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Hans H. Lindén
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Lay-out

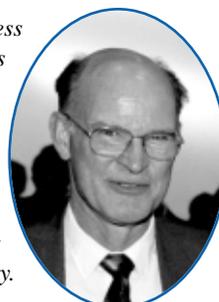
Camilla Boquist/Lådan & Co

The world of pharmaceutical sciences is changing

Visit EUFEPS 2002 in Stockholm

The theme of the EUFEPS 2002 Congress will be "New Safe Medicines Faster". As the situation in the entire field of pharmaceutical sciences is changing rapidly, this will be reflected in the way this scientific conference is organised. We can now see paradigm shifts taking place in several areas of the research and development processes in the pharmaceutical industry. The results of these shifts will be seen in the Congress Programme. You are cordially invited to participate.

Mark your calendar with October 21-23, 2002 and start planning!



Prof. Jörgen Vessman
Chair Organising Committee

Process rather than discipline

The scientific presentations of the 2002 Congress will be clustered around drug discovery and drug development processes, rather than academic disciplines. Therefore, the topics will be arranged in three major fields namely Drug Discovery and Design, Exploratory Drug Development (including scale-up from laboratory and pilot plant to commercial production) and Human Drug Development. In addition, there will be

a fourth stream focusing on drug utilisation and pharmacoepidemiology/pharmacogenomics. The Scientific Programme Committee has started creating a top class series of lectures.

New avenue

Ten years ago, EUFEPS was inaugurated in Strasbourg. Since that time, a number of initiatives to promote pharmaceutical sciences in Europe have been taken. One of them is the biennial Congress, which hitherto has been organised successfully in cooperation with a number of EUFEPS Member Societies. This procedure will now be changed. Next year's Congress will be held in Stockholm, for the first time with EUFEPS as the sole organiser. We intend that this change in responsibility will be accompanied by a number of new initiatives to make the programme even more attractive to the many people involved in the process of creating New Safe Medicines Faster. The following changes are being considered.

More input and events

IPEC and COST B15 have been invited to organise parallel activities, which will highlight hot topics on excipients and clinical trials, etc. Poster abstracts and presentations will be arranged in the traditional way, i.e. according to disciplines to accommodate the high number of presentations that are expected.

Also, there is room for satellite meetings, both before and after the Congress, on topics alluding to the themes of the programme. Plans include a fully-fledged exhibition, in the Stockholm International Fairs, which will be the venue of the EUFEPS 2002 Congress.

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Changing world

The many mergers that have occurred in the recent decade have altered the situation of many experienced researchers, who have been either reshuffled or offered early retirement. As a consequence, many small enterprises have started around those experts left over after the downsizing processes. It has been forecast that this shift in the research process will change the conception of new drugs. More of the discovery process and support to development will take place in small research units but the clinical development, scale-up and regulatory matters will remain the hands of the big companies. Therefore small and medium size companies will have to be placed in focus of a meeting on pharmaceutical sciences.

New education and training needs

Education and training has for some years been in focus on the European arena. The pharmaceutical sciences are much broader than what is taught at the faculties of pharmacy around Europe. We have to look beyond what has been the traditional definition of pharmaceutical education. Many models have been suggested to improve the existing

educational programmes, as well as the interaction between academia and industry. Moreover, it could be questioned whether the need for co-workers, educated and trained for research, is the same in the big companies as in the smaller ones. Of course, such questions should also be highlighted, at a meeting where new visions for the future of the European pharmaceutical scientists will be forming.

Regulators needed

The regulators play an important role in setting the standards for the new medicines, introduced onto the European market, as well as in a global context. Closer co-operation and collaboration on scientific issues, and in setting the rules of the game, are welcome by all parties involved.

Obviously, strong representation of all three major actors; academia, industry and regulators in the pharmaceutical sciences, is crucial for a truly European gathering.

New feature emerging

To reflect all these ongoing changes, a number of 60 - 90 minute "Afternoon Sessions" will be arranged for oral presentations giving

ample time for discussion and debate. Four parallel sets of such sessions are planned; the themes are Innovation and NCE development, Training and education, Small and medium size company issues, and "Meet the regulator".

Watch out and involve

Information on the developing programme will be published in forthcoming issues of this Newsletter. It will be posted on the EUFEPS Website (www.eufeps.org) and it will be circulated in printed announcements. Hardly anything will be as effective, though, as personal communication between individuals. So: Plan to go to Stockholm! Encourage your colleagues to join you in Stockholm! Introduce younger scientists to more experienced people, in Stockholm! Discuss and debate in Stockholm! Make new friends in Stockholm! Tour while in Sweden! And contribute to the development of the pharmaceutical sciences in Europe! All at, or around, EUFEPS 2002, on October 21-23, 2002.

