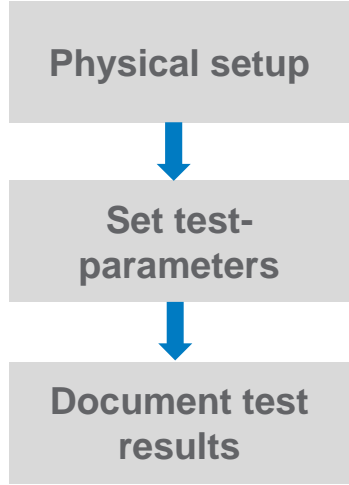
SMART PACKAGING –
IN THE PRODUCTION PROCESS

The package can communicate with packaging machines to increase OEE.

Use cases:

- Machinery settings are controlled/initiated via information on the packaging

- Personalized production, packaging, labelling

- Learning packaging: information is transferred to package
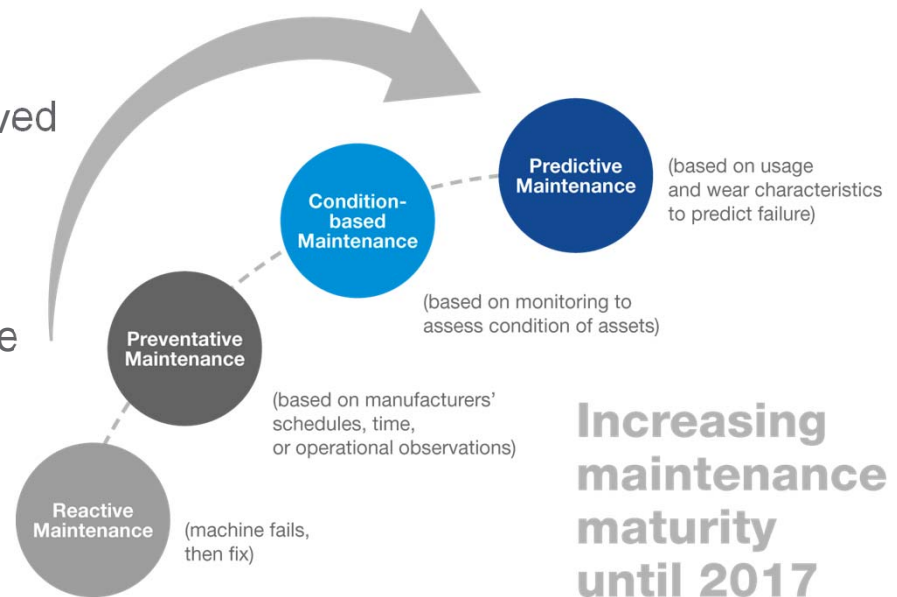
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4.0 PHARMA

SMART DEVICES –
Integrate a Filter Integrity Tester

Physical setup
⬇
Set test-parameters
⬇
Document test results

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CONDITION MONITORING & PREDICTIVE ANALYTICS

- Machine safety and efficiency can be improved by predicting and preventing critical future events

- Based on real time data, the status of a system is supervised and future events are predicted with a model

- Reactive or preventive maintenance is replaced by using data mining, modeling, statistics, machine learning

Predictive Maintenance (based on usage and wear characteristics to predict failure)

Condition-based Maintenance (based on monitoring to assess condition of assets)

Preventative Maintenance (based on manufacturers' schedules, time, or operational observations)

Reactive Maintenance (machine fails, then fix)

Increasing maintenance maturity until 2017

PLUG & PRODUCE – NEW VERTICAL INTEGRATION CONCEPT

Standardizing interfaces between MES, automation and control systems:

