



Digitalization in the Pharmaceutical Industry

With table top exhibitions and Janssen Pharmaceutica site visit (Beerse)

When **Wednesday 21 November 2018**

Location Janssen Pharmaceutica
Turnhoutseweg 30
B-2340 Beerse

[Smoke free campus]

Visits of several digitalization applications at Janssen Pharmaceutica in Beerse will be organised in the afternoon

Table tops will be accessible during the seminar

Digitalization in the Pharmaceutical Industry

8:15 - 9:15 Registration and coffee with table top & networking opportunities

- 9:15 - 9:30 Welcome
(P. Janssen, President ISPE Belgium Affiliate)
- 9:30 – 10:15 Re-Uniting Quality and OPEX in the world of 4.0 transformation: Insights from a decade of research in Operations Excellence and Quality Management
(Prof. Friedli, St Gallen University, CH)
- 10:15 - 10:45 ISPE Pharma 4.0, A Holistic Approach
(C. Woelbeling, Werum)
- 10:45 - 10:50 ISPE Pharma 4.0 Belgium SIG
(J.Godelaine, GSK)

10:50 - 11:05 Coffee break with table top & networking opportunities

- 11:05 - 11:35 Digital Technology Innovations for Health
(W.Eberle, IMEC)
- 11:35 - 12:05 Digital twin in bioprocesses – Application to fermentation and mammalian cells culture
(R. David, Technord)
- 12:05 - 12:35 Leveraging synergies between know-how and data with self-service analytics
(J.De Wolf, Trendminer)

12:35 - 13:50 Lunch with table top & networking opportunities

- 13:50 - 14:20 Creating full transparency through holistic supply chain data sharing: the Global Pharma Tracker Platform
(F. Van Gelder, Pharma Aero)
- 14:20 – 14:50 Deep Learning: a disruption for Big Pharma?
(J. Berte, Robovision)
- 14:50 – 15:20 Introduction to Factory visits: Short Intro on Janssen Campus/JSC Factory Visit Logistics
(GM B.Van Waeyenberge, P. Cappuyns, Janssen Pharmaceutica)
- 15:20 **First wave of factory visits:**
* From paper-labeling to e-labeling in Clinical Supply
* Serialization at Janssen Supply Chain
* Continuous Mfg line at Janssen (back-up in case line is in full operation: Machine learning on automatic inspection line)
* Digitalization at Janssen: vision & achievements
- 16:20 **Second wave of factory visits**

17:20 Closing of the day with networking reception *(sponsored by Janssen Pharmaceutica)*

Digitalization in the Pharmaceutical Industry

Abstracts

Re-Uniting Quality and OPEX in the world of 4.0 transformation: Insights from a decade of research in Operations Excellence and Quality Management

(Thomas Friedli)

Lean production is currently the predominant production paradigm across industries. Steadily increasing customer demands in terms of highest quality, low cost, product variety, and flexibility require companies to continuously explore new approaches. Digitalization and availability of analytics are now opening even more opportunities to understand & improve their production systems, while Digitalization still requires a sound understanding of production management. Therefore this speech will focus on the current state-of-the-art in managing Operational Excellence in the context of 4.0 transformation drawing from the latest findings of the FDA supported Quality Metrics Research at the University of St.Gallen.

ISPE Pharma 4.0, A Holistic Approach

(Christian Woelbeling)

Pharma 4.0 - Linking Digitalization with the ICH Regulatory Guidelines

Applying the ICH Q10 Pharmaceutical Quality System to Industry 4.0 to achieve 6 Sigma in Pharma

The Holistic ISPE approach to the Control Strategy Lifecycle Management enables Data Integrity by Design

Pharma 4.0 - An interdisciplinary approach is key for a predictive Manufacturing Control Strategy

Digital Technology Innovations for Health

(Dr. Wolfgang Eberle)

Health monitoring on the go, avatar advisors, sequencing-based diagnostics, drug discovery using organs-on-chip, cell-based therapy. They benefit from sensors delivering reliable data, miniaturization saving resources and interacting at the nano-bio scale, connecting multi-modal and distributed data, process automation and integration, more efficient data processing, AI-facilitated data analysis. Imec has a long history as an innovator on microchip technology, enabling the semiconductor industry worldwide to deliver ever more computing efficiency and smart chips. Lessons learnt there have been translated to the life sciences, biotech, and medical devices businesses, leveraging digital data, smart process automation, and scalable fabrication.