*Prof. Jörgen Vessman
Chair Organising Committee*

Conference on Optimising Biotech Medicines

Rational development of therapeutic proteins

May 13-15 • 2002 • Berlin • Germany

Scope and aim

The pipeline for pharmaceutical proteins under development is well-filled. A recent survey indicated that in particular a large number of therapeutic monoclonal antibodies and vaccines are on their way to the market.

In a number of aspects the development process for these proteins is different from conventional, low molecular weight active substances. But what makes pharmaceutical proteins different? Why do they stand out?

Pharmaceutical proteins are high molecular weight molecules, with a secondary, tertiary and sometimes quaternary structure mainly stabilised by rather weak physical forces. Moreover, the many amino acids that make up the protein, can readily undergo chemical degradation reactions. The development process has to be designed in such a way that these delicate structures are stable during fermentation, purification, formulation, storage and administration to the patient. The structure of the whole molecule (not only the receptor binding site) should be preserved

during all stages ensuring the proper pharmacokinetic profile and lack of immunogenicity (except for vaccines, of course). At present, the parenteral route ('stick to the needle') is the predominant route of administration for the majority of proteins as bioavailability through other routes of administration is still too low and too variable. But, now methods are emerging to deliver pharmaceutical proteins through controlled delivery technologies and to use needle-free and pulmonary inhaler systems for protein administration. Finally, therapeutic proteins may need special exploratory and human development programmes, e.g. because many show a highly species specific therapeutic effect or bear a high similarity to endogenous molecules.

Emphasis on new findings

In this EUFEPS conference different aspects of pharmaceutical protein development will be discussed by experts, who actually have developed pharmaceutical proteins and guided them through the regulatory process. Emphasis will

be put on new findings and insights in the development process. In addition, there will be a number of break out sessions to give the delegates the opportunity to discuss particular issues in detail with their colleagues. A conference report e.g. highlighting issues for further discussion will be drawn up and used by EUFEPS in support of its broad initiative 'News Safe Medicines Faster'.

Conference Leadership

Ole J. Bjerrum (Chair), Daan Crommelin (Co-Chair), Henk de Jong (Co-Chair), Claus-Michael Lehr (Co-Chair).

Additional information

For more information, consult the EUFEPS Website at: www.eufeps.org or contact the EUFEPS Secretariat, PO Box 1136 SE-111 81 Stockholm, Sweden
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EXECUTIVE SUMMARY

June 2001

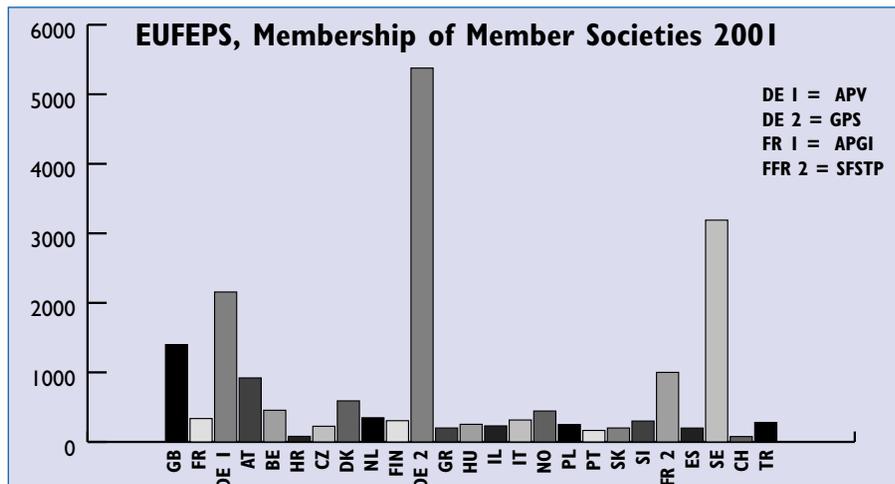
No Executive Committee meeting has taken place between the production of the previous Newsletter (March 2001 issue) and this one, and the Executive Committee will not convene again until late June. Nevertheless, the activity level has been high and there have been frequent contacts through email etc., occasionally complemented by a telephone conference. The period has been characterised by intensive planning for no less than three important EUFEPS meetings.

Membership

In conjunction with the payment of the Membership Fees for 2001, more reliable information has been obtained about the membership denoted as "Pharmaceutical Scientists" within each individual Member Society. The total EUFEPS membership of the 25 Member Societies, representing 23 European countries, amounts to 19 294 individuals. With its 5377 individuals, the German Pharmaceutical Society contributes most members, followed by the Swedish Academy of Pharmaceutical Sciences with 3190. At the bottom end appears the Swiss Society of Pharmaceutical Sciences, numbering 77 brave scientists. Based on the numbers obtained, the representation at the upcoming Council Meeting is now being calculated. Nomination of Individual Members' Representatives to EUFEPS Council is in progress.

