



International Conference on Advances in the Area of Bioequivalence

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

November 14, 2015

**FINAL PROGRAM &
BOOK OF ABSTRACTS**



International Conference on Advances in the Area of Bioequivalence 2015

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

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International Conference on Advances in the Area of Bioequivalence 2015

Final Program & Book of Abstracts
November 14, 2015, Budapest, Hungary

Editors-in-chief: Imre Klebovich, Vinod P. Shah, László Endrényi

Technical editors: Balázs Baksa, Róbert Hohol

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The professional and grammatical level of the materials is the authors' responsibility.

ISBN 978-615-5270-22-2

Printed in Hungary – 2015
OOK-Press Ltd., Veszprém, Hungary
Responsible for printing: Attila Szathmáry



Organized by the

**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 (MTA)
Budapest, Hungary**



**Hungarian Society for Pharmaceutical Sciences (HSPS)
Budapest, Hungary**

under the auspices of the



**European Federation for Pharmaceutical Sciences (EUFEPS)
Järfälla (Stockholm), Sweden**

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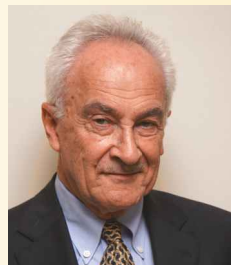
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Imre Klebovich



Prof.
Vinod P. Shah



Prof.
László Endrényi

Co-Chairs of the Symposium

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 (two in one) 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 The conference topic will also update on new BCS draft guidance and biowaivers.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 and biological sample transportation companies assuring GLP and GCP-conform conditions. The exhibition will be well-suited to the professional program of the Conference. The organizers' intention is to give a comprehensive review about the current status of this multidisciplinary field.

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 (two in one) 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 Vinod P. Shah in blue ink.

Handwritten signature of László Endrényi in blue ink.

Scientific Program

9:00 – 9:30

Opening Welcome

Imre Klebovich

Co-Chair of the Conference

Chair of the Committee on Pharmaceutical Sciences,

Chair of the Working Committee on Separation Sciences of the
Hungarian Academy of Sciences (MTA)

Budapest, Hungary

Ferenc Bánhidý

Vice Rector of Semmelweis University

Budapest, Hungary

Hilda Kőszegi-Szalai

Head of the National Institute of Pharmacy Directorate

Budapest, Hungary

Éva Szökő

President of the Hungarian Society for Pharmaceutical Sciences

Budapest, Hungary

Erem Bilensoy

President of the European Federation of Pharmaceutical Sciences (EUFEPS),

Järfälla (Stockholm), Sweden

László Endrényi

Co-Chair of the Conference

Former President of the Canadian Society of Pharmaceutical Sciences

Toronto, ON, Canada

Vinod P. Shah

Co-Chair of the Conference

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: Advances in Bioequivalence

Chairs: **Dominique Duchêne** (Paris, France)
Imre Klebovich (Budapest, Hungary)

- 9:30–9:50 **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 Consultation on Registration & Biopharmaceutics, Education Ltd. Co., Ankara, Turkey
- 9:50–10:10 **Biopharmaceutic Classification of Drugs: An Ever-Evolving Field**
Panos Macheras
National and Kapodistrian University of Athens, Athens, Greece
- 10:10–10:30 **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
- 10:30–10:50 **Some Issues on the Determination of Bioequivalence of Modified-Release Formulations**
László Endrényi¹, László Tóthfalusi²
¹*University of Toronto, Toronto, ON, Canada*
²*Semmelweis University, Budapest, Hungary*
- 10:50–11:20 **Coffee Break, Exhibition**

Session 2: Advances in Analysis

Chairs: *Milena Jadrijević-Mladar Takač* (Zagreb, Croatia)
A. Atilla Hincal (Ankara, Turkey)

