

# Preliminary scientific programme

## November 12, 2018: Day 1

9:00 **OPENING – WELCOME CEREMONY**

### Session I.: EQUIVALENCE

9:30 **What is Equivalence as it Applies to Drug Products**

***Vinod P. Shah***

Pharmaceutical Consultant, North Potomac, MD, USA

Member of NBCD Working Group, North Potomac, MD, USA

10:00 **Landscape of Complex Drugs**

***Jon S.B. de Vlieger***

Lygature, Member of NBCD Working Group, Utrecht, The Netherlands

10:30 ***Coffee Break, Exhibition and Poster Session***

### Session II.: CHALLENGES I

11:00 **Scientific Challenges in Biosimilar and Non-Biological Complex Drugs Similar**

***Stefan Mühlebach***

Vifor Pharma Group, Glattbrugg, Switzerland

University of Basel, Department of Pharmaceutical Sciences, Basel, Switzerland

Chair of NBCD Working Group, Utrecht, The Netherlands

11:30 **Challenges in Bringing Scientific Innovations Into the Market**

***Tamás Szolyák***

National Institute of Pharmacy and Nutrition, Budapest, Hungary

12:00 **1<sup>st</sup> Q & A**

12:30 ***Lunch, Exhibition***

### Session III.: NANOMEDICINES I

13:45 **Bioequivalence Decision Based on Biodistribution**

***Beatriz da Silva Lima***

University of Lisbon, Department of Pharmacological Sciences, Lisbon, Portugal

14:15 **Nanomedicine Characterization: The Spectrum of Complexity**

***Scott E. McNeil***

Frederick National Laboratory, Frederick, MD, USA

14:45 **Nanomedicines in Clinical Practice, Critical Aspects to Consider**

***Beat Flühmann***

Vifor Pharma Group, Glattbrugg, Switzerland

15:15 ***Coffee Break, Exhibition and Poster Session***

## Session IV.: COMPLEXITY OF NANOPARTICLES

15:45 **Complexity of Iron Carbohydrate Preparations and Their Evaluation**

**Gerrit Borchard**

University of Geneva, School of Pharmaceutical Sciences, Geneva, Switzerland

16:15 **Panel Discussion I.:** Critical Quality Attributes for Complex Drugs

**Moderator:**

- **Daan J. A. Crommelin**, Utrecht, The Netherlands
- **Beat Flühmann**, Glattbrugg, Switzerland

**Panelists:**

- **Henning H. Blume**, Oberursel, Germany
- **Ernő Duda**, Szeged, Hungary
- **Stefan Mühlebach**, Glattbrugg, Basel, Switzerland
- **Scott E. McNeil**, Frederick, MD, USA
- **Tamás Szolyák**, Budapest, Hungary

17:45 **End of Day 1**

## November 13, 2018: Day 2

### Session V.: BIOSIMILARS I

9:00 **Biosimilars, Ever Evolving Landscape**

**Erik Bogsch**

Gedeon Richter Plc., Budapest, Hungary

9:30 **Biosimilar Pathway: US Approach**

**Vinod P. Shah**

Pharmaceutical Consultant, North Potomac, MD, USA

Member of NBCD Working Group, North Potomac, MD, USA

10:00 **Opportunities and Challenges in Developing Biosimilar Products**

**Zsolt Holló**

EGIS Pharmaceutical Ltd., Budapest, Hungary

10:30 **Coffee Break, Exhibition and Poster Session**

## Session VI.: BIOSIMILARS II

11:00 **Biosimilar Pathway: EMA Approach – Pharmacist Perspectives**

***Irene Krämer***

University of Johannes Gutenberg, Pharmacy Department at the Medical Center, Mainz, Germany

11:30 **Clinical Evaluation and Interchangeability of Biotech Products and Biosimilars**

***Arnold G. Vulto***

Erasmus University, Medical Center Rotterdam, Rotterdam, The Netherlands

12:00 **Controversies on the Switching and Substitution of Biological and Non-Biological Complex Products**

***László Endrényi<sup>1</sup>, László Tóthfalusi<sup>2</sup>***

<sup>1</sup>University of Toronto, Department of Pharmacology and Toxicology, Toronto, ON, Canada

<sup>2</sup>Semmelweis University, Department of Pharmacodynamics, Budapest, Hungary

12:30 **2<sup>nd</sup> Q & A**

12:45 **Lunch, Exhibition**

## Session VII.: CHALLENGES II

14:00 **Drug-Loaded Micro-and Nano Fibrous System as Enabling Formulations**

***Romána Zelkó***

Semmelweis University, University Pharmacy Department of Pharmacy Administration, Budapest, Hungary

