



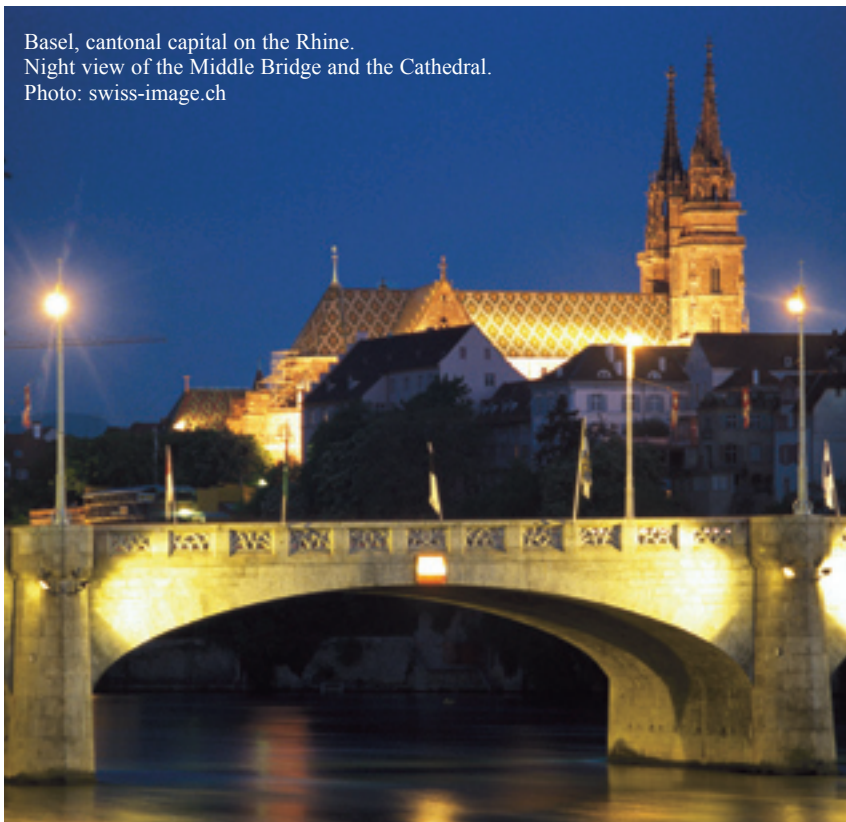
EUROPEAN FEDERATION
FOR PHARMACEUTICAL
SCIENCES

Second Announcement • June • 2003

11th EUFEPS Conference on

Optimising Drug Development:
Integrating New Concepts and Tools

Basel, cantonal capital on the Rhine.
Night view of the Middle Bridge and the Cathedral.
Photo: swiss-image.ch



December 8-10 • 2003

Basel Convention Center • Basel • Switzerland

*Organised by the European Federation for Pharmaceutical Sciences (EUFEPS),
jointly with the European Center of Pharmaceutical Medicine's (ECPM)
Workshop Series on Frontiers in Drug Development*

W
W
W
.
E
U
F
E
P
S
.
O
R
G

11th EUFEPS Conference on
Optimising Drug Development:
Integrating New Concepts and Tools

December 8-10 • 2003
Basel Convention Center • Basel • Switzerland

The Conference opens on Monday, December 8, 2003, at 8:30 and it closes on Wednesday, December 10, 2003, at 13:00.

Scope & Aim

This 2 1/2 days conference is an additional one in the successful series of annual EUFEPS Conferences on “Optimising Drug Development” that have taken place in Basel for several years. This Conference will focus on how to integrate new concepts and tools to make the overall process more efficient. There are still many things that could be further improved in the today and future drug development.

Key issues and topics for discussion include analysis of the current bottlenecks of drug development, the role of R&D and current regulatory activities in Europe and USA. Examples include: Targeted treatment solutions; management initiatives on evidence-based quality assurance; virtual SOPs and portfolio composition; integrated *in silico*, *in vitro* and *in vivo* information for clinical development in rethinking of clinical trial phases.

It will again be a unique and intensive discussion forum, bringing together colleagues from industry, academia and regulatory to identify areas of agreement, as well as areas of disagreement upon possible ways forward toward resolution.