Finance

As previously indicated, the expenditures for the year 2000 were considerably above the revenues. The accounting records, presently in the hands of the auditors, show a net loss for the year 2000 of EUR 36560, out of which EUR 4468 relates to currency changes. The



EUR 176,097 fund balance of December 1999 thus, dropped to EUR 139,537 by the end of December 2000. Happily, I can announce that all the claims, related to delayed contributions etc., and most of the debts have now been settled. Advance payments related to several activities to take place during 2001 have had implications on liquidity. This has necessitated redemption of some of the assets deposited in the Swedish Pharmaceutical Society Foundation.

Publications

The European Journal of Pharmaceutical Sciences (EJPS) continues to make progress. The number of institutional subscribers increased with more than a hundred between 1999 and 2000. Thus, the total royalty income on EJPS, which increased by 50 % between 1998 and 1999 almost doubled between 1999 and 2000. However, the low number of subscriptions by the EUFEPS membership at large is embarrassing.

We are happy to welcome Peter Williams,

UK, who will join the EUFEPS Newsletter Editorial Team and with whom you certainly will become familiar through the Newsletter.

EU-items

The proposed integrated project – Functional Genomics for Medicines development: Drug Disposition, Metabolism and Toxicity – within a programme Functional Genomics relating to Human Health was not endorsed by the EU Commission. However, the New Safe Medicines Faster (NSMF) project continues to make progress. Thus, the Commission has recently asked EFPIA to provide them with input to the project, and EFPIA are writing up a position paper. Pertinent information on the project is posted on the EUFEPS Website.

Congresses and Conferences

The organisation of the World Conference on Drug Absorption and Drug Delivery in Copenhagen, June 18-20, 2001, is making good progress with well over 300 registered participants as of May 28. A preliminary programme for the meeting on Strategies to the Rational Design of Drug Material and Drug Delivery Systems, September 20-21 in Strasbourg is out. The programme for the EUFEPS Conference on the Use of Biomarkers: From Drug Discovery through Clinical Practice – Basle, December 10-12, 2001 is being developed.

Next meeting

The next Executive Committee meeting is planned to June 17-18, 2001, in Copenhagen in conjunction with the World Conference on Drug Absorption and Drug Delivery.

Prof. Björn Lindeke
Secretary-General & Treasurer.

Welcome and Thank You

It is a pleasure to announce that Dr Peter Williams is the new Editor of the EUFEPS Newsletter, and he helped edit this issue. He will welcome articles, announcements and ideas for the forthcoming issues, I am sure. The next one is to be published in September 2001.

In late 1993, as I was asked to take on the responsibility of editing the EUFEPS Newsletter, as well as to make it quarterly from 1994, I certainly did not realise what this would involve. However, with the help of

many, it went on and on, issue by issue. Thank you all for your contributions, suggestions, ideas and other support, which made this possible. The deadlines for the production, printing, distribution etc. have not always been met, so thank you also for your patience.

Thank you Peter for volunteering for the EUFEPS crew. I wish you all possible success in this important endeavour.

Hans H. Lindén
hans.linden@eufeps.org

New Report on Optimising Drug Development

Strategies to assess drug metabolism/transporter interaction potential – towards a consensus

This was the important and topical theme of the EUFEPS Conference on Optimising Drug Development held in Basel, Switzerland, in November 2000, co-sponsored by the US Food and Drug Administration (FDA) and the American Association of Pharmaceutical Scientists (AAPS). Scientists from a variety of academic institutions, pharmaceutical companies and regulatory bodies participated. Geoffrey T Tucker, J Brian Houston and Shiew-Mei Huang have summarised the key discussions and conclusions in a Conference Report. The Report is available (as a pdf) at the Current Meetings section of the EUFEPS Website (www.eufeps.org), and it will also be published in the European Journal of Pharmaceutical Sciences (Eur. J. Pharm. Sci.).

Conference discussions centred around:

- The complexities and hence standardisation of studies *in vitro*
- Transporters
- *In vitro* predictive models
- *In vivo* assessment
- The regulatory view

The conference participants agreed on the appropriate probe compounds for estimation of *in vitro* parameters of human CYP activity/inhibition. They emphasised identification of patients at particular risk of specific drug-drug interactions. Several topics, including mechanism-based enzyme inhibition and drug transporters, remain for further consensus development.

www.eufeps.org

The EUFEPS Website was launched, in September 2000, and many consulted it for information on EUFEPS, and on EUFEPS' activities. May 2001 was the latest update. Did you check what's on, currently? Additional updates will follow.

