NEWS Letter

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LEADER

EUFEPS Vision on Training and Education

Is there a role for EUFEPS? Yes, there is. EUFEPS has made improvements in the pharmaceutical sciences training and education part of its strategy and started new activities. In this article, Hans H. Lindén, Executive Director of EUFEPS, and Bernd Clement, Chair EUFEPS Committee on Training and Education (CTE), present the strategy and some related issues.

Clear Mission

The mission of the European Federation for Pharmaceutical Sciences, EUFEPS, is to serve and advance excellence in the pharmaceutical sciences and innovative drug research in Europe. This includes training and education, as well as representing the interests of scientists engaged in drug research and development, drug regulation, drug utilisation, and drug policy-making.

Agreed Strategy

Among the primary objectives of the EUFEPS Strategic Plan 2002-2006 are active collaboration, cooperation and coordination between all existing players, leading to further advance of the pharmaceutical sciences in Europe. Without doubt, training and education of those already in, and those considering entering the field, are effective tools to pave the way for further development. In EUFEPS, postgraduate training and education will have priority.

Hans H. Lindén, Executive Director of EUFEPS, and Bernd Clement, Chair EUFEPS Committee on Training and Education (CTE).

Widespread Support

Currently, the EUFEPS membership includes 25 Member Societies in 24 European countries, and nearly 500 Individual Members. The total number of individuals embraced, directly and indirectly, is just over 18,000. They pay individual, national and/or federal fees to support local, regional and global efforts in their fields of interest.

Advanced Training Courses

Relevant (short) courses and programmes to meet immediate (continuing/further) training and education needs, particularly in industry are not easily identified, or not at all available in Europe[1].

Stimulated by its Committee on Industrial Relations (CIR), EUFEPS is moving towards a virtual "School of Excellence in the Pharmaceutical Sciences" in Europe. The school is made up of advanced courses and training programmes in key fields and new disciplines. The EUFEPS role, supported by CIR and the Committee on Training and Education (CTE), is to define specific training topics, engage experts and organise the courses, including 'hands-on' sessions. Additionally, EUFEPS will encourage the organisers of relevant local or national training courses to add international faculty and give the courses in English, for a European audience. The CTE has produced a set of criteria for such "EUFEPS Training Courses"; EUFEPS could contribute to their organisation and publicity.

In 2002, three training courses were announced

and one of them, on High-throughput Drug Metabolism/Disposition, was successfully completed. This was in close collaboration with the Amsterdam Free University and the Leiden/Amsterdam Centre for Drug Research (LACDR), both in the Netherlands.

Experience of Training Courses to Date

There has been a long road between the ideas for each training course and the circulation of the final programme. Specialists willing to help to set up advanced training courses are busy people, as is the additional faculty needed to make the course truly European. The EUFEPS Secretariat would need additional staff to assist in the simultaneous development of several training courses. Nevertheless, EUFEPS intends to continue along this avenue, encouraging increased collaboration between current and new institutes and centres of excellence. So, developing additional postgraduate training courses in pharmaceutical sciences is in progress. For topics, date, location and fee etc., consult the EUFEPS Online (www.eufeps.org) and see announcements circulated.

Course Database

EUFEPS also decided to start developing a "database of post-graduate training and education courses", which will be made accessible to its membership. A couple of years ago Janne Tolstrup, who was supported by a special task force, designed a template for this database, utilising MS Access. The Royal Danish School of Pharmacy granted generous funding. A substantial number of courses and training programmes were listed. Unfortunately, for a number of reasons, it was not possible to complete the database and make its contents available.

In 2003, a restart of the project was budgeted; updating and completing the database is in progress. Many more postgraduate courses and programmes, in all areas of pharmaceutical science and available in Europe, have been identified by searching the Internet and added to the database, by the pharmaceutical institute in Kiel, Germany.

Recently, EUFEPS learned that the Young Pharmacists Group of the International Pharmaceutical Federation (FIP) is working on a database of education. EUFEPS indicated that it would be open to collaborate by e.g. exchanging available information. Pharmaceutical sciences courses are the premier concern of EUFEPS. In FIP, there is a much stronger professional pharmacy theme. If there is overlap, it would not be a big problem. Options to identify relevant courses of interest just increase.