- Standardization reduces complexity of integration and enables "Plug & Produce"
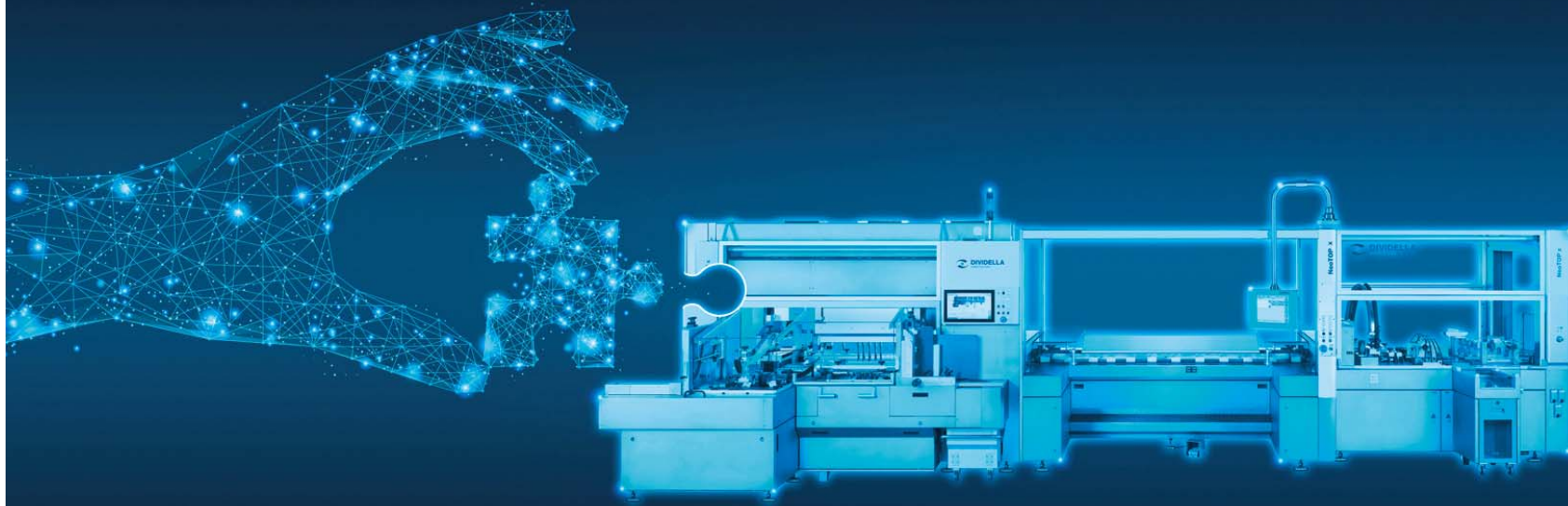- Reduced engineering and qualification efforts in setup phase and production

EMI – ENTERPRISE MANUFACTURING INTELLIGENCE

- Central collection and evaluation of data across different sources to improve product quality (process stability) and productivity (process efficiency)

- Data assessment results in real time analysis, standard reports and investigative analysis

Increase process stability

Improve process performance

Avoid non compliance issues

Accelerate process development

Quality Reporting

Optimize maintenance

EMI

4.0 PHARMA

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PLUG & PRODUCE WITH PAS-X:
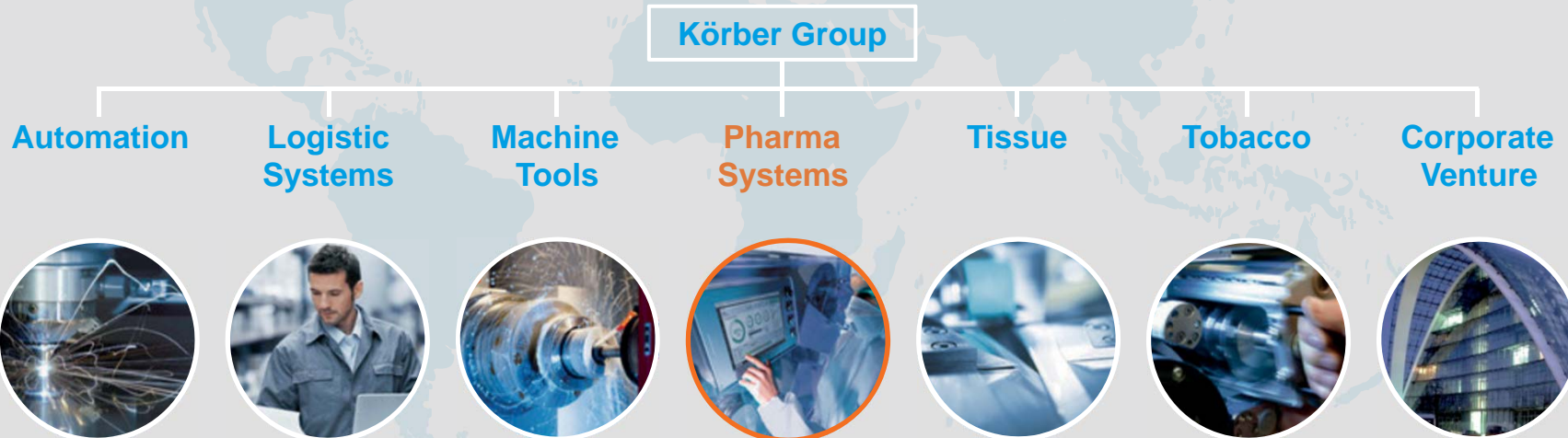UNIVERSAL CONNECTIVITY. MAXIMUM PRODUCTIVITY.

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KÖRBER GROUP.
TECHNOLOGY ACROSS INDUSTRIES.

