Update from the President

July 2010

The European Federation for Pharmaceutical Sciences represents affiliated scientific societies in Europe and provides activities that nurture information exchange, training programmes and scientific events for academia, industry and regulatory bodies.

Time to celebrate

The organisation celebrates its twentieth anniversary in 2011 and we will mark this important event with a yearbook, launched at PharmSciFair. EUFEPS strives to encourage participation – from individuals and from member organisations – that strengthens the progress to better and safer medicines. This is achieved by many interactions at conferences, workshops and collaborative partnerships, and the exploration of common interests with other learned societies that are relevant to membership needs. At the time of printing, EUFEPS has 24 member societies in 24 countries, including Israel and Turkey, fifteen European universities and research institutes and more than four hundred individual members.

Networks and events

An important engine for the EUFEPS is the network structure, and you will be able to find further details in the upcoming yearbook or on the EUFEPS Online site. The networks gradually evolve by crystallisation of interest and are led by steering groups as shown in the plan. Currently there are five established networks and two more, regulatory sciences and nanomedicine, under development. The activities of both member societies and the network structures contribute to PharmSciFair, a celebration of European pharmaceutical sciences held on a biennial basis. The event hosts activities of the member societies and the networks and has a strong programme for young scientists. In addition, EUFEPS plays an important role in programmes organised by FIP, and cosponsors events such as the BBBB (Balaton-Baltic-Bled-Bosphorus) conference series, helping to contribute to southern, eastern and central European activities. The European Journal for Pharmaceutical Sciences publishes EUFEPS conference reports, NewsLetter and announcements, keeping members up to date with new events.

Current governance

Instruments of policy and training, and interaction with industry are taken care of by committee structures. Other events are held within the aegis of EUFEPS, directed by members with assistance of the executive. The Executive Committee meets on a quarterly basis and Member Societies propose candidates for election for a two-year term.

Recently, the formation of a senate structure was initiated. The Senate serves the president in generating ideas for strategic planning, monitoring the health of the organisations and other appropriate tasks. It provides access to a larger and senior network, which can assist in creative solutions about the expansion of EUFEPS.

Central Office

The Headquarters of the EUFEPS has moved but is still based in the Stockholm area under the direction...
of the present Chief Executive Officer, Hans H. Linden. The federation was previously based within the Swedish Academy of Pharmaceutical Sciences, and strong links across Scandinavia have continued. New offices in the Veddesta Business Centre provide central coordination and support of the networks and committees, and link into important European initiatives such as Innovative Medicine Initiative platform (IMI JU) under the 7th Framework Programme for Research and Technological Development through the activity of the CEO.

**Going Forward**

EUFEPS is unique in that it is the only pan-European organisation that supports pharmaceutical/drug scientists, whatever the origin, domain or discipline. It is therefore a powerful rallying point that has the ambition to develop the professional status of the pharmaceutical scientist. This has yet to occur, but it will happen and it will stretch beyond the current constraints of pharmacy, which in some countries (especially my own) is failing as a scientific discipline. The pressures for the formation of such a body are strong, as pharmaceutical sciences are represented at every level of the medicines chain, from discovery in laboratories in industry and academia through to regulation and safety sciences. The backgrounds of our participants include biochemistry, pharmacy, physics and engineering graduates and many others. The contribution that we can make is significant and well recognised but a step-change in setting standards long overdue. Let’s make sure that we use the experience of EUFEPS to represent the ambitions of our members and member organisations to set pan-European standards of the highest order.

Clive G. Wilson, Professor
President EUFEPS
Setting the Research Agenda for Pharmacogenomics in Europe

Recommendations of the EUFEPS European Research Network Pharmacogenetics/genomics

At tendents: L. Becquemont (University Paris-Sud, France), C. VerSTuyft (Hôpital Bicêtre, France), M. Pirzomahed (University of Liverpool, UK), C. Palmer (University of Dundee, UK), L. ’t Hart (Leiden University Medical Center, the Netherlands), M. Wedelius (Uppsala University, Sweden), H. Linden (European Federation for Pharmaceutical Sciences, Sweden), R. Van Schaik (Erasmus University Medical Center, the Netherlands), S. Haenisch (University Hospital Schleswig-Holstein, Germany), E. Pearson (University of Dundee, UK), S. Vrijbergen (Utrecht University, the Netherlands), A.H. Maitland-van der Zee (Utrecht University, the Netherlands)

This report is the distillation of a meeting organised by the EUFEPS European Research Network Pharmacogenetics/genomics (Pgx) held on the 27th of April 2010 in Leiden, the Netherlands. The aim of the meeting was to share visions from Network members on the current state of the art concerning Pgx as well as to come up with recommendations for a European research agenda on Pgx.