Viikki Drug Discovery Technology Center (DDTC)

In this article, Dr. Pia Vuorela introduces the DDTC, a vibrant new organisation in Finland focussed on creating and characterizing preclinical drug candidates of high quality.

Environs

The Biocenter of the University of Helsinki is located in the Viikki Campus in the capital city of Finland. It was built in 1995 as a cooperative venture by the University of Helsinki, the Helsinki Science Park Ltd, the Finnish government, the City of Helsinki, the Finnish National Fund for research and Development (SITRA) and Finnish business organisations.

The Biocenter is an important part of the Helsinki Science Park, which includes as well the University's Faculty of Agriculture and Forestry, the student village, and the Cubile residence for international scholars. The Viikki area is one of the major investment and construction areas of the City of Helsinki. The Biocenter has been expanded by the Information Center, and the Business Incubator building, and a third Biocenter building is under construction. An important objective is to help researchers identify research results suitable for commercial exploita-

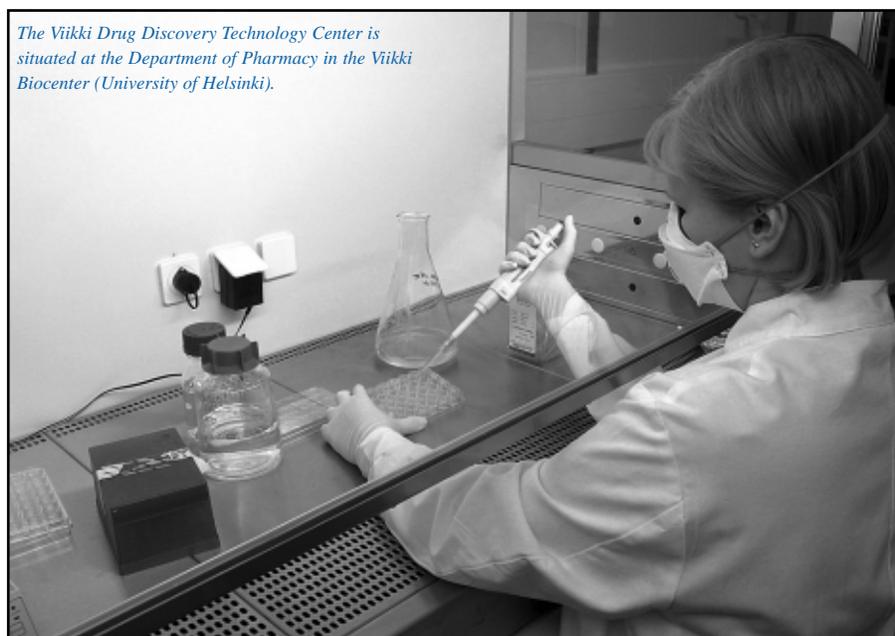
tion. One of the attractions of the Viikki area is a large nature reserve, with two bird observation towers located close to the wetlands.

DDTC Organisation

Viikki Drug Discovery Technology Center (DDTC) is an interdisciplinary research project belonging to the Department of Pharmacy in the University of Helsinki. DDTC started at the beginning of 2000 and is funded mainly by the University of Helsinki, the National Technology Agency, the Academy of Finland, and pharmaceutical companies. Objectives of DDTC are to build up a strong environment for drug discovery research, to develop key technologies, to discover new drug candidates and to educate high level researchers.

The administration of DDTC is organised into a board to which the head of DDTC (Prof. Dr. Risto Kostiaainen) and the management group report. An International Scientific Advisory Board with four members from academy and industry has been established to give expert opinions on the research projects in DDTC.

Research in DDTC is organised into five technology units (see Fig. 1), which integrate the research in several pharmaceutical dis-



The Viikki Drug Discovery Technology Center is situated at the Department of Pharmacy in the Viikki Biocenter (University of Helsinki).

ciplines. Furthermore, two core facilities, analytical and molecular biology laboratories, support the research in the technology projects. The overall aim is to create high quality preclinical drug candidates.

Design and synthesis technology (headed by Dr. Jari Yli-Kauhaluoma)

The focus of the DDTC research projects is on the integration of structure-based design and combinatorial organic synthesis of compound libraries for pharmacological and biological investigations. Relatively small, targeted libraries are prepared using mainly automated, parallel solid-phase synthesis. In particular, the synthetically useful carbon-carbon bond forming reactions on solid supports have been developed. These include the development of both [4p+2p] and dipolar cycloaddition reactions, the transition metal catalysed cross-coupling reactions and heterocyclic chemistry. In addition, methods for prediction of ADME (absorption, distribution, metabolism and excretion) parameters from the molecular structure, docking for structure-based design of combinatorial libraries and computational screens for virtual combinatorial libraries are being developed.

