

FIRST CIRCULAR



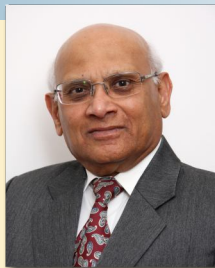
May 19-21, 2014
Hungarian Academy of Sciences,
Budapest, Hungary

**4th INTERNATIONAL
REGULATORY WORKSHOP on A to Z on BIOEQUIVALENCE,
BIOANALYSIS, DISSOLUTION AND BIOSIMILARITY**





Prof.
Imre Klebovich



Prof.
Vinod P. Shah

Co-Chairs of the Workshop

The 4th International Regulatory Workshop on A to Z on Bioequivalence, Bioanalysis, Dissolution and Biosimilarity (BEW 2014) is organized again in **Budapest, 19–21 May, 2014**, in the main Ceremonial Hall of the Hungarian Academy of Sciences (HAS), after a range of internationally acknowledged and highly successful series held in 2006, 2010 and 2012. The history of bioequivalence workshop started in 2001 in Budapest with 120 participants, this rapidly got extended internationally due to the excellent speakers, relevant topics and the wonderful milieu of the HAS building hosting the event. In 2012 we welcomed 280 participants from 38 countries of 5 continents. Altogether the BEW 2014 will be the fifth meeting of bioequivalence in Budapest, Hungary.

The International Regulatory Workshop on Bioequivalence, Bioanalysis, Dissolution and Biosimilarity is designed to provide *a look into the future* of drug regulations. The workshop will discuss the challenges for bioequivalence of certain dosage forms, the concept of value-added generics, the strategies in new and generic drug development, and novel drug delivery systems. The meeting will focus also on bioanalytical regulations, trends of bioanalysis and dissolution performance standards. Regulatory standards are developed to assure that the drug products are safe and effective and quality drug products are produced and marketed. The regulatory standards have undergone rapid and significant changes since the beginning of this century. Several factors have been responsible for this; the introduction of the concept of Biopharmaceutics Classification System (BCS), its regulatory acceptance and industry implementation; increased knowledge of formulation science and widening of biowaiver based on scientific principles without sacrificing the quality of the drug product. Biotech products and biosimilar products are the future wave of drug products, they are coming! The regulatory authorities try to follow the gold standards developed by FDA, EMA and other authorities.

We anticipate of more than 300 scientists from 40 countries around the globe. It is our pleasure to welcome these scientists and provide them an opportunity to discuss challenging topics, to exchange ideas and to learn. During the three days new and returning professionals will come together at one of the most dynamic and enlightening workshops of bioequivalence experts.

The venue of the Workshop, the home of the Hungarian Academy of Sciences, is one of the most distinguished institutions of the 1100-year old Hungary, which will certainly assure the environment where personal contacts can develop in a friendly atmosphere.

We wish all participants an enriching stay benefiting fully from both the beautiful milieu and the exciting science that will be presented at our workshop in Budapest, Hungary.

A handwritten signature in blue ink, reading "Imre Klebovich".

A handwritten signature in blue ink, reading "V. P. Shah".



Organized by the

**Semmelweis University, Department of Pharmaceutics,
Budapest, Hungary**

in co-operation with the



**Committee on Pharmaceutical Sciences,
Working Committee on Separation Sciences and
Sections of Chemical and Medical Sciences of the
Hungarian Academy of Sciences (HAS)**



Hungarian Society for Pharmaceutical Sciences (HSPS)

under the auspices of the



American Association of Pharmaceutical Scientists (AAPS)



International Pharmaceutical Federation (FIP)



European Federation for Pharmaceutical Scientists (EUFEPS)

Co-Chairs

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Main topics of the Workshop

Regulatory Aspects of Bioequivalence

- Updates on EMA and FDA Perspectives on BE Regulations
- Bioequivalence of Biological and Non-biological Complex Drugs
- New Paradigm in BE Evaluation

Bioanalytics

- Regulatory Approaches to Bioanalytical Method Validation
- Global Harmonization of Bioanalytical Method Validation
- Lessons Learned from Bioanalytical Regulatory Inspections
- Bioanalytical LC/MS Methods in Biological Drug Development

