Drug Delivery and Formulation Summit

19 - 20 September 2019 | Munich, Germany

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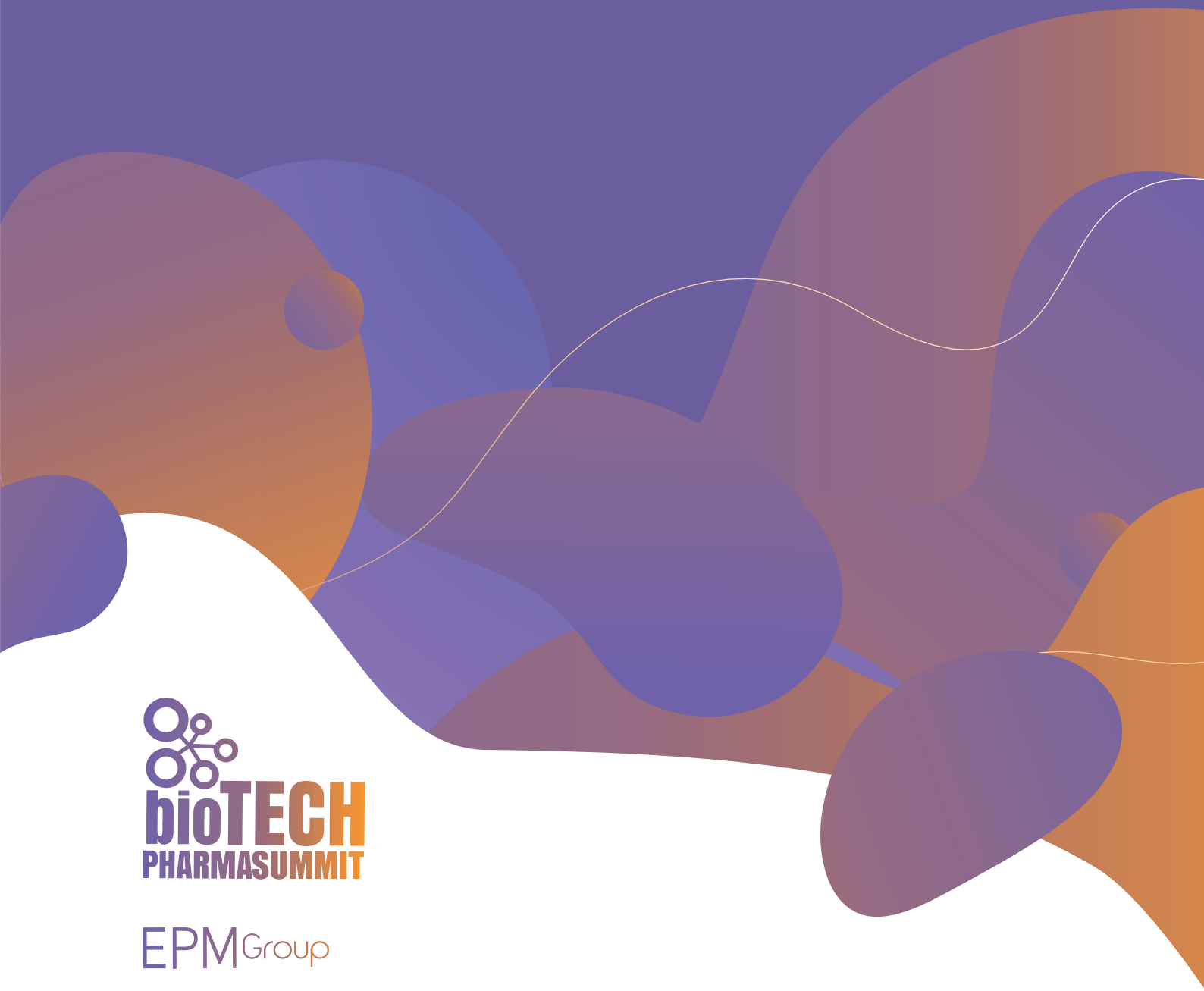

bioTECH PHARMASUMMIT

EPM Group

BIOTECH PHARMA SUMMIT

On 19 & 20 September 2019, Munich (Germany) will host the BioTech Pharma Summit: Drug Delivery & Formulation 2019 conference. This year's event will bring together leaders and senior industry experts in formulation, delivery and product development. Presentations will assess recent technological innovations and discuss their impact on product improvement and patient experience.

