2nd ZICPS

2nd Zagreb International Conference on Pharmaceutical Sciences

Sharing a vision Towards better and safe medicines

Under the high auspices of the President of the Republic of Croatia, Prof. dr. Ivo Josipović

25 – 26 October, 2013
Esplanade Zagreb Hotel, Zagreb, Croatia
www.zicps2013.com

FINAL PROGRAMME

Friday, 25 October 2013

Registration

08:00 – 9:00

Registration at Esplanade Zagreb Hotel

Emerald Ballroom, Esplanade Zagreb Hotel

Welcome addresses and opening remarks

09:00 – 9:30

9:30 - 10:10 *Keynote Lecture*
Moderators: **Meindert Danhof**, EUFEPS & **Vinod P. Shah**, FIP SIG on Regulatory Sciences

The potential outcomes for new concepts in drug discovery and development towards better and safer medicines

Leslie Z. Benet
University of California, San Francisco, CA, USA

Session I

Towards better and safe medicines

10:10 – 12.10

Session Leaders*:*

Daan J.A. Crommelin, Utrecht University, Utrecht, Netherlands
Hans H. Linden, EUFEPS, Stockholm, Sweden

Concerns and hopes for better medicines and their safety

10:10 - 10:40

Vinod P. Shah
FIP SIG on Regulatory Sciences Chair, AAPS Former president, North Potomac, MD, USA

Revolutionising biomedical research education and training in Europe – Experiences, achievements, obstacles and perspectives

10:40 - 11:10

Mike Hardman
IMI JU EMTRAIN Project Coordinator, AstraZeneca R&D Science Policy, Macclesfield, Cheshire, United Kingdom

Harmonizing pharmaceutical science, practice and education towards global health

11:10 - 11:50

Kamal K. Midha
FIP Immediate Past President, Saskatoon, SK, Canada

Q & A

11:50 – 12:10

Coffee/Tea

Session II

Implementation of regulatory sciences leads to better quality of medicines

12:40 – 14.00

Session Leaders*:*

Mike Hardman, IMI JU EMTRAIN, AstraZeneca R&D Science Policy, Macclesfield, Cheshire, United Kingdom
Vinod P. Shah, FIP SIG on Regulatory Sciences (Chair), AAPS (Former president), North Potomac, MD, USA

European Medicines Agency - regulatory perspectives on the safety of medicines

12:40 - 13:10

Sabine Brosch
Business Lead, EudraVigilance and International Standardisation in PhV, European Medicines Agency, European Union, United Kingdom

Research misconduct and publishing ethics

13:10 - 13:40

Jaap van Harten
Elsevier BV, Amsterdam, The Netherlands

Q & A

13:40 – 14:00

Lunch

14:00 – 15:00

Poster Session

Session III

Safety from molecule to medicine's usage – Academia and pharmaceutical industry perspectives

15:00 – 17.50

Session Leaders*:*

Lennart Dencker, EUFEPS, Uppsala University, Uppsala, Sweden
Milena Jadrijević-Mladar Takač, EUFEPS, CPhS, University of Zagreb, Croatia

Systems pharmacology – towards the prediction of efficacy and safety

15:00 - 15:30

Meindert Danhof
EUFEPS, Leiden Amsterdam Center for Drug Research (LACDR), Leiden, The Netherlands

Safety on a molecular level

15:30 - 16:00

Andreas Link
University of Greifswald, Germany

Avoiding interaction between drugs - Industrial versus academic perspectives

16:00 - 16:30

Imre Klebovich
Semmelweis University, Budapest, Hungary

Forty years of academic biopharmaceutical sciences and Its impact on drug development

16:30 - 17:00

Leslie Z. Benet
University of California, San Francisco, CA, *USA*

Bridging the gap between industry and academia in achievement of scientific goals and safety of medicines

17:00 - 17:30

Eva-Maria Muchitsch
EUFEPS, Baxter, Vienna, Austria

Q & A

17:30 – 17:50

Coffee/Tea

Elsevier seminar

How to write great papers: from title to references, from submission to publication

