

Optimising Drug Therapy: An Imperative for World Health

PRELIMINARY SCIENTIFIC

	,, 5, 66 1106667	1	
	Parallel Symposium The era of personalised health care: Impact on drug discovery and development?	Parallel Symposium Is gene/protein delivery delivering?	Parallel Symposium Can ADME and PK be predicted from in silico/ in vitro data?
	Sponsoring Property Organisation		
	Co-chairs M. E. Brewster, Beerse, Belgium W. Sadee, Columbus, OH USA Y. Sugiyama, Tokyo, Japan	Co-chairs <i>H. Harashima</i> , Sapporo, Japan <i>W. Hennink</i> , Utrecht, The Netherlands	Co-chairs S. Pang, Toronto, Canada H. van de Waaterbeemd, Alderly Park, United Kingdom
08:30	Evaluating molecular genetic factors in drug response: Search for targets and biomarkers <i>W.Sadee</i> , Columbus, OH USA	A multi-functional envelope type nano device as a non-viral gene delivery system <i>H. Harashima</i> , Sapporo, Japan	Transformation of <i>in vitro</i> data to the whole organ <i>S. Pang</i> , Toronto, Canada
09:05	Predicting drug disposition and response in individual patients <i>Y. Sugiyama</i> , Tokyo, Japan	Cellular mechanisms of non-viral DNA delivery A. Urtti, Helsinki, Finland	In vitro – in vivo extrapolation: Best use of known-knowns to discover unknown-unknowns A. Rostami-Hodjegan, Sheffield, United Kingdom
09:40	Coffee Break		
10:10	Biomarkers in drug development: How do they influence clinical practice? <i>L.J. Lesko</i> , Bethesda, MD USA	Non-viral delivery of genes and oligonucle- otides <i>L. Huang</i> , Chapel Hill, NC USA	A computational systems biology approach to ADME/Tox S. <i>Ekins</i> , Jenkintown, PA USA
10:45	Short Podium Presentation	Short Podium Presentation	Short Podium Presentation
11:00	Short Podium Presentation	Short Podium Presentation	Short Podium Presentation
11:15	Posters Lunch Break		
	Keynote Presentation	Keynote Presentation	
12:15	What are the main challenges for world health? What should be done now and in the future? <i>R. Laing</i> , Geneva, Switzerland	Transforming 'art' into 'science' in dosage form design – achievements and challenges <i>P. York</i> , Bradford, United Kingdom	
	Round Table Discussion	Round Table Discussion	Round Table Discussion
13:10	Science or business as the driver of new drug development? Convenor <i>L.Z. Benet</i> , San Francisco, CA USA	Does regulation help to 'innovate' or 'stag- nate' drug development? Convenor <i>L.J. Lesko</i> , Silver Spring, MD USA	How can the bioavailability of poorly absorbed compounds be enhanced? Convenor <i>CM. Lehr</i> , Saarbrücken, Germany
	Parallel Symposium Pharmacogenetics at the bedside?	Parallel Symposium What will be the impact of cell-based therapy?	Parallel Symposium Simulation and modelling in drug development improves decisions, saving time and money?
	Co-chairs G.T. Tucker, Sheffield, United Kingdom M. Relling, Memphis, TN USA	Co-chairs E. Cattaneo, Milan, Italy	Co-chairs <i>D. Stanski</i> , Basel Switzerland and East Hanover, NJ USA <i>M. Danhof</i> , Leiden, The Netherlands
14:15	Pharmacogenetics – how far is reality from expectation? <i>G.T. Tucker</i> , Sheffield, United Kingdom	Innovative neurogenic neural stem cell lines for neurodegenerative disease <i>E. Cattaneo</i> , Milan, Italy	Applying mechanistic PK/PD models to drug development <i>M. Danhof</i> , Leiden, The Netherlands
14:50	Multiple gene pharmacogenetics in individu- alized drug therapy <i>I. Ieri</i> , Yonago, Japan	Stem cells for retinal repair S. <i>Nakagawa</i> , Osaka, Japan	Examples of modelling and simulation in the pharmaceutical industry <i>C. Pillai</i> , Basel, Switzerland
15:25	Pharmacogenetics in cancer therapy <i>M. Relling</i> , Memphis, TN USA	Cardiac regeneration: Repopulating the heart <i>L.J. Field</i> , Indianapolis, IN USA	The role of innovative model-based trial design to improve drug development <i>S. Duffull</i> , Brisbane, Australia
16:00	Short Podium Presentation	Short Podium Presentation	Short Podium Presentation
16:15	Short Podium Presentation	Short Podium Presentation	Short Podium Presentation
	EUFEPS Afternoon Session	EUFEPS Afternoon Session	EUFEPS Afternoon Session
16:45	See framed information, page 11	See framed information, page 11	See framed information, page 11