The growth of biopharma, patient compliance issues and ever increasing regulatory requirements have encouraged us to adopt a drug delivery mind set from discovery through to production. Every year we see innovation and breakthroughs at all levels of drug and formulation development. From big pharma, through the smaller biotechnology companies all the way to university research teams and spin outs.

The BioTech Pharma Summit (EPMGroup) are exclusive events consisting of world-class keynote addresses and presentations designed specifically for senior level attendees from research & academic institutions, clinical research institutions and hospital laboratories as well as major pharmaceutical and biotech companies based Worldwide.

KEY PRACTICAL LEARNING POINTS

· Opportunities and Challenges in Drug Development

· Advances in Drug Delivery

· Small and Large Molecule Drug Formulation

· Sustained delivery and formulation of biologics

· Targeted and controlled release technologies and nanoparticles

· Formulation of novel molecule

· Less traditional delivery routes

· The potential of nanotechnology for better deliverability

· Reformulation and biosimilars

· Developing nano-enabled medicines

· The latest controlled released technologies

· Drug-Device compatibility

· Optimizing formulations for continuous manufacturing

· Drug Delivery Devices

· Biopharmaceutical Drug Product Robustness Studies

· User friendly technologies for improving patient convenience and compliance

· Bioanalysis and Stabilisation

· The future of Drug Delivery and Formulation

WHO SHOULD ATTEND

CEOs, VPs, Drug developers, Academics and Researchers, CROs, Evangelists, Scientists and Medical Doctors of:

- Formulation Science
- Biologics Development
- Drug Delivery
- Bioformulations Development
- Solid State Characterisation
- Formulation Characterisation
- Sustained Delivery
- Analytical Investigations
- Drug Delivery Innovation
- Stability Sciences
- Device R&D
- Device Design
- Formulation Development
- Pre-formulation
- Drug Delivery Innovation
- Bioanalytical Sciences
- Delivery Device Development
- Drug Delivery Design
- Small Molecule Development
- Delivery Technologies
- Nanotechnology
- Combination Product Development
- Device Strategy
- Device Engineering

SPEAKERS

DR. SABINE HAUCK
VP Research
& Development
at LEUKOCARE

DE

DR. AUDREY BONESTEBE
Lab Head at the Department of Drug Product Development of Biologics
at Sanofi

FR

YASEMIN KARANIS
Consultant, Thought Leadership
at Iqvia

UK

DR. WEI TIAN
Director Formulation
at Lonza

UK

Chairman - Day 2

DR. ISABEL OTTINGER
Team Head Pharmaceutical Development NBE Early Phase
at Novartis

CH

DR. KORBINIAN LÖBMANN
Assoc. Professor
at University of Copenhagen
CSO
at Zerion

DK

DR. LISE VANDERKELEN
Department Head Pharma and Microbial Services
at Nelson Labs

BE

PROF. DR. EKKEHARD LEBERER
Senior Director, R&D Alliance Management
at Sanofi
Scientific Managing Director
at COMPACT

DE

TANVIR TABISH

Head of Formulation Development for Gene Therapy and Protein Modalities

at Shire/Takeda

AT

DR. ELISABETH VEY

Analytical Project Leader

at Novartis

FR

DR. EVA-MARIA KNOCH

Senior Scientist I, HTS Operations & Analytics, NBE Formulation Sciences

at AbbVie

DE

RAMESH K SHANMUGAM

Scientist II, Early Stage Formulation Sciences

at AstraZeneca

UK

Chairman - Day 1

PROF. DR. IJEOMA UCHEGBU

CSO

at Nanomerics

Prof. Pharmaceutical Nanoscience

at University College London

UK

SHAHID UDDIN

Director of Drug Product, Formulation & Stability

at Immunocore

UK

DR. TANJA HENZLER

Head of Liquid Formulation R&D

at Merck

DE

PROF. DR. TUDOR ARVINTE

Chairman, CEO

at Therapeomic

Professor

at University of Geneva

CH

UNIV.-PROF. DR. ANDREAS BERNKOP-SCHNÜRCH

Head of the Department

at University of Innsbruck

Chief Scientific Officer

at Thiomatrix

AT

SCIENTIFIC AGENDA

Thursday, September 19, 2019

08:00 Registration and Welcome Coffee

08:30 Opening of the BioTech Pharma Summit

CHALLENGING BIOLOGICS

08:40 **Delivering Biopharmaceuticals across Biobarriers: Opportunities and Challenges in Drug Development**

