Pharma 4.0
Smart Manufacturing
Summit

#VLPharma40

Berlin, Germany
March **19-20**, 2020

RIU PLAZA BERLIN | MARTIN-LUTHER-STRASSE | 10777, BERLIN

Key Practical Learning Points of the Summit:

- Data connectivity, data management and impact on IT
- Technical and operational transformation
- Implementation of the digital strategy
- Automation and robotics
- Workforce 4.0
- Environmental monitoring and energy management
- GMP and continuous manufacturing
- Logistics optimisation
- Cyber security

Key Speakers:

Sponsorship-related questions to:
register@vonlanthengroup.com

Richard Denk, CH
Head Containment Group
Skan AG

Dr. Frank Thielmann, CH
PMO & Operational Excellence
Platform Leader, Biologics
Novartis

Davide Smaldone, IT
Corporate IT Demand Manager
MENARINI Group

Dr. Kirsten Frick, DE
Project Engineer
PHARMAPLAN GMBH

Dr. Dieter Peters, CH
President
Make Profit Growth Happen

Zinaid Dzinovic, CH
Program Manager MES
Novartis

Christian Wölbeling, DE
Senior Director Global Accounts
Werum IT Solutions

Thomas Halfmann, CH
Global Head Production IT
NNIT

Marco Stillhard, CH
Digital & Industry 4.0 Scientist
Manufacturing Science, GMS
Takeda Pharmaceuticals International AG

Stephane Dattenny, CH
Principal IT Architect
(Enterprise Architecture)
Biogen

Dr. Miran Denac, IL
SVP, Regional Manager,
IL/APAC-Respiratory
Teva Pharmaceuticals

SPEAKER OPPORTUNITIES AVAILABLE

Sponsors:

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Pharma 4.0
Smart Manufacturing
Summit

Berlin, Germany
March **19—20**, 2020

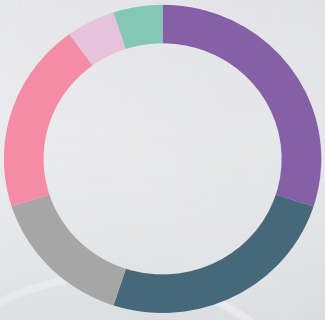
We would like to welcome you

to the *Pharma 4.0 Smart Manufacturing Summit* on March 19th-20th, 2020, in Berlin, Germany.

How does Industry 4.0 change pharmaceutical manufacturing? Transitioning to *Pharma 4.0* offers new opportunities and challenges at the same time. This event provides the appropriate platform for industry professionals and technology leaders to discuss the best practices and experience of introducing, implementing and managing emerging technology capabilities.

This *Summit* will focus on analytics and data integrity, automation, the workforce of the future, technical and operational transformation, and end-to-end integration. Through case studies, interactive presentations and discussions, attendees will discover how to start the digital transformation today!

We are looking forward to your participation this March in this engaging Summit in Berlin!



Company type

- *Pharmaceutical*
- *Biotechnology*
- *CRO*
- *CMO*
- *NOP*
- *Other*

Geographic distribution

- *Europe*
- *United States*
- *Canada*
- *APAC*
- *Other*

Who Should Attend

Chief Executives, Directors, Vice Presidents, Department Heads, Leaders, Senior Managers, Principal Scientists and Engineers specialising in:

- Medical Devices
- Robotics & Control
- CMC
- Continuous Processing
- Cell Culture Technology
- Commercialisation
- Digital Strategy & Transformation
- Data Integrity
- Diagnostics
- Quality Assurance/Control
- Pharmaceutical Manufacturing
- Product Quality
- Process Monitoring
- Pharmaceutical Manufacturing
- Packaging
- Compliance
- Emerging Technologies
- Licensing
- Lifecycle Management
- Regulatory Affairs & Licensing
- Risk Management
- Research & Development
- Track & Trace
- Scale Up & Tech Transfer
- Sterilisation
- Supply Chain
- Research & Development
- Validation
- Vaccines

