



# FREEZE-DRYING TECHNOLOGY SUMMIT

Advances & Implementations in  
Pharmaceutical, Food and  
Cosmetics Industries



Vienna, Austria  
February 13 - 14, 2020  
#VLFreezeDrying

HILTON GARDEN INN VIENNA SOUTH | HERTHA-FIRNBERG-STRASSE 5 | 1100 VIENNA, AUSTRIA

## Key Practical Learning Points of the Summit:

- Current regulatory considerations
- Cleaning and cross-contamination requirements for non-product contact surfaces
- Novel concepts of freeze-drying
- Process optimisation, monitoring and control
- Innovations in formulation development
- QbD and PAT approaches
- Strategies for scaleup from R&D scale to full production level
- Technologies overview and advantages in manufacturing
- What is the new role of sterile and lyophilised products manufacturing in the future
- Spray-drying Applications
- Freeze-drying for food industry

## Keynote Speakers:



Sponsorship-related questions to:  
[register@vonlanthengroup.com](mailto:register@vonlanthengroup.com)



**Dr. Mostafa Nakach, FR**  
Head of Formulation & Process Development  
Biologics Drug Product Development  
**Sanofi**



**Dr. Andrea Weiland-Waibel, DE**  
Managing Director  
**Explicat Pharma GmbH**



**Bert Van Meervenne, BE**  
Senior Manager Aseptic Process Development  
**Pfizer**



**Dr. Stefan Schneid, DE**  
Laboratory Head Development Parenterals  
**Bayer**



**Prof. Davide Fissore, IT**  
Professor of Advanced Process Control, Process  
Design, and Food Processes & Technologies  
**Politecnico di Torino**



**Bernadette Morel, NL**  
Scientist, Bioprocess Development &  
Application  
**DSM Biotechnology Centre**



**Dr. Audrey Maudhuit, FR**  
European Process Engineer  
**Fluid Air**



**Hendrik Kneusels, DE**  
Commercial Director  
**Antares Vision**



**Prof. Geoff Smith, UK**  
Professor of Pharmaceutical Process  
Analytical Technology  
**De Montfort University**



**Franz Bosshammer, DE**  
Global Technology Partner  
**Pharmaplan GmbH**



**Filip Dorozinski, AT**  
Manufacturing Scientist Formulation,  
Fill, Finish  
**Takeda**



**Dr. Maja Anko, SI**  
Senior scientist in Drug Product Development  
**Novartis**



**João Henriques, PT**  
Team Leader –  
R&D Drug Product Development  
**Hovione**



**Dr. Paul Matejschuk, UK**  
Principal Scientist & Section Head,  
Standardization Science  
Analytical & Biological Sciences Division  
**National Institute for  
Biological Standards & Control (NIBSC)**



**Xulei Wu, US**  
Senior Food Scientist  
**Space Food Systems Laboratory  
Human Health and Performance Contract  
MEI Technologies | NASA**

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# FREEZE-DRYING TECHNOLOGY SUMMIT

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Vienna, Austria  
February 13 - 14, 2020

## We are pleased to invite you to the Freeze-Drying Technology Summit

scheduled for **February 13th and 14th 2020**, in **Vienna, Austria**.

**This event provides** the appropriate platform for industry leaders to discuss process innovation and technical aspects in lyophilisation for the pharmaceutical industry, as well as food and cosmetics manufacturers, regulatory agencies and academia.

**The summit will be focussed on** practical considerations for freeze-dried formulation development, process optimisation, validation and control. We will discuss the advancing concepts and regulatory considerations for lyophilised biologics, spray-drying of biologics, vaccines, new-wave of cosmetic ingredients and highly potent products.

We are looking forward to your participation in this engaging Summit in Vienna this coming February!

### Sponsorship

**Vonlanthen Group of Companies has** extensive contacts with key decision makers at the world's biggest companies. Our events and conferences bring industry leaders, deal makers, financiers and investors under one roof, providing you with unique sponsorship and branding opportunities that can deliver an immediate impact and put your message in front of a targeted, specialist audience.