*By **Ekkehard Leberer** - Senior Director, R&D Alliance Management at Sanofi; Scientific Managing Director COMPACT Consortium*

- Biologics such as proteins, peptides and oligonucleotides have a huge pharmacological potential but their widespread therapeutic application has been very limited due to pharmacokinetic and drug disposition limitations at both the tissue and cellular level
- Delivery limitations and summarize the work of a European consortium of pharma companies and academic partners to improve nanocarrier-based delivery technologies that can overcome these limitations (COMPACT Consortium, Innovative Medicines Iniative; www.compact-research.org)

09:20 Speed Networking

09:50 **Viscosity and Aggregation - Challenges in Biomolecule Formulation**

*By **Tanja Henzler** - Head of Liquid Formulation R&D at Merck*

- Aggregation prevention is still one of the most prominent questions in Biomolecule Formulation. High quality excipients can help to reduce the risk of failure during formulation development.
- Subcutaneous injections are getting the preferred way of administration for Large Molecules. However, technical challenges like high viscosity as well as protein aggregation arise in highly concentrated protein formulations. Excipients can reduce protein-protein interactions and therefore reduce viscosity in highly concentrated protein formulations.

10:30 Morning Coffee & Networking Break

11:00 **Challenges of IV in-use stability for Biologics**

*By **Audrey Bonestebe** - Lab Head at the Department of Drug Product Development of Biologics at Sanofi*

- Properly designed IV in-use studies
- Case studies for mAbs and ADC

11:40 **The challenge of low volumes - Implementation of low-consumption analytical methods for automated high throughput formulation screenings of biologics**

*By **Eva-Maria Knoch** - Senior Scientist I, HTS Operations & Analytics, NBE Formulation Sciences at AbbVie*

- Establishment of an automated high-throughput formulation screening platform offers the advantage to generate huge and homogeneous datasets that enable a profound understanding of the behavior of a new molecule, while minimizing resource demands, both for drug substance and personal
- The analytical methods that are commonly available often require high volumes
- The introduction to alternative methods at low-volume consumption for profound characterization of the formulation as well as the approach to systematically perform formulation screenings

12:20 **Sustained delivery of biologics: From benchtop to patients**

*By **Isabel Ottinger** - Team Head Pharmaceutical Development NBE Early Phase at Novartis*

- Drug Delivery for Biologics - Needs
- Biologic specific challenges when developing Drug Delivery systems
- Drug Delivery technology overview & discussion of risks and benefits.
- Case studies

13:00 **Business Lunch**

DEVELOPMENTS AND ADVANCES

14:40 **Developability assessment of biologics and formulation of novel molecule**

*By **Shahid Uddin** - Director of Drug Product, Formulation & Stability at Immunocore*

15:20 **Coffee & Networking Break**

15:40 **TBA**

*By **Elisabeth Vey** - Analytical Project Leader at Novartis*

16:20 **Global Pharma Trends & Opportunities for the Packaging Industry**

*By **Yasemin Karanis** - Consultant, Thought Leadership at Iqvia*

- Trends in Global Pharma
- The shift to specialty & targeted products
- Opportunities for the packaging industry

17:00 **Advanced nanoemulsions: Key to high bioavailability of class 3 drugs**

*By **Andreas Bernkop-Schnürch** - Head of the Department, Center for Chemistry and Biomedicine at University of Innsbruck*

- Improving membrane permeability of charged class 3 drugs
- The destabilizing effect of endogenous counterions in the GI-tract and the concept of hydrophobic ion-pairing
- Hydrophobic ion-pairs reach consequently the absorption membrane in intact form providing comparatively much higher drug absorption
- Evidence for the potential of this novel game changing technology has already been provided by various in vivo studies showing a 10- up to 20-fold improved oral bioavailability of different types of class 3 drugs

17:40 **Developing nano-enabled medicines**

*By **Ijeoma Uchegbu** - Chief Scientific Officer at Nanomerics*

- Nanoparticles have been developed, which have high drug loading and are able to transport hydrophobic and amphiphilic actives across biological barriers
- We have used these nanoparticles to develop investigational new drug ready assets which significantly enhance bioavailability via the nose to brain route, the oral route and the topical ocular route. In certain cases, these drug compounds are effectively switched on by the drug delivery technology
- The key attributes of a desirable pharmaceutical nanotechnology platform will be discussed in the presentation

