



International Symposium on Scientific and Regulatory Advances in Complex Drugs

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

October 27-28, 2014

FIRST CIRCULAR



**Prof.
Imre Klebovich**



**Prof.
Vinod P. Shah**

Co-Chairs of the Symposium

The **International Symposium on Scientific and Regulatory Advances in Complex Drugs** is organized in **Budapest, Hungary, October 27–28, 2014** as a follow-up of very successful series of Bioequivalence Workshops in Hungary. As the science and technologies are advancing, the pharmaceutical world is entering into more complex drug delivery systems and dosage forms. The aim of this and future symposium is to bring the scientific advances and regulatory challenges for generic equivalence of the complex dosage forms.

The symposium will focus on biological and non-biological complex drugs (NBCD). These complex drugs require a paradigm shift for regulatory approval compared to the requirements for small molecules. These complex drugs are difficult to characterize it fully and in many instances the manufacturing process is the product itself. The symposium will discuss NBCDs, what it is and why are they different, scientific and regulatory advances in bioanalytical methodologies to characterize these complex drugs and nanoparticles. The symposium will discuss challenges in bioequivalence evaluation of NBCDs like iron sucrose complex, glatiramoids, and liposome.

The bioequivalence evaluation for complex dosage forms such as highly variable drugs, narrow therapeutic index drugs, orally administered non-absorbed drugs, inhalation drug products such as MDI and DPI and topical drugs require different approaches and considerations, and will also be discussed at the symposium.

With the advancing field of pharmaceutical science, the pharmaceutical industry and CROs also face new challenges, and these will also be discussed. To help young research scientists participate in the international symposium, posters are welcome. At the end of each session, a panel discussion will be held to discuss various viewpoints. The symposium will also provide ample opportunities for the participants to interact with international speakers on different topics. Prominent representatives of pharmaceutical authorities invited from several continents to contribute to the scientific program.

The symposium will end with a new book launch of “History of Hungarian Bioequivalence Workshops”.

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

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 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 Sciences (EUFEPS) (Requested)

Co-Chairs

Prof. Imre Klebovich,
Budapest, Hungary
klebovich.imre@pharma.semmelweis-univ.hu

Prof. Vinod P. Shah,
North Potomac, MD, USA
dr.vpshah@comcast.net

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Symposium Secretariat

Diamond Congress Ltd.
Mr. Attila Varga
H-1255 Budapest, P.O. Box 48,
Hungary



Phone: +36 1 225 0210 **Fax:** +36 1 201 2680
E-mail: diamond@diamond-congress.hu
www.diamond-congress.hu

Main Topics of the Symposium

Biosimilars: Challenges and Regulatory Pathways

Challenges for introduction of biosimilars in the market
Regulatory pathways for biosimilars
Biosimilars in oncology – New concepts with new problems

Non-Biological Complex Drugs

What are NBCDs and what makes them special
Iron sucrose complex
Colloidal (nano-particle) iv iron product
Glatiramoids
Liposomes

Advances in Bioanalytical Testing

Analytical challenges for biosimilar products
Advances in bioanalytical techniques
Challenges in characterizing nanoparticle drugs
Bioanalytical LC/MS Methods in Biological Drug Development

Bioequivalence of Complex Drugs

Bioequivalence of narrow therapeutic index and highly variable drugs
Bioequivalence of topical dosage forms
Bioequivalence of orally administered non-absorbed drugs
Bioequivalence of inhalation drug products

Manufacturing and Formulations

Selection of a drug candidate and dosage form
Challenges in conducting clinical studies
Cyclodextrin formulations of complex drugs
GI absorption models

Monday, October 27, 2014

The Symposium starts on Monday at 9:00 am.

Opening Ceremony

Challenges for Introduction of Biosimilars in the Market

István Greiner

Gedeon Richter Plc., Budapest, Hungary

Regulatory Pathways for Biosimilars

Daan J. A. Crommelin

Utrecht University, Utrecht, The Netherlands

Non-Biological Complex Drugs (NBCDs) – What are the NBCDs and What Makes them Special?

