

Scientific Program

9:00

Opening Welcome

Imre Klebovich

Co-Chair of the Workshop
Co-Chair of the Committee on Pharmaceutical Sciences
Chair of Working Committee on Separation Sciences of the
Hungarian Academy of Sciences (MTA)

Budapest, Hungary

Ágoston Szél

Rector of Semmelweis University

Budapest, Hungary

Sabine Kopp

World Health Organization (WHO)

Geneva, Switzerland

Hilda Kőszegi-Szalai

GYEMSZI – National Institute of Pharmacy,
Deputy Director General

Budapest, Hungary

Roger L. Williams

Former CEO and Chair, Council of Experts
United States Pharmacopeial Convention (USP)

Rockville, MD, USA

Leslie Z. Benet

Founder President of the American Association of
Pharmaceutical Scientists (AAPS)

San Francisco, CA, USA

Clive G. Wilson

Past President of the European Federation for
Pharmaceutical Sciences (EUFEPS)

Glasgow, Scotland, UK

Vinod P. Shah

Co-Chair of the Workshop
International Pharmaceutical Federation/SIG
Chair of Regulatory Sciences (FIP)
Former President of the American Association of
Pharmaceutical Scientists (AAPS)

North Potomac, MD, USA

Session 1:

Regulatory Perspectives

Chairs: Stefan Mühlebach (*Glattbrugg, Basel, Switzerland*)
K. Wayne Riggs (*Vancouver, BC, Canada*)

Hurdles and Challenges in Harmonising Drug Regulations
Tamás L. Paál

9:30

University of Szeged, Szeged, Hungary
GYEMSZI-National Institute of Pharmacy, Budapest, Hungary

Basic Concepts: They Keep Changing
Leslie Z. Benet

10:00

University of California, San Francisco, CA, USA

Coffee Break, Exhibition

10:30

Session 2: Regulatory Perspectives: Quality and Bioequivalence

Chairs: Tamás L. Paál (*Szeged, Budapest, Hungary*),
Romána Zelkó (*Budapest, Hungary*)

FDA Perspective on Product Quality and Bioequivalence
Vinod P. Shah

11:00

International Pharmaceutical Federation / SIG
Chair of Regulatory Sciences, North Potomac, MD, USA

WHO Perspective on Quality Assurance and Medicinal Safety
Sabine Kopp

11:30

World Health Organization, WHO, Geneva, Switzerland

**Newer Considerations and Regulatory Guidance on BE –
EMA Perspective**

12:00

Evangelos Kotzagiorgis

European Medicines Agency, EMA, London, UK

Panel Discussion I.

Q and A

12:30

Moderators: Gordon L. Amidon (*Ann Arbor, MI, USA*)
Roger L. Williams (*Rockville, MD, USA*)

Lunch, Exhibition

13:00

Session 3:

Advances in Pharmacokinetics

Chairs: Surendra K. Bansal (*New York, NY, USA*)
Meir Bialer (*Jerusalem, Israel*)

14:00 Impact of Bioequivalence Studies on the Progresses of Pharmaceutical Sciences in Generic Industry Within Last 35 Years

A. Atilla Hincal

Hacettepe University, Ankara, Turkey
IDE Pharmaceutical Registration Biopharmaceutics
Consultation Education Ltd. Co., Ankara, Turkey

14:30 Advances in Pharmacokinetics Related EMA Regulations

José A. G. Morais

University of Lisbon, Lisbon, Portugal

15:00 Oral Drug Absorption: Science and Regulation

Panos Macheras

National and Kapodistrian University of Athens, Athens, Greece

15:30 **Coffee Break, Exhibition**

Session 4:

Drug and Food Interactions

Chairs: László Endrényi (*Toronto, ON, Canada*)
Peep Veski (*Tartu, Estonia*)

16:00 Drug Interactions - Alcohol, Smoking and Caffeine

Imre Klebovich

Semmelweis University, Budapest, Hungary

16:30 Application of an *In Vitro* Lipolysis Model to Predict Positive Food Effect

James E. Polli

University of Maryland, Baltimore, MD, USA

17:00 **Panel Discussion II.**

Q and A

Moderators: Sabine Kopp (*Geneva, Switzerland*)
Vinod P. Shah (*North Potomac, MD, USA*)

Social Programs

Concert of the Semmelweis Chamber Orchestra

19:00

*in the Matthias Church,
Conductor László Tardy*

1014 Budapest, Szentháromság Square 2.

Entry by badge and invitation card only

Banquet Dinner in the Hungarian National Gallery

20:30

Royal Palace of Buda, Building C.