PROGRAMME • Monday

	Parallel Symposium Metabolomics: What are the opportunities for biomarker discovery?	Parallel Symposium What benefits does Process Analytical Technology (PAT) bring to the design and assurance of product quality?	Parallel Symposium What have we learnt from recent safety cases for new drug development? ISPE Midyear Symposium
	Co-chairs <i>T. Hankemeier</i> , Leiden, The Netherlands <i>G. Harrigan</i> , St Louis, MO USA	Co-chairs S. Folestad, Moelndal, Sweden C. Doherty, Macclesfield, United Kingdom	Co-chairs B. Leufkens, Utrecht, The Netherlands M Sturkenboom, Rotterdam, The Netherlands
08:30	Systems biology and metabolomics: How far are we? <i>T. Hankemeier</i> , Leiden, The Netherlands	Real-time prediction and control of quality - the mechanistic approach to PAT S. Folestad, Moelndal, Sweden	A pharmaco-epidemiological reflection on recent drug safety cases <i>A. Walker</i> , Boston, MA USA
09:05	Metabolomics in Reverse Pharmacology G. Harrigan, St Louis, MO USA	The benefits of PAT in ICH and Japanese regulation <i>Y. Hiyama</i> , Tokyo, Japan	Class effects in drug safety and management H. Leufkens, Utrecht, The Netherlands
09:40	Coffee Break		
10:10	Metabolomics by CE-MS for biomarker	Towards the desired state: a retrospective and	Is industry doing a better job?
	discovery <i>T. Soga</i> , Keio, Japan	prospective view on PAT A. Hussein, Princeton, NJ USA	S. Perez-Gutthann, Barcelóna, Spain
10:45			S. Perez-Gutthann, Barcelona, Spain Short Podium Presentation
10:45 11:00	T. Soga, Keio, Japan	A. Hüssein, Princeton, NJ USA	
	T. Soga, Ќeio, Japan Short Podium Presentation	A. Hussein, Princeton, NJ USA Short Podium Presentation	Short Podium Presentation

13:10

Parallel Symposium How will developments in chemical methods sustain pharmaceutical industrial develop-How effective is the globalisation/harmonisation of Dirty vs selective drugs in the CNS? в G M E pharmacovigilance? Solvay Sponsoring Organisation Pharmaceuticals **Endorsing Organisation** Co-chairs T. Ohwada, Tokyo, Japan Co-chairs Co-chairs F. Lekkerkerker, The Hague, The Netherlands M. Braun, Rockville, MD USA H. Meltzer, Nashville, TN USA C. Kruse, Weesp, The Netherlands Rational polypharmacy within a single molecule: The basis for current antipsychotic Process chemistry as leverage for drug development and profitability in the The science underlying the practice of 14:15 pharmacovigilance pharmaceutical industry T. Konoike, Amagasaki, Japan treatment N. Moore, Bordeaux, France H. Meltzer, Nashville, TN USA Folate conjugates of biologically active compounds – discovery and development *I. Vlahov*, West Lafayette, IN USA The treatment of major depression: Single or International variety in interpretation and 14:50 multiple targets? F. Artigas, Barcelona, Spain management of drug safety N. Wathion, London, United Kingdom Muscarinic receptors as a target in the treatment of disorders of the CNS: Antagonism, The synthetic development of the anti-influenza neuraminidase inhibitor oseltamivir ICH, CIOMS, ISOP, ISPE and other acronymic 15:25 vehicles to enable harmonization of agonism or both? *B. Dean*, Parkville, Australia pharmacovigilance C-K. Shim, Seoul, Korea phosphate (Tamiflu): A challenge for synthesis and process research M. Karpf, Basel, Switzerland **Short Podium Presentation Short Podium Presentation Round Table Discussion** 16:00 16:15 **Short Podium Presentation Short Podium Presentation** Proactive risk management (plans): where Convenor F. Lekkerkerker, The Hague, The Netherlands This Symposium is a special one, organised on the occasion of the retirement of Dr F. Lekkerkerker, Chair of the Dutch Medicines Evaluation Board (MEB), which is supporting it. It will be followed by a Reception for guests invited by the MEB.