Digital twin in bioprocesses – Application to fermentation and mammalian cells culture

(Robert David)

The purpose of the Technord Digital Twin is the instantaneous use and treatment of online data to help the operator in the leading of his process. This copilot is based on mathematical modeling where conceptual modeling is blended with data science (data analytics) to get the most of each approach. This presentation will be illustrated with 2 case studies from bioprocesses: alcoholic fermentation in a champagne house and mammalian cells culture for antibodies production.

Leveraging synergies between know-how and data with self-service analytics

(Jeroen De Wolf)

In this presentation, Jeroen will elaborate on the added value of self-service analytics with TrendMiner, a software platform that enables subject matter experts (SME's) to analyze process data from their PIMS more effectively, without the need of a data science background. TrendMiner packs smart algorithms in a user friendly trend-client and is as easy as using google to find relevant information on the internet. Use cases are ranging from ANALYZING unexpected process behaviour, closer production MONITORING and PREDICTING upcoming asset failures or undesirable events.

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Creating full transparency through holistic supply chain data sharing: the Global Pharma Tracker Platform

(Frank Van Gelder)

The purpose of the Global Pharma Tracker Pilot Project is to assist and support the development of a data sharing platform which makes it possible to monitor and track temperature-controlled pharmaceutical shipments end-to-end, combining standardized cargo documents, available sensor data and quality control data into a coherent and uniform data stream. In order to execute this project, certain lanes with Pharma.Aero members will be identified and set up together with the Pharma.Aero Strategic Pharma Shipper members.

Deep Learning: a disruption for Big Pharma?

(Jonathan Berte)

The previous generation of AI tools was already helpful in many process flows. However, with the advent of deep learning, we have access to powerful needle in the haystack engines, exactly what big pharma needs.

In this talk Jonathan Berte will guide you to the essentials of a typical deep learning pipeline, why it's so dependent on well curated data, and how it can transcend even the insights of field experts.

Janssen Pharmaceutica Site Visits Abstracts

1) From paper-labeling to e-labeling in Clinical Supply

Labeling of Clinical Supplies is quite complex, error prone and labor intensive. See how Clinical Supply Chain at Janssen has replaced a traditional label room by on-demand labeling and has postponed the labeling activity to the point of distribution by implementation of a JIT (just in time) solution. Get a demo of the latest e-label technology ensuring that the most up to date label is provided to the patient at the time the medication is dispensed.

2) Serialization at Janssen Supply Chain

Putting a number on a box, how hard can it be?

You will visit a Beerse packaging line with an integrated system for serialization, aggregation, component verification and brite stock UV code recognition. You will learn about or benchmark on the J&J approach to integration from enterprise L4 to shopfloor L1, our regional and local validation strategy for software & equipment, the roll-out we did across various sites and the E2E supply chain, dozens of packaging lines and on thousands of products in a context of challenging deadlines for various regulations. The importance of standardization and change management will be highlighted as well.

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3) Continuous Manufacturing Line at Janssen Pharmaceutica

You will visit the brand new continuous manufacturing line for oral solid dosage forms installed in the Drug Product Development & Clinical Supply Chain department. New OSD drug products are being developed and produced for clinical supplies on this line using either direct compression, dry granulation or wet granulation process. PAT- and/or model-based control strategies are being applied to ensure process performance and product quality. Digitalization of this production line is crucial for enabling such advanced process control strategies.

Back-up in case Continuous Manufacturing Line is in full operation:

Machine learning on automatic inspection line

To maintain a reliable and performing supply chain in combination with the highest quality standards we need to invest in high quality solutions that will help us in today's economic playing field. Digital platforms and automated solutions are strong enablers here. In this session you will get a guided tour to our automated visual inspection line featuring several digital and automation innovations which provide a competitive advantage for one of our key products at the site

4) Digitalization at Janssen: Vision and Achievements

Within today's manufacturing environment embracing the digital capabilities is key to make the next steps towards a reliable and performing supply chain. In this session we will give you an introduction on how digital is embedded into an overall strategy towards an integrated manufacturing environment and during the tour in our production site we will be able to showcase some examples of achievements and opportunities.

Digitalization in the Pharmaceutical Industry

Who should attend?

