

Predictive

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2010 AND SAVE UP TO £350!**

Toxicology

**'Extremely
valuable. Gave
good overview
of trends'**

**Jesper Roested,
MC2 Biotek**

Main Conference: 23rd-24th February 2011
Pre-conference Focus day : 22nd February 2011
Venue: America Square Conference Centre, London, UK

EMPLOYING PREDICTIVE TOXICOLOGY TO REDUCE LATE STAGE DRUG ATTRITION AND MAXIMISE PROFITABILITY

Attend Predictive Toxicology to Learn How to:

- Enhance the prediction capabilities and in turn **improve your safety assessment approach** with practical lessons on genetic, cardiac and hepatic toxicity testing, insights from **AstraZeneca, Novartis** and **Bayer Healthcare**
- Boost accuracy and reduce late stage drug attrition** by capitalising on new technology and techniques including incorporating stem cell models and high content analysis. Exclusive presentations from **Pfizer, AstraZeneca** and **GSK**
- Enhance the understanding of the toxic action of your drug by **benchmarking against leading industry case studies on in vitro and in vivo pre clinical models** from **Bayer** and **AstraZeneca**
- Accelerate your drug discovery and development** through implementation of sensitive and effective biomarkers to **ultimately reduce development cost**. Updates from **Abbott** and **UCB Pharma**
- Modify your interpretations and ultimately ensure compliance** by drawing conclusions from re-evaluations of the mouse lymphoma assay from a regulatory and industry perspective. Results from the **FDA** and **AstraZeneca**

23+ Internationally Renowned Professionals Share Their Expertise:

Regulatory insight from:

Dr Martha Moore, Division of Genetic and Molecular Toxicology, **FDA**

Dr David Jones, Expert Pharmaco-Toxicologist, **MHRA**

Industry insight from:

Dr Thomas Steger-Hartmann, Head of Investigational Toxicology, **Bayer Healthcare**

Dr Laszlo Urban, Executive Director, **Novartis**

Prof. Ian Cotgreave, Director of Molecular Toxicology, Safety Assessment and Chairman of The Stem Cell Expert Network, **AstraZeneca**

Dr Frank Bonner, Chief Executive, **Stem Cells for Safer Medicines**

Dr Annamaria Rossi, Director of Drug Safety, **Pfizer**

Dr William Suk, Director of the Centre for Risk and Integrated Science, **NIEHS**

Dr Gary Gintant, Research Fellow and Senior Group Leader, Integrative Pharmacology, **Abbott**

Dr Richard Luke, Principal Scientist, **AstraZeneca**

Dr Peter O'Brien, Veterinary Clinical Pathologist, **University College Dublin**

Dr Mick Fellows, Safety Assessment, **AstraZeneca**

Dr Yi Yang, Research Investigator, **Abbott**

Dr Helga Gerets, Senior Scientist *In Vitro* Toxicology, **UCB Pharma**

Dr Barry Hardy, Director, Community of Practice & Research Activities and Project Coordinator, **OpenTox**

Dr Gerry Kenna, Principal Scientist in Molecular Toxicology, **AstraZeneca**

Dr Randal Streck, Senior Principal Scientist, **Pfizer**

Dr Julie Holder, Preclinical, Stem Cell DPU, **GSK**

Dr Sandra Johanssen, Toxicologist, Global Preclinical Development, **Intendis / Bayer Healthcare**

Dr Glyn Stacey, Director, **UK Stem Cell Bank**

Dr David Hay, Principal Investigator, **MRC Centre for Regenerative Medicine**

Dr Ernie Bush, Vice President, Collaborative Projects, **The Drug Safety Executive Council**

Dr Stephane Dhalluin, Director, Investigative Non-Clinical Safety, **UCB Pharma**

BRAND NEW FOR 2011!

1 Focus day dedicated to the use of Stem Cells in predictive toxicology: how robust, reliable and predictive are they? Sessions with SC4SM, Pfizer, Abbott, GSK, NIEHS and AstraZeneca

Page 1

2 Comprehensive insights into all aspects of toxicology testing from cardiac to nephritic toxicity testing to reduce late stage failure and boost profit

Page 2 and 3

3 Interactive panel discussion with the Drug Safety Executive Council (DSEC), get your questions answered!

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Media partners



Bio-IT World



Pharma **VOICE**



PRE-CONFERENCE FOCUS DAY: TUESDAY 22ND FEBRUARY 2011

STEM CELLS IN PREDICTIVE TOXICOLOGY

08:00 Registration and Coffee

08:50 Pharma IQ Welcome and Chairperson's Opening Address

Stem Cells Models for Predictive Toxicology- How Robust, Reliable and Predictive are they?

