EUFEPS

NEWS Letter

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Conference Report

LEADING ARTICLE

Networking in Pharmaceutical Sciences

EUFEPS/CPhS Conference • February 27 • 2009 • Zagreb • Croatia

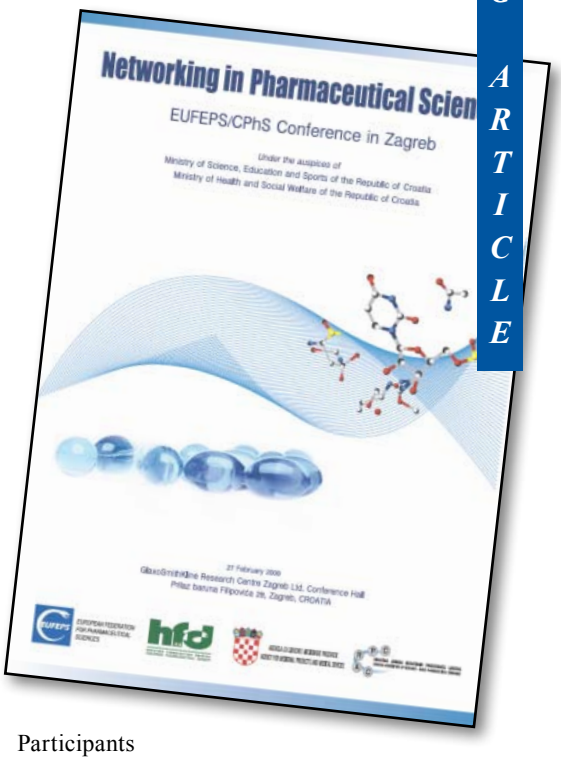
Introduction

The tremendous advances of science and its application in technology, from drug modeling to drug formulation, emphasize the role and importance of networking in pharmaceutical sciences. Scientists know well that they sometimes bear an exceptional responsibility in the world. The spreading of knowledge and information contribute to educational, cultural and intellectual enrichment, which in turn lead to technological advancement and economic advantage. In this context an international conference was organised in Zagreb with the main aim to support pharmaceutical sciences and networking of pharmacists wherever they work, in industry, academia or regulatory bodies.

Conference

The EUFEPS/CPhS Conference in Zagreb 'Networking in Pharmaceutical Sciences' was organized by the European Federation for Pharmaceutical Sciences (EUFEPS) and the Croatian Pharmaceutical Society (CPhS) under the auspices of the Ministry of Science, Education and Sports of the Republic of Croatia and the Ministry of Health and Social Welfare. The event took place at the GlaxoSmithKline Research Centre Zagreb Ltd. Partners in organisation were Croatian Agency for Medicinal Products and Medical Devices (ALMP) and the Croatian Association of Research–Based Pharmaceutical Companies (CARPC), the associated member of the European Federation of Pharmaceutical Industries and Associations (EFPIA).

Participants of this conference were also welcomed by representatives of partner institutions, Dr. Siniša Tomić, the Head of the ALMP and Dr. Dario Naletilić, the Chairman of the CARPC.



Participants (196 registered) representing pharmaceutical industry, regulatory bodies, academia including pharmacy students, pharmaceutical societies and patients' associations were from 16 European countries (Austria, Belgium, Bosnia and Herzegovina, Croatia, Finland, Hungary, Macedonia, Ireland, Kosovo, Lithuania, Serbia, Slovenia, Sweden, The Netherlands, Turkey and United Kingdom).

The conference was officially opened by a welcome speech from Dr. Romana Katalinić, the head of the Medicines Department of the Ministry of Health and Social Welfare. During the Opening Ceremony, the >>>

Participant Vladimir Trkulja during the Opening Forum

audience was addressed by Professor Daan J. A. Crommelin, the EUFEPS president, and by Professor Milena Jadrijević-Mladar Takač, the president of the Section for pharmaceutical sciences of the Croatian pharmaceutical society (CPhS), as well as the chair and co-chair of the conference.

Sessions, Lectures, Open forums and Reflections

The conference consisted of three main sessions:
Challenges and opportunities in pharmaceutical sciences through EUFEPS
The Innovative Medicines Initiative (IMI) – from idea to patients
The scientific needs in pharmaceutical regulation and safety sciences.

After each session, there were Open forum in which participants were able to actively contribute to the conference, thus facilitating mutual understanding of their needs and offering practical solutions.

In the first session, three eminent speakers from the EUFEPS Executive Committee, the President Professor Daan J. A. Crommelin, the immediate Past President Professor Christian Noe and the Executive Director Hans H. Lindén spoke about EUFEPS vision, mission, strategies, people and scientific interactivity. In his presentation, Professor Noe explained, in a philosophical manner, the connections between 'networking', 'challenges' and 'opportunities' in the field of pharmaceutical sciences, by pointing out the importance of scientists and their striving towards excellence.