Sessions of the Conference include:

- Where do we fail in today’s drug development?
- Efficient regulatory approval processes
- Targeted product information and treatment solutions
- Information management and probability-based decision making
- Integrating concepts in the drug development process
- Redesigned clinical trial phases

- New management processes in drug development
- Integration session – new concepts and tools

Format & Preliminary Programme

Using a similar format to previous EUFEPS conferences, key segments of the process are broken down into a number of sessions, each with lectures and discussions. In the breakout sessions, the session topics will be discussed further in smaller groups and supplementary information added from the participants of the session. Rapporteurs will present breakout sessions summary reports on the third morning of the Conference. Based on these reports, a conference report will be produced.

Scientific & Planning Committee

Co-Chairs: Arthur J. Atkinson, Bethesda MD USA; Ole J. Bjerrum, Copenhagen DK; Fritz R. Bühler, Basel CH
Additional Members: Meindert Danhof, Leiden NL; Frank Fildes, Macclesfield UK; Gert Folkers, Zürich CH; Anders Grahnén, Uppsala SE; William Jenkins, Basel CH; Lawrence J. Lesko, Rockville MD USA; Hans H. Lindén, Stockholm SE; Carl C. Peck, Washington DC USA, Paul Rolan, Manchester UK; Malcolm Rowland, Manchester UK; and Donald R. Stanski, Stanford CA USA

Exhibition Information

Companies are invited to exhibit at the Conference. For information on layout, costs etc., as well as an exhibition registration form, please contact the EUFEPS Secretariat.

Call for Posters

Previous Optimising Drug Development Conferences did not attract very many poster presenters, but scientific contributions relating to the conference topic will certainly be welcome and considered for poster presentation. Abstracts should be submitted to the EUFEPS Secretariat (for address, see below), both as an email attachment and as a hard copy, before October 10, 2003, Editorial instructions for the abstract are posted on the EUFEPS Website (for address, see below).

Language

English will be the language of the Conference. No simultaneous translation will be provided.

Organiser

EUFEPS was founded in 1991. Its mission is to advance excellence in the pharmaceutical sciences and innovative drug research, and to represent the interests of scientists engaged in drug research and development, drug regulation and drug policymaking. Currently, it links 24 Member Societies in 23 countries. In addition, there are Individual Members. For more information on EUFEPS and its activities, please visit the EUFEPS Online: www.eufeps.org

Preliminary Programme

Monday, December 8, 2003

Welcome, Introduction and Opening Remarks

Fritz R. Bühler, Basel CH

Session I: Where do we fail in today's drug development?

Chairman: *Ole J. Bjerrum*, Copenhagen DK

- eR+D and Pharma 2010
Steve Arlington, Uxbridge UK
- Faster times – better decisions?
Kenneth I. Kaitin, Boston MA USA
- Factors associated with reliable phase III clinical trials
Carl C. Peck, Washington DC USA
- Corporate culture impacting decisions and time lines
Steward Walker, Surrey UK

Session II: Efficient regulatory approval processes

Chairman: *Anders Grahnén*, Uppsala SE

- Towards optimised EMEA registration procedures
Thomas Lönngren, London UK
- Guidance for efficiency in drug development – one cycle reviewing
Mark McClellan, Rockville MD USA

Session III: Targeted product information and treatment solutions

Chairman: *Arthur J. Atkinson*, Bethesda MD USA

- The FDA initiative
Janice Soreth, Rockville MD USA
- Targeted treatment solutions
Michael Tansey, Bridgewater NJ USA
- Label-driven drug development
Charles V. Grudzinskas, Washington DC USA

Session IV: Information management and probability-based decision making

Chairman: *Donald R. Stanski*, Stanford CA USA

- Making business decisions in high uncertainty:
What can the pharmaceutical industry learn?
Peter Stadler, Cologne DE
- Knowledge management in the pharmaceutical industry:
Where are we?
David Ewbank, Bridgewater NJ USA
- Improving the drug development decision process through portfolio management
Mellor Hennessy, Macclesfield UK

Reception Buffet

Tuesday, December 9, 2003

Session V: Integrating concepts in the drug development process

Chairman: *Lawrence J. Lesko*, Rockville MD USA

- Exploitation of integrated *in-silico*, *in-vitro* and *in-vivo* animal information for (unloading) clinical development
TBA
- System biology
Albert-Laszlo Barabasi, Notre Dame IN USA
- Integrating preclinical data into (exploratory) clinical research
C. Richard Jones, Basel CH

Session VI: Redesigned clinical trial phases

Chairman: *Malcolm Rowland*, Manchester UK

- Module based approach to trial design
Lewis B. Sheiner, San Francisco CA USA
- Dose selection design issues
Mats Karlsson, Uppsala SE
- Redesigning phase III trials
Andrew P. Grieve, Sandwich UK

