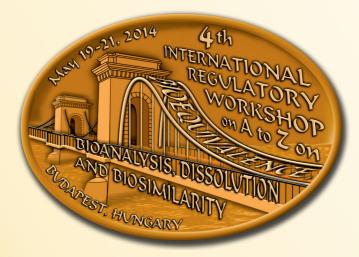
# FINAL PROGRAM





# The Chain Bridge

# The "Bioequivalence Bridge"



## Organizers



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 (MTA)



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)

## **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

# Scientific Advisory Board

Gordon L. Amidon, Ann Arbor, Ml, USA Imre G. Bajusz, Basel, Switzerland Leslie Z. Benet, San Francisco, CA, USA Henning H. Blume, Oberursel, Germany Daan J. A. Crommelin, Utrecht, The Netherlands László Endrényi, Toronto, ON, Canada A. Atilla Hincal, Ankara, Turkey Imre Klebovich, Budapest, Hungary Sabine Kopp, Geneva, Switzerland Panos Macheras, Athens, Greece Kamal K. Midha, London, UK Tamás L. Paál, Budapest, Szeged, Hungary Pat J. Sandra, Ghent, Belgium Vinod P. Shah, North Potomac, MD, USA Sven Stegemann, Bornem, Belgium Clive G. Wilson, Glasgow, Scotland, UK

# Local Organizing Committee

Imre Klebovich (Chair), Budapest István Antal, Budapest György Bagdy, Budapest István Greiner, Budapest Lajos Hegedűs, Gödöllő Tamás Janáky, Szeged Hedvig Juhász, Budapest Lajos Szente, Budapest Imre Szentpéteri, Budapest Éva Szökő, Budapest György Thaler, Budapest László Tóthfalusi, Budapest Romána Zelkó, Budapest

# Workshop Secretariat

H-1255 Budapest, P.O. Box 48, Hungary Phone: +36 1 225 0210 Fax: +36 1 201 2680



Diamond Congress Ltd., Mr. Attila Varga E-mail: diamond@diamond-congress.hu

www.diamond-congress.hu



#### Ladies and Gentlemen, Distinguished Guests,

I am pleased to welcome you to the 4<sup>th</sup> International Regulatory Workshop on A to Z on Bioequivalence, Bioanalysis, Dissolution and Biosimilarity held in this historic venue, the Ceremonial Hall of the



Hungarian Academy of Sciences. The presence of outstanding experts gathering here together ensures that Budapest will be the capital of drug research during the days of the Workshop!

In today's civilisation we take for granted that human life is becoming longer and longer. Living in the age of science, people are getting to know about themselves as biological entities more than ever. However, it also means that healthcare, health sciences and the health industry need to face growing challenges.

By putting new knowledge into practice, science constantly seeks and finds new remedies. As part of this process bringing outstanding results, drug research also faces new challenges. Healing is a complex procedure – so is research into this field! Basic and targeted research, science and practical application should be built upon each other. In this system it is essential for academic and university research institutes, pharmaceutical companies, health authorities and marketing authorisation agencies to conduct responsible cooperation.

The world of pharmaceutical research and industry, like many other healthcare sectors, is currently undergoing a swift transition. Bringing new success requires not only knowledge, but creativity, courage and professional modesty that does not build on the omnipotence of science, but honours the laws of nature.

I hope that the 4<sup>th</sup> International Workshop will be a success, bringing new, inevitable results into the limelight that will contribute to finding remedies for diseases that still cause much suffering and, thus, improving the quality of life.

I wish that the event will provide an adequate framework for fruitful scientific collaboration with new opportunities for finding research perspectives. Outstanding speakers and an expert audience are given – I wish meaningful and valuable discussions!

#### Áder János

President of the Republic of Hungary

Budapest, 7 May 2014



#### Highly Respected Guests, Dear Ladies and Gentlemen,

As resigning President of the Hungarian Academy of Sciences, I am pleased to welcome you to the 4<sup>th</sup> International Regulatory Workshop on A to Z on Bioequivalence, Bioanalysis, Dissolution and Biosimilarity held in Budapest, on May 19–21, 2014 in the



prestigious main building of the Hungarian Academy of Sciences. As pharmaceutics is one of the most successful fields of research in Hungary whose accomplishments are internationally recognised, it is our special pleasure that the Hungarian Academy can provide the venue for this unique conference, the fourth in the line of such scientific gatherings.