Three lectures were also presented in second session. The first was about the organisational structure of IMI, its funding and application processes. Ultimately, IMI aims to re-instate Europe as the world's leader in medicines R&D. This lecture was given by EFPIA speaker, Dr. Jeff Kipling, from GSK R&D's Science Environment Development Group, established to develop new ways of working with academia and publicly funded bodies. The second lecture, *Challenges and perspectives in pharmaceutical companies*, was from Professor Radan Spaventi, the CEO of GSK Research Centre Zagreb Ltd. This review addressed the current environment and implications for R&D activities in today's pharma companies, as well as some approaches that should ensure sustainability and competitiveness in more connected and demanding world. One such approach was the subject of the third presentation, Daan J. A. Crommelin, the Top Institute Pharma's scientific director and EUFEPS President, described the TI Pharma Model – *Practical and successful experiences*,. A public-private-partnership (PPP), the TI Pharma was founded in 2006 and is unique initiative to boost the scientific and economic success of the pharmaceutical sciences in the Netherlands. TI Pharma comprises partnerships of all Dutch universities, 17 globally operating pharmaceutical companies as well as 18 small and medium sized enterprises (SME), with 60 million Euros annual funding from the partners in a 1:1:2 ratio (industry: academia: government).

Trends in pharmaceutical regulations will affect all aspects of medicines R&D.
In the third session, under the title *The scientific needs in pharmaceutical regulation and safety sciences,* four lectures were delivered. The first was entitled *Registering a vaccine in the EU - from concept to assessment*, by Dr. Pieter Neels from Belgian Federal Agency for Medicinal and Health Products and a member of EMEA CHMP. In next lecture, Dr. Kevin O'Donnell from the Irish Medicines Board, pointed out the main issues in market surveillance. Then, Buket Aksu, from Santa Pharma in Istanbul & EGE University (Turkey) reminded the participants of the importance of medicine consumers, in a lecture entitled *Patients' Safety.* Where Croatia stands in the overall context, the audience could recognise from the lecture by Dr. Siniša Tomić, about *Croatian experiences in pharmaceutical regulation approach towards EU and scientific needs in safety sciences.*

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Pia Vuorela, Christian Noe, Milena Jadrijević-Mladar Takač and Daan J. A. Crommelin

Christian Noe during the presentation

Open forums

The Trigger point I – *There are no borders for sciences nor for medicines market*, addressed by Milena Jadrijević-Mladar Takač, opened the first forum, in which an interactive discussion developed regarding relevant issues, such as:

- Benefits from networking through EUFEPS
- Are there borders in pharmaceutical sciences?
- What are obstacles of networking in pharmaceutical sciences?
- Are there borders in medicines market?
- Sciences knows no borders, but funders do
- No border where there are no data
- Needs for networking in pharmaceutical sciences
- Pharmaceutical sciences are core of any pharmacy education.

The Trigger point II – *If science does not underpin clinical practice, what does?* – guided by Professor Pia Vuorela, EUFEPS President-elect, opened the second forum, in which the following issues were discussed:

- Is there always an organic cause of all diseases?
- How much can we translate from omics to clinics?

The pharmaceutical industry is a highly regulated industry, where many of the activities and tasks are defined by regulations and guidelines issued by international regulatory authorities, which flavours the science involved.

Reflections

The first reflection on the main theme was from European Association of Faculties of Pharmacy in the lecture entitled Pharmacy Education in Europe, presented by Professor Bart Rombaut, and second was in Professor Sabina Semiz's presentation regarding the potential of networking in pharmaceutical sciences in Bosnia and Herzegovina.

Pharmaceutical sciences are the backbone of any pharmacy education. It is obvious that EUFEPS should help pharmaceutical scientists in academia to address the current scientific needs in drug R&D. Also, EUFEPS should boost network development with other pharmaceutical stakeholders at all levels and especially in developing European countries.

Conference Message

Europe will not be the world's leader in medicines R&D without involvement all members and all stakeholders in this process. Let us support and use this challenging opportunity.

Milena Jadrijević-Mladar Takač
EUFEPS/CPhS Conference's Co-Chair
(Faculty of Pharmacy and Biochemistry,
University of Zagreb;
Croatian Pharmaceutical Society)

EuPAT 4 - Taking PAT to the Next Level

May 5-6 • 2010 • Hotel Puijonsarvi • Kuopio • Finland

Invitation to Join

The topic of EuPAT4 – taking PAT to the Next Level – underlines the importance of comprehensive process understanding. In addition, EuPAT4 naturally continues to showcase novel PAT methods and their applications.

This is to invite you to start planning for it, the fourth pan-European Science Conference on Process Analytical Technology (PAT), building on the successes of the EuPAT1 in 2006, the EuPAT2 in 2007, and the EuPAT3 in 2008. It will be held on May 5-6, 2010, in Kuopio, Finland, and organised back-to-back to an Academy of Finland Graduate School Course on "Basics and process analytical aspects of biopharmaceutical manufacturing", to be held on May 4, 2009, in Kuopio. The attendees of EuPAT4 are welcome to register to the graduate school course and vice versa.

