

Drug Delivery and Formulation Summit

19 - 20 September 2019 | Munich, Germany



EPMGroup

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. ANDREAS SEIDL
Chief Operating Officer, Member of the Executive Board at LEUKOCARE

DE



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

FR



AURELIO ARIAS
Senior Consultant at Iqvia

UK



DR. WEI TIAN
Director Formulation at Lonza

UK



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

CH



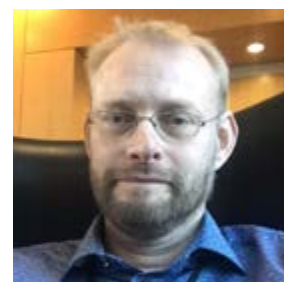
DR. KORBINIAN LÖBMANN
Assoc. Professor at University of Copenhagen CSO at Zerion

DK



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

BE



PROF. DR. RENÉ HOLM
Head and Scientific Director, Drug product development - Liquids & Parenterals at Janssen

DK



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



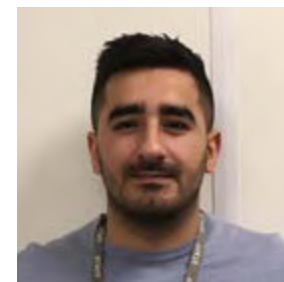
DR. EVA-MARIA KNOCH
Senior Scientist I, HTS Operations & Analytics, NBE Formulation Sciences at AbbVie

DE



RAMESH K SHANMUGAM
Scientist II, Early Stage Formulation Sciences at AstraZeneca

UK



DR. SAIF SHUBBER
Formulation Team Leader at Ipsen

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



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

DE



PROF. DR. IJEOMA UCHEGBU
CSO at Nanomerics Prof. Pharmaceutical Nanoscience at University College London

UK



SCIENTIFIC
AGENDA

08:00 Registration and Welcome Coffee

08:30 Opening of the BioTech Pharma Summit

EVOLUTION AND INNOVATION

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

By **Ekkehard Leberer** - Senior Director, R&D Alliance Management at Sanofi

- 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 Initiative; 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 and 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

- Modern formulation development for biologics still represents an elaborate process that often requires extensive evaluation of numerous excipient combinations at different pH conditions thus leading to the consumption of large amounts of drug substance, resources and time
- 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

14:00 Hard to formulate Biologics

By **Saif Shubber** - Formulation Team Leader at Ipsen

- Introduction: The complexity and high potency of Botulinum neurotoxins (BoNTs) represents a significant challenge in their formulation. Understanding the mechanisms which yield short shelf lives would prompt the design of a formulation to these control critical quality attributes
- Methods: The remit was to design a robust Drug Product formulation strategy for multiple parenteral formulations which would identify key degradation pathways. This would then feed back into the study design to ultimately improve formulation stability both under real and accelerated stability
- Results: The data presented here reveals BoNTs suffer from pH and excipient related degradation pathways. Through the identification of these pathways, formulations were optimised and container closures were screened to control biological activity and adsorption throughout the desired product shelf life.
- Conclusions: Through the understanding and identification of critical quality attributes for BoNT therapeutics, a catalogue and control strategy can be established to deliver fit for purpose, long shelf life formulations. This understanding will feed and form a basis for a platform formulation approach for future novel botulinum toxin therapeutics. This in turn will reflect into more convenient, more user friendly and efficacious medication for our patients.

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 Biologics and the rise of Biosimilars (TBC)

By **Aurelio Arias** - Senior Consultant at Iqvia

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

- Membrane permeability of charged class 3 drugs can be tremendously improved by the formation of hydrophobic ion-pairs; it can efficiently move across the phospholipid bilayer of intestinal epithelial cells
- Because of the destabilizing effect of endogenous counterions in the GI-tract the concept of hydrophobic ion-pairing never developed into a successful story
- Due to the incorporation of hydrophobic ion-pairs in advanced nanoemulsions such as certain self-emulsifying drug delivery systems, however, they are efficiently protected towards these destabilizing interactions
- 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

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 **Andreas Seidl** - Chief Operating Officer, Member of the Executive Board 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
 - Medical 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 Developing robust solutions for injection - physical chemical considerations