18:20 **Chairman's Closing Remarks & Key Takeaways**

18:30 **Evening Drinks Reception & Gala Dinner**

Friday, Semptember 20, 2019

08:00 Morning Coffee

08:30 Opening Address from the Chairperson

OPPORTUNITIES AND FUTURE APPLICATIONS

08:40 **Artificial intelligence and its application in biopharmaceutical formulation development**

*By **Sabine Hauck** - VP Research & Development at LEUKOCARE*

- Missed opportunities in formulation development and value propositions of advanced formulations
- Presentation of algorithm based development approach
- Explanation of three case studies:
  - Antibody
  - Viral Vectors
  - Mecial Devices

09:20 **Drug/Device compatibility - Finding a Perfect match**

*By **Lise Vanderkelen** - Department Head Pharma and Microbial Services at Nelson Labs*

- The challenges for in-use stability testing for drug-device combinations.
- Extractables & Leachables testing for drug -device combination including protein-leachables interaction
- What about biocompatibility

MANUFACTURING, DESIGNING, IMPROVING

10:00 **An Intercompany Perspective on Biopharmaceutical Drug Product Robustness Studies**

*By **Tanvir Tabish** - Head of Formulation Development for Gene Therapy and Protein Modalities at Shire/Takeda*

- The outcome of a survey done as part of the Biophorum Development Group (BPDG). The companies which took part included Takeda, Legacy Shire, GSK, BMS, Hoffmann-La Roche, Abbvie, Merck, Regeneron, Biogen, ImmunoGen and Alexion
- Overall DP robustness is defined by both the formulation and the manufacturing process robustness, robustness integrates the principles of quality by design (QbD), DP robustness is an important factor in setting critical quality attribute control strategies and commercial specifications

10:40 Morning Coffee and Networking Break

11:10 **Solubility increase of poorly soluble oral drugs using whey proteins as excipient**

*By **Korbinian Löbmann** - Associate Professor at University of Copenhagen*

- Novel formulation design for poorly soluble compounds: ZERION has developed a solubility enhancing technology called Dispersomes®, which is a unique amorphous composition of small molecule drug and proteins. The Dispersome® technology provides fast dissolution, enhanced solubility and bioavailability
- Increasing drug load and amorphous stability: The Dispersome® technology outperforms existing technologies achieving higher drug loads (>50wt%) and high stability both at standard and accelerated storage conditions.

11:50 Workshop: Achieve Stability, High Concentration, and Excellent Manufacturing Systems

*By **Tudor Arvinte** - Chairman, CEO at Therapeomic*

- Discussing and assessing tools to tackle formulation challenges such as protein aggregates, protein characterization or particulate matter
- Diving into a real case study to understand the potential of mass spectrometry to acknowledge the characterization of biopharmaceutical higher order structure and conformational dynamics

12:30 Lipid based formulation for enhanced bioavailability

*By **Wei Tian** - Director Formulation at Lonza*

- Fundamental of lipid based formulation: introduction to lipid chemistry and its absorption, leading to the rational design of lipid based formulations
- Formulation design and in-vitro assessment
- Case study of a lipid based formulation

13:10 Business Lunch

14:10 Coffee & Networking Break

14:40 Impact of quality of raw materials to drug product stability

*By **Ramesh K. Shanmugam** - Scientist II, Early Stage Formulation Sciences at AstraZeneca*

15:20 Lyophilisation of AAV Gene Therapy Product

*By **Tanvir Tabish** - Head of Formulation Development for Gene Therapy and Protein Modalities at Shire/Takeda*

- Biopharmaceuticals show varying levels of stability in aqueous solutions for short periods of time. Lyophilisation is a technique commonly used to improve the stability profile of biomolecules through the removal of water resulting in the increasingly restricted mobility of the reacting species.
- The gene therapy adeno-associated virus (AAV) subtype 8 containing Factor IX was formulated in a new proprietary buffer and lyophilized. A stability study was established with the lyophilized material to determine its stability profile at the accelerated temperature of +5˚Cover a 12 month period
- Study demonstrated the feasibility of lyophilisation of the AAV drug product in an appropriate formulation buffer

16:00 **Panel Discussion:** Future, Challenges and Opportunities for the next Generation Drug Delivery

*Moderated by **Chairperson***

- R&D challenges
- A patient-centricity approach
- New drug delivery technologies
- What will the future hold?