Ours is the century of pharmaceutics, I presume. It is an age which urges researchers to answer emerging scientific, social and industrial needs of innovation, healthcare, prevention and therapy. Scientists are facing constant challenges to widen their scope of interest, renew research by integrating multidisciplinary angles, and apply effective methods. The world of pharmaceutical research and industry is currently undergoing a transition where it needs to anticipate and adapt to the expectations and opportunities within an ever-changing scientific landscape to provide the world's population with innovative and value-added medicines through research and development.

Like many other healthcare sectors, in 2020 the pharmaceutical industry will look very different from its state of today. Rising research and development expenditures are, in part, a consequence of the changing industry structure, particularly the emergence of the biotechnology sector. Although the industry is prospering, it needs reinforcement and courage in anticipating, and adapting to the challenges and opportunities of the road ahead.

That is what points to the significance of this highly reputable event at which experts from 40 countries and 5 continents meet to discuss new paradigms in BE evaluations, new perspectives of bioanalytics, in vitro dissolution and drug development, to mention only a few items on the agenda.

I am convinced that this Workshop is to provide a valuable contribution to the mission of pharmaceutics by bringing great minds together from different organisations, from research and development to manufacturing and marketing authorisation.

Hoping that the respectful and inspiring milieu of the Hungarian Academy of Sciences will enhance fruitful discussions, I wish the participants a stimulating and memorable Workshop replete with invigorating enthusiasm for innovative co-operation

Yours faithfully,

Prof. József Pálinkás

Immediate Past President Hungarian Academy of Sciences

Budapest, May 19, 2014



Prof. Imre Klebovich Prof. Vinod P. Shah

**Co-Chairs of the Workshop** 

#### Distinguished Participants, Ladies and Gentlemen,



The 4<sup>th</sup> International Regulatory Workshop on A to Z on Bioequivalence, Bioanalysis, Dissolution and Biosimilarity (BEW) is going to be organized again for the fourth time in Budapest, May 19–21, 2014 in the Ceremonial Hall of the Hungarian Academy of Sciences (MTA), after a range of internationally acknowledged and highly successful series held in 2006, 2010 and 2012. The history of BEW started in 2001 with a Hungarian workshop having about 120 participants and rapidly got extended internationally due to the excellent speakers, actual topics and the wonderful milieu of the MTA building hosting the event. In 2012 we could welcome 270 participants from 37 countries of 5 continents. The BEW 2014 will be a jubilee meeting, the fifth in this row, in Budapest, Hungary.

For this special occasion Magyar Posta (Hungarian Postal Service) is issuing a commemorative sheet on which the Chain Bridge of Budapest, the logo of the Workshop appears referring to the connection of interdisciplinary aspects of this scientific event.

The International Regulatory Workshop on Bioequivalence, Bioanalysis, Dissolution and Biosimilariy 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 generic drug development, and novel drug delivery systems. The meeting will focus also on bioanalytical regulations as well as on trends of bioanalysis. 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 US, EMA and other advanced countries.

We anticipate 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 in Budapest benefiting fully from both our beautiful milieu and the exciting science that will be presented.

