



International Conference on Advances in the Area of Bioequivalence

Hotel Danubius Health Spa Resort Margitsziget **** Superior
Margaret Island, Budapest, Hungary

November 14, 2015

FIRST CIRCULAR

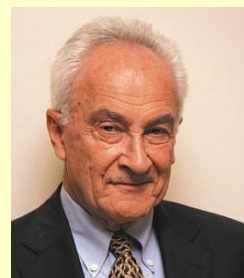
Welcome



Prof. Imre Klebovich



Prof. Vinod. P. Shah



Prof. László Endrényi

Co-Chairs of the Conference

The **International Conference on Advances in the Area of Bioequivalence (ICAB 2015)** will be held on **Margaret Island, Budapest, Hungary, on November 14, 2015**. This one-day conference is unique in nature. It will be focusing on bioequivalence – regulatory aspects of bioequivalence, biosimilars, bioanalytics, *in vitro* dissolution and drug release perspectives, advances in pharmaceutical technology, drug development and beyond. The conference topic will also update on new BCS draft guidance and biowaivers.

The conference will provide ample opportunities for the participants to interact with international speakers on different topics. Researchers are invited to make presentations on new approaches for targeted drug delivery. Interactive panel discussion moderated by well-known professors of the field will provide a platform to answer questions on everyday drug development and registration. Participants could view the exhibition of leading international analytical/bioanalytical and dissolution tester manufacturers, CROs and biological sample transportation companies assuring GLP and GCP-conform conditions. The exhibition will be well-suited to the professional program of the Conference.

We would like to express our sincere gratitude to all the speakers who have decided to come to Budapest to debate the newest results in this important discipline. Finally, our thanks go to all event partners for helping to make **ICAB 2015** a success.

The venue of the conference is the **Hotel Danubius Health Spa Resort Margitsziget****Superior** located on the beautiful Margaret Island in Budapest, Hungary. We look forward to welcoming you all and your colleagues at this one-day International Conference on Advances in the Area of Bioequivalence.

We wish all participants an enriching stay in the beautiful milieu of Margaret Island with a special atmosphere of the UNESCO protected Music Fountain and Water Tower, and the exciting science that will be presented.

Handwritten signature of Imre Klebovich in blue ink.

Handwritten signature of V. P. Shah in blue ink.

Handwritten signature of László Endrényi in blue ink.

Organizers

Organized by



Semmelweis University, Department of Pharmaceutics,
Budapest, Hungary

In co-operation with the



Committee on Pharmaceutical Sciences,
Working Committee on Separation Sciences
of the Hungarian Academy of Sciences (HAS)



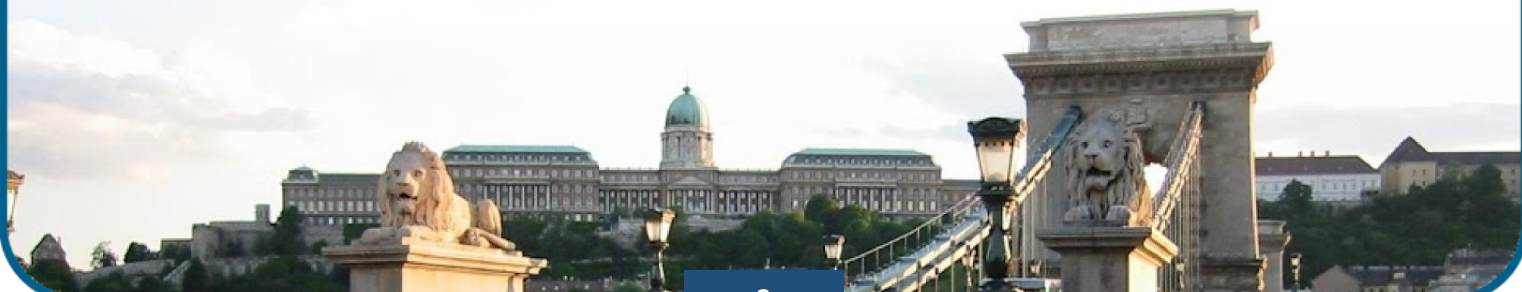
Hungarian Society for Pharmaceutical Sciences (HSPS)

Under the auspices of the



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European Federation for Pharmaceutical Sciences (EUFEPS)



Committees and Contacts

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Prof. Imre Klebovich, Budapest, Hungary

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Prof. László Endrényi, Toronto, ON, Canada

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Main Topics of the Conference