High throughput screening technology (headed by Dr. Pia Vuorela)

New therapeutically relevant targets are identified through genetic engineering. Robotic systems have enabled very high throughput screening (HTS) of compounds. The effectiveness is enhanced by automation and miniaturisation. The aim of our HTS is to discover high quality preclinical candidates.

In the screening technology program, high throughput facilities are built up to screen *in vitro* bioactivity and pharmacological selectivity of the compounds produced by combinatorial and solid-phase synthesis or from natural products and to determine metabolic drug-drug interactions. The HTS methods to be developed in the screening technology program of Viikki DDTC are based mainly on the automated 96 (or higher) microwell plate technology. A more suitable term would be higher throughput screening, since the studies will also include development of new bioassays and their miniaturisation, preferably with fluorescence-based methods. Confocal microscopy will be included for cell membrane studies.

Early-ADME technology (headed by Prof. Dr. Jouni Hirvonen)

A bottleneck in drug discovery is the selection of leads, i.e., identification of the drug candidates with the greatest potential based

on their ADME, physico-chemical and toxicological properties.

In the Viikki DDTC program, we study absorption potential in automated cell culture systems on microwell plates and human epidermal samples in diffusion cells.

The physico-chemical parameters measured in high throughput mode include (water) solubility, lipophilicity, pKa-value, acid stability, and protein binding (albumin, aud-glycoprotein). Chromatographic determinations of drug interactions with phospholipids (oral model) and ceramides (skin model) are combined with MS analyses. Metabolic profile studies of the combinatorial libraries include *in vitro* tests of metabolic stability by selected isoenzymes (CYP, UGT). Mechanisms of N-glucuronidation are elucidated. Mathematical/predictive correlation models are created based on the measurements above.

Drug delivery systems and formulation technology (headed by Prof. Dr. Jouko Yliruusi)

Three different types of site-specific dosage forms are under development: intraoral, intragastric and intracolonic. Intraoral (buccal) dosage forms have been studied especially for prevention of oral carcinoma caused by ethanol. Site-specific drug release into the colon is an important alternative in the local treatment of colonic diseases such as ulcerative colitis and carcinomas.

It is well known that practically all drug molecules and most excipients used in solid dosage forms exist in more or less stable crystalline state. Therefore, it is important to be able to control both crystallization and surface properties of crystals. This means that the formulation should be done so that particle-particle interaction and material behaviour in various process steps are controlled at the molecular level.

The aim in this research project at DDTC can be characterised by two terms: crystal engineering and surface engineering. Crystal engineering includes two parts: development of the crystallization process itself and polymorph screening. The main aim is to obtain crystalline structures which are stable and which have optimal dissolution and solubility properties. The purpose in surface engineering is to enhance powder surface properties so that they have optimal process behaviour as well as optimal dissolution behaviour.

Biological evaluation technology (headed by Prof. Dr. Raimo Tuominen)

The main goal of the program is to perform pharmacological research on the new sub-

stances (possible drug candidates) produced in the DDTC research programs. The effects of a drug substance are evaluated in various levels of organism e.g. in cultured cells, in target tissue, in other tissues and finally in the whole body.

Evaluation of neuronal nicotinic acetylcholine receptors (nAChR) as drug targets is one main research project at the moment. Functional characterisation of nAChR subtypes in cell cultures *in vitro* is performed by cloning and expressing selected subtypes in cell cultures. *In vivo* pharmacology of new ligands for nAChR subtypes will be evaluated after transfection of brain nuclei with nAChR subtypes in rats. *In vivo* pharmacology of new ligands for nAChR subtypes will be studied by brain microdialysis, receptor binding assays and behavioural experiments. Animal species used in biological evaluation include mice (either healthy or gene manipulated) and rats (either healthy or instrumented)

Analytical laboratory (headed by Dr. Tapio Kotiaho)

The main function of the DDTC Analytical laboratory is to provide analytical services for the different technology development areas and to develop new miniaturised and automated higher throughput analytical methods/instruments to speed up drug discovery. The main research interests of the group are the development of new mass spectrometric, and microchip-based analytical devices and methods.

Molecular biology laboratory (headed by Dr. Moshe Finel)

The main role of the molecular biology laboratory is to provide recombinant enzymes and receptors for different DDTC projects. In the future, the laboratory will also participate in solving the structure of selected target proteins, and in developing capabilities for studying the effect of drug candidates on gene expression (e.g. using DNA micro arrays).