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Yours sincerely,

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# **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 Perspe  | ectives |
|---|---------|
| Chairs: Stefan Mühlebach (Glattbrugg, Basel, Switzerland)<br>K. Wayne Riggs (Vancouver, BC, Canada)   |         |
| Hurdles and Challenges in Harmonising Drug Regulations<br>Tamás L. Paál<br>University of Szeged, Szeged, Hungary<br>GYEMSZI-National Institute of Pharmacy, Budapest, Hungary           | 9:30    |
| Basic Concepts: They Keep Changing<br>Leslie Z. Benet<br>University of California, San Francisco, CA, USA   | 10:00   |
| Coffee Break, Exhibition  | 10:30   |
| Session 2: Regulatory Perspectives: Quality and Bioequiv  | alence  |
| Chairs: Tamás L. Paál (Szeged, Budapest, Hungary),<br>Romána Zelkó (Budapest, Hungary)  |         |
| FDA Perspective on Product Quality and Bioequivalence<br>Vinod P. Shah<br>International Pharmaceutical Federation / SIG   | 11:00   |
| Chair of Regulatory Sciences, North Potomac, MD, USA<br>WHO Perspective on Quality Assurance and Medicinal Safety<br>Sabine Kopp<br>World Health Organization, WHO, Geneva, Switzerland | 11:30   |
| Newer Considerations and Regulatory Guidance on BE –<br>EMA Perspective<br>Evangelos Kotzagiorgis   | 12:00   |
| European Medicines Agency, EMA, London, UK  |         |
| Panel Discussion I. Q and A   | 12:30   |
| Moderators: Gordon L. Amidon (Ann Arbor, MI, USA)<br>Roger L. Williams (Rockville, MD, USA)   |         |
| Lunch, Exhibition   | 13:00   |
|   | G       |

| Da    | ay 1: Monday, May 19, 2014   |
|-------|--|
|       |  |
| Sessi | on 3: Advances in Pharmacokinetics   |
|       | Chairs: Surendra K. Bansal (New York, NY, USA)<br>Meir Bialer (Jerusalem, Israel)  |
| 14:00 | Impact of Bioequivalence Studies on the Progresses of Pharma-<br>ceutical Sciences in Generic Industry Within Last 35 Years<br><i>A. Atilla Hincal</i> |
|       | Hacettepe University, Ankara, Turkey<br>İDE Pharmaceutical Registration Biopharmaceutics<br>Consultation Education Ltd. Co., Ankara, Turkey            |
| 14:30 | Advances in Pharmacokinetics Related EMA Regulations<br>José A. G. Morais<br>University of Lisbon, Lisbon, Portugal                                    |
| 15:00 | Oral Drug Absorption: Science and Regulation<br>Panos Macheras<br>National and Kapodistrian University of Athens, Athens, Greece                       |
| 15:30 | Coffee Break, Exhibition   |
|       |  |
| Sessi | on 4: Drug and Food Interactions   |
|       | Chairs: László Endrényi (Toronto, ON, Canada)<br>Peep Veski (Tartu, Estonia)   |
| 16:00 | Drug Interactions - Alcohol, Smoking and Caffeine<br>Imre Klebovich<br>Semmelweis University, Budapest, Hungary  |
| 16:30 | Application of an <i>In Vitro</i> Lipolysis Model to Predict Positive<br>Food Effect<br>James E. Polli<br>University of Maryland, Baltimore, MD, USA   |
| 17:00 | Panel Discussion II. Q and A   |
|       | Moderators: Sabine Kopp (Geneva, Switzerland)<br>Vinod P. Shah (North Potomac, MD, USA)  |
| 10    |  |





| Day 2: Tuesday, May 20, 2014 |  |  |  |
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|                              |  |  |  |
|                              |  |  |  |
| Sessi                        | on 5: BCS, Dissolution and Biowaiver   |  |  |
|                              | Chairs: Olavi Pelkonen (Dulu, Finland)<br>István Tóth (Saint Lucia, Old, Australia)  |  |  |
| 9:00                         | Role of Dissolution in Regulating Pharmaceutical Products<br>Vinod P. Shah<br>International Pharmaceutical Federation / SIG                          |  |  |
| 9:30                         | Chair of Regulatory Sciences, North Potomac, MD, USA<br>BCS and Beyond: Limitations and Harmonization<br>(The New Science of BE)<br>Gordon L. Amidon |  |  |
| 10:00                        | Exploiting BDDCS and the Role of Transporters  |  |  |
|                              | Leslie Z. Benet<br>University of California, San Francisco, CA, USA  |  |  |
| 10:30                        | Coffee Break, Exhibition   |  |  |
|                              |  |  |  |
| Sessi                        |  |  |  |
|                              | Chairs: Evangelos Kotzagiorgis (London, UK)<br>Constantin Mircioiu (Bucharest, Romania)  |  |  |
| 11:00                        | Advances in IVIVC<br>James E. Polli<br>University of Maryland, Baltimore, MD, USA  |  |  |
| 11:30                        | Bioperformance Dissolution Standards:<br>In Vivo Predictive Dissolution (IPD)<br>Gordon L. Amidon  |  |  |
|                              | University of Michigan, Ann Arbor, MI, USA   |  |  |