***Panelists:** Speakers of both days*

16:30 Chairman's Closing Remarks and End of Summit

AUDREY BONESTEBE, FR
Lab Head at the Department of Drug Product Development of Biologics at Sanofi

Industrial process engineer with specialization on pharmaceutical production and control.
16 years in pharmaceutical industry mainly in R&D
5 years in Biologics Formulation and DP development.

WEI TIAN, UK
Director Formulation at Lonza

Wei is an experienced pharmaceutical development professional and has achieved market authorization of several generic and NCE products in the EU and US. Many of these products were approved through the 505(b)2 application route, through reformulation and dosage changes.

ELISABETH VEY, FR
Analytical Project Leader at Novartis

My career focus over the past 10 years has been pharmaceutical materials R&D. My work has covered the development of drug delivery systems, biomaterials design, and conventional drug products. I am currently working in a management role for Ipsen supporting the development of injectable products. I manage a team responsible for the delivery of analytical packages for drug products and excipients in early to late phase development including supporting regulatory documents for our business operating regions (USA, EU & Far East).

YASEMIN KARANIS, UK
Consultant, Thought Leadership at Iqvia

Yasemin is a Consultant in the European Thought Leadership team based in IQVIA's London office. Her primary areas of focus are; trends in innovative launches as well as the oncology market with an emphasis on clinical and commercial trends. Yasemin holds a Masters in Cancer Research and a Bachelor of Science degree in Biomedical Sciences both from Newcastle University. Prior to her role in Thought Leadership, Yasemin was part of the Real-World Insights – Global Oncology a team where she worked on the co-ordination and set-up of reports focusing on various cancers.

KORBINIAN LÖBMANN, DK
Associate Professor University of Copenhagen

Korbinian Löbmann has a strong track record in pharmaceutical formulation and drug delivery. He has 9 years of experience in solid formulation and dosage form development, including preformulation, formulation, processing and manufacturing together with the relevant solid state characterization and quality control. This includes in particular the development of new enabling formulation strategies for poorly soluble drugs using amorphous drug delivery systems. Korbinian Löbmann received his PhD in pharmaceutical sciences in 2013 from the University of Otago, New Zealand.

LISE VANDERKELEN, BE
Department Head Pharma and Microbial Services at Nelson Labs

Lise Vanderkelen received her Ph.D. from the Faculty of Bioscience Engineering at the University of Leuven (Belgium) in 2012. She started at Nelson Labs Europe (formerly known as Toxikon Europe) in 2013 as study director Extractables & Leachables, focusing on parenteral applications and in 2014 she became responsible for the chemical characterization testing of medical devices (ISO 10993-18). In 2016, she became Department Head Pharma Services at Nelson Labs Europe. The main focus of this team is identifying organic impurities in drug products as well as in-use stability for drug-device combinations.

BIOGRAPHIES

EVA-MARIA KNOCH, DE
Senior Scientist I, HTS Operations & Analytics, NBE Formulation Sciences at AbbVie

Eva-Maria Knoch is a Senior Scientist in NBE Drug Product Development at AbbVie Ludwigshafen. In 2013 and 2014 she was runnking her PostDoctoral stidies at AbbVie, focused in Drug Product Development, NBE Formulation and Process Sciences. Since June 2014 she is working as a Senior Scientist at AbbVie, focusing in Drug Product Development, NBE Formulation Sciences.

ANDREAS BERN-KOP-SCHNÜRCH, AT
Head of the Department, Center for Chemistry and Biomedicine at University of Innsbruck

Andreas Bernkop-Schnürch is a leading scientist in the field of drug delivery focusing on mucoadhesive polymers such as in particular thiomers, non-invasive peptide delivery systems and nanoemulsions. He is chairman at the Department of Pharmaceutical Technology at the University of Innsbruck, Austria and CSO of the drug delivery company ThioMatrix GmbH. He has published more than 500 reseach and review articles.

EKKEHARD LEBERER, DE
Senior Director, R&D Alliance Management, Scientific Managing Director, COMPACT Consortium at Sanofi

Dr. Leberer received his Ph.D. in Biology at the University of Konstanz, Germany (1986). He conducted post-doctoral training in molecular biology at the Banting and Best Institute of the University of Toronto, Canada, and then obtained the Habilitation for Professor of Biochemistry at the University of Konstanz, Germany. He is the co-discoverer of the p21 activated protein kinase (PAK) family of cell signaling proteins and of novel virulence-inducing genes in pathogenic fungi. He is a co-author of more than 60 publications in prestigious peer-reviewed journals including Nature and Science.