18:15 - 19:45
Jaap van Harten
Elsevier BV, Amsterdam, The Netherlands

Banquet Dinner/ Pharmaceutical Ball – Pharmaceutical scientists gathering together with practitioner
Emerald Ballroom, Esplanade Zagreb Hotel

21:00

Saturday, 26 October 2013

Session IV

Through education and networking in sciences towards better and safe medicines and patients' wellbeing

08:30 – 10.50

Session Leaders*:*

Leslie Z. Benet, University of California, San Francisco, CA, USA
Meindert Danhof, EUFEPS, Leiden Amsterdam Center for Drug Research (LACDR), Leiden, The Netherlands

Improved sciences education and training: Systems approach and collaboration

08:30 - 9:00

Hans H. Linden
EUFEPS Senate, Leader European Projects, Stockholm, Sweden

New education and training technologies

09:00 - 9:30

Clive G. Wilson
University of Strathclyde, Glasgow, Scotland, United Kingdom

European standards of doctoral training as a way to build evidence based knowledge about medicines

09:30 - 10:00

Zdravko Lacković
ORPHEUS, University of Zagreb, Zagreb, Croatia

Networking of EUFEPS contributes to pharmaceutical sciences advancements

10:00 - 10:30

Lennart Dencker
EUFEPS, University of Uppsala, Uppsala, Sweden

Q & A

10:30 – 10:50

Coffee/Tea

Session V

Regulatory perspectives on bioequivalence and biosimilarity of medicines

11:30 – 13.50

Session Leaders*:*

Kamal K. Midha, FIP, Saskatoon, SK, Canada
Clive G. Wilson, University of Strathclyde, Glasgow, Scotland, United Kingdom

Impact of bioequivalence studies on the progresses of pharmaceutical sciences within last 35 years

11:30 - 13:00

A. Atilla Hincal
IDE Information Center Education and Consultancy Ltd Co, Ankara/İstanbul, Turkey

US-FDA Perspectives on bioequivalence regulations - Challenges in meeting bioequivalence requirements

13:00 - 12:30

Vinod P. Shah
FIP SIG RS (Chair), AAPS (Former president), North Potomac, MD, USA

EMA Perspectives in BE regulations

12:30 - 13:00

José A. G. Morais
University of Lisbon, Lisbon, Portugal

‘Biosimilarity’, an evolving paradigm for biologicals and non-biological complex drugs

13:00 - 13:30

Daan J. A. Crommelin,
Utrecht University, Utrecht, The Netherlands

Q & A

13:30 – 13:50

Lunch

14:00 – 15:00

Poster Session

Session VI

National regulatory approaches versus international trends

15:00 – 17.20

Session Leaders*:*

A. Atilla Hincal, IDE Information Center Education and Consultancy Ltd Co, Ankara/İstanbul, Turkey
Imre Klebovich, Semmelweis University, Budapest, Hungary

Croatian regulatory approaches in the EMA strategic frame

15:00 - 15:30

Viola Macolić Šarinić
HALMED, Zagreb, Croatia

Novel technologies for controlled drug delivery: Balancing innovation with regulatory compliance

15:30 - 16:00

Carla M. Caramella
Department of Drug Sciences – University of Pavia-I, Pavia, Italy

Developmental risk management plan - A living document

16:00 - 16:30

Vid Stanulović
Aprova- an Alten Company, Boulogne-Billancourt Cedex – France

There are no borders for sciences nor for medicines market – Medicines safety is an imperative for health

16:30 - 17:00

Milena Jadrijević-Mladar Takač
EUFEPS, University of Zagreb, Croatia

Q & A

17:00 – 17:20

Closing ceremony

Moderator: **Vinod P. Shah**, FIP SIG on Regulatory Sciences Chair

17:20 – 18:00

Closing ceremony lecture

The faith of pharmaceutical sciences in the frame of regulatory sciences advancements

17:20 - 17:50

Rogério Gaspar
University of Lisbon, Lisbon, Portugal

Concluding remarks

17:50 – 18:00