Specialist Training

There are several emerging new initiatives, all over Europe, to start specialist training in pharmaceutical sciences. EUFEPS welcomes these, of course, as well as strongly supports the idea of establishing Master in Drug Development and Drug Discovery programmes.

Since specialist training would take more than one or two short courses, during the summer or during the school year, an orchestrated action by a number of centres of excellence would be needed. We require a visionary and able conductor, or conducting team, who could make sure that such an orchestra would perform enjoyable music. Certainly, this is not just an interest for future pharmaceutical specialists. Europe will need them to develop new, safe medicines for its own citizens and other populations.

Quality 'starting materials'

To achieve a high standard for a product, the quality of the "starting materials" is crucial. Furthermore, the materials must be handled well during the production process. Obviously, there is a growing concern in several European countries about the quality of the undergraduate pharmacy training. This concern seems to be shared by European Pharmaceutical Students' Association (EPSA), who recently initiated a scientific supplement to their Newsletter.

In a recent article, the Executive Director of the Swedish Pharmaceutical Society/ Academy of Pharmaceutical Sciences, Prof. Björn Lindeke, discussed (in Swedish) risks with establishing new schools of pharmacy (in Sweden). The challenge is to meet the required numerical output for the pharmacy profession[2]. Since the basic training is the same for a professional pharmacist and a scientific career, there may not be a sufficient number of good quality students and teachers to provide a solid base for a career in the pharmaceutical sciences, he argues. In other countries, there are strong movements to reduce the scientific contents of the curricula in schools of pharmacy, in favour of professional pharmacy. If these are trends, and they cannot be reversed, the unique pharmaceutical sciences profile may be in jeopardy.

Of course, one solution would be for the students, who aim for a scientific career, to leave their home country for a school or a university where appropriate training is provided. If there will be not a sufficient number of quality schools available in Europe to meet the industrial drug research needs, Europe will also be in jeopardy. Students, graduates and post-graduates will go elsewhere, as will the industry.

These issues are not explicitly discussed in the current EUFEPS Strategic Plan, for 2002-2006. With hard information about the current situation, such issues would certainly be considered in the next Strategic Plan.

Other Regions

It is in the Strategic Plan 2002-2006 that EUFEPS should collaborate on pharmaceutical sciences training both in its own geographical region and in others. The FIP Board of Pharmaceutical Sciences (BPS) and the American and Japanese pharmaceutical sciences organisations are, for example, collaborating on third-world programmes.

Perhaps, the global platform for advancing the pharmaceutical sciences, FIP BPS, will be the best level for coordinating such efforts, jointly supported by pharmaceutical associations and federations of all regions.

Hans H. Lindén, MSc
Executive Director EUFEPS

Bernd Clement, Professor
Chair EUFEPS Committee on training and Education (CTE)

[1] Workshop Report: Future Training Needs in Pharmaceutical Sciences; www.eufeps.org

[2] Lindeke, B.: Den blomstrande tid som kom; Elixir (Apotekarsocietetens medlems-tidning) 2/2003

Further engagement of the EU Commission in

New Safe Medicines Faster?

Here Prof. Ole J. Bjerrum and Dr. Jørgen Dirach explain the reasons for a major needed Europe-wide effort to rethink pharmaceutical development and approval.

Background

The pharmaceutical industry faces increasing challenges:

- fewer high-selling products, i.e. 'blockbusters'
- spiraling research and development (R&D) expenditure
- falling productivity, in terms of new molecules brought to the market
- large investments in new technologies, which have not yet borne fruit

The response to these challenges may need to be a complete overhaul of the drug development and approval process. A move towards much more individualized medicine, based on more specific diagnostic systems, should support the cost-effectiveness of new medicines.

Drug development and approval are under strict regulation. Over the last decade, a worldwide harmonization has been introduced through the International Conference on Harmonization (ICH), with all the compromises entailed. Introduction of new methodologies and techniques, which could lead to a more rational and efficient process, take a long time to be approved. (For unknown reasons, claims for further guidelines do not disappear from the new guidelines). These strictures cause serious delays to the much-needed transition (paradigm shift?) from the current drug development process. Without rationalization of the process, the price for new medicines may explode – if the innovative pharmaceutical industry survives at all!