ISABEL OTTINGER, CH
Team Head Pharmaceutical Development NBE Early Phase at Novartis

Isabel Ottinger is Team Head Pharmaceutical Development for Novel Biologic Entities (NBE) Early Phase since February 2018. With her team, she is responsible for the execution of all early phase NBE drug product development programs from first clinical dosage forms to post-POC formulations. In addition, she and her group take care about several NBE Drug Delivery programs in different therapeutic indications as LCM as well as first clinical formulation. Isabel has also led a global CMC team taking care of the technical development of several parenteral depot systems for peptides from early phase to MTA.

TANJA HENZLER, DE
Head of Liquid Formulation R&D at Merck

Tanja Henzler studied Biology in Tübingen and received her PhD in Virology at the Ruprechts Karls University Heidelberg. In 2002 she joined Merck in Darmstadt, Germany. Tanja Henzler has a focus in protein characterization and protein analytics. After evaluating new technologies for Merck Life Science she was coordinating an interdisciplinary and cross-divisional innovation project. She is now leading the group Liquid Formulation within Life Science/Process Solutions focusing on protein stability and Controlled Release of Biomolecules.

TANVIR TABISH, AT
Head of Formulation Development for Gene Therapy and Protein Modalities at Shire/ Takeda

Tanvir joined Takeda about three years ago and is presently the Head of Formulation Development and Characterisation. His responsibilities include developing stable formulations for various Gene Therapy and protein-based modalities. Prior to joining Takeda, Tanvir worked as an Associate Director, for Beaufour Ipsen, and managed a trans-national Early and Pre-Formulation Development group with members based in Paris and Boston. The remit of this group was to develop formulations to help with the candidate selection process for small molecules and Biopharmaceuticals.

IJEOMA UCHEGBU, UK
Chief Scientific Officer
at Nanomerics

Ijeoma Uchegbu is Professor of Pharmaceutical Nanoscience at the UCL School of Pharmacy, University College London (UCL), UCL's Pro-Vice Provost for Africa and The Middle East and Chief Scientific Officer of Nanomerics Ltd. Nanomerics is a UCL spin-out company, which was founded by Ijeoma and Andreas G. Schätzlein. Ijeoma has been awarded various prizes for her work, notably the UK Department for Business Innovation Skills' Women of Outstanding Achievement in Science Engineering and Technology award, the Royal Pharmaceutical Society's Pharmaceutical Scientist of the Year 2012 and the Academy of Pharmaceutical Sciences Innovative Science Award 2016.

RAMESH K SHANMUGAM, UK
Scientist II at AstraZeneca

Ramesh K is a Scientist II in Formulation Sciences at AstraZeneca, Cambridge. Being a Pharmaceutical Boo-technologist, he has over 12+ years of broad cross-functional industrial research experiences in drug product formulation, lyophilization process development, biophysical characterization and drug product manufacturing process development for both early, late stage biologics. Ramesh Kumar obtained a B.S. in Pharmacy and M.S. in Pharmaceutical Biotechnology at the TN MGR Medical University and Ph.D. in Pharmacy specialized in Lyophilization technology from JJT University; also holds M.B.A. from Bharathiar University, India. His research interests are expanding the use of AI into biologics formulation development to support and simplify CMC goals.

TUDOR ARVINTE, CH
Chairman, CEO
at Therapeomic

SHAHID UDDIN, UK
Director of Drug Product,
Formulation & Stability
at Immunocore

SABINE HAUCK, DE
VP Research & Development
at LEUKOCARE

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Pharma Technology Focus

LEONARDO ROYAL HOTEL

Leonardo Royal Hotel Munich****
Moosacher Straße 90,
D-80809 Munich
Germany

The 4-star superior Leonardo Royal Hotel Munich is located on the historic ground of Munich's first airport Oberwiesenfeld and welcomes its guests with a clever mix of modern architecture and trendy furnishings. Its ideal location next to the Olympic Park makes the hotel the perfect starting point for every visitor to Munich.

Experience a true symbiosis of modern architecture, tasteful interior and a harmonious colour concept. 424 modern rooms and suites as well as the spacious »Vitruv« Restaurant with its large sunny terrace and the fitness area including a sauna, all speak volumes. The relaxed club atmosphere and the combination of an extraordinary light and music concept turn the trendy »Leo90« lounge into the place-to-be, the perfect location for relaxation or good conversations.