Session VII: New management processes in drug development

Chairman: *Thomas Szucs*, Basel CH

- Risk assessment and management in drug development, there is more than pharmacovigilance
Andrew Mountfield, Basel CH
- Virtual SOPs: From process description to knowledge management
Beat Wilder, Basel CH
- Evidence based quality assurance of the drug development process
Mats Lörstad, Linköping SE

Setting the stage for the breakout sessions 1-6

See also Session VIII

Wednesday, December 10, 2003

Session VIII: Integration session – New concepts and tools

Reports from Breakout Sessions and discussion of position statements on:

- Targeted product information and treatment solutions
- Information management and probability-based decision making
- Integrating the drug development process
- Redesigned clinical trial phases
- New management processes in drug development
- European specialist in drug development – A new curriculum

Conclusions and closing

- What have we learned of the present Conference?

William Jenkins, Basel CH

- Needs for the future

Fritz R. Bühler, Basel CH.

- Concluding remarks

Ole J. Bjerrum, Copenhagen DK



Basel, cantonal capital on the Rhine.

Town hall on the market square.

Photo: swiss-image.ch

Location

The Conference will take place at the Basel Convention Center, Messeplatz 21, CH-4021 Basel, Switzerland. Tel no +41 58 2002020. Fax no +41 58 2062186

How to get there

from the Airport:

- Taxi, travelling time around 15 minutes at an approximate cost of CHF 40,-
- Airport coach to the Railway station SBB where you embark the tram no 2 in the direction City. Stop 'Messeplatz'. Travelling time from airport approximately 40 minutes, cost around CHF 3,-

from the Badischer Bahnhof (Railway station):

- Tram no 2 or 6, direction City. Stop 'Messeplatz'. Travelling time around 5 minutes. Cost approximately CHF 2,-
- Taxi 3 minutes at an approximately cost of CHF 10,-

from the Schweizer Bahnhof SBB (Railway station):

- Tram no 2, direction City. Stop 'Messeplatz'. Travelling time around 12 minutes. Cost approximately CHF 3,-
- Taxi travelling time around 8 minutes at a cost of around CHF 20,-

Registration and Payment

Please complete the Registration Form and return it to the EUFEPS Secretariat. The registration fee (EUFEPS Membership 10 % reduction) includes all conference documentation, all coffee breaks, two lunches and one reception buffet. The cost for hotel accommodation and travel is not included in the registration fee. Additional Registration Forms can be obtained by photocopying the one in this brochure, or (as PDF) on the Conference Website, through the EUFEPS Online (see below).

Conference Registration Fees EUR	EUFEPS	EUFEPS	EUFEPS	EUFEPS
	Members before Sept 15, 2003	Non-Members before Sept 15, 2003	Members after Sept 15, 2003	Non-Members after Sept 15, 2003
Industrial delegate	1000	1200	1200	1400
Academic delegate	500	600	600	700
Government delegate	500	600	600	700
Student delegate	250	300	300	350

Hotel Reservation

A number of rooms have been reserved at specially reduced rates. For Hotel categories and rates (including VAT), see the Hotel Reservation Form. Complete the Hotel Reservation Form and send it to the Basel Tourismus, Incoming Services, Aeschenvorstadt 36, CH-4002 Basel, Switzerland, fax: +41 61 2686870, not later than October 27, 2003.

Cancellations

Pre-registered delegates who are unable to attend the Conference will be refunded, except for an administrative fee of EUR 30, provided the Conference Secretariat receives a written notice of non-attendance, before November 3, 2003. No refunds can be made for cancellations received after this date. Substitutions may, however, be made at any time. The name of the substitute/s should be forwarded to the Conference Secretariat. For cancellations etc. of hotel reservations, please contact the Basel Tourismus to establish what terms apply.

Additional Information

Information on this Conference is posted on the EUFEPS Online (www.eufeps.org). Alternatively, contact the EUFEPS Secretariat (address below) for copies of announcements, the Preliminary Programme and Registration Form. Also, inform your colleagues about this important Conference.