Effect on stakeholders

Who are the losers in the present situation?

- The patients – who do not get the new innovative medicines fast enough. Those with rare diseases may not get them at all.
- The society – which will have to reimburse the exploding cost of medicines.
- The industry – which cannot find the capital to fund all the risks of development. An ultimate result could be that US-based companies take over the industry in the EU.
- The regulatory agencies – whose fees are linked to the declining numbers of applications.
- The universities – who lose students when graduates cannot get jobs in the industry.

Ole Bjerrum, EUFEPS President-Elect, hands the NSMF Report II to Philippe Busquin, DG Research of the EU Commission.

Activities so far

Many of the involved stakeholders have realized the gravity of this situation and want to do something. Indeed, several reports full of suggestions have been published, giving rise to useful incremental improvements, but the recommendations are not directed toward major changes of the process. The EU response to the "G10 report", www.pharmacos.eudra.org/F3/g10/g10home.htm, falls in this category. Thus far, nobody has dared "To rethink the process of drug development and approval" from the very beginning and to implement changes on a rational basis. This is exactly what is needed.

Role of Directorate General Research

Due to the complexity of the drug development process, it is necessary to work on the changes with a 10-year perspective for implementation. Many of the technological solutions, required to make the process more efficient and faster, are at the front edge of research today. Before such improvements can be implemented, they have to be further developed and validated. The critical issue in this connection is obvious: who will have to pay for such investigations? Without doubt, return from the investment will come in the form of novel and affordable medicines. Since it is the consumers who will benefit in the end, it would be reasonable that part of the research work is supported from public funds. Today, the responsibility of such funding falls between the chairs of industry, regulators and academia. All stakeholders must shoulder this burden in a coordinated approach. Only the EU Commission can handle such an enormous task.

A radical overturn of drug development and approval will be met with many objections because of safety concerns. The only way to overcome these concerns is to initiate research on validation, to show that the objections are groundless. For this reason, a good place to start the endeavor will be with the Directorate General (DG) Research of the Commission.

Proposal of a meeting

It is within this framework that EUFEPS has suggested a "First Meeting on New Safe Medicines Faster" to be set up by DG Research of the Commission. Firstly, it should clarify the position of the involved stakeholders and explore what possibilities exist to change the current situation. Secondly, it would give the Commission insight into the strategic research needed to rationalize further both drug development and approval. We are at a stage where it is appropriate to go from harmonization to rationalization of the regulatory guidelines. This means support to precompetitive research i.e. collaborative research aimed at optimizing the processes for everyone, for regulatory purposes.

Taking a 10-year perspective, the objectives for such a meeting should be:

To identify where the drug development and approval processes can be changed giving more efficiency and scientific rationale; to describe the research initiatives, which will be needed to generate precompetitive knowledge, showing through validation that the proposed process changes are safe.

Prof. Ole J. Bjerrum
Dr. Jørgen Dirach

The Pharmacopoeial Column

In this article, Professor Henk de Jong gives insight into 'Harmonisation, Modern Times'

In 1989, the leaders of the European Pharmacopoeia, the Japanese Pharmacopoeia and the United States Pharmacopeia decided to create the Pharmacopoeial Discussion Group (PDG) to respond to the users of these compendia, who wanted harmonised methods and specifications for pharmaceutical ingredients and products.

The PDG started at a similar time as the International Conference on Harmonisation (ICH) where regulators and industrial scientists from USA, Japan and the EU have been working together on harmonised requirements for registration of pharmaceuticals.

PDG attempted harmonisation in two areas:

1) on general methods, here 28 topics were identified
2) on quality monographs for selected (50) excipients.

After an enthusiastic start in which a lot was accomplished, a number of serious difficulties were encountered. These difficulties arose from not only differences in philosophy/policy, but also differences in reagents and equipment. The legal status and decision-making processes are quite different between the three regions. Detection of these difficulties has led to a rethinking of the compendial harmonisation process.