- 11:20–11:40 **Small is Beautiful: Surprising Nanoparticles**
Dominique Duchêne
Paris-Sud University, Châtenay Malabry - Paris, France
- 11:40–12:00 **Nanomedicines and Nanosimilars: Regulatory and Market Landscape**
Erem Bilensoy
Hacettepe University, Ankara, Turkey
- 12:00–12:20 **Applications of *In Vitro* Release Methodologies for Topical Semisolid Drug Products**
Flavian Stefan Rădulescu, Dalia Simona Miron
University of Medicine and Pharmacy “Carol Davila” Bucharest, Bucharest, Romania
- 12:20–12:40 **Analytical Challenges for Bioequivalence and Biosimilar Development**
Surendra K. Bansal
F. Hoffmann-La Roche Innovation Center, New York, NY, USA
- 12:40–13:00 **Panel Discussion I. – Q and A**
Moderators: *Henning H. Blume* (Oberursel, Germany)
Clive G. Wilson (Glasgow, Scotland)
- 13:00–14:00 **Lunch**
at the “Széchenyi Restaurant” of
Grand Hotel Margitsziget **** Superior

Session 3: Advances in Drug Delivery

Chairs: **Erem Bilensoy** (Ankara, Turkey)
Panos Macheras (Athens, Greece)

14:00–14:20 **Bioequivalence Studies in Patient Populations:
New Challenges and Future Trends**

Henning H. Blume

SocraTec C&S Ltd., Oberursel, Germany

14:20–14:40 **New Treatment Perspectives for Spinal Cord Injury**

**Hakan Eroğlu¹, Alice Gaudin^{2,3}, Sinda Lepetre-Mouelhi^{2,3},
Ömer Faruk Türkoğlu⁴, Mustafa F. Sargon⁵, Patrick Couvreur^{2,3}**

¹*Hacettepe University, Faculty of Pharmacy, Ankara, Turkey*

²*Paris-Sud University, Châtenay Malabry - Paris, France*

³*Labex d'Excellence NanoSaclay, Paris-Saclay, France*

⁴*Ankara Atatürk Research and Training Hospital, Ankara, Turkey*

⁵*Hacettepe University, Faculty of Medicine, Ankara, Turkey*

14:40–15:00 **Brain Drug Delivery**

Yilmaz Çapan

Hacettepe University, Ankara, Turkey

15:00–15:20 **Micro- and Nanofibrous Delivery Systems –
A Potential Tool for Tunable Drug Release**

István Sebe, Romána Zelkó

Semmelweis University, Budapest, Hungary

15:20–15:40 **Nanomedicine for Topical Drug Delivery**

Carla M. Caramella

University of Pavia, Pavia, Italy

15:40–16:10 **Coffee Break, Exhibition**

Session 4: Alcohol Resistant Formulations, Clinical Trials and Regulations

Chairs: *Surendra K. Bansal* (New York, NY, USA)
Nilüfer Tarimci (Ankara, Turkey)

16:10–16:30 Between the Beaker and Bottle

Clive G. Wilson

University of Stathclyde, Glasgow, Scotland, UK

16:30–16:50 Avoid the Use of Excessive or Inadequate Numbers of Research Subjects in Clinical Trials

Constantin Mircioiu¹, Valentina Anuta²

¹Department of Biostatistics, University of Medicine and Pharmacy

"Carol Davila" Bucharest, Bucharest, Romania

²Department of Physical Chemistry, University of Medicine and Pharmacy

"Carol Davila" Bucharest, Bucharest, Romania

16:50–17:10 Biowaivers and Common Sense

EU Regulatory Examples

Tamás L. Paál

University of Szeged, Szeged, Hungary

National Institute of Pharmacy and Nutrition (OGYÉI), Budapest, Hungary

17:10–17:30 Panel Discussion II. – Q and A

Moderators: *Vinod P. Shah* (North Potomac, MD, USA)

Tamás L. Paál (Szeged, Budapest, Hungary)