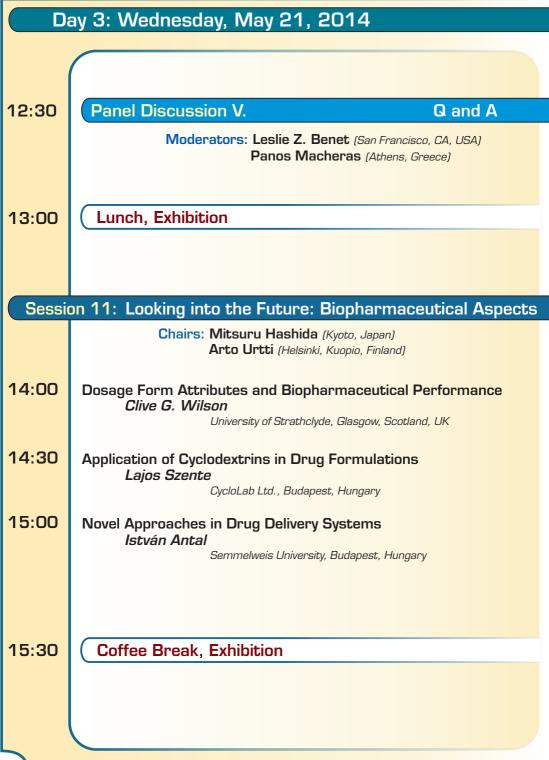
| Day 2: Tuesday, May 20, 20  | 014    |
|---|--------|
|   |        |
|   |        |
| Panel Discussion III. Q and A   | 12:00  |
| Moderators: Daan J. A. Crommelin (Utrecht, The Netherlands)<br>Clive G. Wilson (Glasgow, Scotland, UK)                      |        |
| Lunch, Exhibition   | 12:30  |
|   |        |
| Session 7: Regulatory Trends in Bioar   | alysis |
| Chairs: Hilda Kőszegi-Szalai (Budapest, Hungary)<br>José A. G. Morais (Lisbon, Portugal)                                    |        |
| Bioanalytical Method Validation and Samples Analysis –<br>Lessons Learned from Regulatory Inspections<br>Surendra K. Bansal | 13:30  |
| F. Hoffmann-La Roche Inc., New York, NY, USA  |        |
| Where Are We with Respect to Global Harmonization in<br>Guidance of Bioanalytical Method Validation?<br>Daniel Tang         | 14:00  |
| ICON Development Solutions, APAC, Shanghai, China   |        |
| Analytical Aspects of Biologics Applied in Pharmaceutical<br>Development  | 14:30  |
| Felix Heise, Hanns-Christian Mahler<br>F. Hoffmann-La Roche Ltd., Basel, Switzerland  |        |
| Challenges in Using Capillary Electrophoresis in Analysing<br>Therapeutic Proteins  | 15:00  |
| Jim Thorn<br>AB SCIEX Separations Ltd., Warrington, UK  |        |
| Coffee Break, Exhibition  | 15:30  |
|   | )      |

