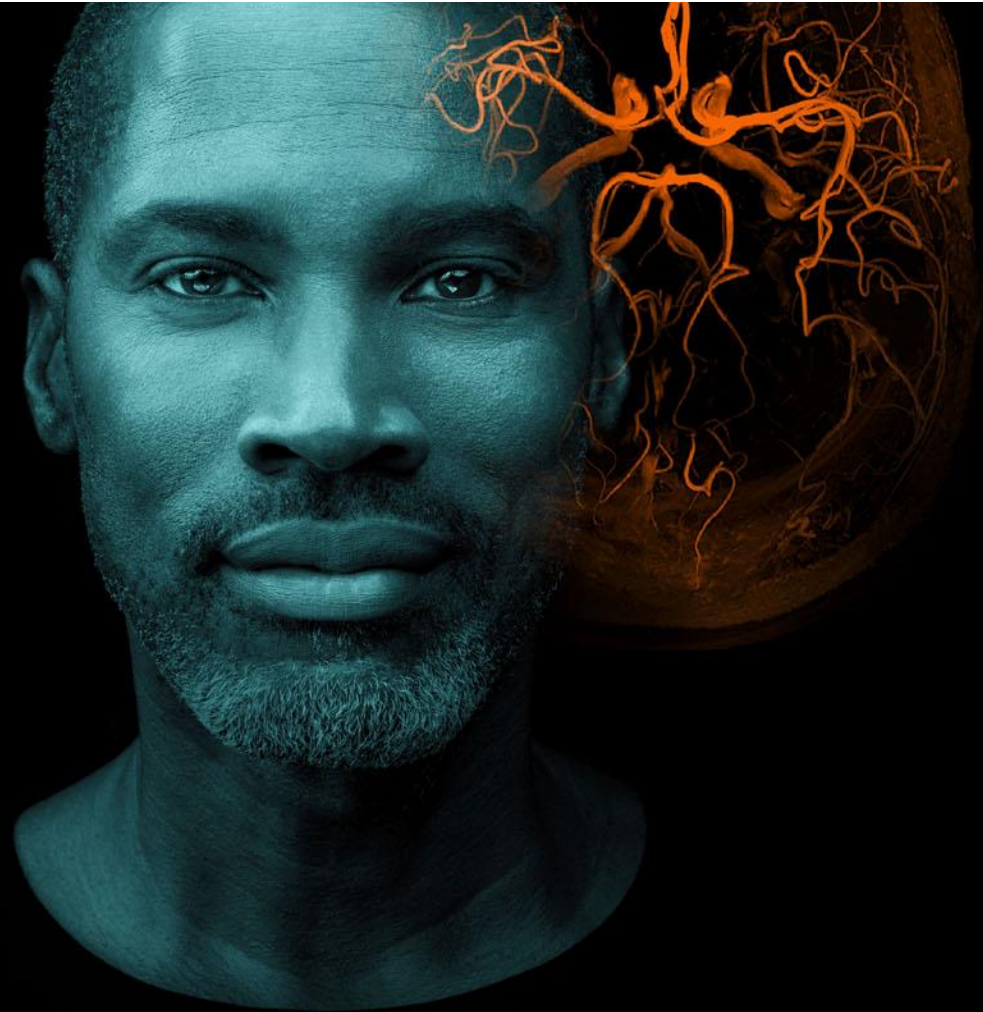
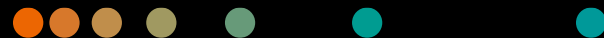


# MES als essentieller Kern eines Design2Operate Prozesses

Waltraud Winter  
June 2023



# Agenda

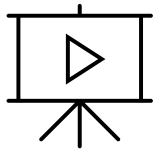
About Siemens Healthineers

Design2Operate at Siemens Healthineers

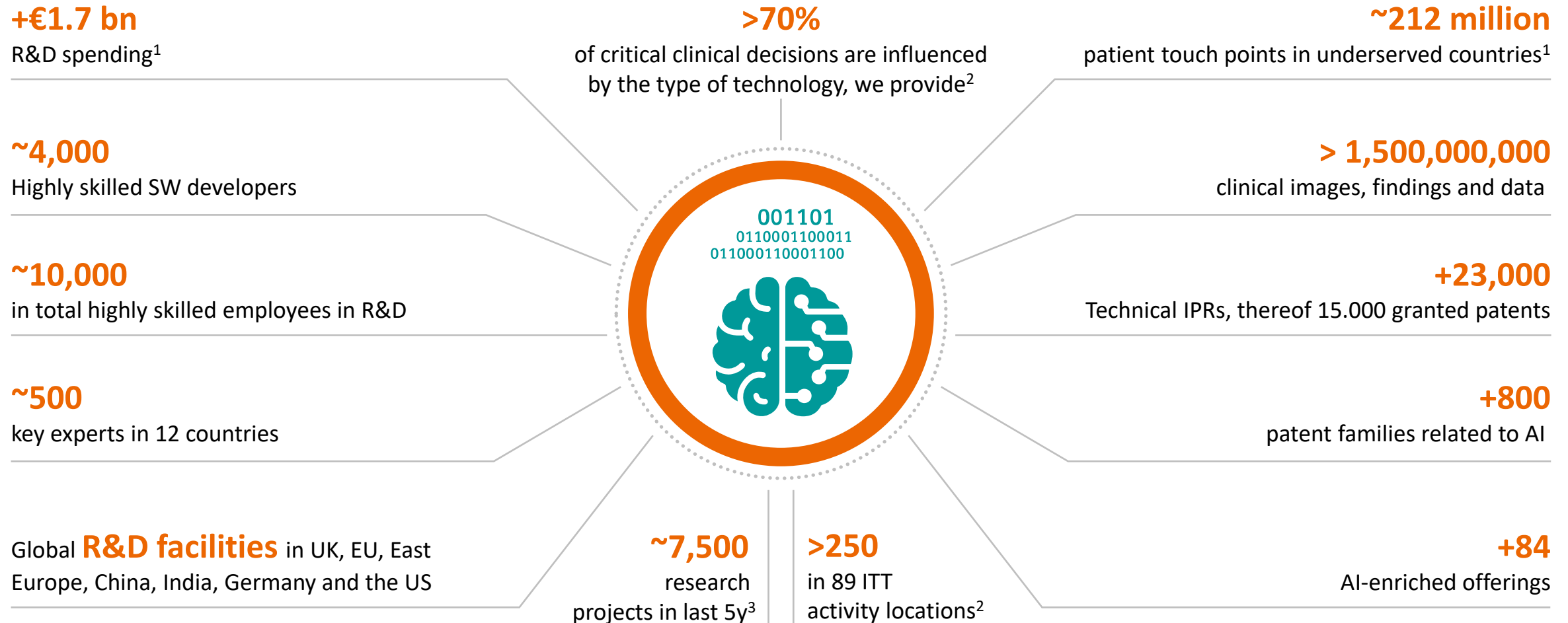
Integration Deep Dives

Digital Manufacturing Cloud

**We pioneer breakthroughs  
in healthcare.**  
**For everyone. Everywhere.**



# Siemens Healthineers facts and figures – Our commitment to Technology and Innovation



<sup>1</sup> FY2022 | <sup>2</sup> AdvaMedDX, “A Policy Primer on Diagnostics”, June 2011, p. 3 |

SW = Software | R&D = Research and development | AI = Artificial Intelligence | <sup>2</sup> ITT = Innovation Think Tank/locations at Healthineers, universities, hospitals and governmental institutions | <sup>3</sup> Contracts with an effective date equal or greater than 01.10.2017

# We are where our customers are



● Headquarter ● Major manufacturing/engineering sites

## Local everywhere with sales and service

- **Americas**  
>6,300 employees

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- **Europe, Middle East, Africa**  
>6,600 employees

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- **Asia Pacific**  
>5,200 employees

# We offer a broad and deep portfolio

## Diagnostic Imaging

Market leader in diagnostic imaging

### Key offerings

- Computed Tomography
- Magnetic Resonance
- Molecular Imaging
- X-Ray/Fluoroscopy
- Mammography Systems
- Digital Health Solutions
- Imaging Software and IT

### Clinical specialties

- Radiology
- Nuclear Medicine



## Ultrasound

Versatility and functionality with real-time clinical imaging

### Key offerings

- Cart-based Systems
- Compact Systems
- Catheters

### Clinical specialties

- General Imaging
- Cardiology
- Interventional cardiology
- Point of Care



## Advanced Therapies

Empowering advanced therapy concepts

### Key offerings

- Angio Suites
- Cath Labs
- Hybrid ORs
- Mobile C-arms
- Endovascular Robotics
- Imaging Solutions for Radiation Therapy

### Clinical specialties

- Interventional Radiology
- Cardiology
- Radiation Oncology
- Surgery



## Laboratory Diagnostics

Delivering clinical and workflow excellence

### Key offerings

- Instruments, reagents and consumables
- Automation and IT Systems
- Consulting and Project Management