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Pharma 4.0 Smart Manufacturing Summit

Day One
March 19, 2020

1 2

08:30 Registration and Welcome Coffee
09:00 Opening Address from the Chairman

REGULATORY STRATEGY

09:10

CASE STUDY

The ISPE Pharma 4.0 Operating Model - Digitizing the regulatory ICH Q10 Holistic Control Strategy and PQS

CHRISTIAN WÖLBELING
Senior Director Global Accounts
Werum IT Solutions

- How are the regulatory guidelines like ICH linked to the digitalized
- Pharma 4.0 process control management
- Can we still do with paper? How to evolve digital maturity in manufacturing and Quality Assurance
- Developing an End to End Holistic Control Strategy lifecycle management from PD, CTM, Tech Transfer up to commercial
- Discussing how digitalization based on Industry 4.0 technologies improves the Product & Process Quality

09:50 SPEED NETWORKING

A special time slot for interaction between sponsors, delegates and speakers. All participants will gather around exhibitors and share experiences with each other while creating new contacts

THE ROAD TO DIGITAL

10:30

CASE STUDY

Productivity Improvement through Digitalization

DR. FRANK THIELMANN
PMO & Operational Excellence
Platform Leader, Biologics
Novartis

- From automatization to digitalization – prerequisites for change
- Leaner process by applying digital tools
- Digital tools for visualization
- Efficient use of process data through data mining
- Data Mining, Data Analysis und Modelling

11:10 MORNING COFFEE AND NETWORKING BREAK

11:40

CASE STUDY

To be Announced

DAVIDE SMALDONE
Corporate IT Demand Manager
MENARINI Group

TECHNICAL AND OPERATIONAL TRANSFORMATION

12:20

CASE STUDY

Industry 4.0 in Aseptic Pharmaceutical Manufacturing. How can Robotics improve Product Quality.

RICHARD DENK
Head Containment Group
Skan AG

- Trend to fully automated systems in the BioPharma Industry
- How does Robotics improve GMP
- Occupational Safety using Robotics

13:00 NETWORKING BUFFET LUNCH

14:00 SPONSORED SPEAKING SLOT - RESERVED FOR

MARCHESINI GROUP

SEAVISION

14:40

CASE STUDY

Return on experience integrating an MES with Enterprise Systems using ISA-95

STEPHANE DATTENNY
Principal IT Architect (Enterprise Architecture)
Biogen

- Problems & Challenges: move from legacy to integration
- Strategy: architecture driven solution based on ISA-95
- Implementation details & benefits
- Issues, gaps and solutions
- Recommendations

15:20

CASE STUDY

Digitalisation Projects in Pharma – Examples from Teva Pharmaceuticals"

DR. MIRAN DENAC
SVP, Regional Manager,
IL/APAC-Respiratory
Teva Pharmaceuticals

- Presentation of smaller and larger digitalisation projects implemented
- Actual Return of Investment from these projects
- What to watch when implementing
- How project Return of Investment for digitalisation projects

16:00 AFTERNOON COFFEE AND NETWORKING BREAK

16:30

CASE STUDY

The Future of MES in IoT and Pharma 4.0

THOMAS HALFMANN
Global Head Production IT
NNIT

The concept of MES as a system to execute, monitor, track and report manufacturing operations in real time has been established in the pharmaceutical industry for more than 20 years. Today MES is a very critical component for most companies to embark onto the journey towards digitalization and Pharma 4.0. Although "MES for Pharma" was designed pre-IoT, it will remain as the core system to manage data and information for manufacturing of medicinal products and therefore is the key fundament for data integrity on the journey towards digitalization and Pharma 4.0. Key topics that will be discussed are:

- MES as being fundamental for safely releasing products to the market (and the patients)
- MES in cell & gene therapy manufacturing (needle-to-needle)
- Integrated information architecture of manufacturing and supply chain to ensure the safe release and supply of medicine to the market and patient

17:10 SPONSORED SPEAKING SLOT

Available opportunity for Sponsors

17:30 PANEL DISCUSSION

18:00 CHAIRMAN'S CLOSING REMARKS AND END OF DAY ONE

18:30 BUSINESS DINNER

Pharma 4.0 Smart Manufacturing Summit

Day Two
March 20, 2020

08:30 Registration and Welcome Coffee
09:00 Opening Address from the Chairman

VIRTUAL AND AUGMENTED REALITY

09:10

CASE STUDY

Virtual Mock-up of a weighing isolator

DR. KIRSTEN FRICK
Project Engineer
PHARMAPLAN GMBH

- Can virtual mock-ups replace physical models? Advantages and drawbacks
- How can virtual planning improve your project phases?
- Pharma 4.0 – beyond the planning phase: what benefits will virtual machine models have for your facility?

09:50

CASE STUDY

Virtual reality training and shop floor communication

MARCO STILLHARD
Digital & Industry 4.0 Scientist
Manufacturing Science, GMS
Takeda Pharmaceuticals International AG

- Virtual reality training for aseptic operations
  - Use-case, implementation, benefits
- Information flow through production
  - How to prototype and internal system

PACKAGING AND LOGISTICS

10:20

CASE STUDY

MES and data integrity

ZINAID DZINOVIC
Program Manager MES
Novartis

11:10 MORNING COFFEE AND NETWORKING BREAK

11:30

CASE STUDY

Transformation and excellence in manufacturing and supply chain

DR. DIETER PETERS
President
Make Profit Growth Happen

- People are the key to successful change
- Holistic business approach as key success factor
- Change of whole business process reduces interfaces & increases transparency
- Fast decision making & flawless execution drive success & culture
- Build lighthouses & win allies on all levels

12:10 NETWORKING BUFFET LUNCH

13:10 SPONSORED SPEAKING SLOT

Available opportunity for Sponsors

13:30 PANEL DISCUSSION

Moderated by Chairman of Day 2

14:00 CHAIRMAN'S CLOSING REMARKS AND END OF SUMMIT

Richard Denk, CH
Head Containment Group
Skan AG, Switzerland

Richard Denk has studied mechanical engineering and did an examination on experts of GMP, qualification and validation, pharmaceutical auditing, pharmaceutical engineering, quality control at the University of Applied Sciences in Albstadt/Sigmaringen Germany. Richard Denk works at SKAN AG, headquartered in Allschwil, as the head of sales containment. Mr. Denk founded the expert Contain¬ment Group of the ISPE DACH eight years ago. The Containment Group published the Containment Manual in September 2015. Mr. Denk has spent nearly 20 years working with highly active/highly hazardous substances and has developed the containment pyramid.

Christian Wölbeling, DE
Senior Director Global Accounts
Werum IT Solutions

Christian Woelbeling is Senior Director Global Accounts at Werum IT Solutions based in Lueneburg, Germany, part of the Körber Medipak Systems Group. Werum IT Solutions is the world's leading supplier of manufacturing execution systems (MES) and manufacturing IT solutions for the pharmaceutical and biopharmaceutical industries. Its PAS-X software product is run by the majority of the world's top 30 pharmaceutical and biotech companies and also by many mid-sized manufacturers including leading global chinese pharmaceutical organizations. He helds a Master Degree in Mechanical Engineering. Since more than 28 years working in Life Sciences Manufacturing IT, Christian has had great experience in all GMP related processes. He has broad activities inside the ISPE as Founder & Chairman of the Special Interest Group "Pharma 4.0", ISPE "GAMP MES Special Interest Group" Co-Chair, ISPE GAMP Member at large of the European Steering Committee, "Knowledge Network Council" Chair, "PAT & Lifecycle Control Strategy" CoP Steering Member, ISPE Affiliate DACH Board Member.