# Day 2: Tuesday, May 20, 2014

| Sessi | on 8: Biosimilars and Complex Drug Products   |
|-------|---|
|       | Chairs: István Greiner (Budapest, Hungary)<br>Milena Jadrijević-Mladar Takač (Zagreb, Croatia)  |
| 16:00 | Biosimilars: Status Regulatory Pathways and Remaining Questions<br>Daan J. A. Crommelin<br>Utrecht University, Utrecht, The Netherlands   |
| 16:30 | Interchangeability:<br>A Challenge for Non-Biological Complex Drugs (NBCDs)<br>Stefan Mühlebach<br>Vifor Pharma Ltd., Glattbrugg, Switzerland<br>University of Basel, Basel, Switzerland  |
| 17:00 | Assessment of the Similarity and Interchangeability of<br>Biological Drug Products<br>László Endrényi <sup>1</sup> , László Tóthfalusi <sup>2</sup><br><sup>1</sup> University of Toronto, Toronto, ON, Canada<br><sup>2</sup> Semmelweis University, Budapest, Hungary |
| 17:30 | Panel Discussion IV. Q and A  |
|       | Moderators: Nicholas M. Fleischer (Washington, DC, USA)<br>Sven Stegemann (Bornem, Belgium)   |
| Socia | l Programs  |
| 19:30 | Concert of the Dohnányi Orchestra Budafok   |
|       | in the Liszt Ferenc Academy of Music<br>Conductor Gábor Hollerung   |
|       | 1061 Budapest, Liszt Ferenc Square 8.   |
|       | The Sponsor of the Concert:   |
|       | After the Concert:<br>Cocktail Reception in the   |
|       | Liszt Ferenc Academy of Music, 1 <sup>st</sup> floor  |
|       | Entry by badge and invitation card only   |
|       |   |

# Day 3: Wednesday, May 21, 2014

| Session 9: Looking into the l   | uture          |
|---|----------------|
| Chairs: István Antal (Budapest, Hungary)<br>A. Atilla Hincal (Ankara, Turkey)   |                |
| Reducing Regulatory Burden for Well-Established Drugs<br>Roger L. Williams<br>US Pharmacopeia, Rockville, MD, USA   | 9:00           |
| New Challenges but Rewarding Opportunities in Translating<br>Pharmaceutical Development Projects into Successful<br>Therapeutics<br>Imre G. Bajusz  | 9:30           |
| Novartis Pharmaceuticals Ltd., Basel, Switzerland   |                |
| Challenges of Biosimilars – A Perspective<br>István Greiner   | 10:00          |
| Gedeon Richter Plc., Budapest, Hungary  |                |
| Coffee Break, Exhibition  | 10:30          |
|   |                |
| Session 10: Looking into the Future: New Tr   | ends?          |
| Session 10: Looking into the Future: New Tr<br>Chairs: Imre G. Bajusz (Basel, Switzerland)<br>Irene Krämer (Mainz, Germany)   | ends?          |
| Chairs: Imre G. Bajusz (Basel, Switzerland)   | ends?<br>11:00 |
| Chairs: Imre G. Bajusz (Basel, Switzerland)<br>Irene Krämer (Mainz, Germany)<br>The Me-Too Paradigm – a Threat for Pharmaceutical Progress?<br>Roadmap Towards a New Quality Target Product Profile (QTPP)  |                |
| Chairs: Imre G. Bajusz (Basel, Switzerland)<br>Irene Krämer (Mainz, Germany)<br>The Me-Too Paradigm – a Threat for Pharmaceutical Progress?<br>Roadmap Towards a New Quality Target Product Profile (QTPP)<br>for Enhanced Therapeutic Entities<br>Sven Stegemann<br>Capsugel, Bornem, Belgium<br>505(b)(2) New Drug Application Pathway vs. Abbreviated<br>New Drug Application Pathway for Drug Approval in the US<br>Nicholas M. Fleischer   |                |
| Chairs: Imre G. Bajusz (Basel, Switzerland)<br>Irene Krämer (Mainz, Germany)<br>The Me-Too Paradigm – a Threat for Pharmaceutical Progress?<br>Roadmap Towards a New Quality Target Product Profile (QTPP)<br>for Enhanced Therapeutic Entities<br>Sven Stegemann<br>Capsugel, Bornem, Belgium<br>505(b)(2) New Drug Application Pathway vs. Abbreviated<br>New Drug Application Pathway for Drug Approval in the US  | 11:00          |
| <ul> <li>Chairs: Imre G. Bajusz (Basel, Switzerland)<br/>Irene Krämer (Mainz, Germany)</li> <li>The Me-Too Paradigm – a Threat for Pharmaceutical Progress?<br/>Roadmap Towards a New Quality Target Product Profile (QTPP)<br/>for Enhanced Therapeutic Entities<br/>Sven Stegemann<br/>Capsugel, Bornem, Belgium</li> <li>505(b)(2) New Drug Application Pathway vs. Abbreviated<br/>New Drug Application Pathway for Drug Approval in the US<br/>Nicholas M. Fleischer<br/>The Weinberg Group Inc., Washington, DC, USA</li> <li>Modified Release Products: It's Time for International<br/>Harmonisation</li> </ul> | 11:00<br>11:30 |
| <ul> <li>Chairs: Imre G. Bajusz (Basel, Switzerland)<br/>Irene Krämer (Mainz, Germany)</li> <li>The Me-Too Paradigm – a Threat for Pharmaceutical Progress?<br/>Roadmap Towards a New Quality Target Product Profile (QTPP)<br/>for Enhanced Therapeutic Entities<br/>Sven Stegemann<br/>Capsugel, Bornem, Belgium</li> <li>505(b)(2) New Drug Application Pathway vs. Abbreviated<br/>New Drug Application Pathway for Drug Approval in the US<br/>Nicholas M. Fleischer<br/>The Weinberg Group Inc., Washington, DC, USA</li> <li>Modified Release Products: It's Time for International</li> </ul>                   | 11:00<br>11:30 |