The present definition of Harmonisation within the PDG is "A pharmacopoeial general chapter or other pharmacopoeial document is harmonised when a pharmaceutical substance or product tested by the document's harmonised procedure yields the same results and the same accept/reject decision is reached". Of course, this states the ultimate goal: worldwide quality standards for pharmaceuticals. Following this definition, one can distinguish "full harmonisation", the ideal of identical monographs (except for language/spelling), from the second best "harmonisation by attribute" where the same attributes are tested in the different regions but with sometimes different methods. Here the demonstration of interchangeability of methods becomes an important item. Work is ongoing to show method equivalence through "mining" of existing data in industrial laboratories e.g. analytical results obtained on batches of ingredients tested using monographs of USP, JP and Ph.Eur. In certain cases, laboratory work is needed to generate the data. IPEC, the International Pharmaceutical Excipients Council, has performed a set of experiments on calcium phosphate to show equivalence of assay methods.

As (the lack of) progress has been criticised by industry, a scheme of regular (twice a year) meetings between PDG and industry representatives has been set up. Efforts are being made to speed up the decision-making process by early identification of "sticky points". Here timely input from industry can be of great help.

To promote transparency, the pharmacopoeias are also publishing a progress report in their magazines: Pharmacopeial Forum, Pharmeuropa and Japanese Pharmacopoeial Forum.

USP and Ph.Eur. also report on their websites.

For those interested in more details and regular updates on the process and its progress, the website: www.pheur.org gives specific information on the PDG work (look under EDQM activities and follow the link to PDG). Similarly, USP can be reached at www.usp.org and JP at www.sjp.or.jp.

For the International Pharmacopoeia, look at the WHO website: www.who.int,

Here one also finds a list of the 43 Pharmacopeias, with contact addresses.

Prof. Henk de Jong

Highlights
from European Journal of Pharmaceutical Sciences, EJPS

Polyethylenimine (PEI) is a promising polymer for gene delivery. However, the usefulness of PEI is hindered by its toxicity, caused by its polycationic nature. **Middaugh et al. (EJPS 19: 191-202, 2003)** added dextran sulfate into self-assembling PEI–DNA complexes with zinc as stabilizing agent. They obtained spherical particles with a mean particle size of approximately 200 nm. The results suggest that DNA is condensed and protected in the complexes. It also appears that the cytotoxicity of DNA nanoparticles decreased with dextran sulfate. Still, the complexes were able to transfect cells and the particles were also active in the presence of serum.

Caco-2 cells are widely used for drug absorption prediction. Different laboratories have reported large differences in permeability of Caco-2 model for actively transported substrates. **Behrens and Kissel (EJPS 19: 433-442, 2003)** investigated the effect of cell culture conditions on the expression of peptide transporters (PepT1, HPT1) and the efflux pump, P-glycoprotein (Pgp), in Caco-2 cell monolayers. Both morphology and the expression of carrier-mediated transporters, varied as a function of the conditions. Strong expression of all carrier-mediated transporters was found up to 3 weeks post seeding. One week later, the expression of Pgp decreased. The full differentiation was reached after 21 days on collagen-coated polycarbonate inserts at an initial seeding density of 6 $x10^4$ cells/cm^2.

Kopecek reviewed **(EJPS 20: 1-16, 2003)** the design, synthesis, and properties of stimuli-sensitive and genetically engineered biomaterials for drug delivery. These systems may allow construction of tailor-made systems that release drugs controlled by outside stimuli. One approach is to improve the synthesis of polymers. The second method uses genetic engineering methods to design hybrid hydrogels composed of synthetic macromolecules and protein domains. Pharmaceutical applications of these materials are also discussed in the review article.

Early prediction of systemic pharmacokinetic parameters (volume of distribution, clearance) would be helpful in the drug discovery process. **Karalis et al. (EJPS 20: 115-123, 2003)** explored the quantitative structure–pharmacokinetic relationships of cephalosporins. The models of clearance (CL), apparent volume of drug distribution (Vap), fractal clearance (CLf), and fractal volume (Vf) were generated for a series of 23 cephalosporins. Chemical descriptors for acidity/basicity, lipophilicity, molecular size and hydrogen bonding properties were estimated using computer packages. For each pharmacokinetic parameter, projection to latent structures was applied to the total dataset. Identical descriptors were significant for the clearance and the volume of distribution. The non-linear correlation models were better than the linear relationships. The worst models found were for Vap (R^2=0.523 and R^2=0.571) and the best models found for Vf (R^2=0.729 and R^2=0.824).