▶ Sales   € 2.2 billion
▶ Employees   11,500
▶ R&D ratio   5.7%
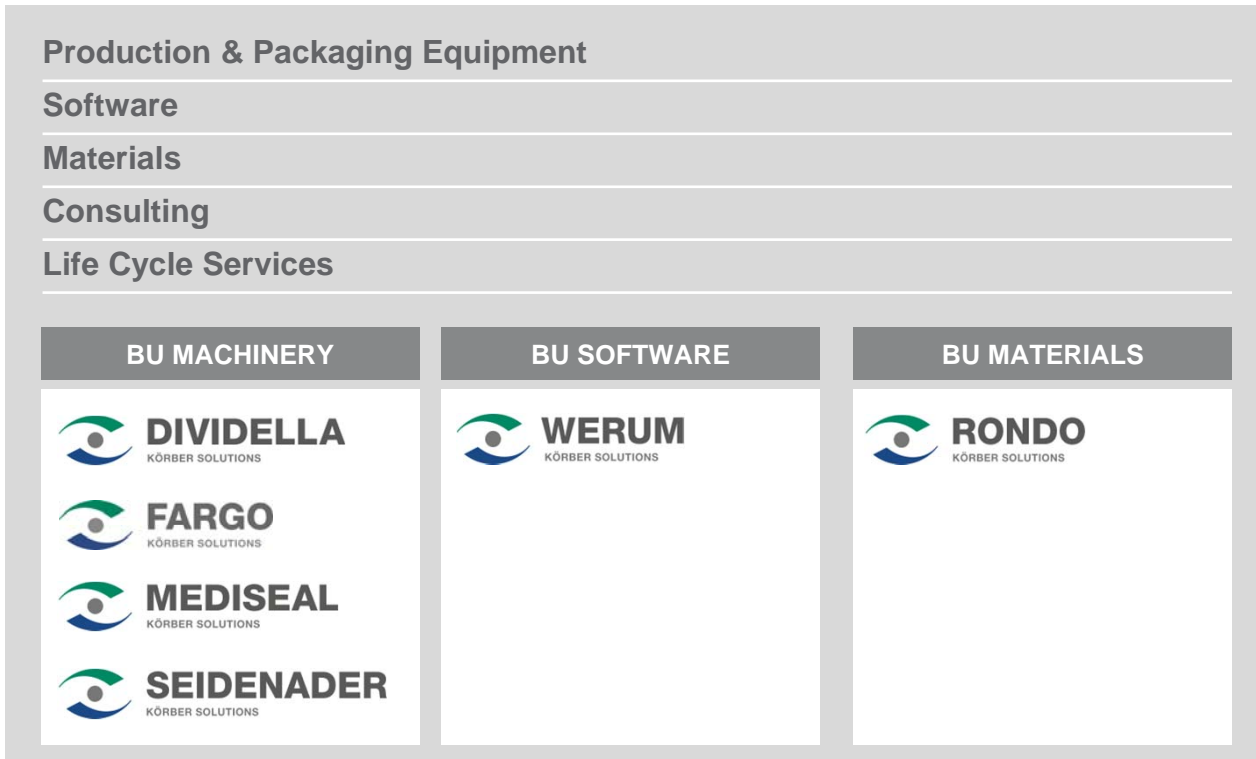
Körber Group

| Automation | Logistic Systems | Machine Tools | Pharma Systems | Tissue | Tobacco | Corporate Venture |

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Werum IT Solutions: A Member of Körber Medipak Systems

Production & Packaging Equipment

Software

Materials

Consulting

Life Cycle Services

BU MACHINERY	BU SOFTWARE	BU MATERIALS
DIVIDELLA KÖRBER SOLUTIONS FARGO KÖRBER SOLUTIONS MEDISEAL KÖRBER SOLUTIONS SEIDENADER KÖRBER SOLUTIONS	WERUM KÖRBER SOLUTIONS	RONDO KÖRBER SOLUTIONS

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The leading MES supplier for Pharma & Biotech