Dr. Frank Thielmann, CH
PMO & Operational Excellence
Platform Leader, Biologics
Novartis

Dr. Frank Thielmann has a PhD in physical chemistry/material science from the University of Duesseldorf, Germany. Frank joined Novartis Pharma (Basel, Switzerland) in July 2007 as formulation lab head. From August 2009 until February 2011 he managed the pharmaceutical development group at the Horsham site, UK. Upon his return to Basel he took on the responsibility for the local formulation technology platform until February 2012. Subsequently he joined Novartis technical operations where he was managing the setup of a new solid dosage form manufacturing facility and the transfer of the corresponding portfolio before moving to the biotechnology department as global Leader for PMO and operational excellence in November 2016. In this role Frank had an additional responsibility as operational excellence head of the new Novartis manufacturing facility for cell and gene therapeutics in Switzerland. In February 2019, Frank moved to a new responsibility in pharmaceutical development where he is a global program associate director in portfolio management. He is member of the steering committee of the material science and biotherapeutics focus group in the British Academy of Pharmaceutical Sciences.

Thomas Halfmann, CH
Global Head Production IT
NNIT

Thomas Halfmann is founder and managing partner of HGP. HGP is a healthcare industry consulting company with offices in Switzerland, Germany and Singapore. Before founding HGP, Thomas was Global Head Biopharmaceutical Operations IT and Head of the Global MES Program, both at Novartis. Thomas is an expert in paperless manufacturing, business process analysis and modelling, project management, quality management, and computer system validation with more than 20 years experience in the healthcare industry.

Marco Stillhard, CH
Digital & Industry 4.0 Scientist
Manufacturing Science, GMS
Takeda Pharmaceuticals International AG

Marco Stillhard holds a master degree in engineering from ETH Zurich. He has a strong focus on biomedical engineering and product development, which lead to an invention of a smart camera system to prevent human errors in industrial production. Before joining Takeda, he gained various intercultural experiences in Pharma through innovation projects and consulting for machine learning and AI partnering. In Takeda he was leading the digital workstream within a greenfield project, before he joined the global digital and data science team.

Dr. Kirsten Frick, DE
Project Engineer
PHARMAPLAN GMBH

Dr. Kirsten Frick studied Biochemical Engineering at the TU Dortmund University and graduated 2009 with a Diploma degree. From October 2009 until May 2014 Dr. Kirsten Frick worked on her PhD thesis at the Laboratory of Chemical Biotechnology in the Department of Biochemical and Chemical Engineering at TU Dortmund University. Her project was funded by the CLIB-Graduate Cluster Industrial Biotechnology. The aim of the project was the optimization of biological n-butanol production processes by characterizing, engineering and applying solvent-tolerant microbial production strains. After she finished her PhD, she remained as research assistant at the Laboratory of Chemical Biotechnology at TU Dortmund University. Since April 2015 Dr. Kirsten Frick works as a Project Engineer at Pharmaplan in Bad Homburg. Since then she worked as a process engineer with focus on biotech, aseptic filling and containment processes, covering all project phases from conceptual designs to full EPCM projects.

Dr. Dieter Peters, CH
President
Make Profit Growth Happen

30+ years experience as Global Operations Executive in pharmaceutical and chemical industry – turn arounds, profit improvement, reliability and supply chain optimization – North America, South America, Europe. Grunenthal: General Manager & Board Member, EVP Global Product Supply (product launch, cost reduction, cash flow & risk optimization, operational excellence, supply chain optimization, good manufacturing practice, strategy development & execution) Celanese: Site Director, Global On-Stream Reliability Champion Hoechst: Production Leader, VP R&D Organic Chemicals & Quality, Business Unit Leadership Team

