



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

PRELIMINARY 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

CPHS, EUFEPS, FIP, AAPS and HR President

Session I

Towards better and safe medicines

09:30 – 11.30

Session Leaders:

Hans H. Linden, EUFEPS, Stockholm, Sweden

Rogerio Gaspar, University of Lisbon, Lisbon, Portugal

Concerns and hopes for better medicines and their safety

09:30 - 10:00

Vinod P. Shah

FIP SIG Regulatory Sciences Chair, AAPS Former president, North Potomac, MD, USA



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

10:00 - 10:30

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

10:30 - 11:00

Kamal K. Midha

FIP Immediate Past President, Saskatoon, SK, Canada



Coffee/Tea

11:00 – 11:30

Session II

Implementation of regulatory sciences leads to better quality of medicines

11:30 – 14:00

Session Leaders:

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

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

Can we predict a future of medicines? – Challenges and needed changes - Where urgent changes have to be made?

11:30 - 12:00

Leslie Z. Benet

University of California, San Francisco, CA, USA



Which factors contribute to better and safe medicines, and which don't? Perspectives, challenges and obstacles

12:00 - 12:30

Henning H. Blume

SocraTec R&D Ltd., Oberursel, Germany

European Medicines Agency - regulatory perspectives on the safety of medicines

12:30 - 13:00

Sabine Brosch

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



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

13:00 - 13:30

Rogerio Gaspar

EUFEPS, University of Lisbon, Lisbon, Portugal



Q & A

13:30 – 14:00

Lunch

14:00 – 15:00

Session III

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

15:00 – 18:30

Session Leaders:

Kamal K. Midha, FIP, Saskatoon, SK, Canada

Lennart Dencker, EUFEPS, Uppsala University, Uppsala, Sweden

Translational drug discovery and development – the role in safety of medicines

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

EUFEPS, University of Greifswald, Germany



Avoiding interaction between drugs - Industrial versus academic perspectives

16:00 - 16:30

Imre Klebovich

Semmelweis University, Budapest, Hungary



Coffee/Tea

16:30 – 17:00

To which extent academia need to follow fast changes in pharmaceutical industry?

17:00 - 17:30

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

17:30 - 18:00

Eva-Maria Muchitsch

EUFEPS, Baxter, Vienna, Austria



Q & A

18:00 – 18:30

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

20:30

Friday, 25 October 2013

Session IV

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

08:30 – 11.00

Session Leaders:

Meindert Danhof, EUFEPS, Leiden Amsterdam Center for Drug Research (LACDR), Leiden, The Netherlands
Milena Jadrijević-Mladar Takač, EUFEPS, CPhS, University of Zagreb, Croatia

Sciences education and training: A systems approach by European 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

EUFEPS, 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 – 11:00

Coffee/Tea

11:00 – 11:30

Session V

Regulatory perspectives on bioequivalence and biosimilarity of medicines

11:30 – 14:00

Session Leaders:

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

Henning H. Blume, SocraTec R&D Ltd., Oberursel, Germany

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

11:30 - 12:00

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

12:00 - 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 – 14:00

Lunch

14:00 – 15:00

Session VI

National regulatory approaches versus international trends

15:00 – 17:00

Session Leaders:

Imre Klebovich, Semmelweis University, Budapest, Hungary

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

Croatian regulatory approaches in the EMA strategic frame

15:00 - 15:30

Viola Macolić Šarinić

HALMED, Zagreb, Croatia



Bridging the gap national versus international in regulatory sciences approaches – Croatian perspectives

15:30 - 16:00

Siniša Tomić

HALMED, Zagreb, Croatia



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

16:00 - 16:30

Milena Jadrijević-Mladar Takač

EUFEPS, University of Zagreb, Croatia



Q & A

16:30 – 17:00

Concluding remarks

17:00 – 17:30