500+
Employees

14
Locations worldwide
Headquarters:
Lüneburg, Germany

25+
Years of experience
in the field of MES
for pharma & biotech

800+
PAS-X MES
installations
worldwide

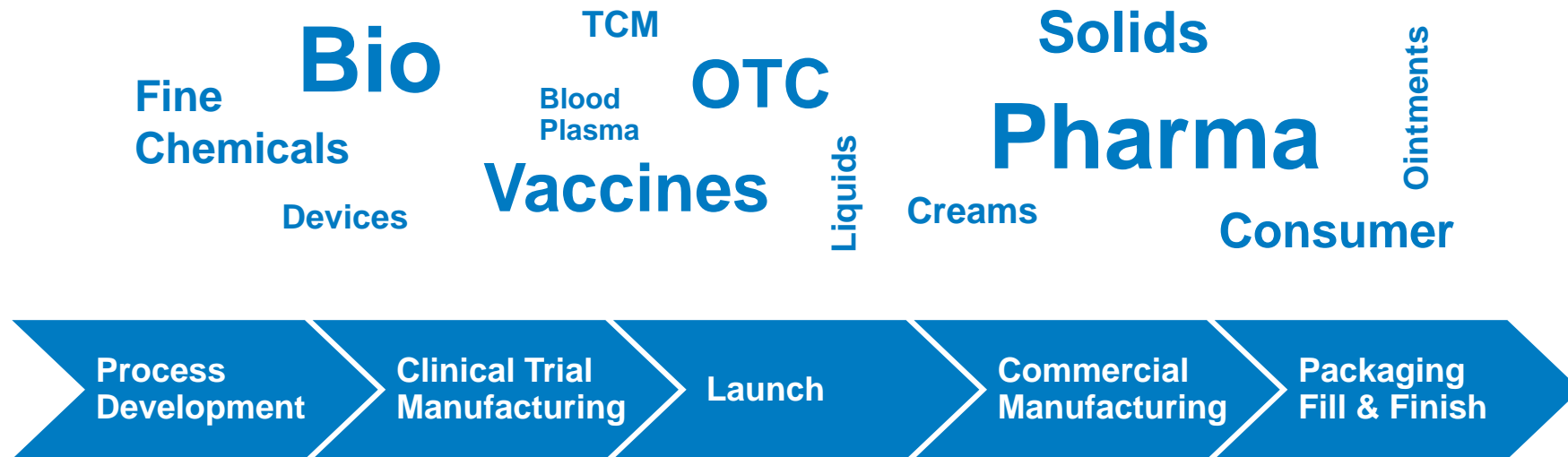# The Pharma & Biotech industry relies on PAS-X MES

We are always available for our customers

Germany
France
Switzerland
California
New Jersey
Japan
North Carolina
China
Thailand
India
Singapore
Brazil

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Your processes requirements are our core business

TCM

Fine Chemicals

Bio

Blood Plasma

Solids

OTC

Ointments

Pharma

Vaccines

Liquids

Creams

Devices

Consumer

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

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Complete MES Out-Of-The-Box

SOFTWARE

Adaptable to the needs of your site

PAS|X

+ Functionally complete

- Customization

100%
80%
60%
40%
20%
0%

1990 ▶   1995 ▶   2000 ▶   2005 ▶   2010 ▶   2015 ▶   2020 ▶
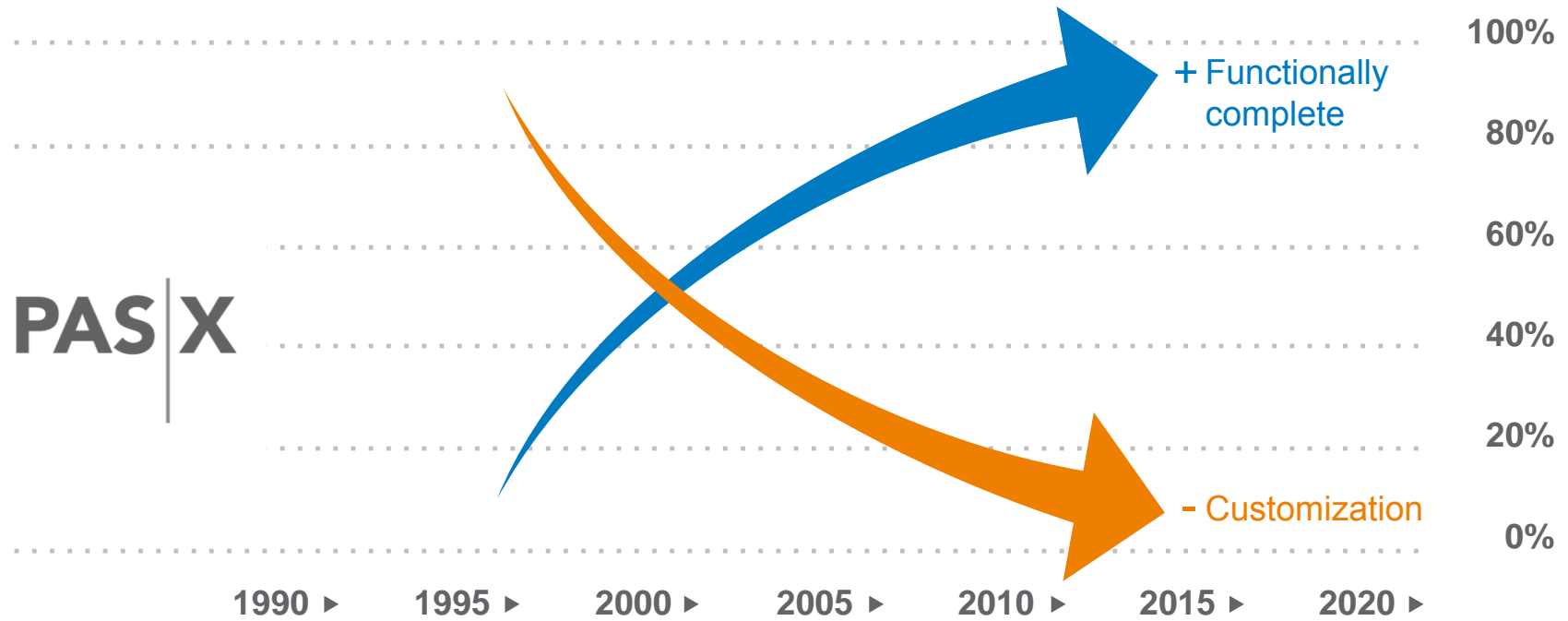
Modular MES Product

