Digital Solutions for the Life Sciences Industry
The connected product and manufacturing concept
An introduction

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MES & Digitalization

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Digitalization
Digitalization changes everything
New business models in the Internet age

From bookstore to e-book

From record store to streaming

From yellow pages to marketplace

From taxi to ride-sharing
Siemens has been at the forefront since the beginning of the Industrial Revolution.

1st Industrial Revolution

Water & Steam

2nd Industrial Revolution

Electrification

3rd Industrial Revolution

Automation

4th Industrial (r)Evolution

Digitalization

Digitalization is still being defined...
The (same old) business drivers

Reducing the time to market
- Shorter innovation cycles
- More complex products
- Wider product portfolios

Enhancing flexibility
- Individualization: high product variety, small campaigns
- Seasonal demand

Increasing Quality
- Closed loop quality processes
- Traceability and integrated genealogy

Increasing efficiency
- Energy efficiency and resource efficiency as key competitive factors

Product and production integrated
Flexible production
Full process transparency
Optimized production resources

Security

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Integrating and digitalizing the entire value chain is key to staying competitive in the future.
Creating a Digital Twin of the entire value chain is key to staying competitive in the future.
Integrating technical domains into ONE data model

- Digital Twin of the product
- Digital Twin of the production process
- Digital Twin of the equipment
Publishing the optimized Digital Twin to all stakeholders, including suppliers, with the collaboration platform.
Smarter products and experiences are changing the Pharma Industry too...
“Every time you talk to Siri, or use Google Maps, you are using a form of artificial intelligence. The same technology could be used in many healthcare applications, such as analyzing cancer patient data and recommending more effective treatments,”

Google Ventures President, Bill Maris
Pharmaceutical plant of the future
Increasing flexibility, faster market readiness and improved productivity

Time to market

- From idea to production
- Continuous Manufacturing
- Smart Modular Standards

Quality / Regulations

- Right first time production
- Data integrity
- Data consistency

Product Lifecycle

- Development
- Drug Substance
- Drug Product

Integrated Operations

- Integrated Engineering
  - Product design
  - Process & Plant design
  - Engineering & Commissioning
  - Operation
  - Services

Flexibility

- Personalized medicine
- Data integrity from lab to patient

Efficiency

- Operational excellence
- Resources
- International collaboration
Summary – The Vision Comes to Life

Key Advantages of Digitalization

Use Simulation to achieve foresight in the Virtual World

1. Product design
2. Process & plant design
3. Production engineering
4. Production execution
5. Services

Use Big Data Analytics to gain insight and drive continuous improvement

Drive intra-company and supplier collaboration via data integration
Innovative concepts to support digitalization initiatives in the pharmaceutical industry

**Integrated Engineering**
- COMOS & SIMATIC PCS 7
- Process planning
- Process monitoring
- Automation infrastructure

**Paperless Production**
- SIMATIC IT R&D Suite
  - LMS
- SIMATIC IT Proxector
  - APS/OPMS
- SIMATIC IT eBR
  - Electronic Work Instruction
  - Graphical Workflow
  - Review by Exception
- SIMATIC Automation
  - SIPAT
  - QBD
  - BATCH
  - DCS
  - HMI

**Continuous Production**
- Coming to commercial manufacturing – Example: Fermentation technology
  - Fermentor
  - Dryer
  - Quality check
  - Freeze storage

**PLM for vaccines production**
- Plausibility & Processes
  - Polio
  - Tetanus
  - Whooping Cough

**Manufacturing of the Future**
- SIPAT
  - Precise molecule model

**Integrated secondary lines**

**Flexible Bio Production**

**Personalized Medicines**
- BIONTECH
  - In-Vessel GMP Monodose
  - In-Vitro Therapy
  - Personalized protein drugs
Innovative concepts to support digitalization initiatives in the pharmaceutical industry

Innovative Manufacturing Concepts for Life Sciences
Continuous Oral Solid Dosage (OSD) line with direct compression is leading reference for continuous manufacturing at Janssen

Use Case → Real Time Product Release: J&J, Puerto Rico

Initial situation

<table>
<thead>
<tr>
<th>Challenges</th>
<th>Value Proposition</th>
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<tbody>
<tr>
<td>Continuous manufacturing for the first time</td>
<td>• Realize continuous quality verification</td>
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<tr>
<td>Coordination of assembled unit operations into continuous setup</td>
<td>• Enable real time product release</td>
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<td>Material tracking to link input materials to end products</td>
<td>• Shorten time to market for existing products</td>
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<td></td>
<td>• Right first time production</td>
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<tr>
<td></td>
<td>• Smaller footprint and reduced waste</td>
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</tbody>
</table>