EUFEPS Afternoon Sessions

EUFEPS agreed to provide a number of parallel Afternoon Sessions, on Monday and Tuesday afternoon, open to all delegates and focussing on current topics and issues not covered in the Symposium Programme, nor in the "Round Table Discussions". They are there to add to the value of attending this important Congress. Topics considered include:

- Strategic, innovative and critical drug research initiatives: one year later
- Pharmaceutical sciences research training and education: needs and supply
- Pharmaceutical sciences in silico learning systems: value and availability
- European drug development centres and European growth areas

- How to start up a new company?
- Drug product quality: needs and performance
- Vaccine delivery
- EUMAPP Project on microdosing
- How to apply for EU money: case
- Can hepatotoxicity be predicted?
- Reformulation of old drugs life cycle management



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	Parallal Community	Parallal Community	Parallal Community
	Parallel Symposium Druggability: A concept that will fill the pipeline?	Parallel Symposium Drug targeting: How successful are we?	Parallel Symposium What is the state-of-the-science in receptor site modelling?
	Sponsoring Organisation Organisation		
	Co-chairs <i>D. Nicholson</i> , Oss, The Netherlands	Co-chairs <i>M. Hashida</i> , Kyoto, Japan	Co-chairs S. <i>Dahl</i> , Tromsoe, Norway <i>M. Ishiguru</i> , Osaka, Japan
08:30	Druggability and the concept of ADME space D. Smith, Sandwich, United Kingdom	Lipid bubbles formed from liposomes for drug and gene delivery <i>K. Maruyama</i> , Tsukui, Japan	Genomics to drug targets by molecular modelling <i>S. Dahl</i> , Tromsoe, Norway
09:05	Druggability: The broader and the physico- chemical views <i>B. Testa</i> , Lausanne, Switzerland	Polymer-based combination therapies as improved anticancer treatments <i>R. Duncan</i> , Cardiff, UK	Functional structural models of G protein coupled receptors <i>M. Ishiguru,</i> Osaka, Japan
09:40	Coffee Break		
10:10	Concave druggability of protein surfaces for accelerating in silico screening <i>H. Shirai</i> , Ibarakai, Japan	Improved Targeting with Molecularly Decorated Nanoparticles N. Peppas, Austin, TX USA	Structure-based virtual screening B. Shoicet, San Francisco, CA USA
10:45	Short Podium Presentation	Short Podium Presentation	Short Podium Presentation
11:00	Short Podium Presentation	Short Podium Presentation	Short Podium Presentation
11:15	Posters Lunch Break		
	Keynote Presentation	Keynote Presentation Sponsoring Solvay Organisation Pharmaceuticals	
12:15	Are we meeting the challenges of resistance to anti-infective drugs and of newly emerging infectious diseases? L. Schlesinger, Columbus OH USA	Will novel approaches to the treatment of cardiovascular disease prove highly effective? J. Kastelein, Amsterdam, The Netherlands	
	Round Table Discussion Sponsoring Organisation Organisation	Round Table Discussion	Round Table Discussion
13:10	Translational science: a solution to the productivity gap? Convenor <i>D. Nicholson</i> , Oss, The Netherlands	Can microdosing accelerate drug develop- ment? Convenor A. Grahnen, Uppsala, Sweden	When is a human bioequivalence study not needed? Convenor <i>L.Z. Benet</i> , San Francisco, CA USA
	Parallel Symposium Drug-drug interactions: Avoid or understand?	Parallel Symposium What is the future of smart, feed-back, ondemand drug delivery systems?	Parallel Symposium How are disease and PK-PD connected?
	Co-chairs K. Thummel, Seattle, WA USA	Co-chairs J. Kopecek, Salt Lake City, USA K. Kataoka, Tokyo, Japan	Co-chairs <i>Y. Tanigawara</i> , Tokyo, Japan <i>R. Bruno</i> , Mountain View, CA USA
14:15	Managing herb-drug interactions: Understanding mechanism and educating the public A. McLachlan, Sydney, Australia	Smart drug delivery systems: State-of-the-art and future directions <i>J. Kopecek</i> , Salt Lake City, USA	Bone disease progression and drug action N. Holford, Auckland, New Zealand
14:50	Role of the pharmacist in avoiding drug-drug interactions with patient self-care <i>E. Nakashima</i> , Tokyo, Japan	Light-induced gene and drug delivery by supramolecular nanocarrier <i>K.Kataoka</i> , Tokyo, Japan	Mechanism-based modelling of disease pro- gression – disease system analysis <i>B. Ploeger</i> , Leiden, The Netherlands
15:25	Application of a drug-drug interaction data base in drug development and clinical education K. Thummel, Seattle, WA USA	Design of pH-responsive and glutathione-re- active polymer therapeutics <i>P. Stayton</i> , Seattle, WA USA	Modelling of cancer progression and drug effects <i>R. Bruno</i> , Mountain View, CA USA
16:00	Short Podium Presentation	Short Podium Presentation	Short Podium Presentation
16:15	Short Podium Presentation	Short Podium Presentation	Short Podium Presentation
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16:45	See framed information, page 11	See framed information, page 11	See framed information, page 11