#1 industry leading MES

5 key benefit areas

| Safeguarding regulatory compliance | Increasing manufacturing performance | Leveraging technology for innovation | Higher quality products and processes | Accelerating time-to-market |
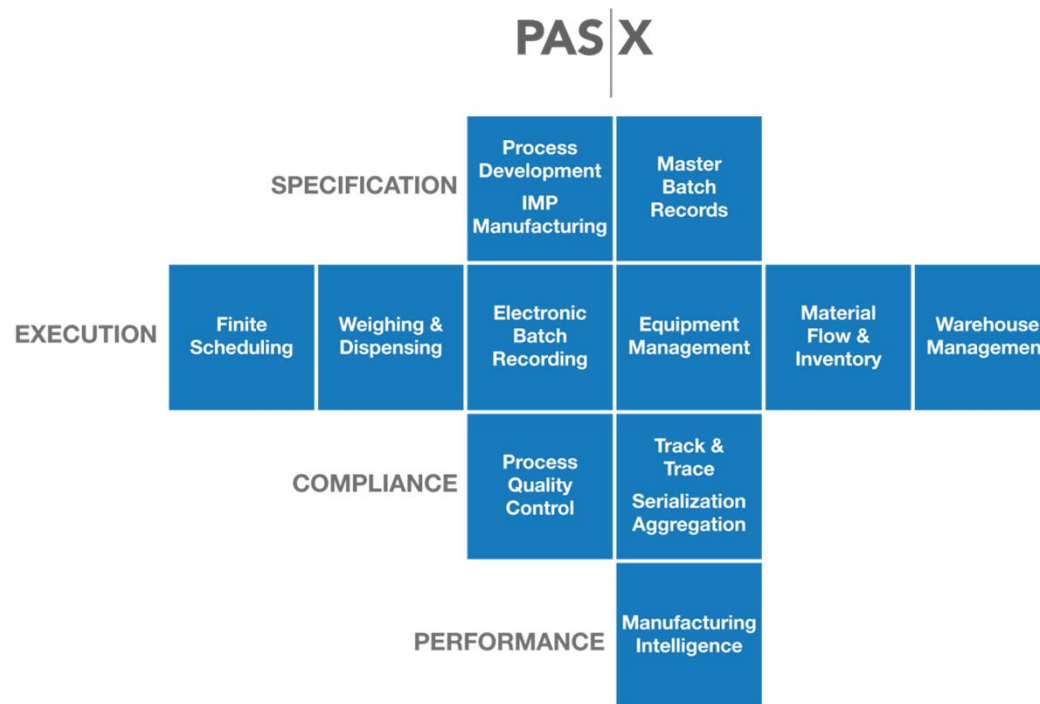
Best in class: Master Batch Records