### Clinical specialties

- Laboratory Diagnostics
- Molecular Diagnostics



## Point of Care Diagnostics

Accurate, actionable and timely results at point of care

### Key offerings

- Chronic Disease Management: Urinalysis, Diabetes
- Critical Care: Blood Gas, Cardiac
- Rapid COVID-19 Antigen Test<sup>1</sup>
- POC Informatics

### Clinical specialties

- Cardiology
- Critical Care
- Diabetology
- Urology
- Nephrology



## Varian

Cancer treatment ecosystem for streamlined, comprehensive patient-centric care

### Key offerings

- Radiation Therapy
- Brachytherapy
- Proton therapy
- Radiosurgery
- Interventional Solutions

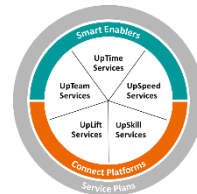
### Clinical specialties

- Radiation Oncology
- Interventional Oncology
- Radiosurgery



## Customer Services

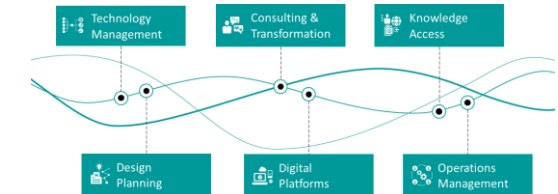
- UpTime Services
- UpSpeed Services
- UpSkill Services
- UpLift Services
- UpTeam Services
- Connect Platforms



## Value Partnerships

Enduring, performance-oriented relationships, comprising

- Technology Management
- Consulting & Transformation
- Knowledge Access
- Design Planning
- Digital Platforms
- Operations Management

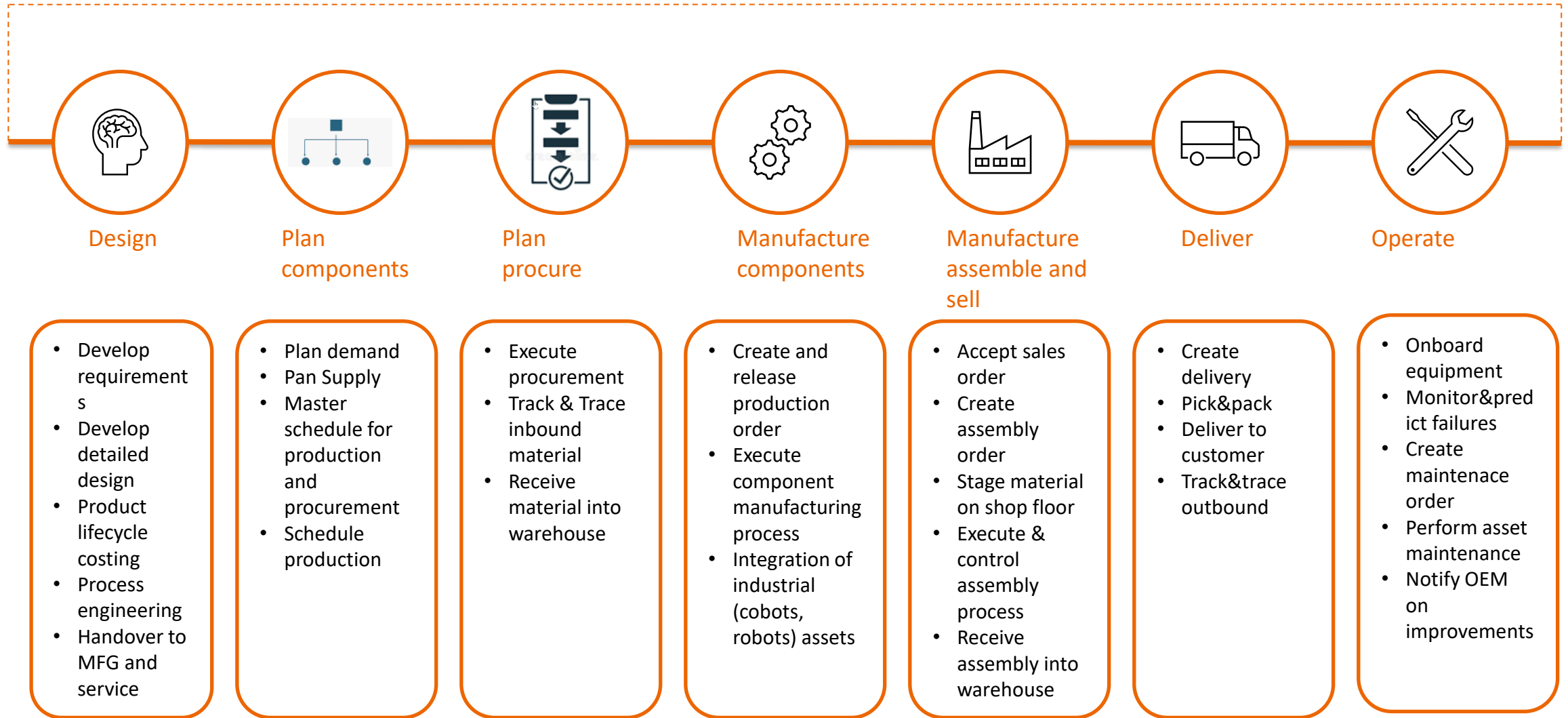


**Note:** The products mentioned above are not commercially available in all countries. Due to regulatory reasons their future availability cannot be guaranteed.

Please contact your local Siemens Healthineers organization for further details.

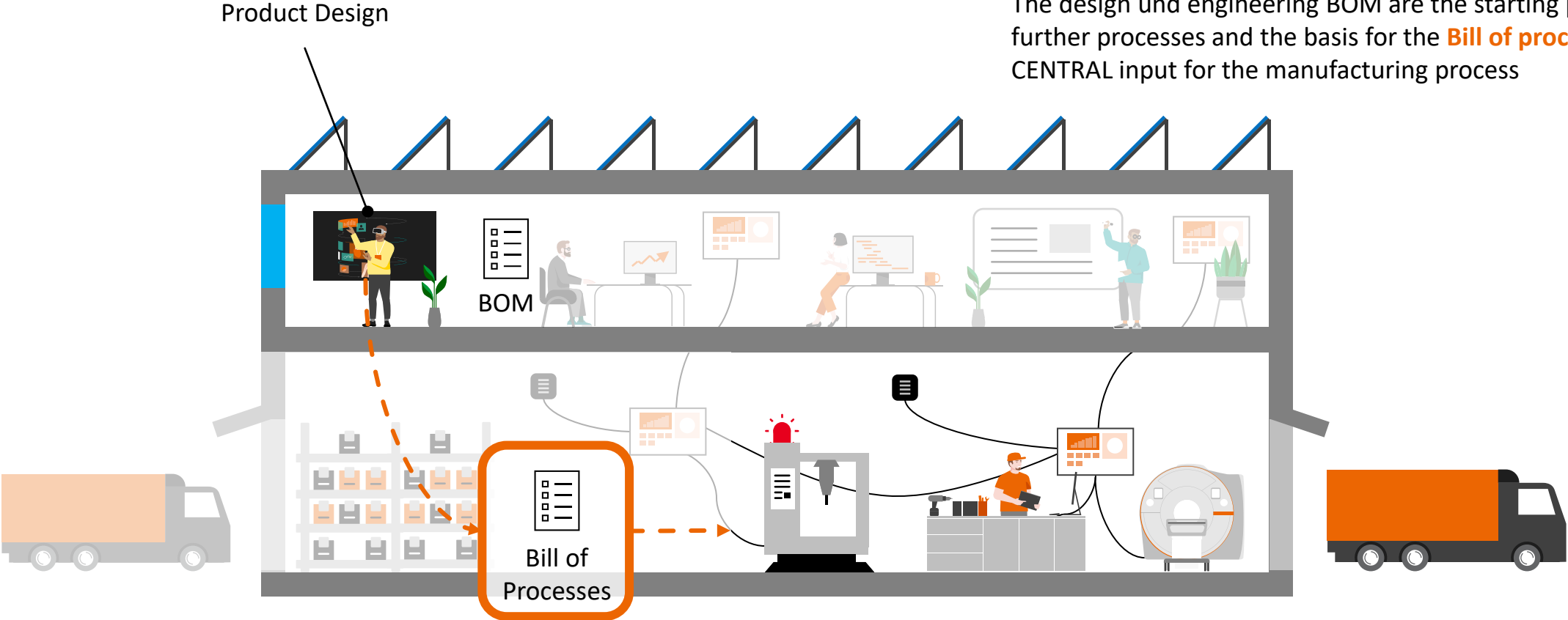
<sup>1</sup> Under review by the U.S. FDA for Emergency Use Authorization (EUA). Product availability may vary by country and is subject to varying regulatory requirements.