Need for standardisation
Although there are important Pgx cohorts in Europe on a broad range of diseases, the members feel there is a lack of overview. Especially in order to replicate, one needs to know where to find a replication cohort. It would be very valuable to draw up a European map of existing cohorts, grouped according to disease area. In this map it should be noted which clinical data are present, how drug exposure is measured and which genes/SNP’s are genotyped.

Need for inventarisation
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Selecting diseases and drugs for Pgx studies
In order to be able to identify priority areas for funding, the members came up with a set of criteria. These criteria focus on the selection of a disease area in which the implementation of a specific gene-drug interaction would be considered to be highly clinically useful. The following set of criteria has been proposed:

1. Disease frequency and non-response to therapy should be substantial
2. Incidence of the disease should be increasing
3. Drug development in this area should be active
4. Drugs should be (rather) expensive
5. The drug of interest should have a low therapeutic index (increased harm)
6. Disease should be rather severe
7. Phenotype responders should be well identified

The following diseases would fit these criteria (more or less): diabetes, asthma, oncology, epilepsy, depression and schizophrenia.

Although there is a lot of scientific profit to obtain in other pharmacogenomics disease areas as well (e.g. CVD), the members do recommend that priority for funding should be given to disease areas that meet the proposed criteria.

However, separately mentioned as an important priority area for funding are the biologicals (such as anti-TNFα). This class of drugs seems to bring along a major problem in terms of ADR. Future pharmacogenomic studies in this area are therefore highly recommended.

Vijbergen SJ, Maitland-van der Zee AH

Clinical relevance versus Lead development
In order to decide where priorities should lie in Pgx research, it would be an option to take clinical relevance as a starting point. However, although clinical research might be considered the aim of Pgx on the long term, it is also important to aim to find new leads for the development of new drugs. Pgx might bring to light new pathways of interest to the pharmaceutical industry.

Clinical Trials seem to be inevitable
Clinical trials are time-consuming and costly; nevertheless, clinical practice seems to demand Clinical Trials for successful implementation of Pgx. This seems inevitable. In general, clinical practice does not seem to be ready for Pgx, with the exception of the field of oncology. In this field, drugs are expensive and response is poor. Other diseases/areas in which Pgx studies are performed include: cardiovascular diseases, diabetes, asthma, immunosuppressants, rare and common Adverse Drug Reactions (ADR), Pain, Depression/Schizophrenia.

Data analysis
There are important differences between genetics and Pgx. In Pgx, there is the interaction between disease and drug-outcome. Data-analysis therefore requires new biostatistic and bioinformatic tools. There should be agreement on which methods to apply in order to be able to compare findings.

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Need for standardisation
In future Pgx studies, outcome and phenotypes should be standardised in order to be able to compare studies and perform meta-analyses. However, with current studies we should be realistic and look at the data we have already gathered.

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Meeting report: EuPAT4, May 5-6, 2010, Kuopio, Finland

Taking PAT to the Next Level

Emil W. Ciurczak¹, Jarkko Ketolainen², Riikka Laitinen², Jaakko Aaltonen³, and Hans H. Lindén³.

¹ Doramaxx Consulting, New York, NY USA
² School of Pharmacy, University of Eastern Finland, Kuopio, Finland
³ EUFEPS Office, Stockholm, Sweden

The International EuPAT4 Conference, organised by the EUFEPS QbD and PAT Sciences Network, was held in Kuopio, Finland, on May 5-6, 2010. This high-quality meeting gathered the most significant experts in the field and almost one hundred participants from 14 countries, among them also many representatives from large international pharmaceutical companies.

New approach

Pharmaceutical industry is facing significant changes at the moment. The current way of quality control dates back to decades and it is based on analysing only a fraction of a production batch. This leads to poor cost-efficiency and poor drug safety. Novel methods, enabling quality control of pharmaceuticals already during their production, help in lowering costs and improving quality. In the EuPAT4 meeting, several novel applications for on-line manufacturing process measurements and techniques already implemented in other fields of industry, were introduced. European and American authorities have encouraged the pharmaceutical companies towards this new type of quality control for a few years now. Thus, it can be anticipated that the number of marketed pharmaceuticals, prepared and analysed along the new guidelines, will be increased in the future.