All stakeholders responsible for:

- Research & Development
- Clinical trials manufacturing and scale up
- Manufacturing & Quality Control
- Technology & Engineering & Automation
- Logistics & Distribution
- Supply Chain
- Regulatory, validation, QA & GMP

and active in:

- Pharmaceuticals
- Biopharmaceuticals
- Biologics
- API
- And related Life Science industries...

Registration

- Open for ISPE Members or Non-ISPE Members
- Registration required (before 14 November) via website : <https://www.ispe2018seminar.be/>
- Each participant will have the opportunity to attend two factory visits [*Smoke free campus*]
- Including Lunch and Networking and transport by bus
- Price :
 - 350 € (for ISPE member)
 - 75 € (for ISPE member – Young Professional (*age under 30*))
 - 600 € (for Non ISPE Member, including 1 year membership)
 - 295 € (for Non ISPE member – Young Professional (*age under 30*), including 1 year membership)
- See registration website for payment details.

Contact : info@ispe.be

- ISPE reserves the right to delay the meeting and modify the program and the place, in case of force majeure.
- Any cancellation received later than one week before the event will not be credited.

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Route to Janssen Pharmaceutica, Beerse, Belgium

From Brussels or Antwerp

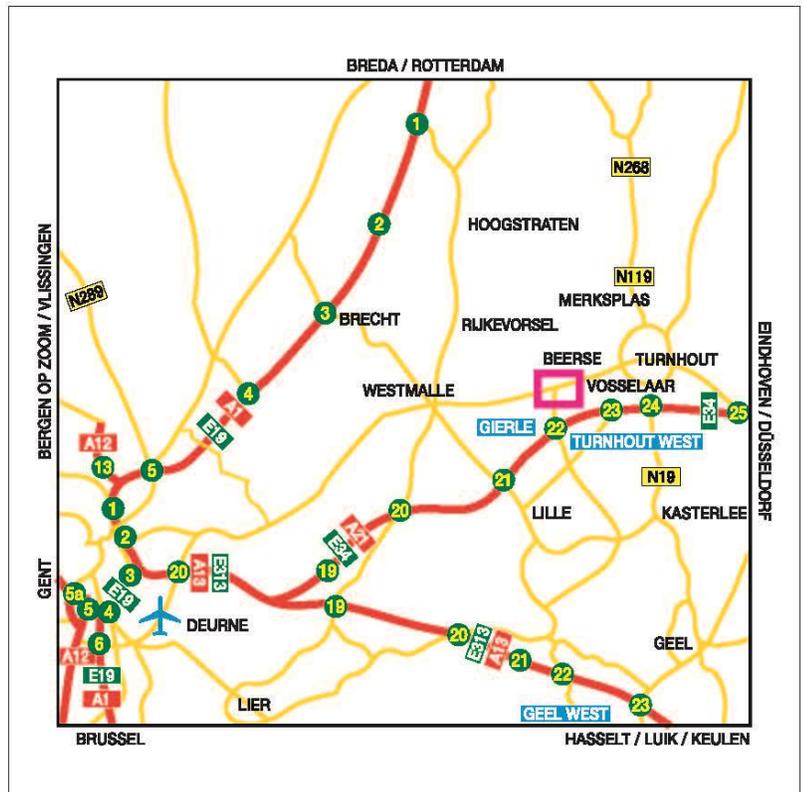
From Brussels, take highway E19 to Antwerp. After entering the tunnel, follow the signs to NL (E34). On the ring road from Antwerp, follow the signs to 'Eindhoven-Hasselt'. On highway E313 to Hasselt, there is a fork and one prong goes to Eindhoven-Turnhout. Follow the E34 until exit 22 to Gierle. Follow the signs to Beerse. At the second set of traffic lights, turn right. Janssen Pharmaceutica is about 500 m further, on the right-hand side.

From Hasselt

Follow the signs on highway E313 to Antwerp. Take exit 23 to Geel. In Geel follow the signs to Kasterlee, and then to Turnhout. Just before Turnhout, take highway E34 to Antwerp. Follow the E34 until exit 22 to Gierle. Follow the signs to Beerse. At the second traffic light, turn right. Janssen Pharmaceutica is about 500 m further, on the right-hand side.

From Eindhoven

On highway E 34 to Turnhout and Antwerp, take exit 22 to Gierle. Follow the signs to Beerse. At the second traffic light, turn right. Janssen Pharmaceutica is about 500 m further, on the right-hand side.



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