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### Who Should Attend:

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

- ▶ Lyophilisation
- ▶ Parenterals
- ▶ Vaccines
- ▶ Pre-Filled Syringes
- ▶ Bioprocess
- ▶ Characterisation
- ▶ Container Development
- ▶ CMC
- ▶ Drug Development
- ▶ Engineering
- ▶ Freeze-Drying
- ▶ Formulation
- ▶ Licensing
- ▶ Packaging & Labelling
- ▶ Process Technology
- ▶ Process Monitoring & Control
- ▶ Process Analytics
- ▶ Product Innovation
- ▶ QA/QC
- ▶ Risk Management
- ▶ Regulatory Affairs
- ▶ Research & Development
- ▶ Stability
- ▶ Standardisation
- ▶ Sterilisation
- ▶ Validation
- ▶ Cell Manufacturing
- ▶ Quality Assurance
- ▶ Plant Management
- ▶ Food Processing
- ▶ Freeze-Dried Foods
- ▶ Expedition/Emergency Food
- ▶ Cosmetics Manufacturing
- ▶ Innovation

**“ We will discuss the advancing concepts and regulatory considerations for lyophilised biologics, vaccines, new-wave of cosmetic ingredients, and highly potent products. ”**





# FREEZE-DRYING TECHNOLOGY SUMMIT

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Cosmetics Industries

Day One  
February 13, 2020

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

1

2

## PROCESS VERIFICATION

09:10

### CASE STUDY

#### **Lyocycles process verification**

**DR. ANDREA WEILAND-WAIBEL**

Managing Director  
Explicat Pharma GmbH



- Recent experiences with continued process verification of lyocycles
- Implementation of product temperature as a control in the process

09:50



### SPEED NETWORKING

An innovative approach to maximize networking capabilities through two minute periods, where delegates can meet their peers and exchange business cards before rotating to the next company representative.

10:30

### CASE STUDY

#### **Data preparation for multivariate process verification of formulation, filtration, filling and lyophilisation in pharmaceutical manufacturing**

**FILIP DOROZINSKI**

Manufacturing Scientist Formulation, Fill, Finish  
Takeda



- Continuous process verification
- Data sourcing and contextualisation
- Algorithmic feature extraction

11:10



### MORNING COFFEE AND NETWORKING BREAK

11:40

### CASE STUDY

#### **Scaleup and transfer of freeze-drying processes**

**DR. STEFAN SCHNEID**

Laboratory Head Development Parenterals  
Bayer



- Introduction and contributing factors
- Influence of vial configuration and loading system
- Practical experiences for project transfers
- Recommendations and conclusions

12:20

### CASE STUDY

#### **Optimisation of industrial freeze-drying cycle**

**DR. MOSTAFA NAKACH**

Head of Formulation & Process Development  
Biologics Drug Product Development  
Sanofi



- Two old products of the 60s (called A and B) performed with historical cycles in subcontract manufacturing, to be transferred back in the company
- Historically very few process or physical chemistry data available due to the age of the products
- Pharmaceutical elegance issues reported for both products
- Redevelopment and validation of industrial freeze-drying cycle taking into account equipment and product constraints

13:00



### NETWORKING BUFFET LUNCH

14:00

### CASE STUDY

#### **Monitoring of a freeze-drying process using infrared thermography and multivariate image analysis**

**PROF. DAVIDE FISSORE**

Professor of Advanced Process Control,  
Process Design, and Food Processes & Technologies  
Politecnico di Torino



- Non-invasive way of using infrared camera for vial temperature measurement
- Enabling the use of in-silico simulation for process design and optimisation with mathematical model
- A statistical process control system designed to efficiently detect undesired events occurring during the process
- Information obtained through a standard RGB camera included in the PAT system



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Day One  
February 13, 2020

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2

14:40



## SPONSORED SPEAKING SLOT

### SPONSORED KEYNOTE

#### Fully automated visual inspection system for freeze-dried products

**HENDRIK KNEUSELS**

Commercial Director  
Antares Vision



- Latest technology
- Research project Horizon 2020
- Savings potential compared to manual control
- Leakage check CCI for freeze-dried products