Excellent presentations

The two-day conference had all in all really good talks. Although there were many good talks, only a few memorable ones are mentioned. The first paper worth mentioning was by Prof. Thomas de Beer (University of Ghent, Belgium), entitled, Control of the Freeze-drying Process of a Protein Formulation. He had a lot of data on real-time measurements of lyophilization, including temperature (of the vial contents), Raman, and NIR.

Mechanistic Modeling and Mechanistic Sensors – Towards the Ultimate Understanding in Multiphase Processing, was the topic of Prof. Staffan Folestad (AstraZeneca and Chalmers University of Technology, Mölndal and Gothenburg, Sweden). This was a fine discussion of how to choose sensors and interpret the data generated. This was a theoretical approach to what had always been considered an empirical topic. “ Normally,” we try different techniques until we find the “best” technique for analysis or monitoring a process.

Modeling Powder Processing: Compaction and Powder Flow was delivered by Dr. Göran Frenning (Uppsala University, Uppsala, Sweden) presenting detailed models of what happens...
when powders are blended/stirred/mixed. Using math and photos, Dr. Frenning showed some of the unknown cavitation and flow properties that can make or break a dry powder process: thermal energy vs. particle energy, dissipation/losses, flow regimes, jamming, and irreversible particle changes.

TeraHertz spectroscopy was the topic in Dr. Axel Zeitler’s (University of Cambridge, UK) paper named Non-invasive Online Measurements of Coating Thickness and Density of Individual Tablets in Real Time during Production Scale Processing using TeraHertz Pulsed Imaging. He included the theory, a feasibility study of tablet coating, how the hardware was implemented, discussed the actual coating process, and showed the in-line approach, using some rather interesting equipment. The coating pan was, in reality, a wide-hole mesh drum. The TeraHertz system was coordinated with the turning drum to measure through the holes to determine the levels of coating. Dr. Zeitler also showed the ability of the system to determine the polymorphic forms of drugs and follow the conversion from one to another in real time. While practical applications of TeraHertz are not being reported yet, there seems to be room for this tool in PAT.

Dr. Pekka Teppola (VTT Optical Instrumentation and Promis Centre, Finland) discussed some of the cutting edge work in his talk, Exploratory Chemical Imaging Made Easy: Matched Spectral Filtering and Chemometrics. The title should give away the use of math treatments, but he also included the “non-chemometric” math (published in Pharmaceutical Manufacturing by Ralf Marbach) that uses the spectra of the analyte and “discards” the noise, both instrumental and experimental.

The last highlight to list is Prof. Marko Vauhkonen’s (University of Eastern Finland and Promis Centre, Kuopio, Finland) presentation Electrical Tomography Techniques as PAT Tools, which turned out to be one of the most illuminating talks of the week. Using transmitters and receivers, he (and his team) used variances in, for instance, dielectric constant to map the densities and chemistries of liquid samples. One really eye-opening experiment showed the lack of continuity of a dissolution tester. The results showed wildly differing velocities (with wildly differing concentrations and dissolution patterns) at very close distances. One conclusion was that a mere centimetre difference of where a tablet came to rest could affect the dissolution pattern by as much as 20%.

Unforeseen manner
All the talks mixed theory and practice in an unforeseen manner. Many conferences contain papers where the ideas of QbD and PAT are discussed in general terms and lack very specific experiments, based on empirical data. The story goes on and the next EuPAT series meeting (EuPAT5) will be held in Ghent, Belgium in 2012.

Kuopio and PROMIS
Why Kuopio in Finland for EuPAT4? In Kuopio there is, for example, the PROMIS Centre, which is a multidisciplinary research centre with three research partners (University of Eastern Finland, Savonia University of Applied Sciences, and the VTT Technical Research Centre of Finland). It is engaging in developments of new methods for analysis and optimisation of pharmaceutical processes. Therefore, Kuopio was a natural choice for the EuPAT4 meeting venue.

In general, the topic of the EuPAT4 is also strategically important to the Kuopio area. The local university has a long and successful tradition in drug development. In addition, strong sensor and automation know-how exists; essentially needed in process analysis.