# Design2Operate: Transfer of the digital to the physical world with MES as the central element



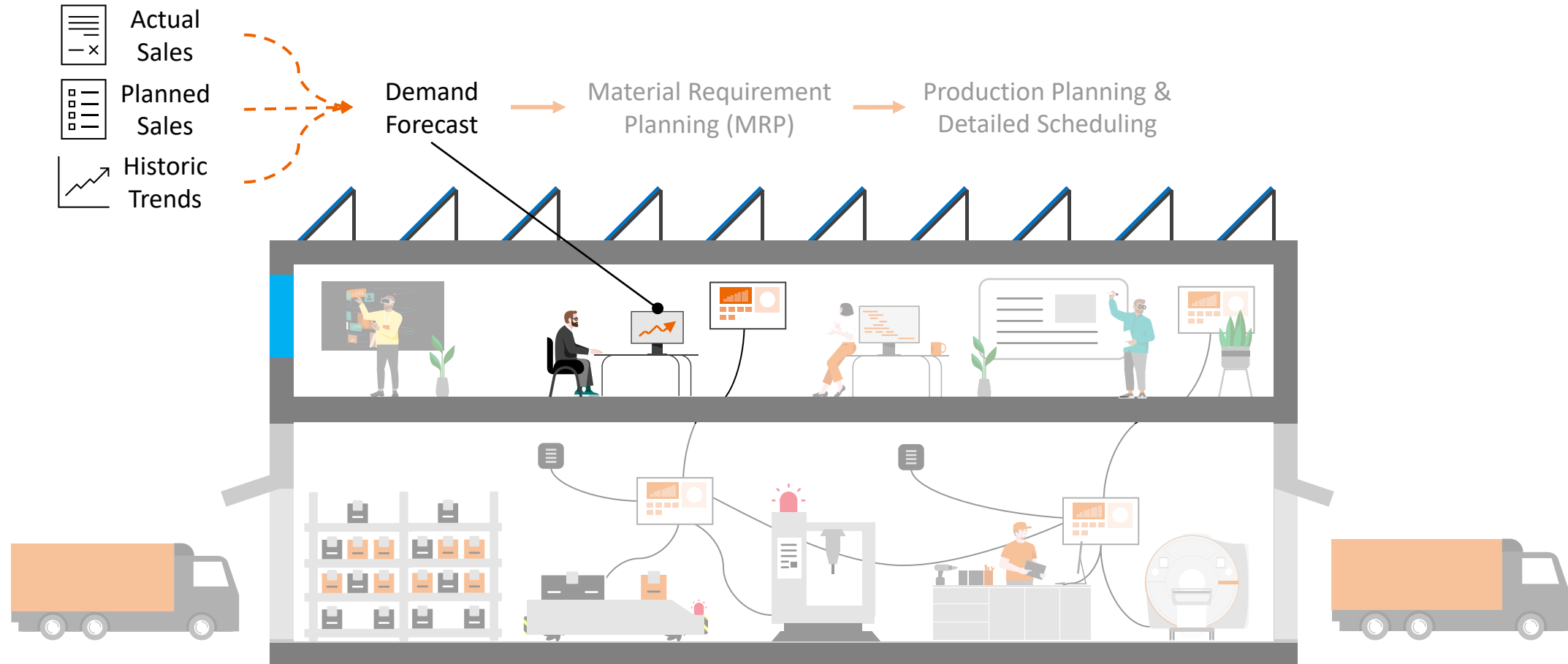
# Virtual models and derived BOMs are the starting point

The product design is described with models and BOMs  
The design and engineering BOM are the starting point for all further processes and the basis for the **Bill of process**, the CENTRAL input for the manufacturing process