15:10

### CASE STUDY

#### Primary drying endpoint determination

**BERT VAN MEERVENNE**

Senior Manager Aseptic Process Development  
Pfizer



- Endpoint determination by temperature measurements
- Endpoint determination by pressure measurements
- More recent PAT tools: RGA, TDLAS

15:50



## AFTERNOON COFFEE AND NETWORKING BREAK

16:20

### CASE STUDY

#### Impact of excipients and its polymorphs on lyophilization process and stability of biopharmaceuticals

**DR. MAJA ANKO**

Senior scientist in Drug Product Development  
Novartis



- Protein/stabilizer ratio and excipients' polymorphs play important role on lyophilization process development and stability of lyophilized protein drugs and therefore should be carefully characterized during the product development
- Real product collapse temperature is heavily dependent of formulation and method of measurement
- In house modelling and simulation software allows automatic construction of the process design space
- With accurately determined collapse temperature and constructed design space most optimal lyophilization cycle can be selected

17:00

### CASE STUDY

#### Impact of vacuum-induced ice nucleation on preparing freeze-dried biologics

**DR. PAUL MATEJTSCHUK**

Principal Scientist & Section Head, Standardisation Science  
Analytical & Biological Sciences Division  
National Institute for Biological Standards & Control (NIBSC)



- The impact of freezing in the lyophilisation of biologics
- Application of vacuum induced nucleation (VIN) technology
- Outcome of drying with VIN applied to reference materials

17:40



## PANEL DISCUSSION

**Moderated by the Chairman**  
**Topic to be announced**

With The Speakers from Day 1

18:20



## CHAIRMAN'S CLOSING REMARKS AND END OF DAY ONE

19:00



## BUSINESS DINNER



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# FREEZE-DRYING TECHNOLOGY SUMMIT

Advances & Implementations in  
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Day Two  
February 14, 2020

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

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## SPRAY-DRYING APPLICATIONS

09:10 **CASE STUDY**  
**Spray-drying of biologics:  
applications and case studies**  
**JOÃO HENRIQUES**  
Team Leader – R&D Drug Product Development  
Hovione



- Basic principles and overview of spray drying
- Spray drying vs. freeze drying
- Spray drying as an enabling technology for biologics
- Advantages and disadvantages of spray-drying for the isolation of biologics

## 09:50 SPONSORED SPEAKING SLOT

**SPONSORED KEYNOTE**  
**Gentle spray-drying process for  
thermosensitive products**  
**DR. AUDREY MAUDHUIT**  
European Process Engineer  
Fluid Air Polar Dry



- The patent pending PolarDry® electrostatic spray dryer utilizes
- electrostatic technology which allows to work at low temperature
- Product drying temperatures as low as ambient to 80 °C
- Good encapsulation efficiency and agglomeration during drying
- Eliminating active ingredient loss, degradation, or denaturalization
- Good flowability and hydration of the products - Applications: bacteria, vitamins, carotenoids, omega 3 and so on 2

## NOVEL CONCEPTS OF FREEZE-DRYING

10:20 **CASE STUDY**  
**Novel electrical impedance methods in  
formulation and process development**  
**PROF. GEOFF SMITH**  
Professor of Pharmaceutical Process  
Analytical Technology  
De Montfort University



- Introduction to electrical impedance and dielectric relaxation spectroscopy
- Micro-scale measurements in a freeze-drying microscope; applications for formulation screening
- In-vial measurements in a freeze-dryer: applications for process development

## 11:00 MORNING COFFEE AND NETWORKING BREAK

11:30 **CASE STUDY**  
**Natural cooling agents in freeze-drying  
or how to shape the future**  
**FRANZ BOSSHAMMER**  
Global Technology Partner  
Pharmaplan GmbH



- "Warm-Up"
- Current Technologies - Trends - Suppliers Strategies
- Fit for Future - Options to Improve existing
- Case Study: Do everything first time
- Resume