In Vitro Dissolution Perspectives

- Role of Dissolution in Regulating Pharmaceutical Products
- Advances in *In Vitro* Dissolution, IVIVC
- Bioperformance Dissolution Standards

Biologicals and Biosimilars

- Regulatory Pathways and Open Questions
- Bioanalytical Challenges
- Biosimilar Drug Industry Perspectives
- Assessment of the Similarity and Interchangeability

Drug Development and Beyond

- Product Quality and BE
- Quality Assurance and Medical Safety
- In Vitro* Models for Predictive Drug Interactions and Food Effects
- BCS, BDDCS and Beyond

Advances in Pharmaceutical Technologies

- Added Value Generics
- Targeted Quality Product Profile
- Optimizing Product Performance
- Cyclodextrins in Drug Formulations
- Targeted Drug and Gene Delivery Systems
- Drug Delivery to the Eye

For the preliminary program please check <http://www.bew2014.hu> where all the updates can be traced, so we ask you to visit the website regularly.

Monday, May 19, 2014

The Workshop starts on Monday at 9:00 am.

Hurdles and Challenges in Harmonizing Drug Regulations – A Perspective

Tamás L. Paál

GYEMSZI-National Institute of Pharmacy, Budapest, Hungary

University of Szeged, Szeged, Hungary

Semmelweis University, Budapest, Hungary

Basic Concepts: They Keep Changing

Leslie Z. Benet

University of California, San Francisco, CA, USA

FDA's Perspective on Product Quality and Bioequivalence

Vinod P. Shah

International Pharmaceutical Federation / SIG,

Chair of Regulatory Sciences, North Potomac, MD, USA

WHO Perspectives on Quality Assurance and Medicinal Safety (Tentative)

Sabine Kopp

World Health Organization, WHO, Geneva, Switzerland

Assessment of the Similarity and Interchangeability of Biological Drug Products

László Endrényi¹, László Tóthfalusi²

¹*University of Toronto, Toronto, ON, Canada*

²*Semmelweis University, Budapest, Hungary*

Challenges in BE Evaluation – A New Paradigm

Panos Macheras

University of Athens, Athens, Greece

Advances in Pharmacokinetics Related EMA Regulations

José A. G. Morais

University of Lisbon, Lisbon, Portugal

Drug Interactions - Alcohol, Smoking and Caffeine

Imre Klebovich

Semmelweis University, Budapest, Hungary

In Vitro Lipolysis Model to Predict Positive Food Effect

James E. Polli

University of Maryland, Baltimore, MD, USA

Role of Dissolution in Regulating Pharmaceutical Products

Vinod P. Shah

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

BCS and Beyond – Limitations and Steps Towards Harmonization

Gordon L. Amidon

University of Michigan, Ann Arbor, MI, USA

Exploiting BDDCS and the Role of Transporters

Leslie Z. Benet

University of California, San Francisco, CA, USA

Advances in IVIVC

James E. Polli

University of Maryland, Baltimore, MD, USA

Bioperformance Dissolution Standards

Gordon L. Amidon

University of Michigan, Ann Arbor, MI, USA

Analytical Aspects of Bringing a Biopharmaceutical to the Market (Tentative)

– To Be Determined

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

Surendra K. Bansal

Hoffmann-La Roche Inc., Nutley, NJ, USA

Where Are We with Respect to Global Harmonization in Bioanalytical Methods Validation?

Daniel Tang

ICON Plc., Shanghai, China, Dublin, Ireland

Biosimilars: Status Regulatory Pathways and Remaining Questions

Daan J. A. Crommelin

Utrecht University, Utrecht, The Netherlands

Interchangeability: A Challenge for Non-Biological Complex Drugs

Stefan Mühlebach

*Vifor Pharma Ltd., Glattbrugg, Switzerland
University of Basel, Basel, Switzerland*

New Challenges but Rewarding Opportunities in Translating Pharmaceutical Development Projects into Successful Therapeutics

Imre Bajusz

Novartis Pharma Ltd., Basel, Switzerland

Challenges of the Biosimilar Drug Industry – A Perspective

István Greiner

Gedeon Richter Plc., Budapest, Hungary

The Me-Too Paradigm - a Threat for Pharmaceutical Progress.