17:30–17:40

Closing Ceremony

17:40–18:15

**75th Birthday Celebration
Honoring Prof. A. Atilla Hincal**

Social Programs

19:30–20:15 **Concert of the Semmelweis Chamber Orchestra**
Conductor László Tardy

Hotel Danubius Health Spa Resort Margitsziget**Superior**
Margaret Island, Budapest, Hungary
Lecture Hall "Magnólia"



Detailed Concert Program on the Invitation Card

Social Programs

20:30-24:00

Conference Banquet Dinner

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

Welcome Addresses by: Vinod. P. Shah, László Endrényi and Imre Klebovich
Co-Chairs of the Conference
North Potomac, Toronto, Budapest



The Performer of the Evening:

Atlantis Band
Salon and Dance Music

Entry by Badge and Invitation Card only

General Information

General Information

Date and Venue

The Conference is held at the

Hotel Danubius Health Spa Resort Margitsziget ****Superior

on November 14, 2015.

**Address: Margaret Island, H-1007 Budapest
Lecture Hall "Magnólia"**

Website of the Conference

www.icab2015.hu

Language of the Conference

The official language of the Conference is English.

No simultaneous translation will be provided.

Conference Assistance

Conference assistants will be recognisable by their badge and T-shirts with a sign:

HELP DESK/ORGANIZER

They will help you in all practical aspects of Conference participation at the registration desk. In case of emergency please call this mobile phone number: +36 20 936 2969.

Registration and Information Desk

The registration desk is located in the lobby of the Hotel.

Opening hours:

08:00 – 17:30 Saturday, November 14, 2015

Conference delegates and their companions will receive their badges, conference materials, concert and social event tickets at the desk.

Badges

All participants and accompanying persons will receive a personal badge upon registration. You are kindly requested to wear your name badge when attending the meetings or social event. Only participants who are wearing their name badge will be admitted to the lecture hall and the social events.

General Information

Internet Access

As a courtesy to all delegates, free wifi is available within the building for your own devices. The name of the network is **Danubius_free**. Password: **danubius40**

Car Parking

Parking place are are available in the parking lot, located in front of the Hotel Danubius Health Spa Resort Margitsziget****Superior.

Parking fees:

9 Euro / car / day for hotel guest.

400 HUF / car / hr for Conference guest, who has no accommodation in the hotels.

Please choose the **HOTEL button** at the entrance to the Margaret Island to be able to get the above mentioned reduced prices.

Mobile Phones

Delegates are politely requested to keep their mobile phones switched off in the meeting room during all sessions.

Smoking

Smoking is strictly prohibited within the building. It is admitted only in front of the entrance.

Liability and Insurance

The organizers cannot accept liability for personal accidents, loss of belongings or damage to private property of participants and accompanying persons that may occur during the Conference. Participants are advised to make their own arrangements to obtain health, travel and property insurance.

Public Transport in Budapest

Public transport in Budapest is provided by Budapest Transport Ltd. (known to all Hungarians simply as BKV). Budapest has an efficient public transport network. In general the buses, trams and trolleybuses operate between 4:30 and 23:00. All night bus service operates on the major thoroughfares in the city (night bus timetables are posted at stops and in most metro stations). The three metro lines intersect at Deák Square in the centre of the town, close to the venue. Metros run at 2-15 minutes intervals from about 4:30 to 23:15.

Telephone

The international code for Hungary is 36, the area code for Budapest is 1. To call a number within Hungary, first dial 06. Budapest telephone numbers have seven digits, all other areas have six digits (in addition to the area codes). To make an international call from Hungary, first dial 00, then the country code followed by the area code and the subscriber's telephone number. Public telephones accept either coins (20, 50, and 100 HUF) or phone cards (available from tobacconists, newsagents, post offices, and petrol stations). To call a (Hungarian) mobile phone, from a public telephone first dial 06, followed by the subscriber's seven-digit number starting with 20-, 30- or 70-.

Important Phone Numbers

(English is usually spoken at the emergency numbers listed below.