SOFTWARE

- Graphical drag & drop workflows
- Process library concept & standard recipes built in
- Low maintenance and management efforts
- Drastically reduced number of recipes
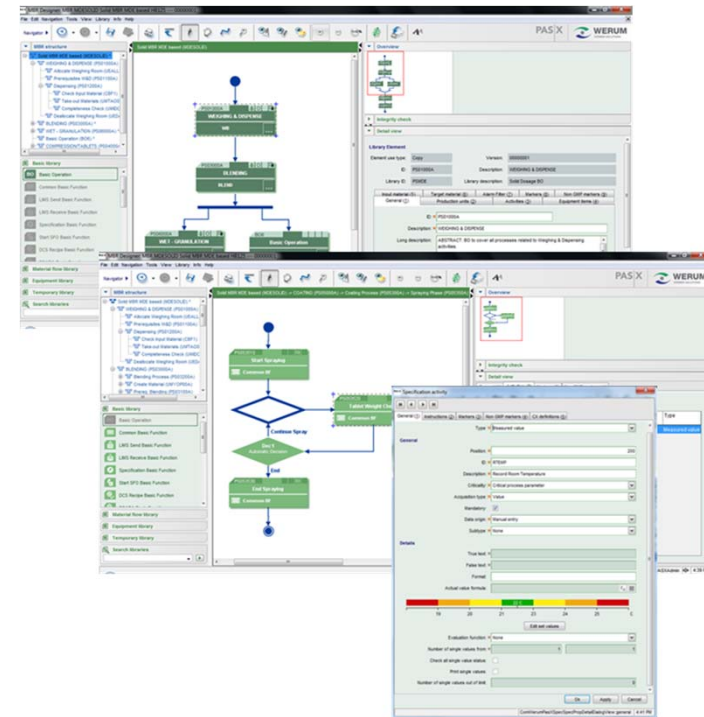
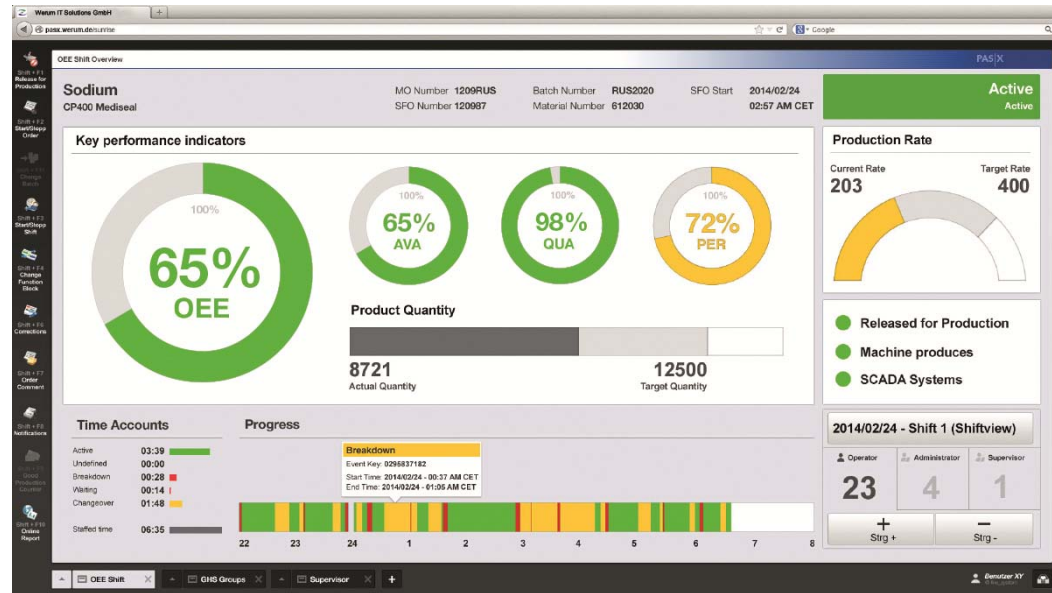# Best in class: Shop Floor Execution