The EuPAT Series
The EuPAT Conference Series is a unique forum for scientists and engineers, encouraging and promoting progress in science behind PAT and strengthening the interdisciplinary scientific discussion that bridges between the various fields underpinning PAT. The focus of it is on scientific progress underpinning innovative manufacturing control and quality by design and new findings. Results from scientific research and technology development are discussed in the four areas that constitute the cornerstones of the sessions: Process Informatics; Process Modelling and Understanding; Advanced Process Sensors; and QbD and PAT Based
Executive Committee of EUFEPS

This year’s EUFEPS Council was held on June 20, 2010, in Budapest Hungary. After the elections, Professor Milena Jadrijevic-Mladar Takac, Zagreb, Croatia, is new member of the Executive Committee, elected for two years. This is the current group:

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

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

Prof. Daan J.A. Crommelin, Past-President
Professor of Pharmaceutics, Utrecht University, and Scientific Director, Dutch Top Institute Pharma, Leiden, The Netherlands

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

Dr Buket Aksu
Corporate Relations Director, Santa Farma, Istanbul & EGE University, Izmir, Turkey

Prof. Ulrike Holzgrabe
Professor of Pharmaceutical Chemistry, University of Würzburg, Würzburg, Germany

Prof. Milena Jadrijevic-Mladar Takac
Professor of Medicinal Chemistry and Drug Biochemistry, Faculty of Pharmacy and Biochemistry, University of Zagreb, Croatia

Hans H. Lindén
Executive Director, EUFEPS, Stockholm, Sweden

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

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

Synergies between foods/food components and medicines

The establishment of some of our networks, such as the BABP Network Steering Committee, headed by Professor Henning Blume, frequently encounters issues around food and drug absorption, particularly in the context of regulatory guidelines and gastrointestinal physiology. Recently, David Featherstone of Copenhagen University proposed a showcase cross-disciplinary research meeting in Denmark, with the overall theme of exploiting synergies between foods/food components and medicines. It is this group’s intention to gather the relevant stakeholders interested in exploring possible synergies between foods & medicines and to facilitate the initiation and development of R&D projects, including consortia formation, funding and strategic alliance discovery, and public-private partnering. For further details, contact David Featherstone at david@biopeople.dk.

We see this as an important opportunity in generating a new, wider EUFEPS Food-Drug Synergy network that would work nicely in partnership with BABP and other existing networks in addition to it’s own conference activities. Please let us have your views.

Time to consider the EMA Guidelines on Investigation of Drug Interactions?

Professor Malcolm Rowland has drawn attention to the draft guidance on drug-drug interactions, which has a deadline for final comments by October 2010. As you will see in the newsletter, BABP is currently considering the modified release guidelines, and a key activity for EUFEPS in the academia-industry-regulatory triangle is to assist in bringing forward ideas for consideration. It would be useful to start a PK/PD-based network, which could include modelers, if we could identify some champions. Suggestions for a group to nucleate this activity are welcome. The following URL facilitates easy and clear notification of the status of these EMA guidances: http://www.ema.europa.eu/hms/human/humanguidelines/efficacy.htm

Copy and paste this into your browser. A click over a diamond will cause the download of the relevant document. Malcolm notes that in addition to the one for DDIs, there are several others that have an October deadline that may be of interest to EUFEPS.

Clive G Wilson
President EUFEPS

Network

Places for New Networks?

European Federation for Pharmaceutical Sciences

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Clive G Wilson
President EUFEPS
PharmSciFair is an important event in the European meetings calendar, and we are building the next one to attract always more people and especially more industrial interest. The two first events were in Nice, France, and we have decided to move towards Eastern Europe with the objective to encourage flow of information across the member societies and professions in this fast growing part of the world. The provision of a scientific venue to new, younger scientists assisting in career development will be also vigorously addressed.

The Opening Session will take place in the afternoon of Monday, June 13, 2011. A prestigious group of influential leaders will contribute to a common vision of pharmaceutical sciences, in both the short and the long term.

The pharmaceutical science as a multi-faceted concept will be reflected in the program of this event, which will be wide-ranging in terms of content, activities and participating partners. Exhibition and networking opportunities will be promoted. These are the tracks that are planned and tentative programme flow:

The First Announcement including session topics, keywords and deadlines will be circulated before the summer, but we already urge you all to participate in the 2011 PharmSciFair and to invite your colleagues to do so as well!

On behalf of the Organising Committee
Alain Cuiné, Chair

5 Parallel Tracks

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Indicative Topics for the

**IMI 3rd Call For Proposals (2010)**

**Safety**
Assessment of drug induced toxicity in relevant organs / surrogates for early drug failure

- **Improved early prediction of Drug Induced Liver Injury (DILI) in man**
DILI is one of the major safety reasons for delays or termination of drug development. The project aims at the identification of a panel of new in vitro assays and in vivo models that allow the early identification of compounds likely to cause DILI in humans. It includes approaches for an improved sharing of data and knowledge of the building of a biobank (tissue and body fluid samples).