In case English is not spoken, dial 112)

Ambulance: 104 Fire brigade: 105 Police: 107 Central help number: 112

General enquiries: 197

Inland enquiries: 198

International enquiries: 199

Hungarian Automobile Club help number: 188

Time

Hungary is in the Central European Time Zone (GMT+1:00)

Weather

The weather in Hungary in November is usually cool and foggy. Temperatures are in the range between 8–13 °C during the day.

Advice for your Departure

Airport Minibus

The Airport Minibus service is relatively cheap and reliable. You can buy the ticket at the arrival hall immediately. Single ticket: 3200 HUF (appr. 10€), return: 5500 HUF (appr. 18€). Public transport buses (#200, air conditioned) circulate between the terminals and the Kőbánya-Kispest terminal of the Metro line 3 ("blue line") at 8–15-minute intervals in daytime. As an alternative, trains from Terminal 1 leave for Nyugati railway station frequently.

You may order your Airport Minibus at your hotel at least one day before your departure. Telephone number: (36-1)296-8555.

Phone numbers of some taxi companies:

Főtaxi: +36 1 222-2222, City Taxi: +36 1 211- 1111, Tele5 Taxi: +36 1 555-5555, Budapest Taxi: +36 1 777-7777, Taxi 2000: +36 1 200-0000.

From 1 September 2013 a new regulation came to force which regulates the taxi fares. No fixed, shuttle or pre-agreed prices are available any more. Taxis are coloured to yellow.

Catering Services in the Venue

Coffee Breaks will be located at the exhibition area in the **Café "Kamilla"**.

Lunch will be served at the **"Széchenyi" Restaurant**.

(in the Grand Hotel Margitsziget**** Superior, short walking from the lecture hall, in case of rain a tunnel is available to the other building).

Dedicated time for the catering:

10:50 – 11:20 Coffee Break

13:00 – 14:00 Lunch

15:40 – 16:10 Coffee Break

20:30 – 24:00 **Conference Banquet Dinner** (Restaurant **"Platán"**, optional)

Exhibition

As one of the sponsors or exhibitors at **ICAB 2015** Conference you can present your products and services to a motivated and well informed specialist public from all over the world. Innovative, forward-looking exhibits and system solutions will be brought together in Budapest, the heart of Europe.

Exhibition will take place between the lecture hall (**Room "Magnólia"**) and the **Café "Kamilla"**. This will also give place for the **Coffee Breaks**.

Location of ICAB 2015 Official Hotels

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

Phone:
+36-1-889-4700

Venue:

Danubius Health SpaResort
Margitsziget ** Superior**

Danubius Grand Hotel
Margitsziget ** Superior**



Venues of the Social Programs

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

Saturday, November 14, 2015

Concert of the Semmelweis Chamber Orchestra

Lecture Hall “Magnólia” 18:30–19:15

Conference Banquet Dinner

Restaurant “Platán” 20:30–24:00



Acknowledgement

Prof. Imre Klebovich, the Chair of the Local Organizing Committee of ICAB 2015 International Conference and its Members wish to express their special thanks to the following individuals for their generous and professional assistance with organizing this special Conference.

Without the self-sacrificing work of the distinguished colleagues and friends listed below, ICAB 2015 would not have been made possible on such a high level.

Our gratitude goes to

Mr. Balázs Baksa graphic artist, designer

Mr. László Barva interpreter, host, language editor

Mr. László Tardy Liszt Award winning conductor, musical advisor

Mr. Tamás Thaler photo artist

Mr. Attila Varga, head of Diamond Congress and all his colleagues:

Mr. Róbert Hohol, **Ms. Gabriella Bánfalvi**, **Ms. Zsuzsanna Heiszler**, who contributed with their unparalleled professional work to the success of this human-centered conference.

And all those who helped in any other way in organizing the Conference.

Last but not least, we would like to express our gratitude to Sponsors and Exhibitors for supporting to ICAB 2015 Conference.



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Margaret Island