- Intuitive shop floor dialogs
- Strong user guidance for Right-First-Time
- Integrated deviation management
- Process and completeness checks
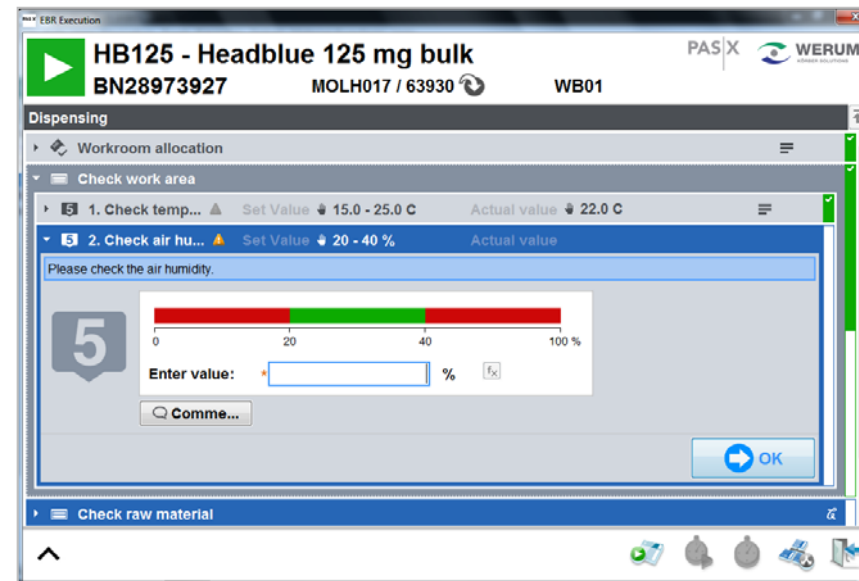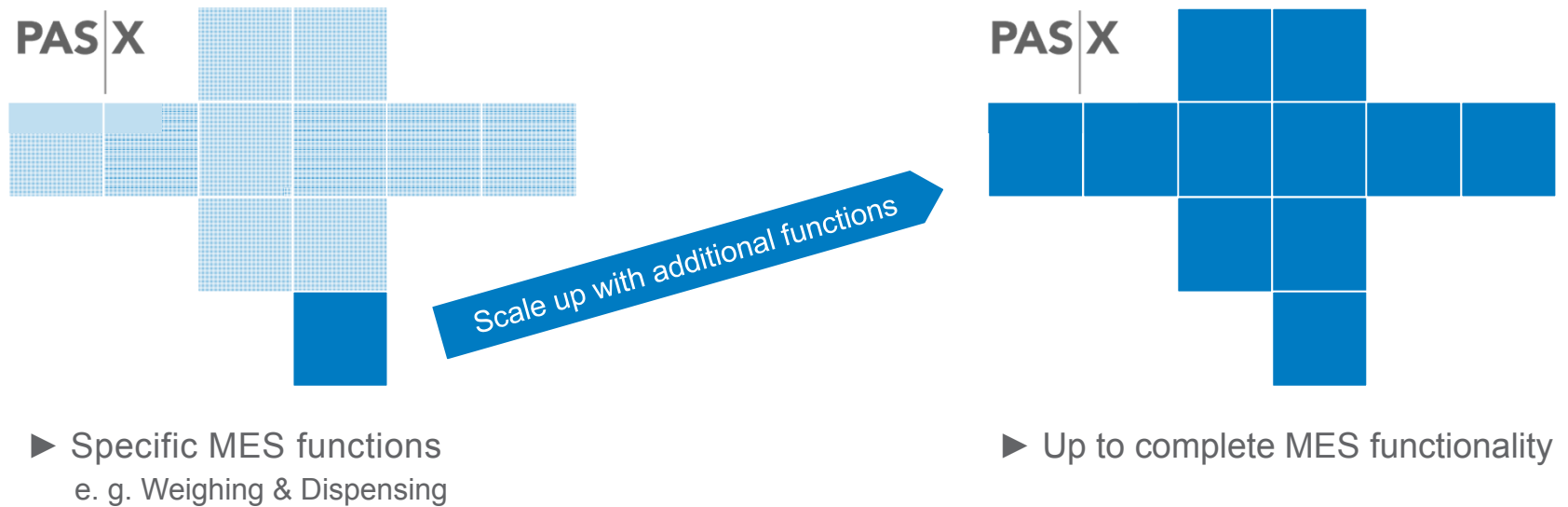
Best in class: Usability

- Intuitive dialogs
- Easy operation with minimum training
- Touchscreen

Start small and scale up later

► Specific MES functions
  e. g. Weighing & Dispensing

► Up to complete MES functionality

MES success requires more than software

- We offer comprehensive packages for fast and efficient deployment
- Software, Content and Services from a single supplier
- With leading industry knowledge and best practice built in