- **Cardiovascular safety**
The aim of the project is the identification of novel biomarkers and models that could help to assess the effects of novel treatments on the heart more efficiently.

**Immunological Safety of Biopharmaceuticals**
- **Immunogenicity: Assessing the Clinical Relevance and Risk Minimization of Antibodies to Biopharmaceuticals**
In this project different technologies will be evaluated which can be used to detect Anti-Drug-Antibodies (ADA). It is planned to establish a comprehensive database of drug and patient data and to identify early activation biomarkers.

- **Immunosafety of vaccines – New biomarkers associated with adverse events (early inflammation and autoimmune disease)**
This project aims at the identification of validated preclinical and clinical biomarkers for early inflammation and autoimmunity and a better understanding of the incidence and epidemiology of these events in the general population.

**Efficacy**
Improve infrastructure for Tuberculosis medicines
- **Improve the scientific and preclinical models and tools for Tuberculosis medicines research**
The project aims at the identification of validated preclinical and clinical biomarkers to speed up the evaluation process, to develop models better reflecting human pathology and to improve preclinical and early clinical models with pharmacokinetic-pharmacodynamic assessment that optimizes clinical development.

**Enhancing translation in neurological disease**
- **Translational endpoints in autism**
The project aims to take advantage of recent progress in the understanding of the underlying neurobiology of Autism Spectrum Disorders (ASD), and to foster the development and validation of in vitro models, in vivo models and translational biomarkers enabling drug discovery. Another key objective of the project is to establish a network of clinical centres of excellence across Europe, that serves as an interactive platform for ASD specialists and clinical trials.

**Development of personalized medicine approaches in diabetes**
- **Personalized Medicine in Diabetes treatment**
The project aims at the identification of novel predictive tools for type 2 diabetes patients, better patient stratification and more specific clinical trials.

**Education & Training**
Fostering a broader understanding of pharmaceutical R&D in the broader public
- **Training programs for the informed patient**
The project aims at the establishment of a pan-European Industry – Patient Organisation network and the joint development of training programs for patients and the broader public.

**All information above is indicative and subject to change. Further details about the IMI 3rd Call topics will be communicated after approval by the IMI Governing Board.**

For current IMI Progress, see the IMI Website www.imi-europe.org

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**20th Anniversary**
EUFES was founded in 1991 – since then serving and advancing excellence in the pharmaceutical sciences and innovative drug research in Europe, also representing the interests of scientists engaged in drug research and development, drug regulation and drug policy-making. 20 successful years will be recognised and celebrated at the 2011 PharmSciFair.

**EUFES Yearbook**
To respond to the increasing needs of networking and communications within the pharmaceutical sciences and related fields, EUFES has decided to launch a EUFES Yearbook, the first issue of which will be a EUFES 20th Anniversary Yearbook, to be published next summer and made available at the next PharmSciFair in Prague (see page 7). It will further facilitate cooperation and exchange between members of associations, networks and groups.

The Yearbook will list and include information on EUFES, all its member societies, organisations, networks and committees etc. There will also be historical highlights, progress and achievement reports, as well as articles on regional, international and global collaboration and future perspectives. It’s also suggested that there should be a number of pages devoted to the Pharmaceutical Sciences Fair (PharmSciFair) and the partnership for it.

As you as representative of your organisation will be approached for it, and would have any questions about it, contact the EUFES President, Clive G. Wilson, or Executive Director, Hans H. Linden.
Improving Global Health Through Advances in Pharmaceutical Sciences

Cultures will Cross and Minds will Meet at the

2010 FIP PSWC/AAPS Annual Meeting & Exposition

Update information

**Plenary Session**

Don’t miss the insightful Plenary Session on Monday, November 15, 2010 in New Orleans.

Our speakers are:

- Dr. Masakatsu Shibasaki, Tokyo, Japan
- Dr. Michael Karas, Frankfurt, Germany
- Dr. Leslie Z. Benet, San Francisco, California, USA

Want to learn more? Visit the PSWC2010 website to view the Preliminary Programme!

**Pharmaceuticals Without Borders**

The development and delivery of pharmaceutical products has become a global endeavor. Diseases and other treatable health conditions do not recognize borders. Therefore, it is incumbent upon the Pharmaceutical Industry to maintain a global perspective. This Theme Stream consists of three half-day sessions, one scheduled every afternoon from November 15 – 17, addressing critical needs and challenges in providing quality medicines to the entire global population.