Bioequivalence Regulatory and Methodology

Philosophical and Social Interpretations for the Impact of Bioequivalence Studies on Public Health
Bioequivalence Studies in Patient Populations: New Challenges and Future Trends
Determination of Bioequivalence of Modified-release Formulations
Avoid Excessive Numbers of Subjects in Clinical Trials

Regulatory Update of BCS and Biowaivers

Update on New BCS Draft Guidance Biowaivers and Beyond...
BCS of Drugs: An Ever-evolving Field
Biowaivers and Common Sense, EU Regulatory Examples

Biosimilars and Nanosimilars: Challenges and Regulatory Pathways

Nanomedicines and Nanosimilars: Regulatory and Market Landscape
Analytical Challenges of Biosimilars

Advances in Bioanalytical Testing

Analytical Challenges for Bioequivalence and Biosimilar Development
Challenges in Characterizing Nanoparticle Drugs
Advances in Bioanalytical Techniques
Bioanalytical LC/MS Methods in Generic and Biological Drug Development

In Vitro Dissolution Perspectives

Advances in In Vitro Dissolution
In Vitro Release Methodology for Topical Semisolid Drug Products

Advances in Pharmaceutical Technology, Drug Development and Beyond

Small is Beautiful: Surprising Nanoparticles
Nanomedicine for Topical Drug Delivery
Micro- and Nanofibrous Delivery Systems
Alcohol Resistant Formulations
Brain Drug Delivery
New Treatment Perspectives for Spinal Cord Injury



Scientific Program

The Conference starts on Saturday at 9:00 am.

Opening Ceremony

Session 1

Philosophical and Social Interpretations for the Impact of Bioequivalence Studies on Public Health: Long-Term Life Experiences

A. Atilla Hincal

Hacettepe University, Ankara, Turkey

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

Biopharmaceutic Classification of Drugs: An Ever-Evolving Field

Panos Macheras

National and Kapodistrian University of Athens, Athens, Greece

Regulatory Update – What is New in BCS and Biowaivers and Beyond...

Vinod P. Shah

International Pharmaceutical Federation / SIG,

Chair of Regulatory Sciences, North Potomac, MD, USA

Some Issues on the Determination of Bioequivalence of Modified-Release Formulations

László Endrényi¹, László Tóthfalusi²

¹University of Toronto, ON, Canada; ²Semmelweis University, Budapest, Hungary

Coffee Break, Exhibition

Session 2

Small is Beautiful: Surprising Nanoparticles

Dominique Duchêne

Université Paris-Sud, Paris, France

Nanomedicines and Nanosimilars: Regulatory and Market Landscape

Erem Bilensoy

Hacettepe University, Ankara, Turkey

Applications of *In Vitro* Release Methodologies for Topical Semisolid Drug Products

Flavian Stefan Rădulescu

University of Medicine and Pharmacy Carol Davila Bucharest, Bucharest, Romania

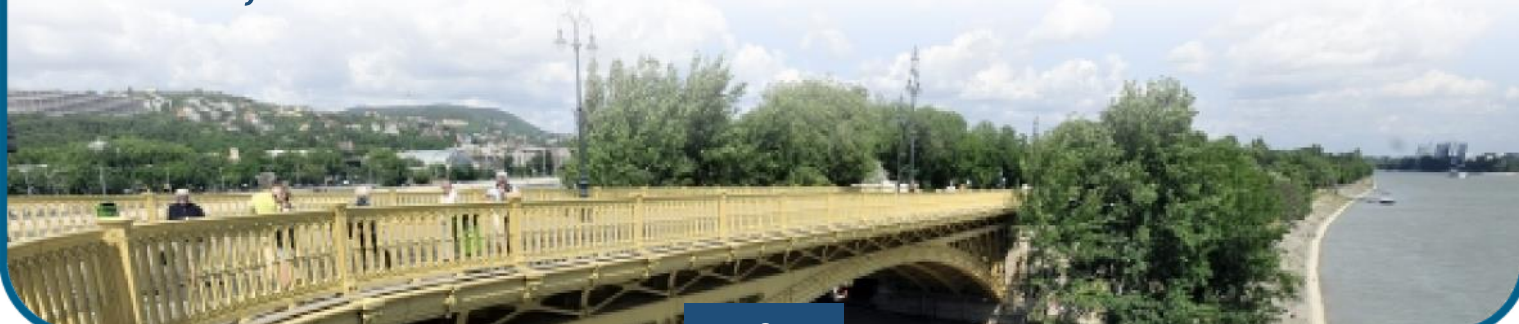
Analytical Challenges for Bioequivalence and Biosimilar Development