# Day 3: Wednesday, May 21, 2014

| Session 12: Looking into the Future: New Delivery Sy  | stems          |
|---|----------------|
| Chairs: Daniel Tang (Shanghai, China)<br>Lajos Szente (Budapest, Hungary)   |                |
| Pharmacovigilance Aspects of Biosimilar Products<br>Irene Krämer  | 16:00          |
| University of Johannes Gutenberg, Mainz, Germany  |                |
| Advances in Targeted and Gene Delivery<br>Mitsuru Hashida<br>Kyoto University, Kyoto, Japan   | 16:30          |
| Ocular Drug Delivery: Formulation and Bioequivalence Issues   | 17:00          |
| Centre for Drug Research, University of Helsinki, Helsinki, Finland<br>School of Pharmacy, University of Eastern Finland, Kuopio, Finland       |                |
|   |                |
| Panel Discussion VI Q and A   | 17.30          |
| Panel Discussion VI.     Q and A       Moderators: James E. Polli (Baltimore, MD, USA)<br>Henning H. Blume (Oberursel, Germany)                 | 17:30          |
| Moderators: James E. Polli (Baltimore, MD, USA)   | 17:30<br>18:00 |
| Moderators: James E. Polli (Baltimore, MD, USA)<br>Henning H. Blume (Oberursel, Germany)  |                |
| Moderators: James E. Polli (Baltimore, MD, USA)<br>Henning H. Blume (Oberursel, Germany)<br>Closing Remarks                                     |                |
| Moderators: James E. Polli (Baltimore, MD, USA)<br>Henning H. Blume (Oberursel, Germany)<br>Closing Remarks<br>Vinod P. Shah and Imre Klebovich |                |





# **General Information**

# **General Information**

#### Date and Venue

The Workshop is held at the Hungarian Academy of Sciences between May 19-21, 2014. Address: H-1051 Budapest, Széchenyi István Sq. 9. 1<sup>st</sup> Floor



#### Website of the Workshop



#### Language of the Workshop

The official language of the Workshop is English. No simultaneous translation will be provided.

#### Workshop assistance

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

#### ORGANIZER

They will help you in all practical aspects of workshop participation at the registration desk.

In case of emergency please call this mobile phone number: +36 20 936 2969

**Registration and information desk** of the main **Ceremonial Hall** on the 1<sup>st</sup> floor.

Opening hours:

 16:00 - 19:00
 Sunday,
 May 18, 2014

 7:30 - 18:00
 Monday,
 May 19, 2014

 8:00 - 18:00
 Tuesday,
 May 20, 2014

 8:00 - 18:00
 Wednesday,
 May 21, 2014

Workshop delegates and their companions will receive their badges, workshop materials 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 events. Only participants who are wearing their name badge will be admitted to the lecture halls and social events.