Jon de Vlieger

TI Pharma, Leiden, The Netherlands

Non-Biological Complex Drugs – Iron Sucrose Complex

Stefan Mühlebach

Vifor Pharma Ltd., Glattbrugg, Switzerland

University of Basel, Basel, Switzerland

GI Absorption Models for Early Drug Development and for Prediction of In Vivo Performance of Oral Formulations

Panos Macheras

National and Kapodistrian University of Athens, Athens, Greece

Panel Discussion

Analytical Challenges for Biosimilar Products

Pat J. Sandra

University of Ghent, Ghent, Belgium

Advances in Analytical Techniques

Surendra Bansal

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

Non-Biological Complex Dugs – Challenges in Characterizing Glatiramoids

Vera Weinstein

TEVA Pharmaceuticals, Petach Tikva, Israel

Non-Biological Complex Dugs – Liposomes

Rogério Gaspar (Tentatively Confirmed)

University of Lisbon, Lisbon, Portugal

Challenges with Characterization of Nanoparticle Drugs

Scott McNeil (Tentatively Confirmed)

National Institute of Health (NIH), National Cancer Institute (NCI),

Frederick, MD, USA

Bibliographic Documentation to Authorize a Colloidal (Nano-Particle) IV Iron Product in EU?

Stefan Blesse

Granzer Regulatory Consulting & Services, München, Germany

Panel Discussion

Preliminary Scientific Program – Day 2

Tuesday, October 28, 2014

Complex Drugs: Bioequivalence of Topical Drug Products

Vinod P. Shah

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

Complex Drugs: Bioequivalence of Orally Administered Non-Absorbed Drugs

Henning H. Blume

SocraTec R&D Ltd., Oberursel, Germany

Complex Drugs: Bioequivalence of Inhalation Drug Products - MDI and DPI

Sven Stegemann

*Technical University in Graz, Graz, Austria
Capsugel, Bornem, Belgium*

Special Category of Drugs: Bioequivalence of Narrow Therapeutic Index and Highly Variable Drugs

Leslie Z. Benet

University of California, San Francisco, CA, USA

Challenges in Conducting Clinical Studies by a CRO

A. Atilla Hincal

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

Panel Discussion

Industry Perspectives: Selection of a Drug Candidate and Dosage Form

Avraham Yacobi

DOLE Pharma LLC, Englewood, NJ, USA

Biosimilars in Oncology: New Concepts with New Problems

András Telekes

*Bajcsy-Zsilinszky Hospital, Budapest, Hungary
Semmelweis University, Budapest, Hungary*

Advances in Cyclodextrin Formulations in Complex Drugs

*(Participation confirmed, Speaker to be identified)
CycloLab Ltd.*

Poster Session

Panel Discussion

"History of Hungarian Bioequivalence Workshops"

– A new book launch

Imre Klebovich

Semmelweis University, Budapest, Hungary

Closing Ceremony

The Symposium ends on Tuesday at 6:00 pm.

For the preliminary program please check <http://www.sracd2014.hu> where all the updates can be traced, so we ask you to visit the website regularly.

In addition to the invited speakers as a novelty of this symposium poster presentations are also welcome to encourage the participation of young scientists and researchers from both academic and industrial background.

The main streams of the symposium are organized around the five main topics as follows:

- **Biosimilars: Challenges and Regulatory Pathways**
- **Non-Biological Complex Drugs**
- **Advances in Bioanalytical Testing**
- **Bioequivalence of Complex Drugs**
- **Manufacturing and Formulations**

Participants interested in presenting a poster are kindly requested to submit their one-page abstract online via the Symposium website **latest by September 30, 2014**. Authors will receive notification on acceptance **latest by October 10, 2014**.