Surendra K. Bansal

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

Panel Discussion I. – Q and A

Lunch, Exhibition



Session 3

Bioequivalence Studies in Patient Populations: New Challenges and Future Trends

Henning H. Blume

SocraTec R&D Ltd., Oberursel, Germany

The New Treatment Perspectives for Spinal Cord Injury

Hakan Eroğlu

Hacettepe University, Ankara, Turkey

Brain Drug Delivery

Yilmaz Capan

Hacettepe University, Ankara, Turkey

Micro- and Nanofibrous Delivery Systems – A Potential Tool for Tunable Drug Release

István Sebe, Romána Zelkó

Semmelweis University, Budapest, Hungary

Nanomedicine for Topical Drug Delivery

Carla M. Caramella

University of Pavia, Pavia, Italy

Coffee Break, Exhibition

Session 4

Between the Beaker and Bottle

Clive G. Wilson

University of Stathclyde, Glasgow, Scotland, UK

Avoid Excessive Numbers of Subjects in Clinical Trials

Constantin Mircioiu, Valentina Anuta

University of Medicine and Pharmacy Carol Davila Bucharest, Bucharest, Romania

Biowaivers and Common Sense EU Regulatory Examples

Tamás L. Paál

University of Szeged, Szeged, Hungary

National Institute of Pharmacy and Nutrition, Budapest, Hungary

Panel Discussion II. – Q and A

75th Birthday Celebration in the honour of Prof. A. Atilla Hincal

Closing Ceremony



Registration

Registration is required for all conference participants preferably **until November 1, 2015**. It is recommended to make the registration online. In order to avoid double charges, please register only **ONCE**. **The deadline to pay the early bird fees is November 1, 2015 also**. Any registration and payment received after that date will be accepted as regular registration. Confirmation will be sent to all participants by the organisers upon receipt of registration and payment.

Registration fee:

150 EUR
(incl. VAT)

Our fees include:

- Access to all scientific sessions
- Admission to the exhibition
- Printed material of the workshop
- Conference folder
- Coffee breaks
- Lunch
- Conference banquet dinner

For accompanying persons:

100 EUR
(incl. VAT)

For accompanies:

- Coffee breaks
- Lunch
- Conference banquet dinner

*Access to scientific sessions
is NOT INCLUDED*

For further details and online registration please visit: icab2015.hu

Cancellation policy of registration

All the 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 handling fee of 50 Euro) – in case of cancellation received before November 7, 2015
- No refund – in case of cancellation, received after November 7, 2015

Payment

All payments should be made in Euro. 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

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Venue

Hotel Danubius Health Spa Resort Margitsziget**Superior**

Margitsziget (Margaret Island) H-1007 Budapest, Hungary

Accommodation

Danubius Health Spa Resort Margitsziget****Superior is the official conference hotel. You can book a room at the special conference rates by using the special hotel reservation link from the website: [http://www.icab2015.hu / VAT](http://www.icab2015.hu/VAT), city tax and the breakfast are included in the prices./

Danubius Health Spa Resort Margitsziget**Superior**

Address: H-1007 Budapest, Margitsziget (Margaret Island)

Location from the Symposium venue: on site

Prices:

Single occupancy guest room: 75 EUR/room/night

Double occupancy guest room: 85 EUR/room/night

267 rooms (227 twin, 12 double, 4 single, 16 Junior suite, 8 suite); Rooms for disabled people, Connecting rooms. Executive floor with Executive breakfast lounge. Air-conditioning, balcony, bathrobe, hairdryer, minibar, safe, TV, free WiFi, telephone, coffee- and tea-making facilities. Business centre, room service, laundry, souvenir shop, concierge service, transfer, car-rental service, car park and garage.

SPA, WELLNESS, FITNESS: Indoor and outdoor pools, adventure pool with jacuzzi, thermal bath, therapeutic exercise thermal bath, sauna, steam room, aroma cabin and fitness room. The use of spa and fitness area included the hotel room rate.

Further services (extra): salt cave, cardio centre, laser eye clinic, dental clinic, solarium, infra-sauna, Emporium Hair and Beauty, cosmetic surgery.

For further hotel recommendations please contact the Conference Secretariat by e-mail.



Exhibition and Sponsorship

The Organizers of the Conference 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 meeting, 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.

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

icab2015.hu



Post Conference Excursion

After a day of full of science we cordially invite you to a facultative excursion to the magnificent Danube Bend, which is one of the most beautiful parts of Hungary very close to the capital city, Budapest. During the trip we will see the most important towns along the way: Szentendre, Visegrád and Esztergom. Join the trip and come with us to discover this wonderful region.

Price: 90 EUR

**full day trip, including bus transportation,
all meals and programs**