Prof. Arto Urtti, Editor EJPS

NEXT STEP IN PHARMACY EDUCATION

Suryadevara Pratap introduces his book, which helps pharmacy students choose their career beyond undergraduate studies. He appeals for your assistance in making this guide more widely available.

Help One to Help Two

Dear Colleagues from Pharmaceutical Industries, Organizations, Societies, Schools and Fellow Pharmacists,

I have pleasure to inform you that I have published a book entitled "NEXT STEP IN PHARMACY EDUCATION" for pharmacy students. My 8 years of experience in pharmacy profession have revealed that pharmacy students should know much about their career prospects before completing their undergraduate studies. Availability of limited written information and the cost of accessing Internet websites are the main constraints preventing the students receiving sufficient information. Considering the above facts, I started to think about the solution and finally came out with the answer in the form of book.

This book is very useful for pharmacy students who would like to pursue higher studies after their first degree, Ph.D. or continuing education. This book provides a list of pharmacy schools across the world, relevant websites, details of scholarships and loans available to pharmacy students at national and international levels, working opportunities in different countries, pharmacist registration procedures, requirements for visas and work permits, different qualifying exams and much more that a student may require to plan for success. This book not only provides information but also motivation. For example, the life stories of successful entrepreneurs in the pharmaceutical industry may motivate some students to choose that career path.

My problem is how to provide this book to each and every pharmacy student in the country. In India, we have 350 pharmacy schools and more than 75,000 Pharmacy students. In a short span of seven months, we have published 3000 copies, which have been distributed in two major states in India. Every pharmacist should able to receive this book at very minimal cost. We would like to provide this book free of charge to outstanding students and those who could not otherwise afford it. In this regard, I am in the process of gathering funds for publication and distribution, in the form of paid advertisements from different organizations and individuals who are supportive of young pharmacists. Your help in this way may be very useful for every budding pharmacist. In this regard, I request that you send an advertisement for publication in the book. We would like to collect an amount of US$ 200 for each advertisement (Please contact me for details of the required format). We also accept individual anonymous donations (without advertisements).

Thank you for your help in this important pharmacy education effort.

Please send your donations by bank transfer, cheque or direct debit to

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Regulatory Agencies and the pharmaceutical industry have realised that current GMPs for drug development and manufacturing need to change fundamentally and become more science-based. Risk Assessment should become a leading principle for GMP decision-making, for inspections and for regulatory evaluation of post-approval changes.

The new Quality System within the Agencies and manufacturers must incorporate good science and risk management. The new Quality System should be applicable throughout the entire lifecycle of the product and be fully harmonized across the three ICH-regions to allow for mutual recognition.

EUFEPS, EMEA, EFPIA, FDA and FIP representatives will hold an interactive workshop from November 19 – 21 in The Netherlands, to move towards such a Quality System in Europe and to create a shared vision for industry and regulators.

The workshop has taken its title from a recent EFPIA discussion paper entitled "Quality Systems and Regulatory Innovation for the 21st century". The workshop in Noordwijk is the second on this topic as FDA and PQRI organized a first workshop in Washington DC, USA in April 2003. That workshop drew more than 500 attendees both from agencies and industry. The conclusions of the first workshop have been published (see background section of www.qualityworkshop.nl for EFPIA paper and FDA discussions).

At the level of the International Conference on Harmonization (ICH), the following topics will be presented during ICH-6 in Osaka, Japan:

- Quality Systems/Quality Management
- Risk Management
- Pharmaceutical Development/Quality by Design/Manufacturing Science

(for background information go to www.ich.org).

The week after ICH-6, this second Quality Workshop will present a programme with EMEA, FDA, WHO and industry speakers on these 3 topics in Noordwijk. A 4th topic to be discussed will be inspection issues.

We invite you to register for this groundbreaking workshop and share your opinions with colleagues from industry and authorities. This is an excellent opportunity to get acquainted with the new ideas, to meet the decision-makers, and to influence the decision-making process. You cannot afford not to come to Noordwijk!