By **René Holm** - Head and Scientific Director, Drug product development - Liquids & Parenterals at Janssen

- > Buffer pKa sensitivities as a function of temperature, pressure and ionic strength
- > Solubilising excipients - complexations with cyclodextrins

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

14:30 Solubility increase of poorly soluble drugs using whey proteins as excipients in amorphous compositions

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

- > Formulation design for poorly soluble compounds
- > Increasing stability of amorphous solid dispersions
- > Small Molecule Drug Formulation

15:10 Impact of quality of raw materials to drug product stability

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

15:50 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°C over a 12 month period
- > Study demonstrated the feasibility of lyophilisation of the AAV drug product in an appropriate formulation buffer

16:30 **Panel Discussion:** Future, Challenges and Opportunities for the next Generation Drug DeliveryModerated by **Chairperson**

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

Panelists: Speakers of both days

17:00 Chairman's Closing Remarks and End of Summit

BIOGRAPHIES



AUDREY BONESTEBÉ, 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.



SAIF SHUBBER, UK
Formulation Team Leader
at Ipsen



Completed PhD in 2014 from University of Nottingham in drug delivery and tissue engineering, worked at Medimmune in the formulation of antibodies and peptides in the formulation department and moved to Ipsen in 2016 where I lead a team of scientists and specialists looking into novel toxin/ biologic formulations for therapeutic and aesthetic applications.



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 running her PostDoctoral studies 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 BERNKOP-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 research and review articles.



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).



AURELIO ARIAS, UK
Senior Consultant
at Iqvia



Aurelio is a Senior Consultant in the European Thought Leadership team based in IQVIA's London office. His primary focus is on off-patent markets where he generates evidence-led insights with a view to spark high-level discourse in biosimilars, generics and value added medicines. He is considered a subject matter expert in these areas where he speaks at numerous conferences worldwide, presents to clients and engages in consulting projects in an advisory capacity. Prior to IQVIA, Aurelio has worked as a strategy consultant in Life Sciences for LEK and Accenture and in R&D for Pfizer and GlaxoSmithKline.



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.



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.



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 Rupprechts 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.



ANDREAS SEIDL, DE
Chief Operating Officer, Member of the Executive Board at LEUKOCARE



Andreas Seidl is a chemist by training and got his PhD from the University of Constance/Germany in the area of protein analytics and mass spectrometry. Since April 2019 he is Chief Operating Officer of LEUKOCARE AG, a Munich based biotech company providing innovative formulation development approaches. Before he held different positions at Novartis in analytical & pharmaceutical development, analytical characterization and quality control of biopharmaceuticals: As Head Global Analytical Characterization & Bioanalytics Andreas Seidl was responsible for characterization and comparability/similarity activities for all biosimilar projects of Sandoz/Novartis.



RAMESH K SHANMUGAM, UK
Scientist II at AstraZeneca



Ramesh K is a Scientist II in Formulation Sciences at AstraZeneca, Cambridge. Being a Pharmaceutical Bio-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.



RENÉ HOLM, DK
Head and Scientific Director, Drug product development - Liquids & Parenterals at Janssen



René Holm received his pharmaceutical training and PhD in biopharmaceutics at the Royal Danish School of Pharmacy, now the school of pharmacy at University of Copenhagen, Denmark. Dr. Holm joined Lundbeck in 2001 and changed to Janssen in 2016. Dr. Holm has worked within pharmaceutical development, formulations for non-clinical testing in drug discovery, physical chemistry, and material science covering both small and large molecules and is now responsible for the functional unit ensuring the development of all non-solid formulations for Janssens small molecule value stream.



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.



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



TUDOR ARVINTE, CH
Chairman, CEO at Therapeomic



REGISTRATION

PACKAGE NAME

Title:

Name:

Position:

E-mail:

Title:

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Position:

E-mail:

Company:

Address:

City:

VAT No:

Signature:

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Gala Dinner

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	Super Early Bird Until June 7	Early Bird Until July 26	Discounted Ticket Until August 16	Normal Ticket After September 6
Academic/ Med./ NPO Package	500€	600€	650€	850€
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