Session Topics of EuPAT4

- PAT in solid dosage form processing
- Novel measurement technologies
- Modelling and simulation
- PAT in bioactive production and downstream processing

Confirmed Speakers of EuPAT4

Dr *Emil Ciurzak*, Cadrai Technology Group, New York, NY USA

Dr *Thomas De Beer*, Ghent University, Ghent, Belgium

Professor *Staffan Folestad*, AstraZeneca and Chalmers University of Technology, Mölndal and Göteborg, Sweden

Professor *Robert T. Forbes*, University of Bradford, United Kingdom

Dr *Göran Frenning*, Uppsala University, Uppsala, Sweden

Dr *Henning Gieseler*, University of Erlangen, Erlangen, Germany

Professor *Niklas Sandler*, University of Helsinki/Åbo Akademi University, Turku, Finland

Dr *J. Axel Zeitler*, Cambridge University, United Kingdom

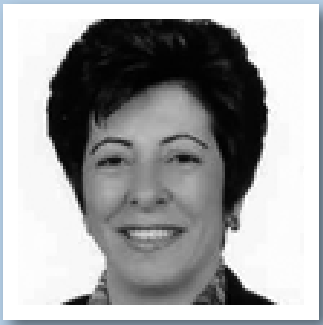
Additional Information

For more information, see circulating announcements or updates on www.eufeps.org , or contact:

EUFEPS Meetings and Events
PO Box 1136, SE-11181 Stockholm
Sweden
Tel +46 8 7601050
Email conferences@eufeps.org

Executive Committee of EUFEPS

Following the EUFEPS Council meeting, the nomination and election process is now complete, so that the new Committee, all elected for the next two years, comprises;



Dr Buket Aksu

Prof. Rogerio Gaspar*
Full Professor of Pharmacy at the University of Lisbon, Portugal

Dr James G. Murray*
Associate Director in charge of Analytical Development at AstraZeneca, Macclesfield, UK

Dr Alain Cuiné*
Director of R&D for Becton Dickinson, Grenoble, France

Prof. Ulrike Holzgrabe

Prof. Clive G. Wilson*, President
JP Todd Chair of Pharmaceutics, Strathclyde Institute of Pharmacy & Biomedical Sciences, University of Strathclyde, Glasgow, UK

Prof. Daan J.A. Crommelin, Past-President

Hans H. Lindén, Executive Director

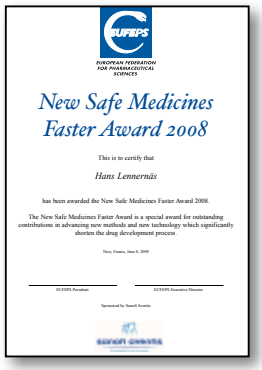
* Indicates newly elected to the Executive Committee.

Prof. Lennart Dencker*
Vice-Chairman of the Faculties of Medicine and Pharmacy at the University of Uppsala, Sweden

Dr Eva-Maria Muchitsch*
Director of Global Preclinical R&D at Baxter, Vienna, Austria

EUROPEAN FEDERATION FOR PHARMACEUTICAL SCIENCES

Awards Presented at PharmSciFair 2009



New Safe Medicines Faster Award

To honour a scientist who significantly has contributed to advance new methodologies or technologies which will contribute to shorten the development process significantly.

At the PharmSciFair on June 9th 2009, it was announced that Professor Hans Lennernäs received the NSMF award for 2008. Professor Lennernäs, of the Department of Pharmacy at Uppsala University, Sweden, has pioneered the use of advanced techniques to investigate site-specific processes of drug absorption and delivery. The scientific information generated by his research has been key to the development of improved drug formulations.


Prof. Hans Lennernäs

The award consists of a prize of 2000 € and travel grant of 1000 € to the EUFEPS congress.

The Award is sponsored by sanofi-aventis.

Giorgio Segré Prize 2008 in Pharmacokinetics and Pharmacodynamics

EUFEPS established, in partnership with the Segré family, a special award for investigators showing distinction in the field of PK and PD, to honour the memory of the late Professor Giorgio Segré of the Università di Siena.

The Giorgio Segré Prize was presented for the sixth time, during the Opening Session of the 2009 PharmSciFair, on June 8, 2009. On this occasion, the recipient was Dr. Lena Friberg of the Department of Pharmaceutical Biosciences at Uppsala University, Sweden. Dr. Friberg has applied advanced modelling techniques, such as population pharmacokinetic analysis, to a variety of therapeutic problems concerning the side-effects of anti-cancer drugs, overdoses, etc. Insights gained at the level of the population of patients can be useful to improve treatment for individual patients.

The winner of this Prize received 1000 Euro with the Prize Certificate, plus expenses for travel and accommodation (up to 800 Euro) at the PharmSciFair.

The Scheele Prize 2009

In honour of the world-renowned Swedish chemist and pharmacist Carl Wilhelm Scheele, the Swedish Academy of Pharmaceutical Sciences has since 1961 given the Scheele Award to prominent scientists in drug research or related disciplines. By tradition the Award Ceremony is accompanied by a symposium carrying the signature of the winner of the Scheele Prize.