12:10 **CASE STUDY**  
**Freeze-drying for food culture products**  
**BERNADETTE MOREL**  
Scientist, Bioprocess Development & Application  
DSM Biotechnology Centre



- Formulation
- Defining freeze-drying process conditions for commercial production scale
- Product stability

## 13:00 NETWORKING BUFFET LUNCH





## FREEZE-DRYING TECHNOLOGY SUMMIT

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Day Two  
February 14, 2020

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14:00

### CASE STUDY

#### Freeze-Drying Application and Challenges for Space Food System

##### XULEI WU

Senior Food Scientist  
Space Food Systems Laboratory  
Human Health and Performance Contract MEI  
Technologies | NASA

- Brief space food history
- Freeze-dried food quality measures
- Freeze-drying cycle optimization to deliver best food quality
- Nutrition, Texture, Odor, Flavor
- Shelf life of freeze-dried food
- Challenges of developing food system to support future space exploration missions

14:40



### SPONSORED SPEAKING SLOT

Sponsored Presentation Slot Available

15:10



### PANEL DISCUSSION

Moderated by the Chairman  
Topic to be announced

With The Speakers from Day 2

15:50



### CHAIRMAN'S CLOSING REMARKS AND END OF SUMMIT

16:00



### FAREWELL COFFEE

## Our Upcoming Events:

**Pharma 4.0 Smart Manufacturing Summit**  
Berlin, Germany | March 19 - 20, 2020 |



Sponsorship-related questions to:  
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## Speakers' Biographies

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**Dr. Mostafa Nakach, FR**  
Head of Formulation & Process Development  
Biologics Drug Product Development  
**Sanofi**



Dr. Mostafa Nakach is a PhD from Toulouse University. He has prepared his thesis on stabilisation and production of nanocrystalline suspension. He is also a Master II graduate from Paris-Sud University in pharmacotechnie and biopharmacy, and a pharmaceutical engineer from École des mines d'Albi. Mostafa has been working within Sanofi Group for 32 years. His current position is a head of formulation and process development section within biologics drug product development. His mission is to build and to manage the required skills and capabilities in order to support R&D projects development mainly for fill and finish commercial process development of biotech products, including freeze-drying.



**Dr. Andrea Weiland-Waibel, DE**  
Managing Director  
**Explicat Pharma GmbH**



Dr. Andrea Weiland is a managing director of Explicat® Pharma GmbH, a privately-owned company, providing technical project management services and pharmaceutical development services to the pharmaceutical industry (CMC). Andrea is a pharmacist with a PhD in pharmaceutical technology on biodegradable microspheres and cyclodextrins (Ludwig Maximilian University, Munich). She held several leading roles within Pfizer, working as project manager in process technology and being responsible for technology transfer and process development, mainly on sustained release solid dosage forms. Within R&D she was a responsible scientist for pharmaceutical development (Phase I - III, candidate characterisation, and lyophilisation projects). After joining IDEA AG, a biotechnology company based in Munich, Andrea held the position of director of pharmaceutical development and was responsible for process technology development, drug delivery system development (liposomes, patches), formulation of recombinant proteins, analytical development and clinical supplies manufacturing. She also served as IDEA's QP and is the founder of Explicat Pharma GmbH and has been the managing director since 2005. She and her team's experience cover the development of biopharmaceuticals (e.g. recombinant factor VIII), development of lyoformulations and lyocycles, analytical development, related QA and regulatory issues. Explicat Pharma has been assigned several projects, involving the modern process validation approach, including lyocycle robustness testing. Andrea is a qualified individual and a member of AAPS and several other professional institutions, based in Europe, including APV, DphG, Bay, LAK and A3P.



**Franz Bosshammer, DE**  
Global Technology Partner  
**Pharmaplan GmbH**



Franz Bosshammer has a degree in mechanical engineering, as well as an MBA. Prior to joining NNE Pharmaplan in October 2012, Franz has filled various positions, such as process engineer and sales director in the supplying industry for pharmaceutical, aseptic fill and finish machines. His latest employment was as a general manager at Optima Group Pharma. He started his career in the field of process engineering in 1986. Franz has more than 30 years of experience in development and manufacturing of machines for aseptic pharmaceutical operations, with a special focus on freeze-drying technology. Franz has been engaged in various international fill and finish projects over the course of his career.