PROGRAMME • Tuesday

13:10

	Parallel Symposium What's new in methods of measuring human drug response?	Parallel Symposium In silico product development from molecule to man: Dream or reality?	Parallel Symposium Nutraceuticals: Are new methods of evaluating risk/benefit required?
	Co-chairs A. Cohen, Leiden, The Netherlands P. Macheras, Athens, Greece	Co-chairs P. York, Bradford, United Kingdom V. Venkatasubramanian, West Lafayette, IN USA	Co-chairs H. Ohama, Tokyo, Japan R. Oledzka, Warsaw, Poland
08:30	The data intensive first administration to man study – functional outcome replaces tolerability: The impact of new measurement techniques A. Cohen, Leiden, The Netherlands	Thermodynamics of pharmaceutical systems from molecular simulation <i>J. Anwar</i> , Bradford, United Kingdom	Risk analysis and evaluation of scientific evidence for nutraceuticals in Japan <i>H. Ohama</i> , Tokyo, Japan
09:05	Pathophysiological concepts as a basis for the measurement of treatment response in inflammatory and obstructive airway disease H. Reddel, Sydney, Australia	Computer aided design and optimisation for pharmaceutical formulations <i>K. Takayama</i> , Tokyo, Japan	Risk assessment for low risk nutraceuticals J. Hathcock, Washington, DC USA
09:40	Coffee Break		
10:10	PET imaging for evaluation of drug effects in neuropsychiatric disease <i>M. Laurelle</i> , Greenford, United Kingdom, and New York, NY USA	Towards intelligent decision support for product development challenges and opportunities V. Venkatasubramanian, West Lafayette, IN USA	The philosophy of the evaluation and regulation of nutraceuticals in the European Union <i>A. Somogyi</i> , Budapest, Hungary
10:45	Short Podium Presentation	Short Podium Presentation	Short Podium Presentation
11:00	Short Podium Presentation	Short Podium Presentation	Short Podium Presentation
11:15	Posters Lunch Break		
12:15			