Tom Sam,
President Industrial Pharmacy Section, FIP
Joyce Ramsbotham,
Work Group Leader GMP, EFPIA
Menno van der Waart,
Committee on Industrial Relations CIR, EUFEPS

Programme in brief, for details see www.qualityworkshop.nl

Day 1
FDA and ICH Initiative – background, progress and next steps
Ajaz Hussain, FDA
Harmonised, risk-based, science-based Quality Systems – industry perspective
Joyce Ramsbotham, EFPIA
Risk-based regulations, assessments and inspections
Gordon Munro, MHRA
Quality Systems/Management, a European perspective
Peter Gough, Lilly, UK
Quality Systems in inspections
Jacques Morénas, AFSSAPS
Introduction into risk management
Greg Guyer, Merck, USA
Change management in the context of managing risk: European perspective
Tim Marten, AstraZeneca, UK
Designing quality into product and process
Erik Frijlink, Groningen Univ
Impact of API's on Quality by Design
Patricia Rafidison, IPEC
Process Analytical Technology
Ken Leiper, Benson Cons, UK
Development and the development report see *www.qualityworkshop.nl*

Day 2
Integration of knowledge: sharing and transfer
Joseph Famulare, FDA
Integration of assessor reviews and inspections: current situation and future perspectives
Emer Cooke, EMEA
BREAKOUT SESSIONS (3x)

Day 3
Quality Systems, Risk Management and Manufacturing Science in Japan
Yukio Hiama, National Institute of Health Sciences, Japan
Risk-based Quality Systems: WHO point of view
Sabine Kopp, WHO
REPORTS FROM SESSIONS
Summary and Conclusions: towards Harmonization
Gordon Munro, MHRA

Good News from EJPS and Elsevier

Dramatic Increase in Impact Factor

The European Journal of Pharmaceutical Sciences (EJPS) now has much more impact. The factor rose to 2.436 in 2002 from 1.842 in 2001.

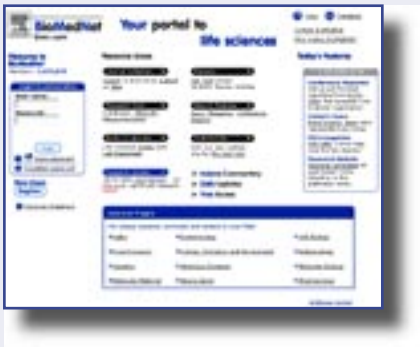
A new Gateway to Pharmacology

Elsevier Life Sciences are launching a series of online Gateways in the Life Sciences, which will serve as 'shop windows' for the excellent material published in their journals including the European Journal of Pharmaceutical Sciences, online products and books. They are a useful community site with news, features and commentaries.

These subject gateways are hosted on BioMedNet, www.bmn.com, Elsevier's portal to Life Sciences. If you are not already a member, the first time you visit the Gateways you will need to register on the site. Registering is a one-time, free process, which only takes a few minutes.

Elsevier partnership with IUTOX

Elsevier is partnering with the International Union of Toxicology to promote education in toxicology. The publishers have donated copies of the Comprehensive Toxicology Series 1-13 to libraries in 24 countries across Eastern Europe, South America and Asia.



Pharmaceutical Sciences World Congress (PSWC2004)

2nd World Congress of the Board of Pharmaceutical Sciences of FIP
"The Global Translation of Science into Drug Development in Advancing Therapy"
www.fip.org/PSWC/

Venue: Kyoto International Conference Hall, Japan

Distinguished Lectures

'Molecular Catalysis: Science and Opportunities' by Ryoji Noyori, 2001 Nobel Laureate in Chemistry (Nagoya Univ., Japan)

'Nitric Oxide is a Unique Signaling Molecule in Mammalian Physiology' by Louis J. Ignarro, 1998 Nobel Laureate in Physiology or Medicine (UCLA, USA)