Zinaid Dzinovic, CH
Program Manager MES
Novartis

Since January 2015, Zinaid Dzinovic is the Program Manager MES at Novartis Pharma Stein AG, in Stein, Switzerland. Zinaid is accountable for MES PAS-X V3 rollout including technical equipment integration and replacement of legacy systems in the Novartis sites in Stein. He is furthermore a member of the unit for Strategic Planning & PMO Stein Steriles, leading the Digital transformation initiatives and projects. In parallel, Zinaid Dzinovic hold the position as the Global Business Process Integration Lead until 2018 at Novartis AG, in Basel HQ, Switzerland. His core responsibility areas focused on the strategic planning of global Novartis MES templates and roadmap such as the development of global MES governance and process structures. In addition, he was leading the global process harmonization projects within the Novartis Steriles platform. Before taking on his current position at Novartis, Zinaid was Team Leader at Werum IT Solutions GmbH, in Lüneburg, Germany. Since 2018, Zinaid is member of the Advosory Board MES & Process Minds. Zinaid holds a Diploma in Business Science from the Osnabrück University, Osnabrück, Germany, and a Master in Business Process & Supply Chain Management from the Linnaeus University, Växjö, Schweden.

Dr. Miran Denac, IL
SVP, Regional Manager,
IL/APAC-Respiratory
Teva Pharmaceuticals

Miran is responsible for the Israel, Asia-Pacific and respiratory manufacturing and in Teva Pharmaceuticals. This comprises currently ten final dosage production plants with approximately 4000 employees and various production technologies. He held previously a cluster lead role in Europe and Site General Manager positions in Teva, including Germany (Merckle, Ratiopharm) and Croatia (Pliva). Before that, he worked in various technical and sales roles in the Swiss mechanical industry, with a significant international export market orientation. Miran graduated in Chemical Engineering and completed a Ph.D. degree at the Federal Institute of Technology (ETH) in Zurich, Switzerland. Recent business focus has been on site network consolidation, efficiency and reliability in manufacturing and supply in a competitive generic market as well as implementation of digitalisation projects for better business performance.

Thomas Halfmann, CH
Global Head Production IT
NNIT

Thomas Halfmann has more than 25 years of experience in manufacturing IT and automation in the life sciences industry. After various management positions at Novartis, including Head Global Project Office, Global MES Program Manager and Global Head Biopharmaceutical Operations IT, Thomas founded the international life sciences consulting company HGP in 2008. HGP had offices in Switzerland, Germany, Singapore, Poland and Indonesia and was acquired by NNIT in 2019. Since October 2019 Thomas is the Global Head Production IT for NNIT.

Stephane Dattenny, CH
Principal IT Architect
(Enterprise Architecture)
Biogen

Stephane is an Enterprise Architect at Biogen, responsible for the Pharmaceutical Operations & Technology functional area. Acting as Principal IT architect, he drove the integration solution for the Biogen's new Next Generation Automation program, specifically between Manufacturing and Enterprise applications, based on ISA-95 industry standard. Before Biogen, he spent more than a decade in defining and driving solutions architectures within various functional areas in a large computer and IT services company. With 22 years' experience in various IT roles, Stephane is a graduate of the Institute of Technology of Montluçon in Industrial Automation and Electrotechnics, as well as the Engineering School for Studies and Research in Informatics and Electronics of Nimes in Software Engineering and Digital Processing. The aspect of his job he finds most interesting is the possibility to dive into architecture from enterprise business and technology strategy to detailed solution architecture and design, solving complex problems through collaboration.

Our Upcoming Event:

4th Annual Aseptic Processing Summit
Frankfurt, Germany | November 19 – 20, 2020

PRE-REGISTRATION FORM

VONLANTHEN® CONFERENCES

Pharma 4.0 Smart Manufacturing Summit

Date of registration:

E-mail this form to: ***register@vonlanthengroup.com***

Upon receiving the registration form, you will get an invoice for payment.