	Have omics technologies improved the chance for successful drug development?	Are pharmaceutical manufacturing technologies in stagnation?	Are we using the right outcome measures to ascertain patient benefit from drug therapy?
	Co-chairs T. Guentert, Basel, Switzerland	Co-chairs J. Fix, Lawrence, KS USA Y. Capan, Ankara, Turkey	Co-chairs <i>L. Bootman</i> , Tucson, TX USA <i>A. Hussain</i> , Dubai, United Arab Emirates
14:15	Genomics and drug discovery: Have the promises been fulfilled? K. Lindpaintner, Basel, Switzerland	The changing landscape of pharmaceutical manufacturing: Incremental or breaking new ground? J. Fix, Lawrence, KS USA	Outcomes measurement: Overview of theoretical and applied issues <i>L. Bootman</i> , Tucson, TX USA
14:50	Omics and the search for improved biomarkers <i>M. Bleavins</i> , Ann Arbor, MI USA	Innovation needed in pharmaceutical research and technology in the 21st century <i>R. Ibuki</i> , Shizuoka, Japan	Outcome measurement: Issues and strategies for pre-market development <i>W-F Huang</i> , Taipei, Taiwan
15:25	Changing the drug development paradigm: Opportunities offered by new technologies J. Kuromitsu, Ibaraki, Japan	Can new production technologies and new excipients meet the demands of future drugs? <i>H. Frijlink</i> , Groningen, The Netherlands	Outcomes measurement: Issues and strategies for post-marketing development J. Cooke, Manchester, United Kingdom
16:00	Short Podium Presentation	Short Podium Presentation	Short Podium Presentation
16:15	Short Podium Presentation	Short Podium Presentation	Short Podium Presentation





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	Parallel Symposium How to manage drug therapy at the extremes of age?	Parallel Symposium How can nanotechnology and materials science solve drug delivery problems?	Parallel Symposium How important is genetic and physiological variability in drug transporters?
	Co-chairs H. Derendorf, Gainesville, FL USA H. Christensen, Oslo, Norway	Co-chairs C-M. Lehr, Saarbrucken, Germany H. Ghandehari, Baltimore, USA	Co-chairs K. Giacomini, San Francisco, CA USA
08:30	Pharmacotherapy in the elderly H. Derendorf, Gainesville, FL USA	Nanotechnology for overcoming biological barriers <i>C-M. Lehr</i> , Saarbrucken, Germany	Functional genomics of membrane transporters <i>K. Giacomini</i> , San Francisco, CA USA
09:05	Pharmacokinetics and pharmacodynamics in neonates and infants <i>T. Dalla Costa</i> , Porto Alegre, Brazil	Particle design for absorption enhancement using a 4-nozzle spray drier and DNA vaccine by self-organised Tat nanospheres <i>H. Okada</i> , Tokyo, Japan	Pharmacogenomics of MDR1/ABCB1 and CYP3As in tacrolimus therapy after organ transplantation <i>K</i> . <i>Inui</i> , Kyoto, Japan
09:40	Coffee Break		
10:10	Dose optimisation in children S. <i>Higuchi</i> , Fukuoka, Japan	Can higher definition of the nanoscale result in better drug delivery systems in the 21st century? H. Ghandehari, Baltimore, USA	Assessing the impact of variability in ABC drug transporters using mouse models A. Schinkel, Amsterdam, The Netherlands
10:45	Short Podium Presentation	Short Podium Presentation	Short Podium Presentation
11:00	Short Podium Presentation	Short Podium Presentation	Short Podium Presentation
11:15	Posters Lunch Break		
	Keynote Presentation Sponsoring Organisation AstraZeneca Iffe inspiring ideas	Keynote Presentation	
12:15	Drug resistance in cancer chemotherapy <i>T. Tsuruo</i> , Tokyo, Japan	Will an understanding of the molecular ge- netic basis of neurodegenerative disease lead to effective treatments? A. Aguzzi, Zurich, Switzerland	
	Round Table Discussion	Round Table Discussion	Round Table Discussion
13:10	Round Table Discussion What is the value of observational data post-marketing to assess safety and efficacy? Convenor M. Rowland, Manchester, United Kingdom	Round Table Discussion Life-style drugs: a new burden to the health system? Convenor G. Alvan, Uppsala, Sweden	Round Table Discussion
13:10	What is the value of observational data post-marketing to assess safety and efficacy? Convenor M. Rowland, Manchester, United	Life-style drugs: a new burden to the health system? Convenor G. Alvan, Uppsala, Sweden Parallel Symposium Developing biotech products: What are the challenges and solutions? Sponsoring AstraZeneca	Parallel Symposium Control of intracellular pharmacokinetics: Advantages for drug therapy?
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PROGRAMME • Wednesday