**João Henriques, PT**  
Team Leader – R&D Drug Product Development  
**Hovione**



João Henriques is a biological engineer by training. He specialised in process monitoring and control for pharma and biopharma processes, having trained in Bayer and Merck KGaA and worked in Roche as a consultant before joining Hovione in 2008 as a PAT specialist. João has worked in the manufacturing systems efficiency group and later as a formulation and process development scientist since 2013. He has supported development and validation of spray-drying, jet-milling, roller compaction and tabletting projects. João is currently the team leader for the formulation group at Hovione's drug product development.



**Dr. Paul Matejschuk, UK**  
Principal Scientist & Section Head,  
Standardization Science  
Analytical & Biological Sciences Division  
**National Institute for  
Biological Standards & Control (NIBSC)**



Dr. Paul Matejschuk leads a formulation and freeze-drying team at NIBSC focussed on delivering lyo solutions for biological reference materials, many of them WHO international reference preparations (joined NIBSC in 2001). He has over 30 years' postdoctoral experience in downstream processing and analysis of biologics, and has co-authored over 40 peer-reviewed papers and co-supervised several PhD students with Prof. Paul Dalby (UCL, London). Paul is one of a number of directors of the International Society for Lyophilisation Freeze Drying, a not-for-profit society whose aim is to enhance global understanding and uptake of best lyophilisation practices. Co-edited (2019) with Dr. Kevin Ward (Biopharma Technology Ltd, UK) a recent volume on "Lyophilization of Pharmaceuticals & Biopharmaceuticals" for Springer in the "Methods in Pharmacology & Toxicology" series.



**Dr. Stefan Schneid, DE**  
Laboratory Head Development Parenterals  
**Bayer**



Dr. Stefan Schneid is currently a laboratory head in the formulation development department at Bayer AG. In this function, he develops formulations and processes for novel biological entities and small molecules, and is involved in development projects from pre-clinical stage up to transfer to commercial production. Previously, Stefan worked as R&D manager at Syntacoll GmbH in Saal, Germany, where he was responsible for the development of novel formulations and analytical methods for drug-containing biodegradable implants for parenteral application. Until 2010, he was a post-doctoral research fellow in the freeze-drying focus group at the University of Erlangen, and spent one year as a visiting scientist in Prof. Michael Pikal's lab at the University of Connecticut. Stefan holds a degree of pharmacy from the University of Munich, and received his PhD in pharmaceuticals from the University of Erlangen in 2009 for his dissertation thesis titled "Investigation of Novel Process Analytical Technology (PAT) Tools for Use in Freeze-Drying Processes". He developed and optimised the formulation and manufacturing process of various predominantly lyophilised pharmaceuticals including proteins, peptides, vaccines and small molecules.



**Bert Van Meervenne, BE**  
Senior Manager Aseptic Process Development  
**Pfizer**



Bert Van Meervenne graduated in 1989 as a chemical engineer with a focus on processing techniques. He joined Pfizer (Upjohn at that time) in 1991 and worked in aseptic production until 2017, covering batch formulation, autoclaving, stopper processing, filling and visual inspection, but for the larger part of this period (20-plus years) the main focus was on commercial lyophilisation. In his years as a supervisor, Bert was also the production representative in several projects, including a highly automated formulation area, a new stopper sterilisation centre and installation of a number of new lyophilisers. Since 2017, Bert has been working on lyophilisation in Pfizer global technology and engineering, mostly involved in product transfers and problem solving.



**Bernadette Morel, NL**  
Scientist, Bioprocess Development &  
Application  
**DSM Biotechnology Centre**



Bernadette Morel (MSc) is a food scientist from Wageningen University focussed on industrial microbiology. Bernadette filled various positions such as biotechnology process development engineer and a major producer of flavours, fragrances and food ingredients; process engineer at a pharmaceutical company developing formulations and freeze-drying process up to pre-clinical trials. Since 2012, Bernadette has been a scientist at DSM, developing innovative savoury products applying enzyme technology and spray-drying, and freeze-dried culture products for food applications. She has designed, optimised and transferred processes successfully into full-scale manufacturing sites all over the world.