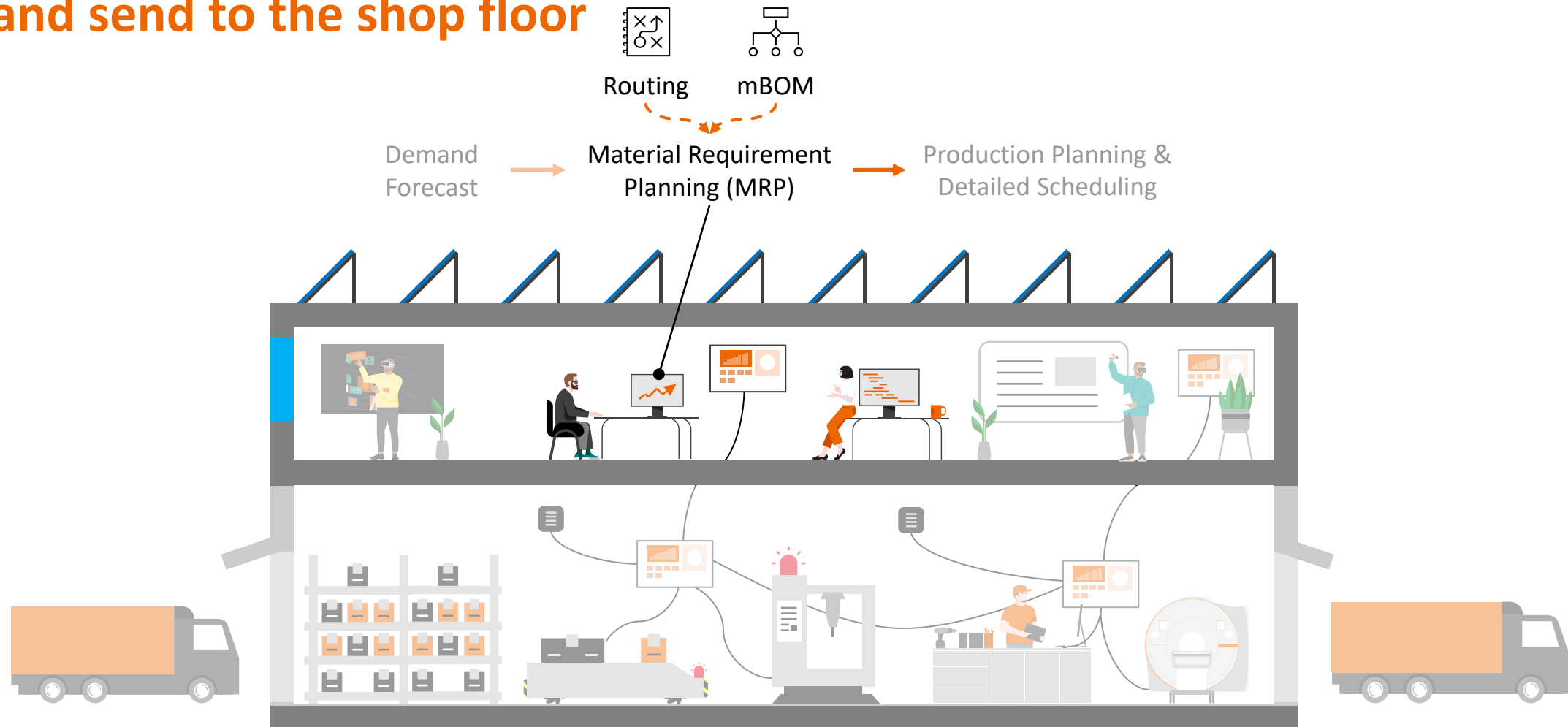




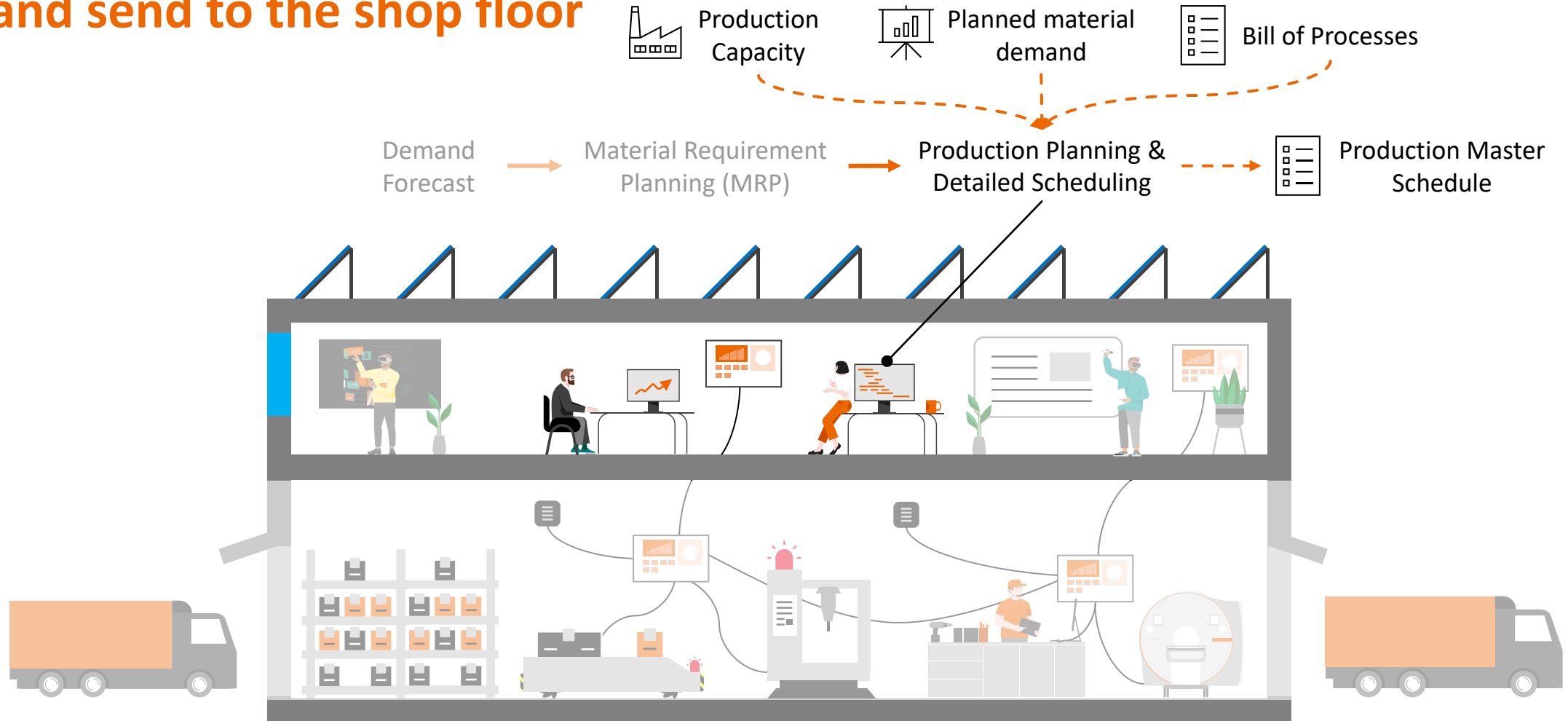
# The production master and the production order are scheduled and send to the shop floor



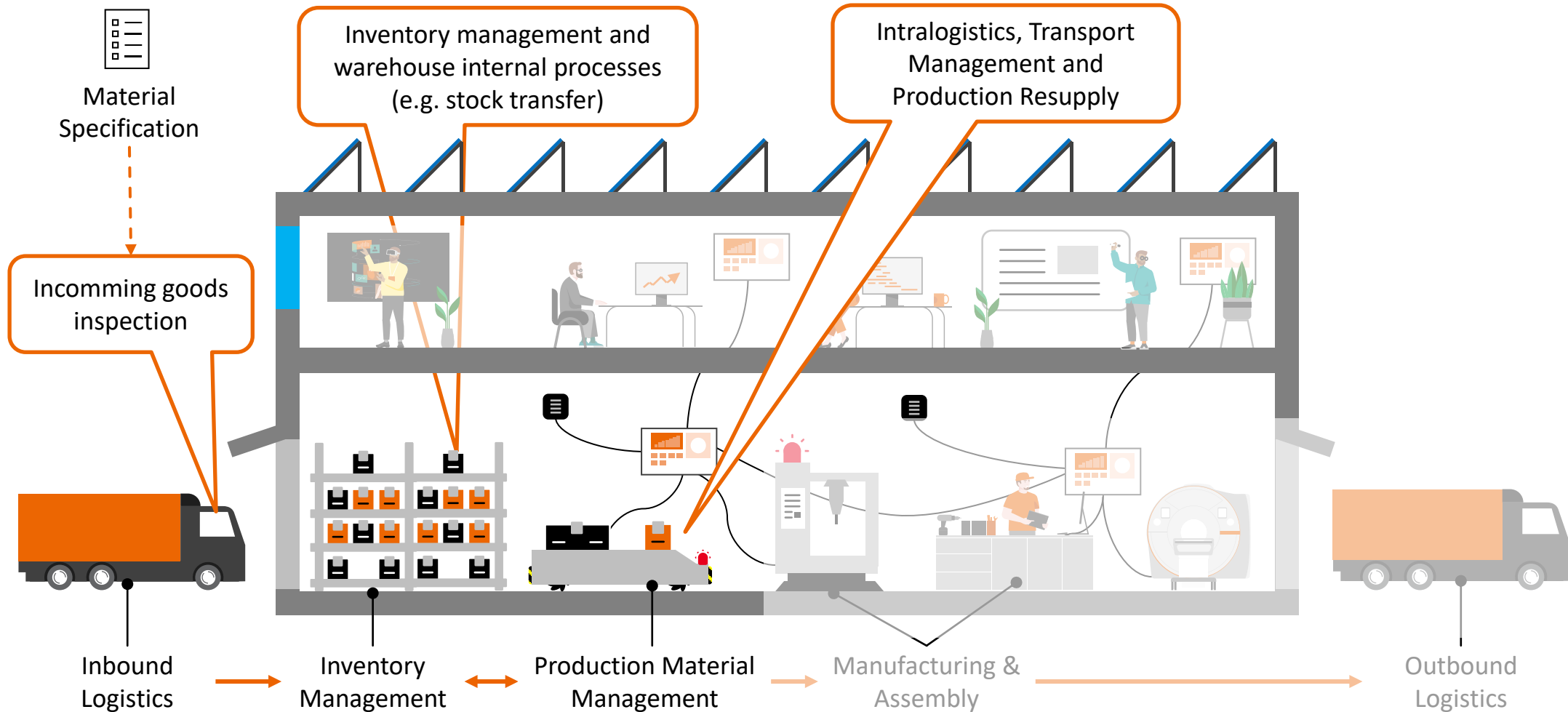
# The production master and the production order are scheduled and send to the shop floor