Professor Dennis J Slamon, University of California, Los Angeles CA USA, is the 2009 Scheele Prize Winner. This is for his clinical research on trastuzumab and the possibility to postulate the outcome in breast cancer therapy, which led to the registration of Herceptin. It is a significant step towards personalised medicines.

The 2009 Scheele Symposium will be held on November 11, 2009, in Stockholm, Sweden (info from Agneta Larhed, SAPS, at: agneta.larhed@lakemedelsakademin.se).s.

Best Paper Award, 2008

The award for the best paper published in the European Journal of Pharmaceutical Sciences during 2007 went to; Mathias Norrman, Frantisek Hubáleka, Gerhard Schluckebier for their paper entitled "Structural characterization of insulin NPH formulations" European Journal of Pharmaceutical Sciences, 30 (2007) 414 - 423.

The activity of therapeutic insulin is prolonged by formulation as insulin NPH (neutral protamine hagedorn). The authors used X-ray crystallography to elucidate the binding between protamine, a basic poly-arginine peptide, and insulin.


Drs Mathias Norrman and Gerd Schluckebier receives their Award

Best Paper Award, 2009

The award for the best paper published in the European Journal of Pharmaceutical Sciences during 2008 went to; Carolin Fella, Greg F. Walker, Manfred Ogris and Ernst Wagner for their paper entitled "Amine-reactive pyridylhydrazone-based PEG reagents for ph-reversible PEI polyplex shielding" uropean Journal of Pharmaceutical Sciences, 34 (2008) 309-320.

The authors addressed novel ways to shield DNA polyplexes from the extracellular milieu. They demonstrated increased transgene expression from their polyplexes if the shielding could be removed at the lower pH of the intracellular endosome, close to the site of incorporation.

These Awards are sponsored by Elsevier.

PharmSciFair session

Pharmaceuticals in the environment

June 10 • 2009 • Nice • France

For the first time ever a session was devoted, under the EUFEPS 'umbrella', to the topic "Pharmaceuticals in the Environment" at the PharmaSciFair in Nice June 2009. About 25 people attended the session from more than 10 countries. The overall aim of the session was to report on the latest news in the field in four talks covering; Regulatory guidelines to assess the environmental risk of pharmaceuticals, green pharmacy, and biosimulation as a tool to assess the predicted concentration of pharmaceuticals in the environment. At the session, a fruitful discussion took place after the presentations, especially discussing pollution with pharmaceuticals in countries like China and India where the active ingredients are produced.

Pharmaceuticals are indispensable for a high quality of life. However, their use also has an environmental downside that we as pharmacists must help to handle. In recent years, a huge amount of data has been collected demonstrating the wide spread of a variety of active drug ingredients in the aquatic environment and sporadically even in drinking water. Being only insufficiently eliminated in the conventional sewage treatment plants, there is a growing evidence that the substances and their metabolites have adverse effects on aquatic and in some case terrestrial organisms on both the individual and population level.

The question is what can we as pharmacists do to adequately address the problems?

For an increasing number of pharmaceutical substances, the classification of their environmental hazard and the environmental risk assessment is in the process of being carried out. For a few substances, an environmental risk has been assessed. For others, gaps of knowledge still exist.

There are presently only two known cases of pharmaceuticals affecting wildlife on ecosystem level:
The first has been reported from many countries and is the exposure to estrogens i.e ethinyl estradiol that is responsible for the feminisation of male fish. The second known example is the anti-inflammatory drug diclofenac – also used as a veterinary drug in second world countries – that has killed tens of millions of vultures in India.

These are the only well documented cases presently. Other pharmaceuticals – e.g. antibiotics, antiepileptics, cancer drugs, etc. – may have an effect on wildlife but this is not proven. We have quite a lot of laboratory data identifying possible effects – but nothing at an ecosystem level.

During the last years, the total European sales of pharmaceutical products remained rather constant with a slight decline in 2008. The European antibiotics market is slightly growing, whereas the hormone market shows, after a decline, a recovery (both 2006 – 2008). During the last decades, the number of fluorinated pharmaceuticals increased. Generally, these substances have an improved bioavailability in the human body. At the same time, a higher persistence in the environment may be expected. So many new problems may have to be addressed in this field.

Green Pharmacy may be one of the solutions to the problem but is still a field in its infancy. Green Pharmacy is the design of pharmaceutical products and processes, which eliminate or reduce the use and generation of hazardous substances. Following these principles, pharmaceuticals can be generated with less impact on the environment during production or after use. The development of such processes and pharmaceuticals is currently not a high priority for pharmaceutical industry. Using this kind of thinking in the development of future generations of pharmaceuticals will probably lead to fewer residues in the environment.

As the knowledge of environmental effects of pharmaceuticals is still limited amongst producers, doctors, pharmacists and patients, communication about these effects is crucial. The environmental issues can be introduced in already existing information schemes to increase the awareness that the choice of certain pharmaceuticals may have an environmental impact beyond all desired health effects.