**Session 1**

- Developing New Treatments to Address the Global Burden of Disease

**Session 2**

- The Regulatory and Supply Chain Challenges of Providing Medicines to Emerging Markets

**Session 3**

- Ensuring the Integrity and Quality of Medicines Reaching the Patient

To start preparing now for the excitement of the Pharmaceutical Sciences World Congress 2010 (PSWC2010). Do it, today!

**Pre-Congress Workshops**

An additional fee is required to attend pre-congress workshops.

- AAPS Workshop on Contemporary Challenges and Advances Impacting the development of Veterinary pharmaceuticals
- AAPS Workshop on Harmonization of Regulatory Approaches for Evaluating Therapeutic Equivalence and Interchangeability of Multisource and Complex Drug Products
- USP Workshop on Impurities, Adulteration and the Changing role of the USp in Global drug Quality
- ACCP Frontiers Symposium: 6th International Symposium on Microdialysis in drug research and development 2010

**Short Courses**

An additional fee is required to attend short courses.

- Stability testing in pharmaceutical development
- Mechanistic pK/pd Modeling
- ICH Guidelines Q8, Q9, Q10 and Q11: How do they all Fit together?
- Nanotechnology from A-Z: Achievement in drug delivery and tissue Engineering
- Helping the Medicine Go down - pediatric Medicines: Formulation, Manufacturing and Compliance Challenges
- Developments in Technologies for Process Related Impurities Detection and Identification for Biologics

**Short Course/Workshop Lunch**

**PSCW2010 Opening Session**

**Additional Information**

Visit www.pswc2010.org for up to date meeting information, information on registration and accommodation as well as recent webisodes.
Revision of BE Requirements for Modified Release Products

February 23-24 • 2011 • Barcelona • Spain

Scope & Aim
A concept paper was recently published by the European Medicines Agency on the need for revision of the CPMP Note for Guidance on modified release oral and transdermal dosage forms. The aim of this conference is to discuss the relevant issues on specific regulations and open questions for the assessment of bioequivalence of modified release products in order to contribute scientifically to the development of the forthcoming draft guideline. The scientific community is invited to share their experience with the scientists of regulatory agencies. The intention of this conference is therefore to give scientists from pharmaceutical industry and academia the chance to present their views – including experimental results – during the discussions. Based on the existing experience derived from bioavailability and bioequivalence (BA/BE) studies performed by pharmaceutical companies with their development products, the scientific rationale for appropriate requirements for the approval of medicinal products in the European Union should be defined.

Who should attend?
This Conference is designed to meet the requirements and expectations of professionals from academia, generic and research based industry, CRO and regulatory authorities. Heads of department, project managers, scientists and consultants in R&D, formulation development, quality control, regulatory affairs, pharmacokinetics, or clinical studies should attend in order to share their experience in the field with regulatory scientists from the European Agencies. All participants will have the chance to contribute actively to the scientific discussions in order to achieve consensus in open issues in BA/BE, -or to learn facts and trends in the field from presentations and discussions.

Conference Sessions
• In-vitro vs. in-vivo characterisation of MR preparations
• Factors affecting the in-vivo performance of MR products
• Pharmacokinetic characteristics for MR products and assessment of bioequivalence
• Assessment of bioequivalence for special MR preparations

Scientific and Planning Committee
Gerald Beuerle, Ratiopharm, Ulm, Germany
Henning Blume, SocraTec R&D, Oberursel, Germany (Conference Chair)
Erich Brendefel, Bayer HealthCare, Wuppertal, Germany
Andrzej Dzierbicki, Polpharma, Warsaw, Poland
Hilda Koeszegi-Szalai, National Institute of Pharmacy, Budapest, Hungary
Hans H. Linden, EUFEPS, Stockholm, Sweden
Henrike Potthast, BfArM, Bonn, Germany (Conference Co-Chair)
Tomas Salmonson, Medical Products Agency, Uppsala, Sweden
Hans Schaefer, Boehringer Ingelheim, Biberach, Germany
Clive Wilson, University of Strathclyde, Glasgow, United Kingdom

Mark your calendar! Plan to join! Consult the EUFEPS Online for updates!
Or contact the European Federation for Pharmaceutical Sciences (EUFEPS): Veddesta Business Center SE-175 72 Järfälla (Stockholm)
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