The more specific aims and targets of DDTC are worked out together with our collaborators. More information is available on our web-site <http://www.ddtc.helsinki.fi/>

Dr. Pia Vuorela
Head of Screening Unit
Viikki Drug Discovery Technology Center,
DDTC



EUFEPS Decennial Anniversary Conference

Rational Design of Drug Materials and Drug Delivery Systems

September 20–21 • 2001 • European Parliament • Strasbourg • France
Avenue Robert Schuman • Bâtiment Winston Churchill (WIC)

Scope and Aim

Pharmaceutical and Biopharmaceutical Performances of New Chemical Entities (NCE) are largely dependent on the formulations and/or drug delivery systems available for their study. This Conference will focus on how to select and design the drug material, the formulations and/or the drug delivery systems that will be needed for NCE Developability Assessment (Bioavailability, Manufacturability, Stability), as well as on how to conduct the studies from lead identification to First in Man.

Call for Abstracts

Scientific contributions relating to any aspect of drug material and drug delivery will be considered for poster presentation. Abstracts should be submitted to the EUFEPS Secretariat, both as an email attachment and as a hard copy, before July 15, 2001. Editorial instructions for the abstract are posted on the EUFEPS Website. Forward material to the EUFEPS Secretariat by email or by fax. For address, see below.

Thursday, September 20, 2001

Theme Selection of drug candidates for standard development: The materials design approach

Session I Setting the scene: What does rational design imply?

Moderator: *Franck Leveiller*, Paris, FR
The biopharmaceutical assessment of NCE candidates

Gordon Amidon, Ann Arbor, MI USA

The manufacturability assessment of drug materials and drug delivery systems

Staffan Folestad, Molndal, SE

Session II From medicinal chemicals to pharmaceuticals

Moderator: *Francis Schuber*, Strasbourg, FR

Solid state: The missing link

Franck Leveiller, Paris, FR

Solid properties relevant in salt selection

Danielle Giron, Basel, CH

Polymorph prediction: Myth or reality?

Angelo Gavezzotti, Milan, IT

Session III Biopharmaceutical assessment of pharmaceutical materials: Part I

Moderator: *Per Artursson*, Uppsala, SE

The relevance of physico-chemical determinants

Manfred Kansy, Basel, CH

The *in vitro* dissolution testing of candidates

Christos Reppas, Athens, GR

Session IV Biopharmaceutical assessment of pharmaceutical materials: Part II

Moderator: *Gordon Amidon*, Ann Arbor, MI USA

How to generate an early estimate of the absorbable dose fraction in human

Per Artursson, Uppsala, SE

Animal models and relevant preclinical formulations

Anna-Lena Ungell, Molndal, SE

In vitro predictions and the biopharmaceutical classification index

Brian Henry, Sandwich, UK

Round Table Questions and Answers

Moderators: *Per Artursson*; *Gordon Amidon*; *Franck Leveiller*; *Francis Schuber*; *Michel Veillard*

Friday, September 21, 2001

Theme Non-standard development of drug candidates: The drug delivery systems design approach

Session V Drivers for drug delivery design

Moderator: *Graham Buckton*, London, UK

Decision making for standard versus non-standard development processes

Michel Veillard, Paris, FR

Process engineering as a major contributor to drug materials design and/or drug delivery systems design

Michel Baron, Albi, FR

Physical characterisation as a driver for drug delivery design

Graham Buckton, London, UK

Session VI Drug delivery systems opportunities to overcome pharmaceutical and biopharmaceutical limitations

Moderator: *Henning Kristensen*, Copenhagen, DK

Cyclodextrins as a tool to overcome solubility, dissolution, permeation and stability limitations

Dominique Duchêne, Paris, FR

Self-emulsifying drug delivery systems to overcome solubility, dissolution, permeation and stability limitations

Caitriona O'Driscoll, Dublin, IR

Timed release drug delivery systems to overcome PK/PD limitations

Ubaldo Conte, Pavia, IT

The transfer of emphasis from drug materials to drug delivery systems development

Henning H. Blume, Oberursel, DE

Session VII How to reconcile sciences, development processes and regulatory aspects: Translating sciences into specifications and quality control management

Moderator: *Agnès Artiges*, Strasbourg, FR

The USA viewpoint

Ajaz Hussain, Rockville, MD USA

The European viewpoint

Henning Kristensen, Copenhagen, DK

Round Table Questions and Answers

Moderators: *Agnès Artiges*; *Graham Buckton*; *Ajaz Hussain*; *Henning Kristensen*; *Michel Veillard*

EUFEPS Decennial Anniversary and Gala Cocktail

To conclude the celebration of the Decennial Anniversary, all attendees are cordially invited to a short ceremony starting at 4:30 p.m. on Friday that follows the scientific programme. After the Anniversary Addresses, there will follow a cocktail reception at 6:00 p.m.

Conference Registration

Please consult the EUFEPS Website, or contact the EUFEPS Secretariat, for a Registration Form, complete it and return it to the Secretariat. Registration fees (in Euro) include: Industry delegate EUR 790, Academic delegate EUR 330, and Student delegate EUR 190. EUFEPS members will receive 10 % reduction. The cost for hotel accommodation and travel is not included in the registration fee.