A considerable amount of unused pharmaceutical product is put into waste water or household waste. Although special collection systems are offered in most of European countries, the amounts collected throughout these systems differ widely. This may partly due to uncertainties or lack of awareness in the population about environmentally correct disposal.

There is a general recognition all over Europe that there is a broad variety of pharmaceutical substances and their metabolites in treated waste water and rivers. Therefore waste water treatment has to face this for the time being unavoidable pollution and has to consider intensified treatment measures which allow the preparation of drinking water. Especially in countries were drinking water is produced from surface water it is observed that drug residues occur in drinking water in the low ng/l. Modern methods like UV treatment or advanced oxidation processes to reduce the pharmaceutical residues are available but very costly.

In Nice, the above aspects were covered by the following four talks in the session

Prof. *Bent Halling-Sørensen*, Copenhagen University. Faculty of Pharmaceutical Sciences. bhs@farma.ku.dk
Introduction to the topic "drugs and the environment" and outline of the legislation to assess the environmental risk of drugs

Prof. *Klaus Kümmere*. Freiburg University Hospital. Germany. Klaus.Kummere@uniklinik-freiburg.de
Status and potential of "Green Pharmacy" How are the structures of environmental friendly drugs? – The story about persistence of drugs.

Prof. *Sven Erik Jørgensen*. Copenhagen University. Faculty of Pharmaceutical Sciences. sej@farma.ku.dk
The use of mathematical models to assess the fate of pharmaceuticals in the environment

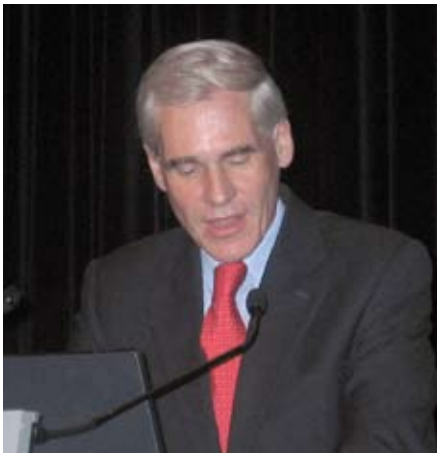
Prof. *Bent Halling-Sørensen*. Copenhagen University. Faculty of Pharmaceutical Sciences. bhs@farma.ku.dk
Pharmaceuticals in the Danish environment. Identified pharmaceuticals that may pose a threat to the environment

Photos

The 2nd PharmSciFair was organised on June 8-12, 2009, in Nice, France. The scientific programme comprised more sessions than ever in a full week, delivered by many PharmSciFair Programme Providing Partners and excellent speakers. In this issue, there is a report from one session – environment and pharmaceuticals (page 6).

Below are photos from the Opening Session and Welcome Reception.

Dr Maria CM Orr, Alderly Park UK, Speaker



Prof. Hans-Georg Eichler, London UK, Speaker

Prof. Michael Karas, Frankfurt DE, receives the European Pharmaceutical Scientist Award

Prof. Patrick Couvreur, Paris FR, Speaker

Prof. Dominique Duchene, Paris FR, Chair Opening Session

Profs. Pia Vuorela, Turku FIN, Chair PharmSciFair Planning Committee; Ulrike Holzgrabe, Wuerzburg DE, Co-Chair Opening Session; and Bert Leufkens, Utrecht NL, Co-Chair Opening Session and Speaker

Welcome Reception on the Terrace of the Nice Acropolis

EUFEPS Network:
BioAvailability and BioPharmaceutics

Background
The initiation of this Network appeared to be a natural progression of the EUFEPS vision as biopharmaceutics forms the bedrock of many of the activities of the contributing societies. It is also an important opportunity to assist legislature in defining a harmonised approach across Europe.

A Current Focal Point
Proposed changes in European Guidelines in bioavailability and bioequivalence have prompted the scientific community to engage in a more comprehensive communication with regulatory scientists and to stimulate exchange between both groups. In particular, efforts focus on scientific questions, which arise from poorly resolved areas and to provide a focal point from which best practice can be developed. There is now a platform for discussion for all interested scientists from academia, regulatory authorities and industry.

Recent and Current Activities
New Regulations in Bioequivalence: Revised European CHMP Note for Guidance Conference
June 17-18, 2008, Bad Homburg, Germany
Revised European Guidelines on Bioequivalence Open Discussion Forum
January 14-15, 2009, Bonn, Germany
Two sessions in the 2009 PharmSciFair scientific programme
June 2009, Nice, France

Join this Network
All interested in these matters and issues are welcome to become members of this EUFEPS Network (no fee). To become a member, please approach any of the following people;

Network Chair: Henning Blume at: henning.blume@socratec-pharma.de
Network Secretary: Andrzej Dzierbicki at: andrzej.dzierbicki@polpharma.com
EUFEPS Secretariat: Hans H. Linden at: hans.linden@eufeps.org

EUFEPS Network:
PAT Process Analytical Technology and Underpinning Sciences

Background
Building quality into drug products should commence during the early phases of research and development. Consideration and implementation of the quality requirements for new medicines at these early stages should facilitate effective process development and robust large-scale manufacture. The Network, established in 2004, should therefore play a crucial role in design, analysis, and control of manufacturing processes based on timely in-process measurements for integrated system approaches, innovative developments and cutting edge scientific advances.