Roadmap Towards a New Targeted Quality Product Profile (TQPP) for Added Value Generics

Sven Stegemann

Capsugel, Bornem, Belgium

Modified Release Medicinal Products – It's Time for International Harmonization

Henning H. Blume

SocraTec R&D Ltd., Oberursel, Germany

Impact of BE Studies on Scientific Development of Generic Pharma Industry

A. Atilla Hincal

İDE Pharmaceutical Consultation Ltd. Co., Ankara, Turkey

Dosage Form Attributes and Biopharmaceutical Performance

Clive G. Wilson

University of Strathclyde, Glasgow, Scotland, UK

Applications of Cyclodextrine in Drug Formulations

Lajos Szente

Cyclolab Ltd., Budapest, Hungary

Novel Approaches in Drug Delivery Systems

István Antal

Semmelweis University, Budapest, Hungary

Advances in Targeted and Gene Delivery

Mitsuru Hashida

Kyoto University, Kyoto, Japan

Ocular Drug Delivery: Formulation and Bioequivalence Issues

Arto Urtti

University of Helsinki, Helsinki, Finland

Role of Pharmaceutical Sciences and Pharmacy Practice Towards Better Health Care

Kamal K. Midha (Invited)

FIP, Immediate Past President, London, UK

The Workshop ends on Wednesday at 5:00 pm.

Accommodation

Hotels listed below are the official conference hotels recommended by the Organizers. You can book a room in the hotel's online booking system accessible via

<http://www.bew2014.hu>

from September 2013. Please note that prices listed below can be selected only in case of online booking via the official BEW2014 website. VAT, city tax and the breakfast are included in the prices.

InterContinental Budapest * * * * *

Address: H-1052 Budapest,
Apáczai Csere János utca 12-14.

Location from the congress venue:
5 minutes on foot.

Prices: Superior room with Danube view
Single occupancy 179 EUR
Double occupancy 199 EUR

Description

402 elegantly appointed rooms and suites - functional and comfortable with all expected modern amenities - appealing to discerning business and leisure travellers equally.

Experience 180-degree panoramic views over Chain Bridge, the Danube and the former Royal Palace that are as intriguing by day as by night. The use of WiFi and fitness center is available free of charge for participants.

Access to the conference venue

The conference is just on the opposite side of the "Széchenyi István tér" so you can just walk to the building of the Hungarian Academy of Sciences.



art'otel Budapest * * * *

Address: H-1011 Budapest, Bem rakpart 16-19.

Location from the congress venue:
10 minutes by public transport.

Prices: Art room with Danube view
Single occupancy 99 EUR
Double occupancy 109 EUR
Art suite 159 EUR

Description

Located opposite the Hungarian Parliament on the Danube river, art'otel Budapest displays over 600 original works by Donald Sultan, a renowned contemporary artist. The hotel features convenient amenities for the business and leisure traveller, including free WiFi, a Fitness Centre and a Business Centre. Guests also enjoy our hotel's castle and Danube River views.

Access to the conference venue

You can take the tram no. 19 or 41 for 1 stop till the Chain Bridge ("Lánchíd") and walk over the Danube to the venue.



Mercure Budapest City Center * * * *

Address: H-1052 Budapest, Váci utca 20.
 Location from the congress venue:
 10 minutes by public transport or on foot.

Prices:

Single occupancy 99 EUR
 Double occupancy 113 EUR

Description

The hotel is located in the heart of the historical and business center of Budapest in the Váci street. River Danube, museums, stylish restaurants and famous baths are within an easy reach. They offer free WiFi in the entire area of the hotel and Internet corner at the bar. The road from the airport is downright to the hotel, onsite parking possibility is available.