Plenary Lectures

Pharmacoproteomic-Based Drug Discovery and Development Using Mutant Cytokines-Displayed Phage Libraries
Tadanori Mayumi (Osaka Univ., Japan)
Mechanisms of Drug-Induced Liver Injury
Neil Kaplowitz (USC, USA)
Glycobiology in Pharmaceutical Sciences
Toshisuke Kawasaki (Kyoto Univ., Japan)
Pharmacogenomics of Membrane Transporters
Kathleen Giacomini (UCSF, USA)
Molecular and Neural Mechanisms of Classical Conditioning
Yutaka Kirino (Univ. of Tokyo, Japan)
Fibroblast Growth Factors and Chemoresistance: From Laboratory to Bedside
Jessie L.-S. Au (Ohio State Univ., USA)
Pharmacological Taming of Natural Toxins: Conversion of Mushroom Toxin into Novel Class of Hypnotic
Povl Krogsgaard-Larsen (Royal Danish School of Pharmacy, Denmark)
Challenges in Mucosal Vaccination Strategies
Hans E. Junginger (Leiden Univ., The Netherlands)

Symposia

Proteomics in Drug Discovery and Design: Analytical Aspects / New Mass Spectrometric Methodologies in Drug Development / Microchip-based Analytical Systems / Drug Metabolism and Transport Studies in the Drug Discovery and Development / Drug Interactions on Drug Metabolism and Drug Transport / Interplay Between Drug Metabolizing Enzymes and Transporters / Regulation of Gene Expression of Drug Metabolizing Enzymes and Transporters / Receptors and Ion Channels as Targets for Drug Development / Signal Transduction: New Concepts and Trends / Growth Factors: Receptors and Beyond / New Strategies for Mucosal Drug Delivery: Bioadhesion, Particulate Carriers, etc. / Intelligent Biomaterials and Microprocessor Control in Drug Delivery / Nanotechnologies in Gene and Vaccine Delivery / From Hit-to-Candidate: Optimizing Lead Development and Timelines in Medicinal Chemistry / Synthesis and Chemical Modification of Drugs and Bioactive Natural Products: New Methodologies / Natural Products and Traditional Medicines: Isolation, Structure Determination, Biosynthesis, Engineered Biosynthesis, and Clinical Exploitation / Technical and Regulatory Challenges of Using Transgenic Plants and Animals to Produce Protein Therapeutics / DNA as a Drug: Recent Advances in Gene Therapy / Recent Advances in Stem Cell Therapy for Human Disease / Challenges in Oral Delivery of Drugs with Inherent Difficulties for Absorption / New Technologies for Protein Delivery Systems / Computer-aided Formulation Design and Optimization / Drug Target Validation: A Key Step in Drug Discovery / Bioinformatics in Drug Discovery / Structural Genomics; The Next Step / Prion Diseases in Animals and Human / Genetic Issues on BA-BE Studies for Oral Drug Products / Evaluation and Prediction of BA-BE for Oral Drug Products: Design and Criteria / PK-PD Modeling in Drug Therapies: Conventional and Population PK-PD Modeling / Tailor-made Drug Therapy: Genotyping and Phenotyping / Translational Research for Incurable Diseases / Therapeutic Drug Monitoring: Variability in Drug Response / Prospective and Retrospective Strategies for Bridging Studies / Current and Future Uses of Toxicogenomics: Regulatory Aspects / Exposure-response Relationship: Mechanism-based PK-PD and the Associated Models and Simulation

Important Dates:

Abstract Submission Deadline:
January 14, 2004
Deadline for Early Bird Registration:
January 28, 2004
Deadline for Advance Registration:
April 14, 2004

Organizing Committee

Chair: Yuichi Sugiyama (Japan)
Scientific Program Co-chairs: Mitsuru Hashida (Japan), Vincent H.L. Lee (USA), Hans E. Junginger (The Netherlands)
Fund-raising Co-chairs: Hiroshi Terada (Japan), Gordon L. Amidon (USA), Malcolm Rowland (UK)
Publicity Co-chairs: Toshio Honda (Japan), Kamal K. Midha (Canada), Claus-Michael Lehr (Germany)
Scientific Advisory Committee Co-chairs: Tsuneji Nagai (Japan), Leslie Z. Benet (USA)
FIP Head Office
General Secretary: Ton Hoek
Congress Director: Gretie R.v.d. Baumen
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AAPS, APGI, APSGB, APSTJ, CRS, EUFEPS and PSJ
Contact:
PSWC2004 Secretariat
c/o Business Center for Academic Societies Japan, 7F Flora Building, 4-2-8 Hongo, Bunkyo-ku, Tokyo 113-0033 JAPAN: Tel: +81-3-3815-1681,Fax: +81-3-3815-1691
E-mail: pswc2004@bcasj.or.jp