# The production master and the production order are scheduled and send to the shop floor

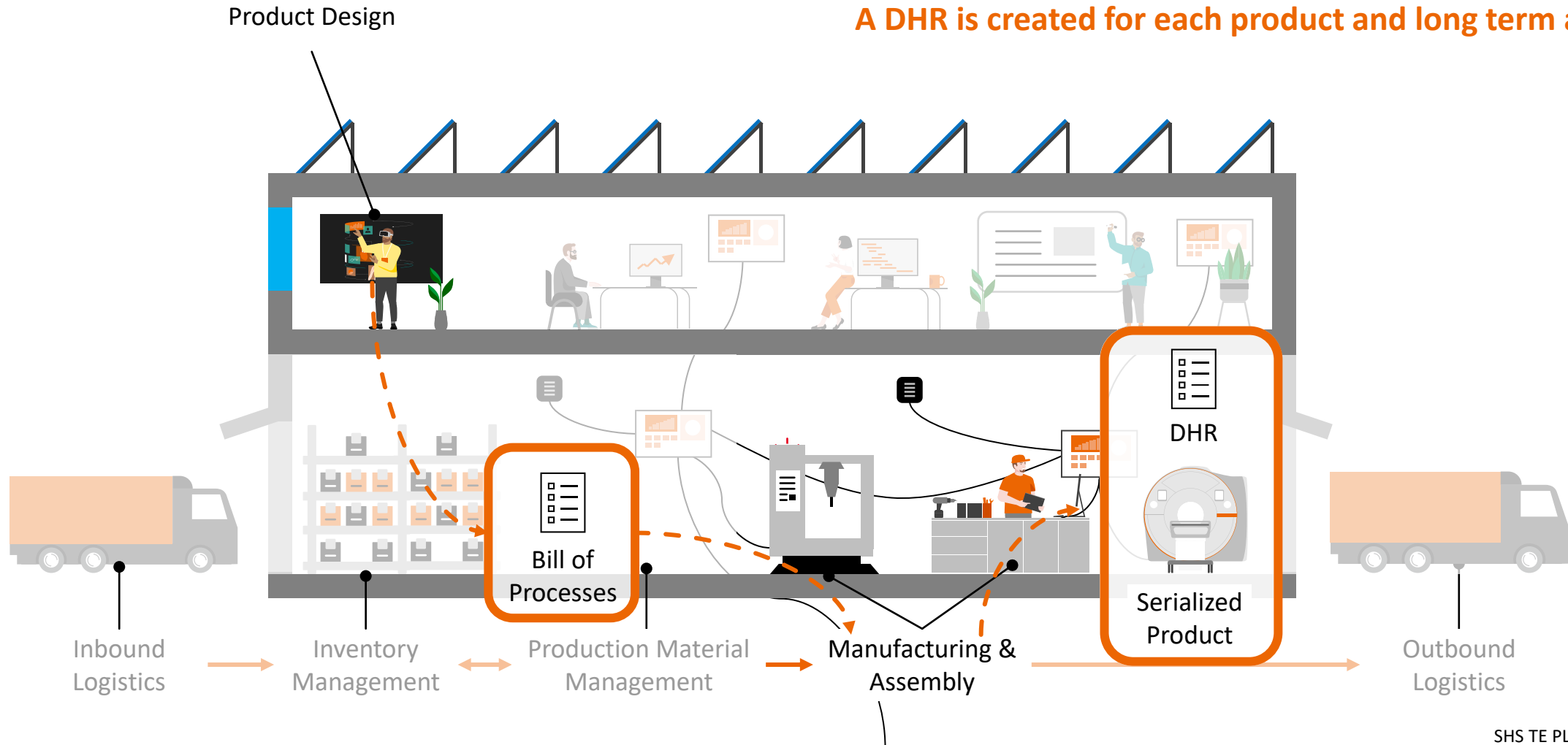


# The digital product is now converted in the physical product starting with providing material and logistics

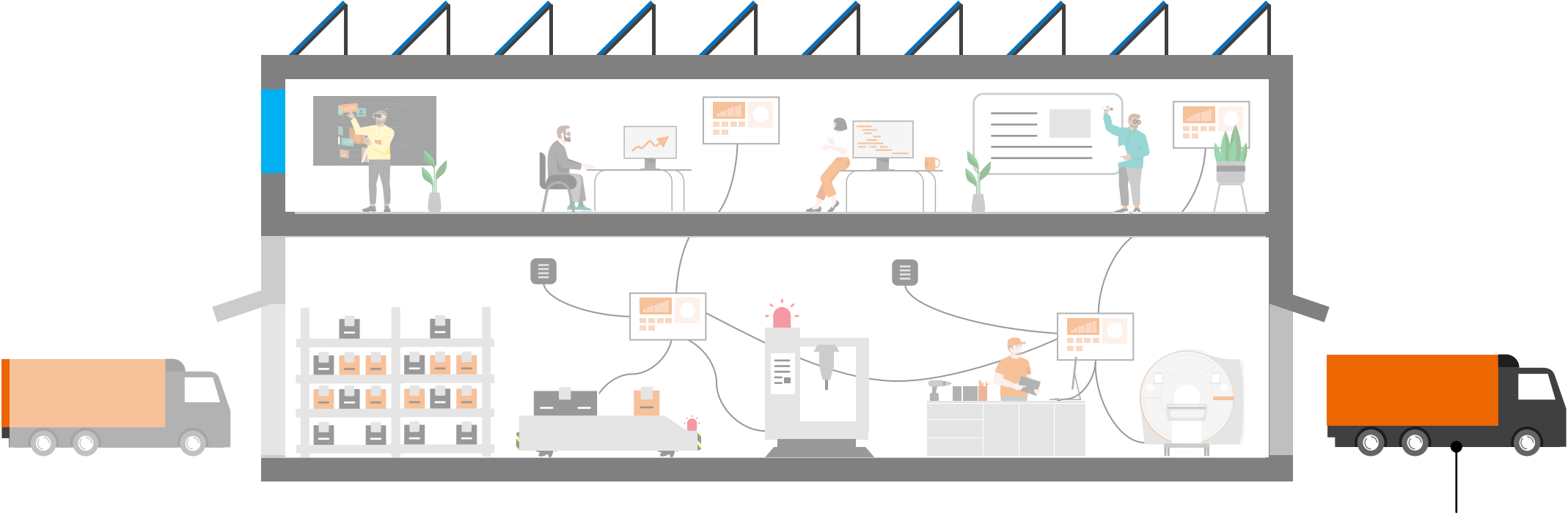


# The production order and the bill of processes are the central input for the manufacturing execution system

A DHR is created for each product and long term archived

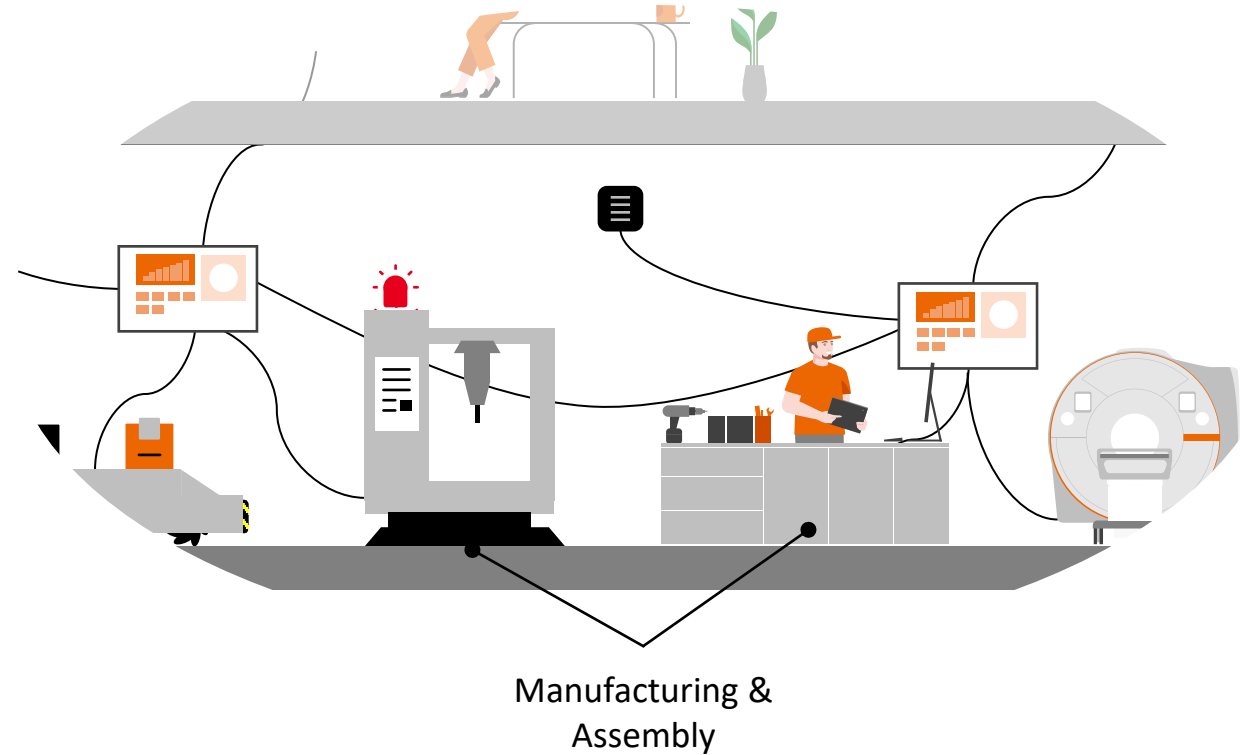
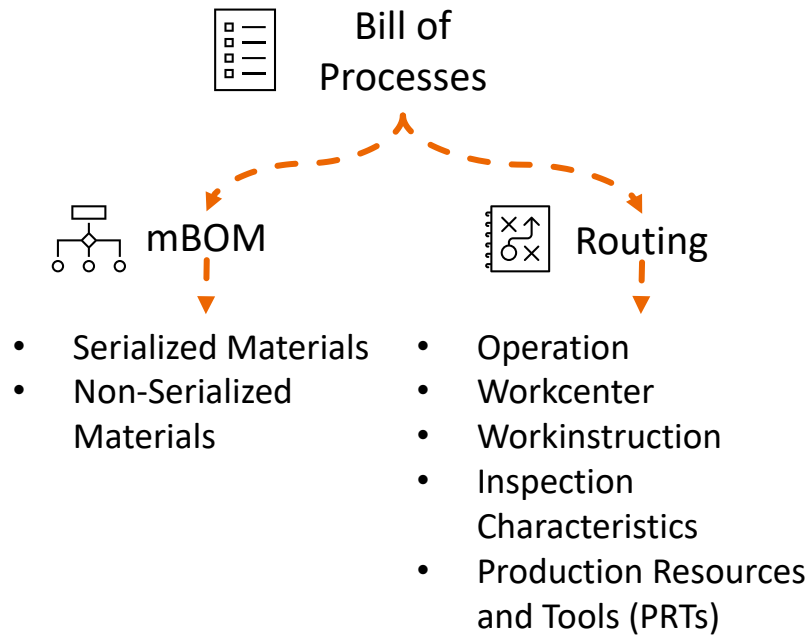