Formal requirements

- All abstracts must be written in English
- The abstract text should be within 2500 characters (together with space) and typeface: Arial Type, 12 pt, single space
- The abstract title must be brief (max. 2 lines allowed in "Title Case" format) and clearly indicate the nature of the investigation
- Authors number: will be maximized: 10 names
- Workplaces: max. 10 different workplaces
- The abstract must represent original work and should be as informative as possible. Conclusions must be supported by data. Please include 5 keywords at the end of the abstract text.
- It is the author's responsibility to submit a correct abstract. Any error in spelling, grammar or scientific fact will be reproduced as typed by the author
- Submitted abstracts can be seen, modified or deleted within the whole period of the abstract submission online
- Once the abstract has been submitted, modified or deleted, the corresponding author will automatically receive an acknowledgement of receipt, modification or cancellation (by e-mail)
- Correspondence regarding the abstracts such as confirmation of submission, notification of acceptance or rejection and instructions for presentation will only be sent to the corresponding author. It is his/her responsibility to forward the information to all co-authors.
- The presenting author is required to register for the Symposium and pay the registration fee as a condition of presenting the poster.

Poster dimensions

- Posters will be mounted throughout the whole symposium.
- The recommended poster size is a standing A/O (84 cm x 118 cm) as the size of the poster board is 90 cm at width and 120 cm at height.

Registration

Registration is required for all Symposium participants preferably until September 30, 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 September 30, 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 2014 at
<http://www.sracd2014.hu>**

Registration fees

Registration Type	Early Bird Fee paid until September 30, 2014	Regular Fee paid after September 30, 2014
Registration fee for participants	390 EUR	490 EUR
Registration fee for PhD Students	250 EUR	280 EUR
Accompanying person's fee	200 EUR	200 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 Symposium
- Conference bag
- Banquet dinner with musical performance
- Coffee breaks
- Lunches

Accompanying persons' fee include:

- Lunches
- Banquet dinner with musical performance
- Sightseeing tour

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 Symposium. 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 September 30, 2014
- 50% refund – in case of cancellation received before October 10, 2014
- No refund – in case of cancellation received after October 10, 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. – SRACD2014

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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) are needed during the online registration.

Hotels listed below are the official conference hotels recommended by the Organizers. You can book a room at the special conference rates by using the special hotel reservation form downloadable from the website: <http://www.sracd2014.hu>
VAT, city tax and the breakfast are included in the prices.

Danubius Health Spa Resort Margitsziget***Superior

Description

267 rooms (227 twin, 12 double-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.

Address: H-1007 Budapest, Margitsziget (Margaret Island)
Location from the Symposium venue: on site



Prices:

Single occupancy guest room: 84 EUR/room/night
Double occupancy guest room: 92 EUR/room/night

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.

Danubius Grand Hotel Margitsziget***Superior

Description

164 rooms (79 double, 61 twin 12 double-double, 2 single, 8 suites, 2 presidential suites).
Allergy-friendly rooms, connecting rooms, Air-conditioning, bathrobe, hairdryer, TV, telephone, internet, minibar, coffee- and tea-making facilities, safe.
Room service, laundry, souvenir shop, travel agency, concierge service, car-rental service, free WiFi, car park, garage in the neighbouring Danubius Health Spa Resort Margitsziget.

Address: H-1007 Budapest, Margitsziget (Margaret Island)
Location from the congress venue: 2 minutes on foot.
The conference rooms are located in the neighbouring hotel which is accessible via a connecting corridor, too.



Prices:

Single occupancy guest room: 84 EUR/room/night
Double occupancy guest room: 92 EUR/room/night

SPA, WELLNESS, FITNESS: *(connecting corridor to the spa therapy section of Danubius Health Spa Resort Margitsziget)*

Spa and fitness, wellness: 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.

Address of the Symposium Venue

Danubius Health Spa Resort Margitsziget** Superior**
Address: H-1007 Budapest, Margitsziget (Margaret Island), Hungary



Symposium Banquet Dinner



An elegant seated banquet dinner will be held on a boat cruising on the river Danube at the first night of the Symposium on Monday, October 27, 2014.

All participants, exhibitors and accompanying persons are invited to attend. Departure and landing place from the pier of Margaret Island opposite Grand Hotel Margitsziget. A surprise musical performance will also be organized.

Exhibition and Sponsorship

The Symposium 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 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: <http://www.sracd2014.hu>

Spectacular Sights at Night from the Danube