1014 Budapest, Szent György Square 2.

Entry by badge and invitation card only

Welcome Addresses by:

Ferenc Joó

*President of Section of Chemical Sciences of the
Hungarian Academy of Sciences (MTA)*

Éva Szökő

*President of the Hungarian Society for Pharmaceutical
Sciences (HSPS)*

László Vécsei

*President of the Section of Medical Sciences of the
Hungarian Academy of Sciences (MTA)*

Vinod P. Shah and Imre Klebovich

Co-Chairs of the Workshop

The performers of the evening:

Botafogo Dance Ensemble

Jenő Esze's Dance and Salon Music Band

Event Sponsor: CAPSUGEL®

Session 5:

BCS, Dissolution and Biowaiver

Chairs: Olavi Pelkonen (*Oulu, Finland*)

István Tóth (*Saint Lucia, Qld, Australia*)

9:00 Role of Dissolution in Regulating Pharmaceutical Products

Vinod P. Shah

International Pharmaceutical Federation / SIG

Chair of Regulatory Sciences, North Potomac, MD, USA

9:30 BCS and Beyond: Limitations and Harmonization
(The New Science of BE)

Gordon L. Amidon

University of Michigan, Ann Arbor, MI, USA

10:00 Exploiting BDDCS and the Role of Transporters

Leslie Z. Benet

University of California, San Francisco, CA, USA

10:30 **Coffee Break, Exhibition**

Session 6:

Advances in Dissolution

Chairs: Evangelos Kotzagiorgis (*London, UK*)

Constantin Mircioiu (*Bucharest, Romania*)

11:00 Advances in IIVC

James E. Polli

University of Maryland, Baltimore, MD, USA

11:30 Bioperformance Dissolution Standards:

In Vivo Predictive Dissolution (IPD)

Gordon L. Amidon

University of Michigan, Ann Arbor, MI, USA

Panel Discussion III.

Q and A

12:00

Moderators: **Daan J. A. Crommelin** (*Utrecht, The Netherlands*)
Clive G. Wilson (*Glasgow, Scotland, UK*)

Lunch, Exhibition

12:30

Session 7:

Regulatory Trends in Bioanalysis

Chairs: **Hilda Kőszegi-Szalai** (*Budapest, Hungary*)
José A. G. Morais (*Lisbon, Portugal*)

**Bioanalytical Method Validation and Samples Analysis –
Lessons Learned from Regulatory Inspections**

13:30

Surendra K. Bansal

F. Hoffmann-La Roche Inc., New York, NY, USA

**Where Are We with Respect to Global Harmonization in
Guidance of Bioanalytical Method Validation?**

14:00

Daniel Tang

ICON Development Solutions, APAC, Shanghai, China

**Analytical Aspects of Biologics Applied in Pharmaceutical
Development**

14:30

Felix Heise, Hanns-Christian Mahler

F. Hoffmann-La Roche Ltd., Basel, Switzerland

**Challenges in Using Capillary Electrophoresis in Analysing
Therapeutic Proteins**

15:00

Jim Thorn

AB SCIEX Separations Ltd., Warrington, UK

Coffee Break, Exhibition

15:30

Session 8: Biosimilars and Complex Drug Products

Chairs: István Greiner (*Budapest, Hungary*)

Milena Jadrijević-Mladar Takač (*Zagreb, Croatia*)

16:00 **Biosimilars: Status Regulatory Pathways and Remaining Questions**
Daan J. A. Crommelin
Utrecht University, Utrecht, The Netherlands

16:30 **Interchangeability:
A Challenge for Non-Biological Complex Drugs (NBCDs)**
Stefan Mühlebach
Vifor Pharma Ltd., Glattbrugg, Switzerland
University of Basel, Basel, Switzerland