Posttidning B EUFEPS Newsletter
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SE–111 81 Stockholm
Sweden

CALENDAR

AAPS Workshop on Method Validation and Measurement of Biomarkers in Nonclinical and Clinical Samples in Drug Development
October 24-25, 2003, Salt Lake City, UT, USA
Contact: American Association of Pharmaceutical Scientists, 2107 Wilson Blvd Suite 700, Arlington, VA, USA
Fax +1 703 243 9650, Email aaps@aaps.org

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AAPS 2003 Annual Meeting & Exposition
October 26-30, 2003, Salt Lake City, UT, USA
Contact: American Association of Pharmaceutical Scientists, 2107 Wilson Blvd Suite 700, Arlington, VA, USA
Fax +1 703 243 9650, Email aaps@aaps.org
www.aapspharmaceutica.com/meetings/annualmeety/am03

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Pharmacy education – change or crisis: professional training vs science education
November 17, 2003, London, UK
Contact: Mrs J Callanan, Room 304
Royal Pharmaceutical Society of Great Britain
1 Lambeth High Street, London SE1 7JN, UK
Fax +44 20 7572 2506
Email science@rpsgb.org.uk

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Tabletting Technology
November 24-26, 2003, Cambridge, UK
Contact: Mrs J Callanan, Room 304, Royal Pharmaceutical Society of Great Britain
1 Lambeth High Street, London SE1 7JN, UK
Fax +44 20 7572 2506
Email science@rpsgb.org.uk

BioTech Forum Science Conference 2003
November 26-28, 2003, Stockholm, Sweden
Contact: Stockholm Convention Bureau
P.O. Box 6911, SE-102 39 Stockholm
Sweden, Fax +46 8 5465 1599
Email confirmation@stocon.se
www.biotechforum.org

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11th EUFEPS Conference on Optimising Drug Development: Integrating New Concepts and Tools
December 8-10, 2003, Basel, Switzerland
Contact: EUFEPS Secretariat, P.O. Box 1136
SE-111 81 Stockholm, Sweden
Fax +46 8 4113217, Email secretariat@eufeps.org
Website www.eufeps.org

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AAPS Workshop on Achieving Sterility: Future Direction in Aseptic Processing
December 8-10, 2003, Arlington, VA, USA
Contact: American Association of Pharmaceutical Scientists, 2107 Wilson Blvd Suite 700, Arlington, VA, USA
Fax +1 703 243 9650, Email aaps@aaps.org

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LogP2004/3rd Lipophilicity Symposium: Physicochemical and Biological Profiling in Drug Research
February 29-March 4, 2004, Zürich, Switzerland
Contact: http://www.logP2004.ethz.ch

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8th European Symposium on Controlled Drug Delivery
April 7-9, 2004, Noordwijk aan Zee, The Netherlands
Contact: Miranda Wiehink, University of Twente/BMTI, P.O. Box 217, NL-7500 AE Enschede, The Netherlands, Fax +31 53 4892319, Email m.a.g.wiehink@utwente.nl
www.utwente.nl/bmti.nl

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9th International Conference on Perspectives in Percutaneous Penetration
April 13-17, 2004, La Grande Motte, France
Contact: PPP Conference, Redwood Building, King Edward VII Avenue, Cardiff, CF10 3XF, UK, Fax +44 2920 875247, Email info@pppconference.org

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EUFEPS Conference on Drug Transporters: Integrative approaches in ADME research
April 19-21, 2004, Copenhagen, Denmark
Contact: EUFEPS Secretariat, P.O. Box 1136
SE-111 81 Stockholm, Sweden
Fax +46 8 4113217, Email secretariat@eufeps.org
Website www.eufeps.org

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EUFEPS Training Course on HT Drug Metabolism/Disposition
April 22-29, 2004, Amsterdam, The Netherlands
Contact: EUFEPS Secretariat, P.O. Box 1136
SE-111 81 Stockholm, Sweden
Fax +46 8 4113217, Email secretariat@eufeps.org
Website www.eufeps.org