	Parallel Symposium Systems biology: A driver of drug discovery	Parallel Symposium How to engineer desired particle properties	Parallel Symposium Off-label use of medicines: Abuse or a vehicle
	and development?	for drug delivery?	for innovation?
	Co-chairs <i>C.R. Noe,</i> Vienna, Austria	Co-chairs <i>E. Fattal</i> , Paris, France <i>T. Nagai</i> , Tokyo, Japan	Co-chairs A. Kalis, The Hague, The Netherlands
08:30	Theory of biological robustness and system drug design <i>H. Kitano</i> , Tokyo, Japan	Particle design for nucleic acids and contrast agents <i>E. Fattal</i> , Paris, France	Two worlds and why the twain will never meet <i>J. Lisman</i> , The Hague, The Netherlands
09:05	Systems Biology: What does it mean for phar- maceutical sciences? A. Aszódi and C.R. Noe, Vienna, Austria	Novel particle design for drug deliver H. Takeuchi, Gifu, Japan	Regulatory and ecomonic aspects of the off- label use of medicines A. Wertheimer, Philadelphia, PA USA
09:40	Coffee Break		
10:10	Title to be confirmed <i>B. Palsson</i> , San Diego, CA USA	How to optimize particle properties for pul- monary drug delivery <i>G. Hochhaus</i> , Gainesville, FL USA	Benefits of off-label use and how to use it <i>K. Tsutani</i> , Tokyo, Japan
10:45	Short Podium Presentation	Short Podium Presentation	Short Podium Presentation
11:00	Short Podium Presentation	Short Podium Presentation	Short Podium Presentation
11:15	Posters Lunch Break		
12.15			
12:15			
13:10	Parallel Symposium	Parallel Symposium	Parallel Symposium

	Parallel Symposium Molecular targeting in cancer chemotherapy?	Parallel Symposium Miniaturisation in analytical methods: Is small always beautiful?	Parallel Symposium Counterfeiting of medicines: Detection and prevention?
	Co-chairs J. Au, Columbus, OH USA	Co-chairs S. <i>Lunte</i> , Lawrence, KS USA <i>J. Haginaka</i> , Nishinomiya, Japan	Co-chairs A. Moffat, London, United Kingdom Z. Y. Yang, Guangzhou, China
14:15	Suramin: A systems modulator of multiple molecular targets <i>J. Au</i> , Columbus, OH USA	Separation based sensors for pharmaceutical analysis using microdialysis and microchip electrophoresis S. Lunte, Lawrence, KS USA	New methods of detection of counterfeit medicines for laboratory and field use A. Moffat, London, United Kingdom
14:50	A systems pharmacology: Targeting p53 networks <i>E. Liu</i> , Singapore, Singapore	Micro and nano chemical systems on chips for analytical and biological sciences <i>T. Kitamori</i> , Tokyo, Japan	The FDA initiative on combating counterfeit drugs <i>F. Fricke,</i> Cincinnati, USA
15:25	The challenges of developing targeted cancer therapies: An industry perspective <i>S. Eck</i> , Ann Arbor, MI USA	Microchip strategies for biomarker detection and screening utilizing fluorescence and MALDI-TOF MS readout <i>T. Laurell</i> , Lund, Sweden	Combating counterfeiting in Asia Z. Y. Yang, Guangzhou, China
16:00	Short Podium Presentation	Short Podium Presentation	Short Podium Presentation
16:15	Short Podium Presentation	Short Podium Presentation	Short Podium Presentation