Conference Secretariat

EUFEPS Secretariat
Attn: Annika Nyman
PO Box 1136
SE-111 81 Stockholm, Sweden
Phone +46 8 7235000
Fax +46 8 4113217
Email conferences@eufeps.org
Website <http://www.eufeps.org>

ECPM Secretariat

University Hospital
CH-4031 Basel, Switzerland
Tel +41 61 2657650
Fax +41 61 2657655
Email ecpm@unibas.ch
Website <http://www.ecpm.ch>

Hotel Reservation

Basel Tourismus
Incoming Services
Aeschenvorstadt 36
CH-4002 Basel
Switzerland
Fax +41 61 2686870

Conference Venue

Basel Convention Center
Messeplatz 21
CH-4021 Basel
Switzerland
Phone +41 58 2002020
Fax +41 58 2062186

Conference Registration Form

This form is intended for the use of one person only. If you need more copies, please visit the Conference Website, on the EUFEPS Online, where it is posted, in PDF, or make a photocopy.

Fill in with block letters or type and return by regular mail or fax to:
 EUFEPS Secretariat, Attn: Annika Nyman
 PO Box 1136, SE-111 81 Stockholm, Sweden. Fax +46 8 4113217

Title _____ Organisation _____

First Name _____ Family Name _____

Address _____

Postal address _____

Country _____

Tel _____ Fax _____

Email _____

Conference Registration Fees EUR	EUFEPS	EUFEPS	EUFEPS	EUFEPS
	Members before Sept 15, 2003	Non-Members before Sept 15, 2003	Members after Sept 15, 2003	Non-Members after Sept 15, 2003
Industrial delegate	<input type="checkbox"/> 1000	<input type="checkbox"/> 1200	<input type="checkbox"/> 1200	<input type="checkbox"/> 1400
Academic delegate	<input type="checkbox"/> 500	<input type="checkbox"/> 600	<input type="checkbox"/> 600	<input type="checkbox"/> 700
Government delegate	<input type="checkbox"/> 500	<input type="checkbox"/> 600	<input type="checkbox"/> 600	<input type="checkbox"/> 700
Student delegate	<input type="checkbox"/> 250	<input type="checkbox"/> 300	<input type="checkbox"/> 300	<input type="checkbox"/> 350

- I am a member of EUFEPS (2003)
 Charge me the Membership Fee (EUR 45) Student Fee (EUR 30)

Charge my credit card as follows (in SEK):

- Visa Mastercard Eurocard (American Express can not be handled)

Card Number _____ Expiry Date _____

Cardholder Name _____

Authorised Signature _____

Send an invoice and instructions on how to pay by bank transfer

- Yes, I am interested in a commercial exhibition, please send me further information.

Hotel Reservation Form

This form is intended for the use of one person only. If you need more copies, please visit the Conference Website, on the EUFEPS Online, where it is posted, in PDF, or make a photocopy.

Accommodation has been reserved at special rates in CHF (Swiss Francs) at the below hotel rate categories. All rates include VAT:

Fill in your name and address etc. with block letters or type and return, **before October 27, 2003**, by regular mail or fax to:

Basel Tourismus, Incoming Services, Aeschenvorstadt 36, CH-4002 Basel, Switzerland, Fax +41 61 2686870

As soon as Basel Tourismus has received the completed Hotel Reservation Form, they will report back the name and address of the hotel at which the reservation was made. Payment and cancellation instructions, including the reservation fee of CHF 15 will also be provided.

Title	Organisation	
First Name	Family Name	
Address		
Postal address		
Country		
Tel	Fax	
Email		
Arrival date	Departure date	Nights

Hotel Rates

Category	CHF	CHF	CHF	CHF
	Single room	Double room	Breakfast	Rate available until
*****	<input type="checkbox"/> 295	<input type="checkbox"/> 325	included	October 27
****	<input type="checkbox"/> 230	<input type="checkbox"/> 250-320	included	October 27
***	<input type="checkbox"/> 150-179	<input type="checkbox"/> 240	included	October 27

A Reservation Fee of CHF 15 will be added.

1 EUR = approx. 1.5 CHF

Date	Signature
------	-----------

Sverige
Porto
Betalt
Port
Payé



Martigny at the bend of the Rhone,
Canton Valais. View of the Batiatz Tower
ruin, with the Grand-Chavalard mountain
rising in the background.

Photo: swiss-image.ch



EUROPEAN FEDERATION
FOR PHARMACEUTICAL
SCIENCES

EUFEPS Secretariat

PO Box 1136, SE-111 81 Stockholm, Sweden

Phone +46 8 7235000 Fax +46 8 4113217

Email conferences@eufeps.org

Website www.eufeps.org

W
W
W
·
E
U
F
E
P
S
·
O
R
G