SERVICES
SOFTWARE
CONTENT

Best practice content for fast MES deployments

- Libraries with industry templates for your business
- Ready to use descriptions, lists, process maps and controls
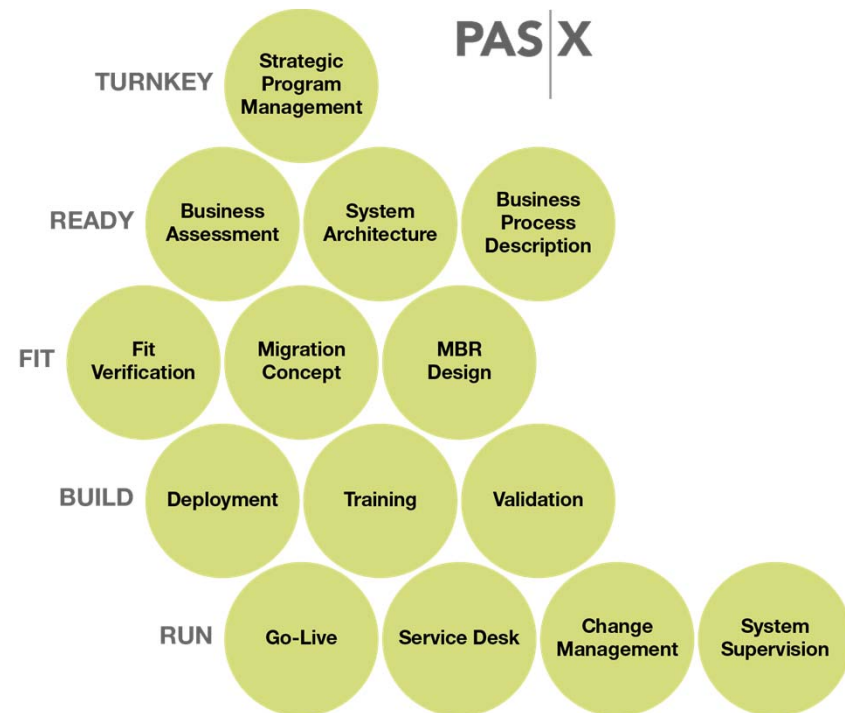- Virtual manufacturing site concept
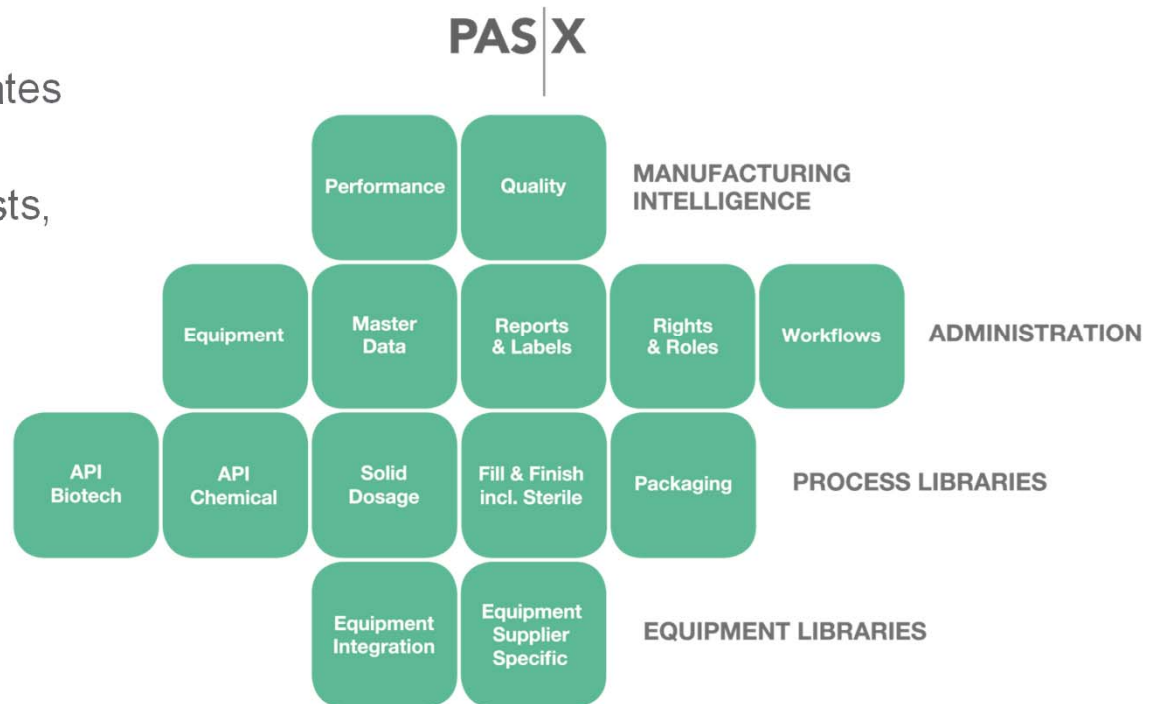
Professional Services
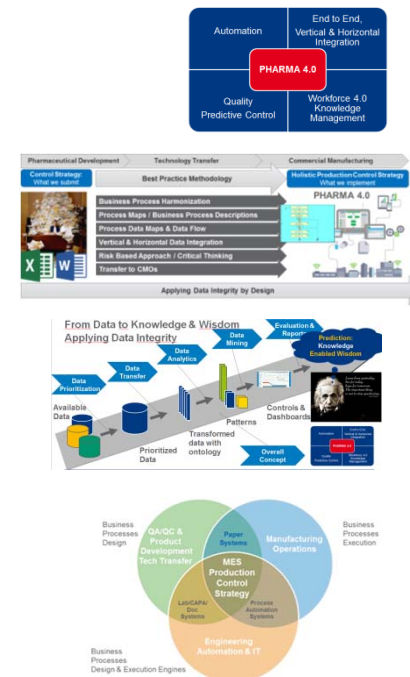
Support during all implemention phases

- Portfolio is based on industry best-practice and requirements of PAS-X user community
- Consultants & trainers highly specialized in pharmaceutical and bio-manufacturing
- Short response and solution times

PAS|X

TURNKEY — Strategic Program Management

READY — Business Assessment, System Architecture, Business Process Description

FIT — Fit Verification, Migration Concept, MBR Design

BUILD — Deployment, Training, Validation

RUN — Go-Live, Service Desk, Change Management, System Supervision

Summary & Conclusions

PHARMA 4.0 is not only Automation – Its an End to End Holistic Manufacturing Control Strategy

- Business process based Best Practice Methodology to transform the Development based Control Strategy to the Holistic Manufacturing Control Strategy

- Data Integrity by Design & Data turned into Knowledge & Wisdom

- Interdisciplinary Collaboration

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Thank you for your attention.