17:00 **Assessment of the Similarity and Interchangeability of
Biological Drug Products**
László Endrényi¹, László Tóthfalusi²
¹University of Toronto, Toronto, ON, Canada
²Semmelweis University, Budapest, Hungary

17:30 **Panel Discussion IV. Q and A**

Moderators: Nicholas M. Fleischer (*Washington, DC, USA*)
Sven Stegemann (*Bornem, Belgium*)

Social Programs

19:30 **Concert of the Dohnányi Orchestra Budafok**

in the Liszt Ferenc Academy of Music
Conductor Gábor Hollerung

1061 Budapest, Liszt Ferenc Square 8.

The Sponsor of the Concert:



After the Concert:

**Cocktail Reception in the
Liszt Ferenc Academy of Music, 1st floor**

Entry by badge and invitation card only

Session 9:

Looking into the Future

Chairs: István Antal (*Budapest, Hungary*)
A. Atilla Hincal (*Ankara, Turkey*)

Reducing Regulatory Burden for Well-Established Drugs 9:00
Roger L. Williams

US Pharmacopeia, Rockville, MD, USA

**New Challenges but Rewarding Opportunities in Translating
Pharmaceutical Development Projects into Successful
Therapeutics** 9:30

Imre G. Bajusz

Novartis Pharmaceuticals Ltd., Basel, Switzerland

Challenges of Biosimilars – A Perspective 10:00
István Greiner

Gedeon Richter Plc., Budapest, Hungary

Coffee Break, Exhibition 10:30

Session 10:

Looking into the Future: New Trends?

Chairs: Imre G. Bajusz (*Basel, Switzerland*)
Irene Krämer (*Mainz, Germany*)

**The Me-Too Paradigm – a Threat for Pharmaceutical Progress?
Roadmap Towards a New Quality Target Product Profile (QTPP)
for Enhanced Therapeutic Entities** 11:00

Sven Stegemann

Capsugel, Bornem, Belgium

**505(b)(2) New Drug Application Pathway vs. Abbreviated
New Drug Application Pathway for Drug Approval in the US** 11:30

Nicholas M. Fleischer

The Weinberg Group Inc., Washington, DC, USA

**Modified Release Products: It's Time for International
Harmonisation** 12:00

Henning H. Blume

SocraTec R&D Ltd., Oberursel, Germany

12:30

Panel Discussion V.

Q and A

Moderators: **Leslie Z. Benet** (*San Francisco, CA, USA*)
Panos Macheras (*Athens, Greece*)

13:00

Lunch, Exhibition

Session 11: Looking into the Future: Biopharmaceutical Aspects

Chairs: **Mitsuru Hashida** (*Kyoto, Japan*)
Arto Urtti (*Helsinki, Kuopio, Finland*)

14:00

Dosage Form Attributes and Biopharmaceutical Performance
Clive G. Wilson
University of Strathclyde, Glasgow, Scotland, UK

14:30

Application of Cyclodextrins in Drug Formulations
Lajos Szente
CycloLab Ltd., Budapest, Hungary

15:00

Novel Approaches in Drug Delivery Systems
István Antal
Semmelweis University, Budapest, Hungary

15:30

Coffee Break, Exhibition

Session 12: Looking into the Future: New Delivery Systems

Chairs: Daniel Tang (*Shanghai, China*)
Lajos Szente (*Budapest, Hungary*)

Pharmacovigilance Aspects of Biosimilar Products
Irene Krämer

University of Johannes Gutenberg, Mainz, Germany

16:00

Advances in Targeted and Gene Delivery
Mitsuru Hashida

Kyoto University, Kyoto, Japan

16:30

Ocular Drug Delivery: Formulation and Bioequivalence Issues
Arto Urtti

Centre for Drug Research, University of Helsinki, Helsinki, Finland
School of Pharmacy, University of Eastern Finland, Kuopio, Finland

17:00

Panel Discussion VI.

Q and A

Moderators: James E. Polli (*Baltimore, MD, USA*)
Henning H. Blume (*Oberursel, Germany*)

17:30

Closing Remarks

Vinod P. Shah and Imre Klebovich
Co-Chairs of the Workshop

18:00