# The finished product is transported to the customer



Outbound  
Logistics

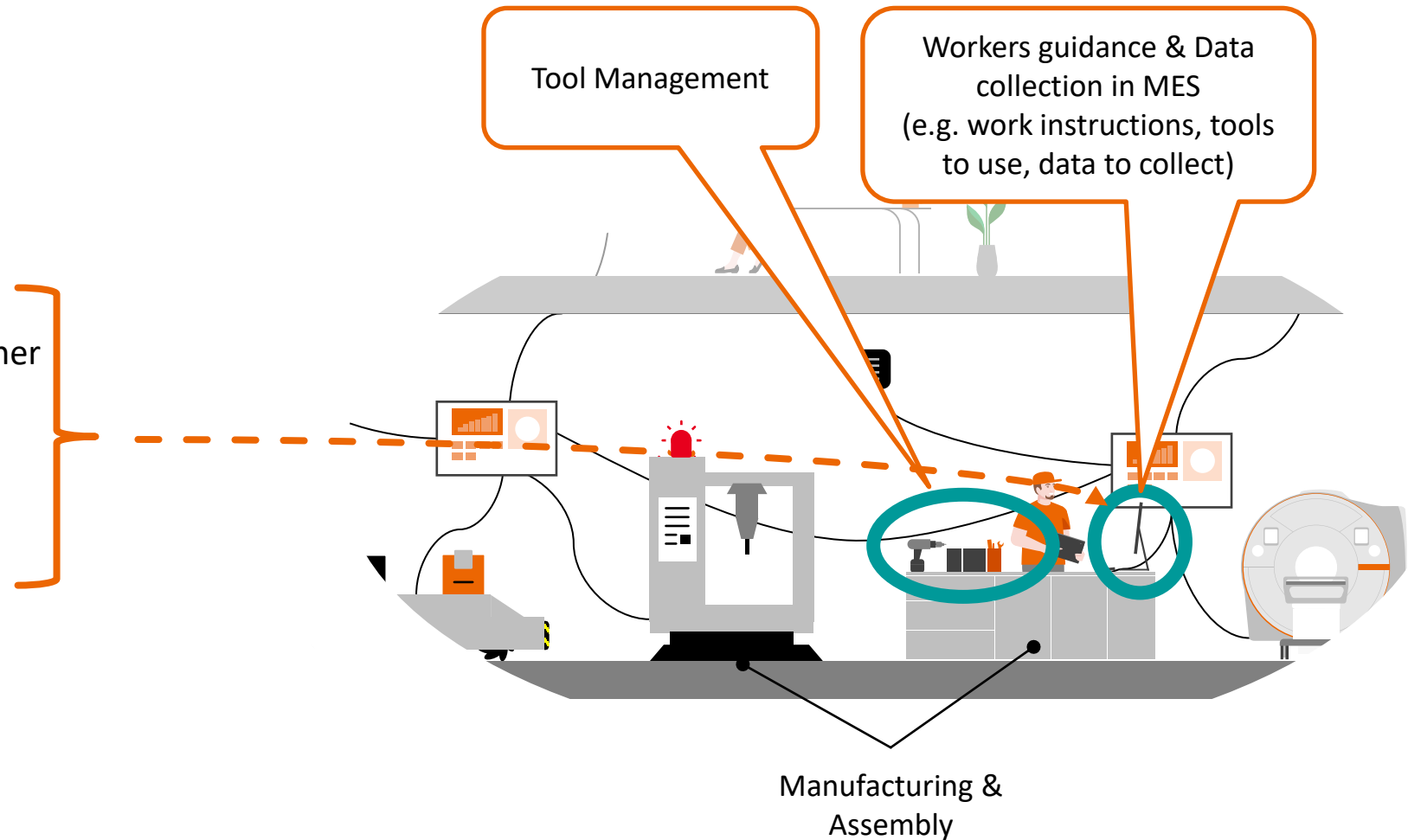
# Deep Dive: The Manufacturing Execution System is the central shop floor tool and is based upon a comprehensive Bill of Processes



# The routing describes all manufacturing steps and all information needed for a compliant production process

## Exemplary Routing

- 010: Assembly step 1
- 015: ZMT1 collection with scanner
- 020: Final machining
- 030: Assembly step 2
- 090: Testing
- 095: Check cable ties
- 900: Q-Review, 4-eyes check