14:30 **Strategies in Developing a Transdermal Dosage Form**

***Dange Veerapaneni***

Sparsha Pharma International Pvt. Ltd., Hyderabad, India

15:00 **In Vitro Release and Q3 Measurements for Topical drugs**

***Flavian S. Radulescu***

University of Medicine and Pharmacy "Carol Davila", Department of Biopharmaceutics, Bucharest, Romania

15:30 **Coffee Break, Exhibition and Poster Session**

## Session VIII.: COMPLEXITIES OF BIOSIMILARS

16:00 **Advances in the Analysis of Originator and Biosimilar Protein Therapeutics**

***Pat J. Sandra***

Ghent University, Department of Organic Chemistry, Gent, Belgium  
Research Institute for Chromatography, Kortrijk, Belgium

16:30 **Glycosylation Aspects of Biosimilarity**

***András Guttman***

The Scripps Research Institute, San Diego, CA, USA

## Session IX.: REGULATORY HARMONIZATION

17:00 **Is there a Possibility of Regulatory Harmonization?**

***Tamás L. Paál***

University of Szeged, Szeged, Hungary

National Institute of Pharmacy and Nutrition, Budapest, Hungary

17:30 **Panel Discussion II.: Moving Towards Harmonization**

### Moderator:

- ***Henning H. Blume***, Oberursel, Germany
- ***Vinod P. Shah***, North Potomac, MD, USA

### Panelists:

- ***Beatriz da Silva Lima***, Lisbon, Portugal
- ***Tamás L. Paál***, Budapest, Hungary
- ***Tamás Szolyák***, Budapest, Hungary

18:00 **End of Day 2**

## November 14, 2018: Day 3

### Session X.: NANOMEDICINES II

9:00 **Complexities Involved with Liposome Formulations**

***Daan J.A. Crommelin***

Utrecht University, Department of Pharmaceutics, Department of Pharmaceutical Sciences,  
Utrecht, The Netherlands

9:30 **Bioequivalence of Liposomal Parenterals: Nice-to-Know vs. Need-to-Know**

***Henning H. Blume***

SocraTec C&S Ltd., Oberursel, Germany

10:00 **Application of Nanotechnology to Targeted and Innovative Therapies**

***Erem Bilensoy***

Hacettepe University, Department of Pharmaceutical Technology, Ankara, Turkey

10:30 ***Coffee Break, Exhibition and Poster Session***

11:00 **Panel Discussion III.: United States Government Accountability Office (GAO) Report and Draft Guidance on Drug Products, Including Biological Products that Contain Nanomaterials, December 2017**

**Moderator:**

- **Stefan Mühlebach**, Glattbrugg, Basel, Switzerland
- **Jon S.B. de Vileger**, Utrecht, The Netherlands

**Panelists:**

- **Sesha Neervannan**, Irvine, CA, USA
- **Scott E. McNeil**, Frederick, MD, USA

12:30 **Lunch, Exhibition**

### **Session XI.: BIOEQUIVALENCE, Dissolution**

13:45 **The Gut in the Beaker: What Matters in Simulated Media**

**Clive G. Wilson**

University of Strathclyde, Strathclyde Institute of Pharmacy & Biomedical Sciences, Glasgow, Scotland, UK

14:15 **A Reaction-Limited *In Vivo* Dissolution Model for the Study of Drug Absorption: Implications for the Biopharmaceutic Classification of Drugs**

**Panos Macheras**

National and Kapodistrian University of Athens, Department of Pharmacy, Athens, Greece

14:45 **Bioequivalence Studies and Evaluations for DPI Drug Products: Regulatory Authorities Challenges**

**A. Atilla Hincal**

Hacettepe University, Department of Pharmaceutical Technology, Ankara, Turkey

15:15 **Coffee break, Exhibition and Poster Session**

### **Session XII.: PROGRESS IN ANALYTICAL TECHNOLOGIES**

15:45 **Advances in Bioanalytical Mass Spectrometry in Support of Drug Therapies**

**László Prókai**

University of North Texas, Health Science Center, Fort Worth, TX, USA

16:15 **Characterization of Complex Drug Molecules**

**Speaker to be identified**

16:45 **Characterization of Proteins**

**Speaker to be identified**

17:00 **POSTER AWARDS CEREMONY, CLOSING REMARKS**