Hotel Reservation

For hotel reservations, you are kindly requested to contact the Strasbourg Tourist Office, by telephone +33 3 90297314, or by telefax +33 3 88522829. Please, also visit their website at: www.strasbourg.com for more information on and reservation of accommodation. Please note that, due to possible European events in Strasbourg, an early reservation is recommended.

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9th EUFEPS Optimising Drug Development Conference

Use of Biomarkers: From Drug Discovery through Clinical Practice

December 10–12 • 2001 • Basel Convention Center • Switzerland

Aim & Format

This two and a half day Conference will encompass the needs and the latest scientific opportunities to improve biomarkers of disease and their use in assessing therapeutic interventions from drug development and regulatory decision making, through to clinical practice.

Using a similar format to previous EUFEPS Conferences on “human drug development” (Wiesbaden 1998 and Basel in 1999; see EUFEPS Website for reports) at this Conference, there will be lectures and discussions, together with open discussions in evening workshops. Workshop summary reports will be integrated and presented by rapporteurs on the third morning of the conference, and future perspectives will be discussed before closing the meeting. A report of the meeting will be published.

Scientific & Planning Committee

Art Atkinson (Co-Chair), Ole J. Bjerrum, Fritz Bühler, Meindert Danhof, Anders Grahnén, Larry Lesko (Co-Chair), Hans H. Lindén, Carl Peck, Paul Rolan (Co-Chair), and Malcolm Rowland.

Contents

SESSION I – Setting the stage

- Outcome of COST B15 meetings on biomarker issues
- Why do we need biomarkers now, more than ever?
- What common language is needed, including definitions and terminology?
- Use of biomarkers in decisional analysis
- Understanding the mechanism of drug action and disease process: Alzheimer’s disease as a model for biomarker-based, disease-oriented approach
- Understanding the mechanism of drug action and disease process: Systematic search using new technologies, biomarkers and bioinformatics

SESSION II – Anticipated benefits in identifying and using safety and efficacy biomarkers in drug development: From pre-clinical to end of phase II

- Preclinical biomarkers and use in first dose in man
- Tapping the potential of pharmacogenomics/genetics in applications of biomarkers in early drug development (imaging, gene-

arrays, receptor genotypes etc); defining toxicity

- Value and use of biomarkers in antiviral drug development
- Value and use of biomarkers in the development of osteoporosis drugs
- Value and use of biomarkers in the development of drugs for congestive heart failure
- Potential new biomarkers in the development of drugs for diabetes
- COX-2 enzyme inhibition success story: Role of biomarkers from drug discovery to clinical practice

SESSION III – Biomarker applications in late drug development and life cycle management: Anticipated benefits and differences in risk acceptance of using a biomarker

- Measurement of cholesterol and DNA analysis as biomarkers in the development and use of cholesterol-lowering drugs
- Use of single and multiple biomarkers in cardiovascular medicine from an outcome point of view
- Bridging Studies: Use of biomarker studies (eg., PK-PD) for bridging efficacy/safety to new populations (e.g. pediatrics, ethnic groups), new formulations, new dosage forms, new routes of administration
- Biostatistics—General concept for validating biomarkers as surrogate endpoints and integrating biostatistics into clinical drug development
- Clinical Biomarker Study Design I: Academic Perspective
- Clinical Biomarker Study Design II: Industry Perspective
- Clinical Biomarker Study Design III: Academic Perspective

SESSION IV – Biomarker applications from regulatory review through clinical practice

- The role of biomarkers in the development and approval of drugs for AIDS: What will it take to repeat the success in other chronic diseases?
- European regulatory perspective on biomarkers: Use, value in supporting safety and efficacy, and limitations – what more needs to be done?
- US regulatory perspective on biomarkers: Use, value in supporting safety and efficacy and limitations – what more needs to be done?

- The impact and use of biomarker-based diagnostic kits in drug development and clinical practice: An industry perspective
- The impact and use of biomarker-based diagnostic kits in drug development and clinical practice: A US regulatory perspective
- The current role, and future possibilities, of using biomarkers based on pharmacogenetics or pharmacogenomics in drug development, regulatory decision making and clinical practice

SESSION V – Where do we go from here?

- Modelling and simulation: What is current status – examples, improvement needed and lessons learned in drug development?
- Modelling and simulation in drug development
- Use of modelling and simulation in drug development: Case study on how has it helped and what are the challenges

Integration discussion session

Reports from break-out sessions and discussion of position statements.

Closing of the conference

Future perspective on biomarkers, drug development and trends in regulations.

Exhibition Information

Companies are invited to exhibit at the Conference. For further information on layout, costs and such matters, contact the EUFEPS Secretariat.