# The routing describes all manufacturing steps and all information needed for a compliant production process

## Exemplary Routing

010: Assembly step 1

015: ZMT1 collection with scanner

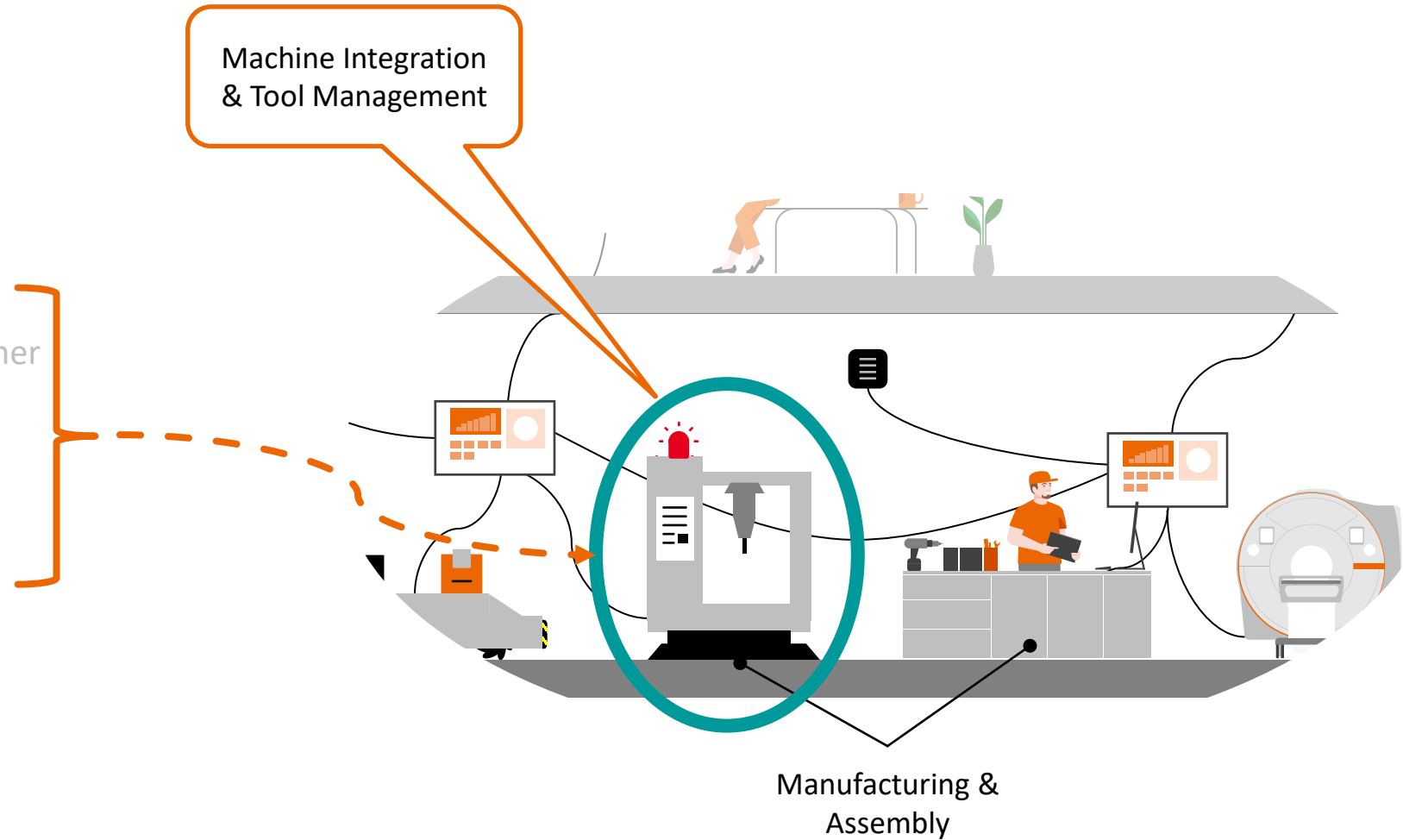
020: Final machining

030: Assembly step 2

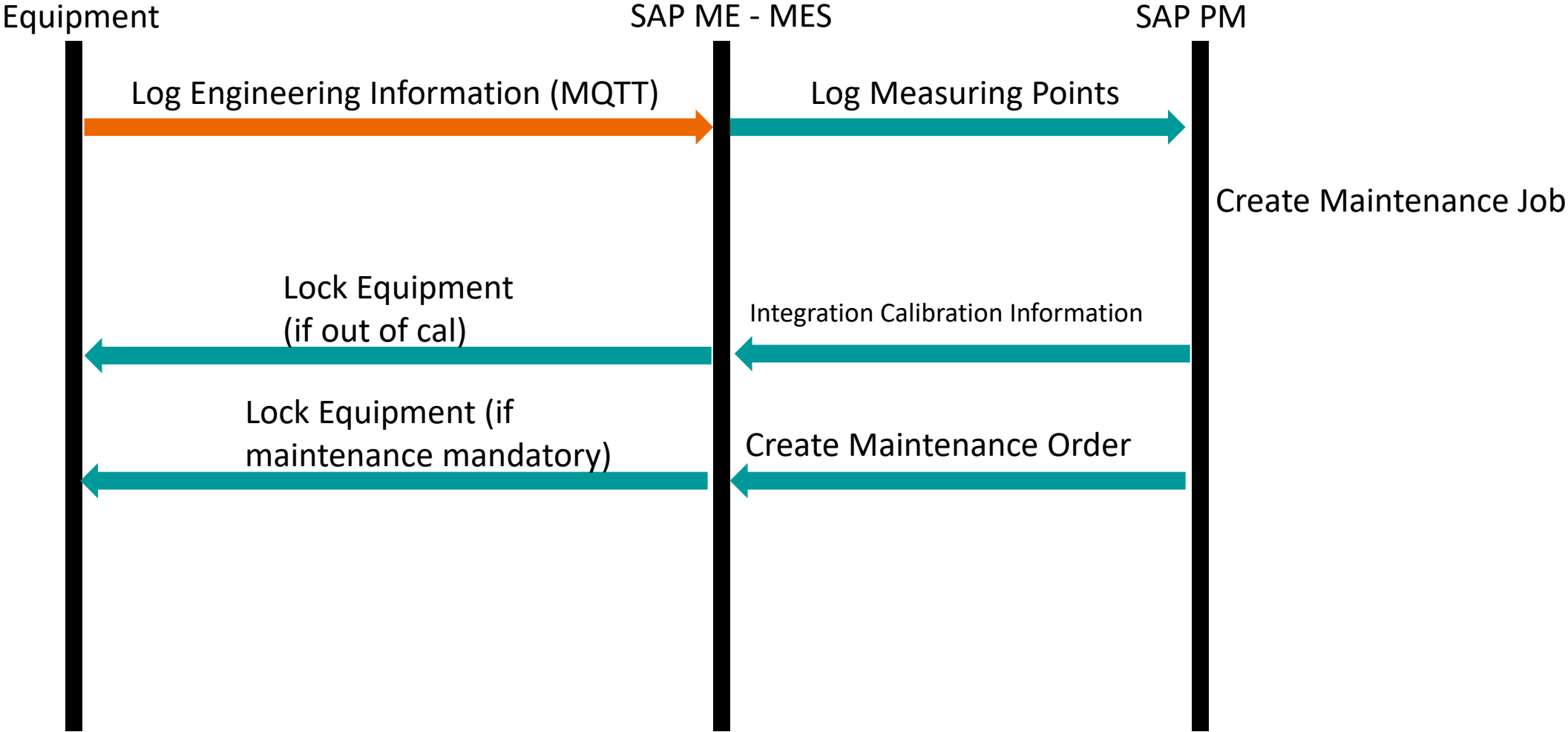
090: Testing

095: Check cable ties

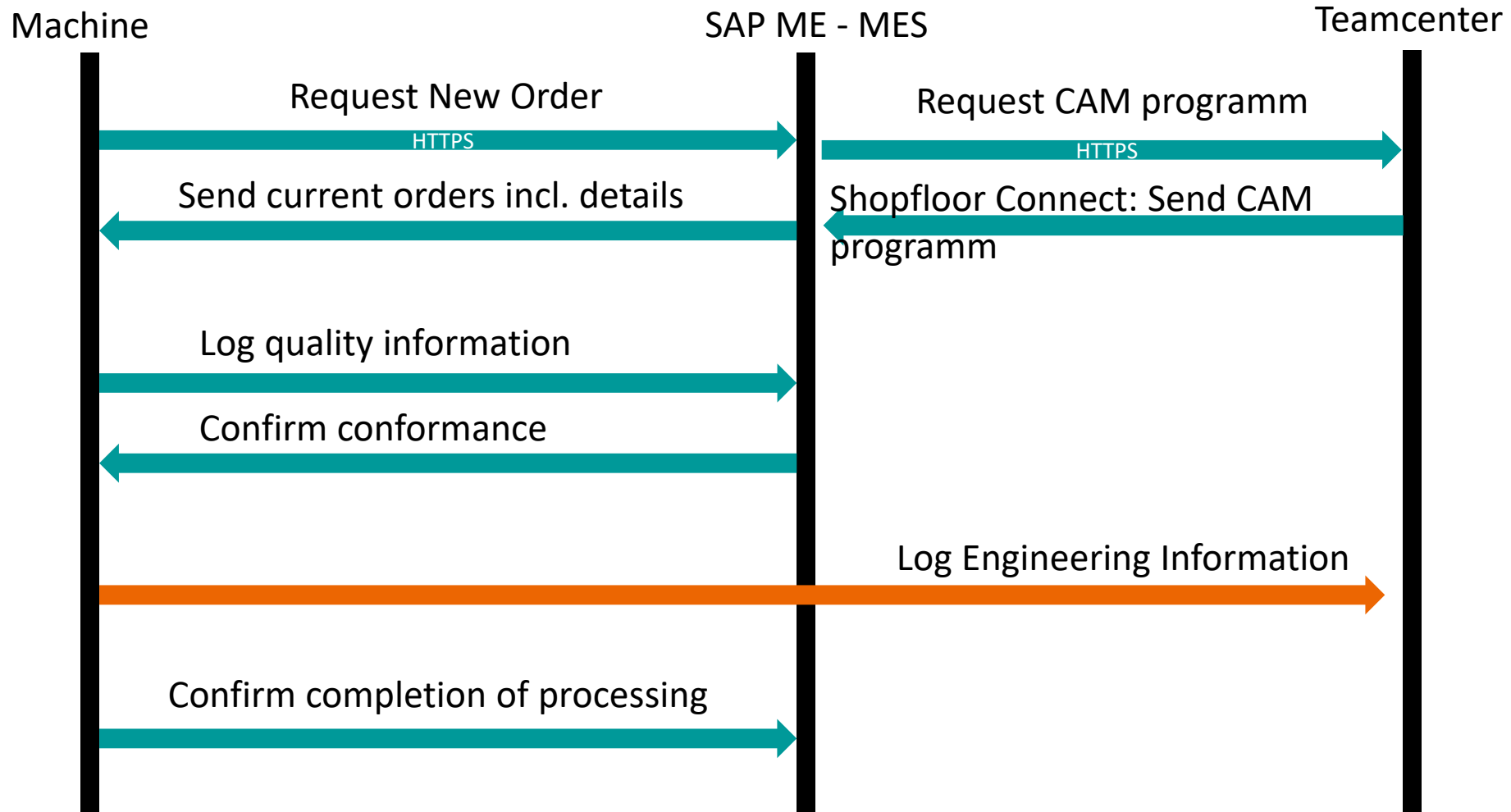
900: Q-Review, 4-eyes check



# Deep Dive: Based on the information from the equipment, the SAP Plant Maintenance module creates a maintenance order

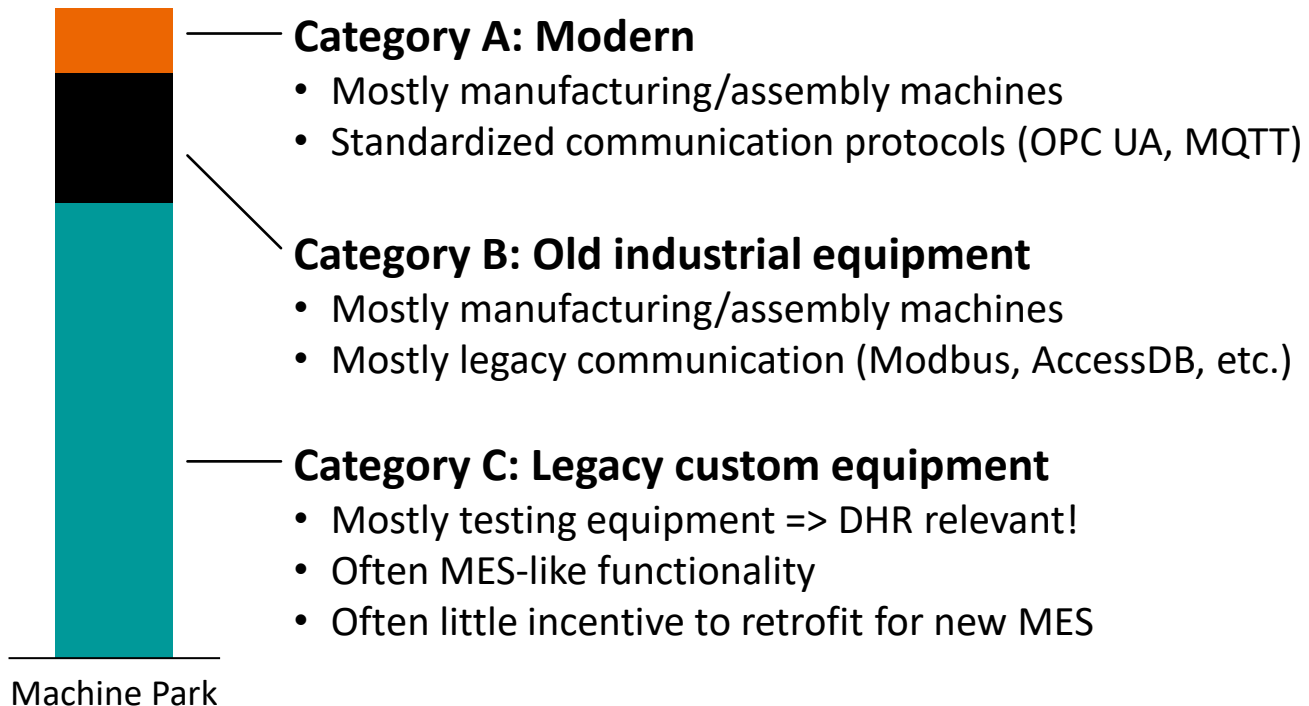


# Deep Dive: Computer aided manufacturing programs can be send from teamcenter to the machine



# Deep Dive: Siemens Healthineers brownfield approach to machine integration with SAP ME

Siemens Healthineers shopfloors: a vast, highly diverse brownfield



How to **harmonize** integration to SAP ME?