Network Sample Objectives
- To develop a network for academic, industrial and regulatory professionals in the various scientific fields underpinning PAT, sharing and discussing findings in cutting edge research and establishing effective and innovative collaboration
- To promote and facilitate the advancement of fundamental underpinning science and process understanding
- To contribute to education and training in the field as well as to foster hands-on implementation of systems approaches
- To educate and equip industrialists and regulators with requisite knowledge and
- cutting-edge process understanding
- To promote and support collaborative research projects established from inter-academic, academic-industrial and public-private partnerships

Network Activities
Two sessions in the 2009 PharmSciFair scientific programme, one in collaboration with ISPE
- Continuous processing
- Predicting the product and process: Advances in model building for quality by design (QbD)

The pan-European EuPAT Conference Series on PAT
- EuPAT1 in 2006, EuPAT2 in 2007, and EuPAT3 in 2008

The EuPAT4 on May 5-6, 2010, in Kuopio, Finland

Join this Network
All scientists involved in Process Analytical Technology and Underpinning Sciences are more than welcome to become members of the EUFEPS Network on PAT (no fee). To become a member, please send an email to the Network Secretary (see below).

Network Chair: Staffan Folestad at: Staffan.Folestad@astrazeneca.com
Network Secretary: Thomas.DeBeer@UGent.be
EUFEPS Secretariat: Hans H. Linden at: hans.linden@eufeps.org

EUFEPS Network:
Environment and Pharmaceuticals

About us: The Network Environment and Pharmaceuticals (EP) held its first session at the PharmSciFair in Nice to discuss and present various issues on exposure of pharmaceuticals to the environment and attempts towards global harmonisation.

Activities: One of the Network's major activities is to enable information exchange on its core subjects, through different events such as in future international conferences and workshops.

Background: Pharmaceuticals are indispensable for a high quality of life. Their use however also has an environmental downside that we as pharmaceutical scientists and pharmacists must help to handle. In recent years, a huge amount of data has been collected, demonstrating the widespread of a variety of active drug ingredients in the aquatic environment and sporadically even in drinking water. Being only insufficiently eliminated in the conventional sewage treatment plants, there is a growing evidence that the substances and their metabolites have adverse effects on aquatic and in some cases terrestrial organisms on both the individual and population level.

The question is what can we as pharmaceutical scientists and pharmacists do to adequately address the issues?

Contact Points for further information, and to join this Network;

Network Chair: Bent Halling-Sørensen at: bhs@farma.ku.dk
EUFEPS Secretariat: Hans H. Linden at: hans.linden@eufeps.org

EUFEPS Network:
PharmacoGenetics and PharmacoGenomics

This Network would be the voice of the European science community in pharmacogenetics and pharmacogenomics.

Network Objectives

- Provide a platform of experts for gathering and disseminating knowledge, determining PGX strategies
- Serve as a knowledge-bank for EU research programme calls
- Provide a platform for collaborations between academic institutions and industry
- Provide a mechanism for set up and exchange of databases
- Enhance education through lectures and exchange of PhD students
- Provide a platform for gathering and promoting knowledge about pharmacogenetics in Europe

Recent and Current Network Activities

Conference on BioBanking in Pharmaco-Genetics in April 2009
Slides available on the members-only section of the website

Two sessions in the 2009 PharmSciFair scientific programme

- Pharmacogenomics of adverse drug reactions
- Clinical implementation of pharma-cogenomics

Ongoing pilot project on how to establish a European Adverse Drug Reactions BioBank
Funded by the Dutch Government and four big Pharma Companies

Contact Points

Network Chair: Anke-Hilse Maitland-van der Zee at: a.h.maitland@uu.nl
EUFEPS Secretariat: Hans H. Linden at: hans.linden@eufeps.org

EUFEPS Network:
Safety Sciences

Background

The Safety Sciences Network was established to develop and implement educational programmes to meet the training needs of scientists working in the field of safety sciences, primarily, and to provide input for the New Safe and Innovative Medicines initiatives. To achieve this, it is actively engaging with stakeholders in enhancing and coordinating a multi-disciplinary, holistic approach in the development of new medicines through education and continuous training of scientists capable of contributing to the innovative and continual development of new medicines.