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## Speakers' Biographies

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**Dr. Maja Anko, SI**  
Senior scientist in Drug Product Development  
**Novartis**



Dr. Maja Anko is currently working as Senior Scientist in Technical Research and Development (TRD) Novartis. She is supporting new biological entities projects as well as biosimilar projects covering the whole formulation and process development including Tech transfer. She is an expert in lyo cycle development and transfer using cutting-edge technology and modelling approach. Maja Anko obtained Master's degree in the field of Molecular biology in Biotechnical Faculty, University of Ljubljana and made her PhD and post doctoral training in Biochemistry and Molecular biology in Faculty of Medicine, University of Ljubljana. During her academic career she focused in the fields of biochemistry, cell biology and biophysics on working with RNA/cDNA, proteins and lipid membranes or scientist in Drug product development.



**Filip Dorozinski, AT**  
Manufacturing Scientist Formulation, Fill, Finish  
**Takeda**



Filip Dorozinski has a BSc in technical chemistry from TU Vienna and 13 years of experience in the pharmaceutical industry (Baxter, Baxalta, Shire, Takeda). He has held several roles in manufacturing, and is since early 2018 he has been a manufacturing scientist with a focus on formulation, fill and finishing.



**Dr. Audrey Maudhuit, FR**  
European Process Engineer  
**Fluid Air**



Dr. Audrey Maudhuit is the Process Engineer at Fluid Air, a division of Spraying Systems Co®. She is a Ph.D. in Process Development, specializing in microencapsulation. She graduated from the French engineering school Ecole des Mines. She has developed both R&D and commercial processes for the production of food and feed, as well as managed production teams.



**Xulei Wu, US**  
Senior Food Scientist  
**Space Food Systems Laboratory**  
**Human Health and Performance**  
**Contract MEI Technologies | NASA**

Xulei Wu serves as a MEIT Senior Food Scientist in the Space Food Systems Laboratory at NASA Johnson Space Center. In this role, she leads the freeze-drying production to support Human Space Exploration, conducts R&D work to optimize freeze-drying cycle, and guarantee the safety, nutrition, and palatability of the space food. She recruits and trains R&D sensory panel to support freeze drying cycle optimization and shelf life study. Prior to joining MEIT / NASA in 2018, she was with Oregon Freeze Dry in various QA and R&D roles. Her specialty is in freeze drying technology, low moisture food, sensory evaluation, and shelf life study. She earned a B.S. in food science and engineering from Shanghai Jiao Tong University, and a M.S. in food science and technology from Oregon State University.



**Prof. Davide Fissore, IT**  
Professor of Advanced Process Control,  
Process Design, and Food Processes & Technologies  
**Politecnico di Torino**



Prof. Davide Fissore is a professor of process control and food processing technologies at Politecnico di Torino (Italy), where he is the leader of the process system engineering group. In the field of the freeze-drying of pharmaceuticals products, Davide's research activity is focussed on the use of mathematical models to optimise in-line (using a control system) and off-line (using the design space of the product) the operating conditions for a given product, and on the design of tools combining mathematical models and process measurements to monitor in-line both the primary and secondary drying steps of the process. Davide acted as principal investigator in several research projects granted by pharmaceutical companies focussed on the design/optimisation/scale-up of batch freeze-drying processes.



**Hendrik Kneusels, DE**  
Commercial Director  
**Antares Vision**



After studying Physical Engineering at Wiesbaden University of Applied Sciences, Mr. Kneusels began his professional career at a pharmaceutical safety engineering company, where, after working in development, project management and sales, he took over management and lectured at international congresses and symposia on key topics such as serialisation and camera-based quality control. Since 2014, he has headed the German-speaking subsidiary of Antares Vision, the leading company for Track Trace and inspection machines in the pharmaceutical industry.



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- Minimize amount of active
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