Additional Information

For preliminary programme, detailed information on registration and accommodation etc., see the Second Announcement of this Conference, which will also be posted on the EUFEPS Website. For a personal copy of the printed version of it, contact:

EUFEPS Secretariat
Attn: Maria Norrlander
PO Box 1136
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C A L E N D A R

Optimising Drug Development: Strategies to the Rational Design of Drug Material and Drug Delivery Systems – Towards a Consensus

September 20-21, 2001, Strasbourg, France
Contact: EUFEPS Secretariat, PO Box 1136
 SE-111 81 Stockholm, Sweden
 Fax +46 8 4113217
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4th Central European Symposium on Pharmaceutical Technology and 16th Congress of the Austrian Pharmaceutical Society

September 23-25, 2001, Vienna, Austria
Contact: Institute of Pharmaceutical Technology and Biopharmaceutics, Fax +43 1 42779554
 Email symposium.pharm-tech@univie.ac.at

Intermediate Level Workshop on Pharmacokinetic/Pharmacodynamic Data Analysis: A Hands-on Course Using WinNonlin

October 15-18, 2001, Château de Maffliers, (Paris), France
Contact: APGI, Faculté de Pharmacie Université Paris-Sud, 5 Rue Jean Baptiste Clément, FR-92290 Chatenay Malabry, France
 Fax +33 1 46835308
 Email apgi.apgi@cep.u-psud.fr

Optimising Drug Development: Use of Biomarkers and Regulatory Decision Making

December 10-12, 2001, Basel, Switzerland
Contact: EUFEPS Secretariat, PO Box 1136
 SE-111 81 Stockholm, Sweden
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 Email conferences@eufeps.org
 Website www.eufeps.org

Optimising Biotech Medicines: Rational Development of Therapeutic Proteins

May 13-15, 2002, Berlin, Germany
Contact: EUFEPS Secretariat, P.O. Box 1136
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 Email conferences@eufeps.org
 Website www.eufeps.org

EUFEPS 2002: New Safe Medicines Faster

October 20-23, 2002, Stockholm, Sweden
Contact: EUFEPS Secretariat, PO Box 1136
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2001 Scheele Award

To commemorate the famous Swedish pharmacist and scientist, Carl Wilhelm Scheele, the Swedish Academy of Pharmaceutical Sciences every year invites a highly distinguished scientist, in drug research or related disciplines, to give the Scheele Lecture on his own research. On this occasion, the Scheele Lecturer is also awarded a special diploma, the Scheele Medal and a Prize Sum of SEK 100,000.

The 2001 Scheele Lecturer is Professor Andrew Wyllie, Department of Pathology, University of Cambridge, U.K. He is awarded the Scheele Medal and Prize for his outstanding contributions to the field of apoptosis. The lecture will be held at the Scheele Symposium, on October 10, 2001, in Stockholm, which constitutes part of the Annual Swedish Pharmaceutical Congress.

Increasing throughput in early PK/PD!



Hands-on course in microsurgery on rats, implantation of catheters in blood vessels. Novel methods for direct sampling of blood by means of automated equipment makes it necessary to have direct and uninterrupted access to the blood stream of the animal. By achieving this, on an unrestrained animal, the blood sampling is simplified and the accuracy is improved. During the course animals will be connected to the AccuSampler[®] produced by DiLab[®] and blood will be drawn and collected into refrigerated vials. This will show how the throughput of drugs in reasearch can be increased.

<http://www.DiLab.com>

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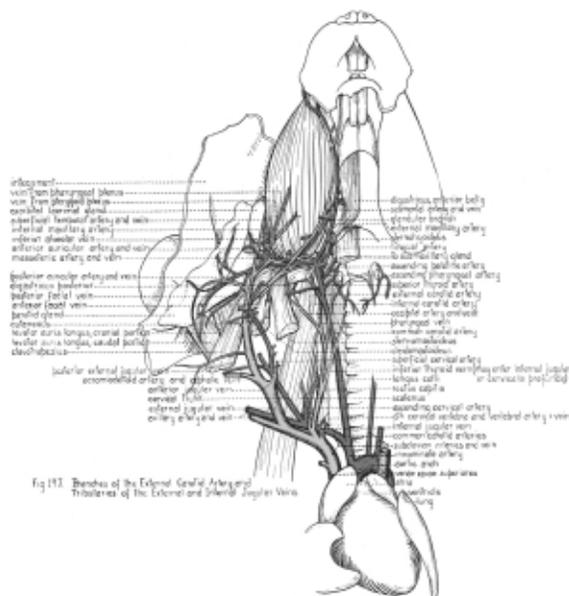


Fig 112. Branches of the External Carotid Artery and Jugular Veins of the External and Internal Jugular Veins