March 2003
Position Paper on "Safety Sciences – a way out of the attrition dilemma"
April 2004
EUFEPS Workshop I and Report on Safety Sciences
Brainstorm about a first rational approach for enhanced training in safety sciences.
July 2007
EUFEPS Workshop II and Report on Safety Sciences
Recommendations for a post-graduate level "European Safety Science Curriculum", incl. Innovative Medicines Initiative (IMI) input.
July 2008
Consortium Expression of Interest filed to establish an IMI JU-funded one-year modular post-graduate (pan-European) education and training programme in safety sciences, to meet industrial, regulatory and academic needs.
January 2009
Project Proposal submitted to the IMI JU.
June 2009
Two sessions in the 2009 PharmSciFair scientific programme;
Safety sciences aspects of biologics
Safety education and training in Europe
July 2009
Contract negotiations on the "European Modular Education and Training Programme in Safety Sciences for Medicines (SafeSciMET)"

Join this Network

To register as a member (no fee), contact:

Network Chair: Eva-Maria Muchitsch at: eva_muchitsch@baxter.com
Network Co-chair: Ole J. Bjerrum at: ojb@farma.ku.dk
EUFEPS Secretariat: Hans H. Linden at: hans.linden@eufeps.org

Professor Julia Kirchheiner wins the Utrecht Award for Excellence in Pharmaceutical Research

Prof Julia Kirchheiner (1971, Nürnberg, Germany) has won the Utrecht Award for Excellence in Pharmaceutical Research, 2009. Professor Kirchheiner is known as a very enthusiastic and successful researcher in the field of Pharmacogenetics. She is striving for drugs for individuals rather than diseases. The award is meant for individuals who have shown over the year's excellence, vision and leadership in pharmaceutical research and will be presented June 16, 2009 in Utrecht, the Netherlands.

Since 2006 Kirchheiner is a professor of Clinical Pharmacology at the Department of Natural Medicine and Clinical Pharmacology, University of Ulm, in Germany. She aims her own research closely at the patient. She has conducted numerous studies to test the effect of antidepressants or antidiabetic drugs on different patient genotypes. Driven by the conviction that these findings must enter clinical application, Kirchheiner has prepared systematic studies on pharmacogenetics-based dose recommendations for psychopharmaceuticals, anti-cancer and other drugs.

In the case of cancer, Kirchheiner is investigating pharmacogenetic mechanisms that might be the cause of the severe side effects some of these strong drugs have on some patients. Some patients experience a strong reduction in normal blood cells, which results in a high risk of contracting infections such as pneumonia. The time required by the normal blood cells to recover from the therapy varies from patient to patient. Currently, no biomarkers are known that would help predict the duration of the changes of the blood picture.

The Utrecht department of Pharmaceutical Sciences recognizes that it would not be able to fulfil its successful leadership role in both the pharmaceutical sciences and pharmacy practice, without the encouragement, dedication and excellence of pharmaceutical scientists and practitioners all over the world. In this spirit of recognition two awards are given out: one (even years) for Excellence in Pharmacy Practice and the other (odd years) for Excellence in Pharmaceutical Research to persons who have demonstrated excellence either in pharmacy practice or pharmaceutical sciences, or in both. To strengthen the idea of reaching out to the pharmacy practice and pharmaceutical research community worldwide, the successful nominees should be selected from candidates outside the Utrecht department of Pharmaceutical Sciences.

Information: Prof.dr. A. de Boer, A.deBoer@uu.nl, Head of the Department of Pharmaceutical Sciences, Faculty of Science, Utrecht University

Modular Training Course: Quality Management in Pharma and Biotech

Quality is crucial in the development and manufacturing of all pharmaceutical products. Recognizing the need for accessible training in this area, Biotechnology Studies Delft Leiden (BSDL) have constructed a convenient course. The course offers an integrated approach on quality management in the pharmaceutical, biotechnological, medical device industries and hospitals to safeguard the quality of their products.
Expert knowledge and real life case studies are combined, and presented and coached by professionals from Industry, Universities and Health Care Inspectorates. The training is interactive.

The course will teach

- Essentials of Quality Management and is addressed to:
- Professionals in pharma and biotech industry
- Professionals in institutions and contract research organisations
- Hospital pharmacists
- Postgraduate students considering an industrial career

EUFEPS is delighted to be co-sponsor of this highly relevant training course which will be given in four modules:

Quality Management, the role of the Qualified Person
October 12-14, 2009, Noordwijk-de Duinen NL
GxP's applied in drug development within the pharmaceutical industry and hospital pharmacy
November 30-December 3, 2009, Oegstgeest NL
Sterile manufacturing
February 3-5, 2010, Nijmegen/Berg en Daal NL
Quality and safety of biopharmaceuticals - From genetics to downstream processing
April 7-9, 2010, Delft NL

Further information at Current Courses section of EUFEPS Online, www.eufeps.org or e-mail BSDL at bsdl-edu@tudelft.nl

BioMedical Transporters 2009 Conference: Membrane transporters and their impact on drug discovery
9-13 August, 2009, Thun, Switzerland
Contact: Professor Matthias A. Hediger University of Berne, Bühlstrasse 28, CH-3012 Bern, Switzerland. Fax: + 41 31 6313410 Email matthias.hediger@mci.unibe.ch www.bioparadigms.org/biomedical09/09.htm

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Symposium on High-Performance Separation Methods and Separation Science
2-4 September, 2009, Siofok, Hungary
Contact: Chemistry Institute, University of Pécs Ifjúság útja 6, HU-7624 Pécs, Hungary Fax +36 72 501518. Email info@mett.hu