#### Internet access

As a courtesy to all delegates, free wifi is available within the building for your own laptop. The name of the network is **WORKSHOP** Password: **20BEW414** 

#### Car parking

A limited number of parking places (payable) are available in the parking lot, located in front of the Academy.

#### **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.

#### Foreign exchange, Banking facilities

The official national Hungarian currency is the Hungarian Forint (HUF). All the major credit cards are accepted in Hungary in places displaying the emblem at the entrance. Though Hungary is a member of the European Union, only a few shops and restaurants accept Euros (EUR) for payment. Currency exchange booths are available in Budapest at the airport terminals, railway stations, travel agencies, banks and various places in the city. The exchange rates applied may vary. Traveller's cheques and convertible currency may be exchanged at these facilities. Major credit cards are usually accepted in most hotels, restaurants and certain shops in the city. Obtaining cash against ATM or credit cards is very easy from the ATM cash machines that can be found at almost every office, hotel or on the street.

#### 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 Workshop. 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). Three of the four 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 O6. 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 OO, 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 O6, 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 | General enquiries:                     | 197 |
|----------------------|-----|--|-----|
| Fire brigade:        | 105 | Inland enquiries:                      | 198 |
| Police:              | 107 | International enquiries:               | 199 |
| General help number: | 112 | Hungarian Automobile Club help number: | 188 |

#### Time

Hungary is in the Central European Time Zone. In the summer months clocks are set at GMT + 2 hours.

#### Weather

The weather in Hungary in May is usually sunny and warm. Temperatures are usually in the range between 22 and 24 °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 (app. 18€). Public transport buses (#200E, 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,
 Tele 5 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. The taxis are coloured to yellow.



# **Catering services in Hungarian Academy of Sciences**

Catering (coffee breaks and lunches) will take place in room Vörösmarty and Kodály Hall

in **Academic Club Restaurant** on the ground floor of the venue.

This will also give place for the **exhibition**.

#### Dedicated time for the catering:

#### Monday, May 19, 2014

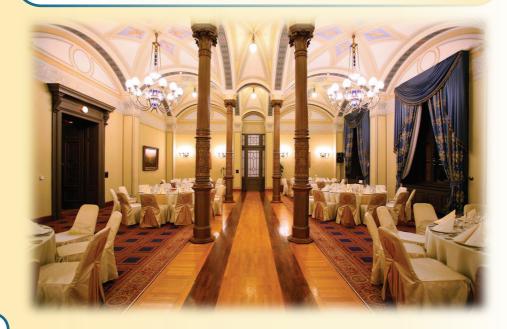
10:30 – 11:00 Coffee break 13:00 – 14:00 Lunch 15:30 – 16:00 Coffee break

#### Tuesday, May 20, 2014

10:30 – 11:00 Coffee break 12:30 – 13:30 Lunch 15:30 – 16:00 Coffee break

#### Wednesday, May 21, 2014

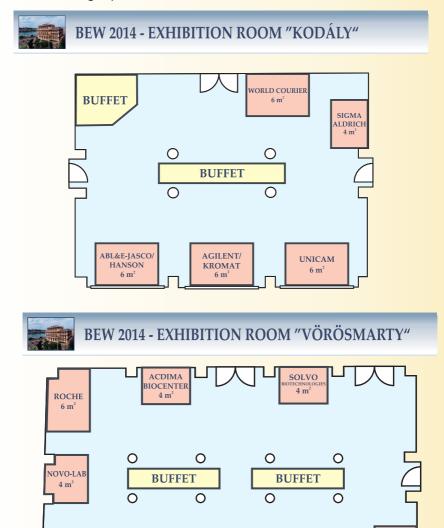
10:30 – 11:00 Coffee break 13:00 – 14:00 Lunch 15:30 – 16:00 Coffee break



## Exhibition

As one of the sponsors or exhibitors at BEW 2014 Workshop 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, where East meets West. Delegates attending BEW 2014 Workshop are mainly researchers from academic and industrial institutions, opinion leaders and decision makers.

**Exhibition** will take place in room **Vörösmarty** and **Kodály Hall** on the ground floor of the venue. This will also give place for the **coffee breaks and lunches**.