Package name	Register in January	Register in February	Standard
☐ **Delegate: Standard**	€1495 **(save €500)**	€1795 **(save €200)**	€1995
☐ **Group Delegates: 2 +** **price per person*	€1295 **(save €700)**	€1695 **(save €300)**	€1995
☐ **Group Delegates: 4 +** **price per person*	€1195 **(save €800)**	€1495 **(save €500)**	€1995
☐ **Non-profit** [fixed price] **institutions and academics*	€1195	€1195	€1195

Hotel accommodation & travel costs are not included in the registration fee.

*As soon as a **venue** is confirmed, organizer will post the information on its website. Registered delegates will be informed by e-mail.*

To register for the Summit, please provide the details below. *This registration form is editable.*

1

Name: Surname:
Position:
Company: *If different from invoicing details*
E-mail:
Special dietary requirements: ☐ Vegetarian ☐ Gluten-free ☐ Other (please specify)

2

Name: Surname:
Position:
Company: *If different from invoicing details*
E-mail:
Special dietary requirements: ☐ Vegetarian ☐ Gluten-free ☐ Other (please specify)

3

Name: Surname:
Position:
Company: *If different from invoicing details*
E-mail:
Special dietary requirements: ☐ Vegetarian ☐ Gluten-free ☐ Other (please specify)

4

Name: Surname:
Position:
Company: *If different from invoicing details*
E-mail:
Special dietary requirements: ☐ Vegetarian ☐ Gluten-free ☐ Other (please specify)

Payment method: ☐ Wire transfer ☐ Credit card

Terms and Conditions:

By sending this form, I confirm that I have read and accepted the Terms and Conditions.

Registration Confirmation and Payment Policy: *The organizer will confirm your participation after receiving the signed registration form. The client will receive the invoice within 24hrs of sending the signed form. The organizer requires the full payment of the registration fee within 10 working days of the invoice issue date. Registration fee includes 2 days participation, refreshments, lunches, dinner, and documentation package. Payments can be made by bank transfer or credit card. Payments by bank transfer are in Euros.*

Cancellations and Substitutions: *A delegate may be substituted up to 5 days before the event. Cancellation made one month prior to the start date of the event will be refunded less 50% of the registration fee. Refunds will be made after the event. Cancellations made within one month of the event start date will result in no refund. A written notice is required for cancellation. But the organizer understands that there are unforeseen circumstances that cause cancellations, in such events the organizer can provide a delegate-pass to an upcoming event that will be valid for one year from original event start date. Please note that the delegate-pass cannot be refunded due to further cancellation.*

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Promotional material distribution:	**Price**
☐ *Distribution of your company's promotional materials to all conference attendees*	€999
Documentation package:	
☐ *I cannot attend but would like to purchase the documentation package for this event*	€499

***Presentations** that are available for download will be subject to distribution rights by speaker*

Sponsorship packages	Presentation ☐ €2,999	Pop-up Stand ☐ €3,999	Bronze ☐ €5,999	Silver ☐ €6,999	Gold ☐ €8,999	Platinum ☐ €11,999
People attending	1	1	2	2	3	4
Logo on conference website, program, and pre/post-event communication activities	◆	◆	◆	◆	◆	◆
Discount on additional passes	10%	10%	15%	20%	30%	40%
Promotional material distribution (provided by sponsor)	◆	◆	◆	◆	◆	◆
Recognition on Vonlanthen Group's SM channels			◆	◆	◆	◆
Ad placed in final conference program			¼ Page	¼ Page	½ Page	Full Page
Recognition in chairman's opening address			◆	◆	◆	◆
Speaking slot	20 min			30 min	40 min	20 min
Pop-up Stand		◆	◆	◆	◆	
Host own seminar/workshop within the conference						40 min
Recognition in press release					◆	◆
Exhibition Booth with monitor for video presentations						◆

For more information on the packages and to discuss your sponsorships requirements, please contact:* ***sponsorship@vonlanthengroup.com*