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Introduction to Quantitative Pharmacology and PK/PD for Drug Discovery & Development Scientists
8-9 September, 2009, Munich, Germany
Contact: Project Manager Erik Ahlzén Email erik.ahlzen@lakemedelsakademin.se www.lakemedelsakademin.se/PKPD-Munich

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Translational Research in Paediatric Rheumatology -TRiPR
Adaptive Immunity and the Pathogenesis of Rheumatic Diseases
24-27 September, 2009, Genoa, Italy
Contact: Alberto Martini, Giannina Gaslini Institute and University of Genoa Email tripr@ospedale-gaslini.ge.it www.tripr.sispge.com

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EuroNanoMedicine Conference
28-30 September 2009, Bled, Slovenia
Contact: DECHEMA e.V. Attn.: Ms Claudia Martz, Theodor-Heuss-Allee 25 60486 Frankfurt am Main/Germany. Fax +49 69 7564176 Email martz@dechema.de

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Pharmacokinetics: Spearheading Advances and Delivering the Science
International Conference On the Occasion of Professor Malcolm Rowland's 70th Birthday
5 October 2009, London, UK
Contact: APS, 840 Melton Road, Thurmaston Leicester LE4 8BN, United Kingdom Fax +44 116 2640141 Email info@apsgb.org www.apsgb.co.uk also see EUFEPS Online, www.eufeps.org

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Modular Training Course Quality Management in Pharma and Biotech
Quality Management, the role of the Qualified Person:
12-14 October 2009, Noordwijk-de Duinen The Netherlands
GxP's applied in drug development within the pharmaceutical industry and hospital pharmacy:
30 November-3 December, 2009, Oegstgeest The Netherlands
Contact: Biotechnology Studies Delft Leiden (BSDL-EDU) dr.ir. L.A. van der Meer-Lerk (coordinator) or Ms. Ger Aggenbach Department of Biotechnology Julianalaan 67, 2628 BC Delft The Netherlands Fax +31 15 27 82355 Email bsdl-edu@tudelft.nl

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The 16th Intermediate Workshop on PK/PD Data Analysis: A four-day Course Using WinNonlin
25-28 October, Barcelona, Spain
Contact: Annica Flodin Email Annica.Flodin@lakemedelsakademin.se www.lakemedelsakademin.se/templates/kurs/kurstillfalle.aspx?kId=3258&id=3259 also see EUFEPS Online, www.eufeps.org

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3rd BBBB Conference
26-28 October, 2009, Antalya, Turkey
Contact: Assoc. Prof. Dr. Nilüfer YÜKSEL Ankara University, School of Pharmacy Department of Pharmaceutical Technology 06100 Tandogan, Ankara, Turkey Fax +90 312 2131081 Email nyuksel@pharmacy.ankara.edu.tr or bbbb.bosphorus@bbbb-eufeps.org

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Second Open Scientific EIP Symposium: Immunogenicity of Biopharmaceuticals
17-19 November, Leiden, The Netherlands
Contact: Prof Dr Wim Jiskoot, Leiden/Amsterdam Center for Drug Research (LACDR) P.O. Box 9502, Einsteinweg 55, 2300 RA Leiden The Netherlands. Fax +31 71 527 4565 Email w.jiskoot@lacdr.leidenuniv.nl www.brpl.nl

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Tenth Eilat Conference on New Antiepileptic Drugs (EILAT X)
25-29 April 2010, Eilat, Israel
Contact: Secretariat, Fax +972 3 5175155 eilatx@targetconf.com

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EuPAT 4 - Taking PAT to the Next Level
5-6 May, 2010, Kuopio, Finland
Contact: EUFEPS Meetings and Events PO Box 1136, SE-11181 Stockholm, Sweden Fax +46 8 4113217 Email conferences@eufeps.org www.eufeps.org

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3rd BBBB-Bosphorus International Conference on Pharmaceutical Sciences *October 26-28, 2009, Antalya, Turkey*

This third conference, in the well-established Baltic-Balaton-Bled-Bosphorus series, will bring together pharmaceutical scientists from universities, industry and regulatory bodies. The conference is co-sponsored by EUFEPS and by the Turkish Pharmaceutical Technology Scientists Association, TÜFTAD.

The wide-ranging Scientific Programme will cover the latest information and advances in;

- Regulatory Issues
- Innovative Drug Delivery Systems
- Biotechnology, Delivery of Biologics and Vaccination
- Medicinal Chemistry and Analytical Techniques
- Clinical Pharmacy
- Pharmacy Education

You are welcome to submit an abstract covering your latest findings, before July 31, 2009, at the website http://www.bbbb-eufeps.org/Poster_Presentations.html
The conference location is the excellent Talya Hotel in the historic city of Antalya on the beautiful Turkish Riviera.

For further information and registration, please go to www.bbbb-eufeps.org

FIP-TÜFTAD Pre-Conference Workshop on

Quality by Design for Generic and Innovator Manufacturers

Full Day Workshop on October 25, 2009

Workshop Leader: Dr. Tom Sam
Director Global Regulatory Affairs CMC, Schering-Plough, The Netherlands