Access to the conference venue

You can take tram no. 2 for 2 stops from "Vigadó tér" to "Széchenyi István tér" and just walk to the venue. The hotel is located cca. 500 m from the conference venue so you can reach the building of the Hungarian Academy of Sciences on foot as well.



Hotel Central Basilica * * *

Address: H-1051 Budapest, Hercegprímás utca 8.
 Location from the congress venue:
 5 minutes on foot.

Prices: Single room 72 EUR
 Double room 82 EUR

WiFi connection can be used for a surcharge of 5 EUR/day.

Description

The building of the hotel was built in 1879 and functioned as a town house. It was rebuilt in 1908 first and they covered the courtyard this time. There were many constructions till 1990's when the building was abandoned. The building has been operating as Hotel Central Basilica since 2007.

Hotel Central Basilica is situated in the cultural, tourism and business centre of Budapest, in the adjacent of the best restaurants and entertaining places.

Access to the conference venue

The hotel is located cca. 800 m from the conference venue so you can reach the building of the Hungarian Academy of Sciences on foot.



Registration

Registration is required for all workshop participants preferably until March 20, 2014. It is recommended to make the registration online. In order to avoid double charges, please register only ONCE. Early bird fees are available until March 20, 2014. Any registration and payment received after that date will be accepted as regular registration. Confirmation will be sent to all participants by the organizers upon receipt of registration and payment.

Online registration facility opens in September 2013 at
<http://www.bew2014.hu>

Registration fees

Registration Type	Early Bird Fee paid until March 20, 2014	Regular Fee paid after March 20, 2014
Registration fee for participants / PhD students	520 EUR	630 EUR
Accompanying person's fee	240 EUR	280 EUR

Registration fees include VAT

Delegate and PhD student registration fees include:

- Access to all scientific sessions
- Admission to the exhibition
- Printed material of the workshop
- Conference bag
- Concert and banquet dinner
- Cultural program with dinner
- Coffee breaks
- Lunches

Accompanying persons' fee include:

- Lunches
- Concert and banquet dinner
- Cultural program with dinner

Cancellation policy of registration

All cancellations and changes must be sent to Diamond Congress Ltd. in written form. All refunds will be processed after the Workshop. Please send your exact bank account details in the written cancellation, unless you paid by credit card.

Refund of the registration fee will be made as follows:

- 100% refund (minus an administrative fee of 50 EUR) – in case of cancellation received before April 30, 2014
- 50% refund – in case of cancellation received before May 15, 2014
- No refund – in case of cancellation received after May 15, 2014

Payment

All payments should be made in EUR. All charges due to bank transfers have to be paid by the sender. In any case please bring the proof of payment with you to the registration desk.

Bank transfer has to be made to Diamond Congress Ltd. – BEW2014

Raiffeisen Bank Zrt.

Address: H-1015 Budapest, Széna tér 1/a.

International Bank Account Number **HU79 12010154 00175156 00200001**

SWIFT code: **UBRT HUHB**

Credit Card

VISA, EuroCard/MasterCard, American Express Card number with expiry date, card holder's name, billing address of the cardholder, CVV code (the last three digits on the back of the credit card where the signature is – only VISA and EC/MC) and signature of the cardholder are needed.

Address of the Workshop venue

Hungarian Academy of Sciences (HAS)

Ceremonial Hall

H-1051 Budapest, Széchenyi István tér 9, Hungary



Concert and banquet dinner in the Buda Castle

Matthias Church



National Gallery



Exhibition and sponsorship

The BEW2014 organizers invite and expect many exhibitors, sponsors and advertisers from all branches of related sciences, profit-oriented or non-profit institutions for the conference.

If you are interested in sponsoring / exhibiting at the **BEW 2014 Workshop**, we can offer you floor space for your own stand. Diamond Congress Ltd., our partner for the workshop and exhibition organization offers numerous alternatives for you to promote your business and can work closely with you to create a package tailored to your company's needs.

Your advantages:

The exhibition will be visited by your core target group from all over the world.

You will have the opportunity to promote your products and services and discuss their merits in detail with interested visitors and specialists.

For further information please visit: <http://www.bew2014.hu>