How to enable **communication** for SAP ME?



How to enable **integration** to SAP ME and transition to replacements?



# Deep Dive: Siemens Healthineers brownfield approach to machine integration with SAP ME

Siemens Healthineers shopfloors: a vast, highly diverse brownfield



How to **harmonize** integration to SAP ME?



Document best practice solutions:  
**Machine Integration Blueprint**



How to enable **communication** for SAP ME?



Standardize industrial communication to OPC UA using middleware:  
**KepServerEX as a Service**



How to enable **integration** to SAP ME and transition to replacements?



Provide well documented API for business developers to develop against:  
**Manufacturing Execution API**



# Machine Integration Blueprint

## Identified Use Cases



### DHR Creation

- Automated data collection for SAP ME eDHR
- NO consideration of BL specific infrastructure!



### Job Management

- Automated dispatching of jobs to equipment
- Possible integration of program management



### Machine Analytics

- Collection & analysis of operative machine data
- KPI generation, dashboarding, etc.

# Recent Machine Integrations

## Torque Tools

**System:** Torque Tool Drivers

**Task:** Generate eDHR Data/Transfer Setpoints

### Details

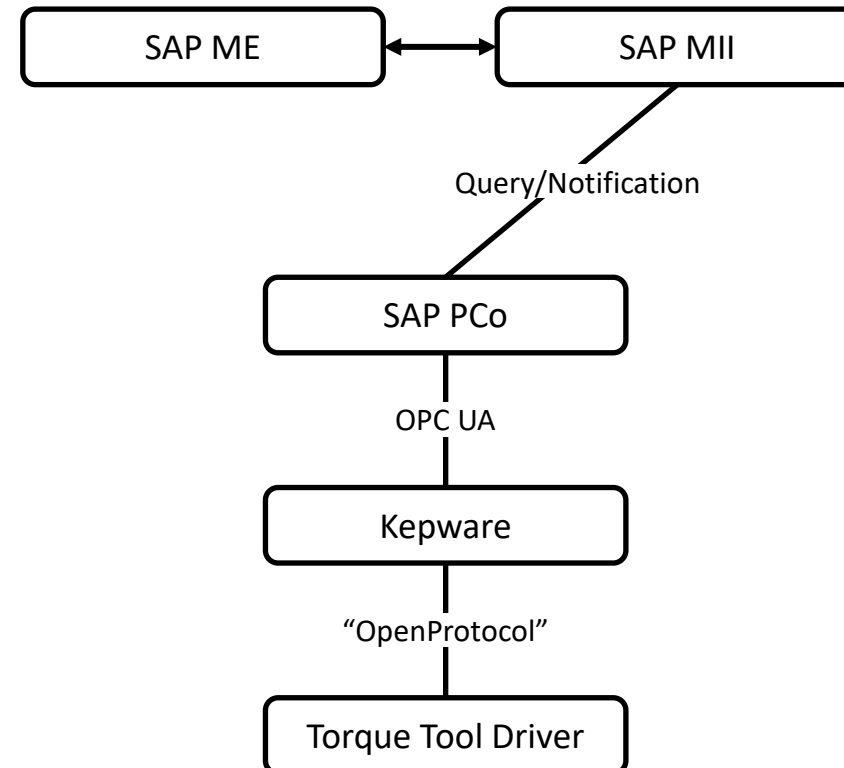
- Setpoints for required torque sent to torque tool driver\*
- Record fastening result in eDHR (numeric, pass/fail)

### Solution

- Kepware to translate vendor-specific protocol to OPC UA
- PIC to manage OPC UA tags on resource
- MII Transaction triggered by activity hooks in custom POD
- Reading/Writing to OPC UA tags via notification/query

### Challenges

- Unclear migration path to DMC



# Recent Machine Integrations

## Ovens/Autoclaves

**System:** Ovens

**Task:** Generate eDHR Data, collect analytical data

### Details

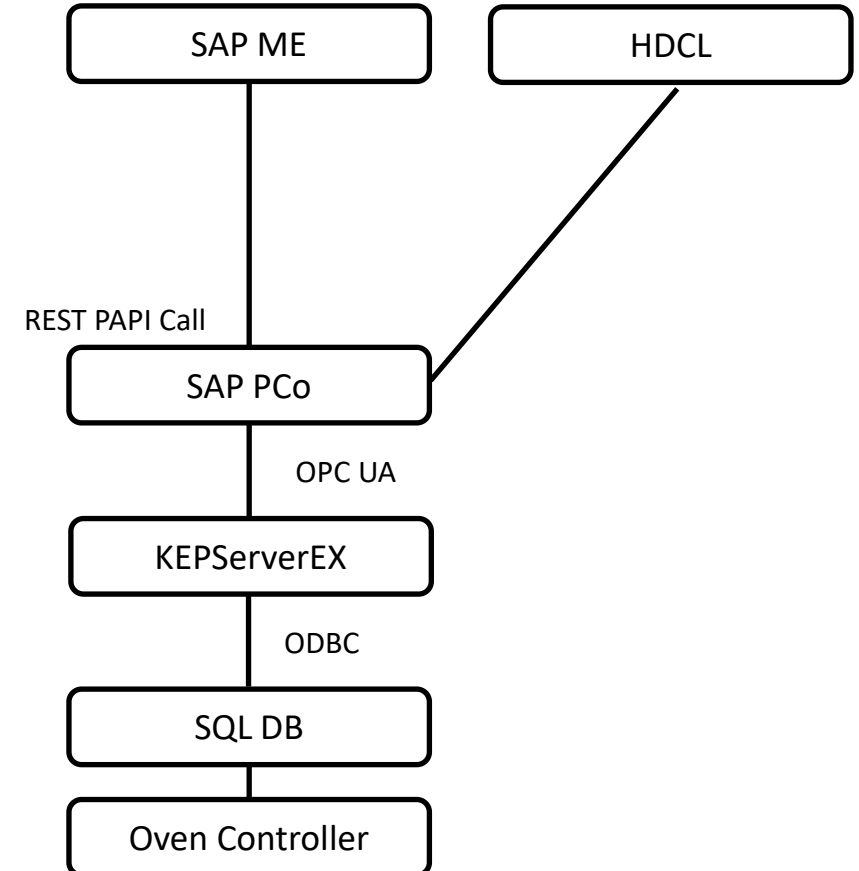
- Oven/Autoclave to impregnate magnets
- Logging in which chamber product has been processed

### Solution

- Local SQL DB to via ODBC
- KEPServerEX to access the SQL DB and trigger message to PCO

### Challenges

- Challenging network setup





# The DMC is the future solution for manufacturing execution

There are opportunities and challenges moving from SAP ME to DMC

## Opportunities

The core concepts of SAP ME and DMC are the same.

Skills and expertise from SAP ME can be transferred to the DMC.

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DMC is a **cloud-native re-implementation**. Its **service-oriented architecture** as well as the **powerful production process designer** offer the shop floor the possibility to manage integrations and process controls.

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**Shorter time to value**, as the DMC enables the shop floor to design and monitor processes and automations.

---

The DMC has a **stronger commitment to supporting GxP requirements** on its roadmap.

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**Value drivers:** Shorter training period, better guidance through the UI and shorter time to value for operations.

## Challenges

- **New qualifications** required to administer shop floor processes.
- Existing **configurations and customizations need to be re-implemented** (not re-designed) on a new technology stack.
- **Migration path** from SAP ME to DMC not yet available
- SHS requires a new **operational approach to operate and validate** this solution at scale.
- Outsourcing the Manufacturing Execution System means **outsourcing activities which are in the responsibility of the legal manufacturer**. Liability cannot be outsourced.  
→ Compliance as a service

## Next Steps

Establish a **compliance framework** that is capable to support this solution SHS-wide.

Establish a **validation approach** that can support such a solution.

Establish a **contractual relationship** that enables the outsourcing of such a manufacturing tool (compliance as a service).

Thank you  
for your enthusiasm!

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**Waltraud Winter**

Head of Smart Factory

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