Actual status

Janssen’s leading reference for continuous manufacturing: Continuous solid dosage manufacturing area (Janssen, Puerto Rico)

- IMATIC SIPAT
- SIMATIC PCS 7

Use Case → Real Time Product Release: J&J, Puerto Rico

Challenges

- Continuous manufacturing for the first time
- Coordination of assembled unit operations into continuous setup
- Material tracking to link input materials to end products

Value Proposition

- Realize continuous quality verification
- Enable real time product release
- Shorten time to market for existing products
- Right first time production
- Smaller footprint and reduced waste
Innovation Project at Siemens Austria (CT)

Use Case → Siemens Corporate Technology Lab Showcase for Biotechnological Processes

### Initial situation

- **1 large scale fermentor**
- ... 1 million doses

### Challenges

- Broad Range of Process Organisms
- High Variability of Process Designs
- High Flexibility in Process Executions

### Actual status

- **1,000 small scale fermentors**, each producing 1,000 doses
- ... 1 million doses

### Value Proposition

- Improved Production Processes Know-How
- Embedding into Plant Environment
- Smooth Interplay and Connection on all Manufacturing Layers
- Integration into complete Manufacturing LifeCycle:
  - From Suppliers & Materials to Production to Logistics

### Modular Equipment
- Parallelization and Multiplexing of Sensors
- Inline and Online Measurement
- Real-time Monitoring and Analysis
- Advanced Process Control

Included:
- COMOS
- SIMATIC PCS7
- SIMATIC IT eBR
- SIMATIC SIPAT
- SIMIT
- RAPIDLab

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Paperless manufacturing based on SIMATIC IT eBR reduces cycle time and discards and ensures 99% right at first time

Use Case → Paperless Manufacturing: *Baxter Healthcare, Ireland*

**Initial situation**

*Baxter Healthcare, Ireland:*
- Intravenous (IV) solutions and administration sets, premixed drugs and drug reconstitution systems
- First site in a multi-site rollout across Europe and US

**Challenges**
- Products need to be manufactured **right first time** – no remanufacturing possible
- **Verification** at the point of entry and **review** by exception
- **Reengineer** the recording and review process

**Value Proposition**
- Enhanced quota of **“right at first time”**
- Increased manufacturing **flexibility**
- Reduced discards
- Improved **compliance** and **traceability**

**Offering: Improved compliance**

**Customer Benefits**
- **Right First Time (RFT) ratio:** > 99%
- **Production schedule:** reduced to 30 min
- **Batch-release cycle time:** from **days to hours**
- **Improved compliance**
- **Large savings** due to reduced discards
Five key steps towards an integrated MES and Automation
Reducing cost and risk during engineering, review and operations

- Less cost, less risk during operations & review
- Standardized S88 model for Automated and Manual Operations
- Integrated Recipe
- Integrated Workflow
- Integrated HMI
- Integrated Deviations
- Integrated Appendices

Less cost, less risk during engineering & config
Siemens has different tools that allow manufacturers to simulate product, process and production flow

**Product and Material Simulation**

- **Accurately** predict effects of design changes
- **Earlier** in the design phases
- **Simulate complex designs** with complex physics in real-world environment
- More timely and **affordable** than physical prototyping and testing
- **Common plant model and integration** ...to discover better designs, *faster.*

**Process and Equipment Flow**

**Virtual Process Commissioning**
Test the original automation software using a simulation model

**Operator training (OTS):**
Train the interaction with the original automation software by the use of a simulation model

...to ensure efficient production and cope with increased complexity plants.

**Product and Production Flow**

**Virtual Plant Simulation**
Simulation of entire secondary production plant

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Pharmaceutical future factory - The Art of the Possible

- Novel technologies in existing and new IT systems
- Process robustness and visibility of process data
- Continuous tableting process

- User centered design and operation
- Demonstrate innovative and immersive operator experience
- Siemens automation as a cornerstone to a real industrial context
- Technology incubation and deployment
- Optimized operations and visibility
Paperless manufacturing helps to create a digital plant for personalized immunotherapies

- Central access point for data
- Avoid manual data transfer
- Enable fast scale up
- Eliminate paper-based batch reports and release by exception
- Provide intelligent guidance and planning throughout the process

- Considerable reduction in manufacturing cost
- Approaching individualized mass production
- Higher throughput without compromise on quality

“We are pleased to partner with Siemens on automating a specialized, proprietary manufacturing process for truly personalized medicine.” Ugur Sahin, CEO BioNTtech
Realization of the Digital Enterprise through Integrated Engineering and Integrated Operations

Integrated Engineering optimizes engineering and lifecycle management ...

Integrated Operations improves productivity and flexibility
Additional informations

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www.siemens.com/mindsphere