**UNILABS** 

6 m<sup>2</sup>

ANNONPHARM

4 m

ERWEKA

4 m<sup>2</sup>

WATERS

6 m

PION Inc.

6 m<sup>2</sup>

# Venue of the social programs Monday, May 19, 2014

19:00-20:30



Conductor László Tardy



Address: 1014 Budapest Szentháromság Square 2.



# Venue of the social programs Monday, May 19, 2014

20:30-24:00





Botalogo Danca Enaambla

> Janő Esza's Dancs and Salon Music Band,



Venue: Hungarian National Gallery

Address:

Royal Palace of Buda Building C. 1014 Budapest, Szent György Square 2.

Justice Canada Annald Martin Canada



Entry by badge only



# Venue: Liszt Ferenc Academy of Music



The Sponsor of the Concert:



After the Concert: Cocktall Reception at Liszt Ferenc Academy of Music 1\* floor

Entry by badge only

Address: 1061 Budapest, Liszt Ferenc Square 8.



# List of BEW 2014 official hotels

#### InterContinental Budapest \* \* \* \* \*

Address: H-1052 Budapest, Apáczai Csere János St. 12-14. Location from the congress venue: 5 minutes on foot. Phone: +36 1 327 6333 Fax: +36 1 327 6357 E-mail: budapest@ihg.com





#### art'otel Budapest \*\*\*\*

Address: H-1011 Budapest, Bem Rakpart 16-19. Location from the congress venue: 10 minutes by public transport. Phone: +36 1 487 9487 Fax: +36 1 487 9488 E-mail: budapest@artotel.hu

#### Mercure Budapest City Center\*\*\*

Address: H-1052 Budapest, Váci St. 20. Location from the congress venue: 10 minutes by public transport or on foot. Phone: +36 1 485 3100 Fax: +36 1 485 3111 E-mail: H6565@accor.com

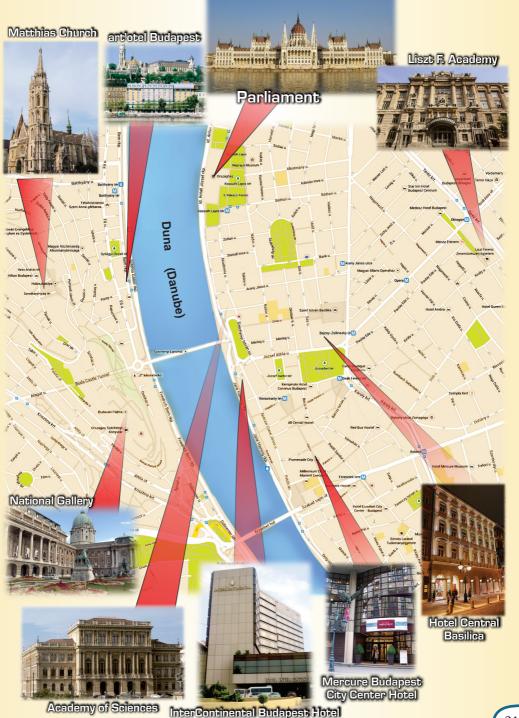




### Hotel Central Basilica \* \* \*

Address: H-1051 Budapest, Hercegprímás St. 8. Location from the congress venue: 5 minutes on foot. Phone: +36 1 328 5010 Fax: +36 1 328 5019 E-mail: info@hotelcentral-basilica.hu

# Location of venues and hotels



## **Sponsors**



# Supporters, Exhibitors



Exhibitors

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## Acknowledgement

Prof. Imre Klebovich, the Chair of the Local Organizing Committee of BEW 2014 International Workshop and its Members wish to express their special thanks to the following individuals for their generous and professional assistance with organizing this special Workshop.

Without the self-sacrificing work of the distinguished colleagues and friends listed below, BEW 2014 would not have been made possible on such a high level.

Our gratitude goes to

Mr. Balázs Baksa animation film direktor, graphic artist, designer Mr. László Barva interpreter, host, tour guide, language editor Mr. László Tardy Liszt Award winning conductor, musical advisor Mr. Tamás Thaler photo artist Mrs. Katalin Vikár hostess of the Workshop, tour guide

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