09:00 Exploring the Potential of Stem Cell Assays in Predictive Toxicology Testing of Drugs and Chemicals to Understand Future Opportunities

- The need for improved cell based models for toxicity screening
- Overview of the key considerations in the application of stem cell assays
- Challenges and opportunities in the development of predictive assays
- SC4SM Predictive Toxicology Consortium: update on progress and future direction

Dr Frank Bonner, Chief Executive, *Stem Cells for Safer Medicines*

09:40 Practical Insights into the Use of Stem Cells to Support Drug Discovery and Development

- Analysis of business needs, desired application and characteristics of Stem Cells to support drug development
- Update on the current status of the differentiated Stem Cells as *in vitro* tool for toxicology prediction
- Exploring tools, condition and technologies that could improve differentiation of Stem Cells
- Critical debate: Embryonic Stem Cells versus Induced Pluripotent Stem Cells for use in safety assessment

Dr Annamaria Rossi, Director of Drug Safety, *Pfizer*

10:20 Networking Coffee Break

10:50 Monitoring Differentiation of Mouse Embryonic Stem Cells to Screen for Developmental Toxicity of Pharmaceuticals

- Animal testing for developmental toxicity is extremely expensive and usually occurs only after a major investment in development of a drug candidate
- Differentiating mouse embryonic Stem Cells are good models for early gestation mammalian embryos
- In order to develop a robust predictive assay, Pfizer has assayed numerous molecular and functional endpoints in this *in vitro* model for more than 60 pharmaceutical compounds that previously had been tested *in vivo*
- Our evolving model for predicting the risk for developmental toxicity will be presented

Dr Randal Streck, Senior Principal Scientist, *Pfizer*

11:30 Considering Stem Cells as "Role Models" for Preclinical Cardiac Safety Assessment

- Exploring emerging opportunities for Stem Cells
- Models and examples of present systems to predict cardiac toxicity
- Case studies: failures and successes of current stem cell models and applying them in your safety assessment program
- Paths forward to successful implementation of stem cell models for cardiac toxicity testing

Dr Gary Gintant, Research Fellow and Senior Group Leader, Integrative Pharmacology, *Abbott*

12:10 Generating Metabolically Active Hepatocytes from Pluripotent Stem Cells

- Introduction to hESC-derived hepatic endoderm (HE) as a potential *in vitro* tool for the prediction of hepatic toxicity
- Insights into polymer screening to identify culture matrices which can regulate cell phenotypes
- Achieving hESC-derived HE phenotypic stability through use of a novel polymer matrix
- Application of high through put polymer screening to enhance the stability of your stem cell models for predictive toxicology in the future

Dr David Hay, Principal Investigator, *MRC Centre for Regenerative Medicine*

12:50 Networking Lunch Break

14:10 Realising the Potential of Stem Cells to Identify Cardiotoxic and Hepatotoxic Compounds Early in Drug Discovery

- What stem cell assay model ensures consistency and superiority to existing *in vitro* assays?
- Characterization and validation of tissue specific cells derived from iPS cells which are currently being evaluated by the Pharma industry for their utility in identifying cardiotoxic and hepatotoxic compounds
- Scale up and demonstration of added value to the Pharmaceutical Industry

Dr Julie Holder, Preclinical, Stem Cell DPU, *GSK*

14:50 Human Stem Cells: Understanding Mechanisms of Chemical Toxicity and Individual Responses

- Evaluation of predictive toxicology in drug discovery and development
- Predictive toxicology in environmental health
 - Stem Cells and environmental health assessment
 - Biomonitoring and human surveillance
 - Toxicity and individual susceptibility
- Technological advances impacting stem cell use
 - Computational, systems-based and *in silico* strategies
 - Biobanking
- Multidisciplinary team approaches and information bidirection for the implementation of Stem Cells

Dr William Suk, Director of the Centre for Risk and Integrated Science, *NIEHS*

15:30 Networking Coffee Break

16:00 Insights into Work at UK Stem Cell Bank and How it Will Support the Development of Your Stem Cell Models for Safety Testing

- Introduction to the UK Stem Cell Bank and its relationship with the industry
- Update on recent work at the UK Stem Cell Bank: development of *in vitro* stem cell assays to enhance your predictive toxicology approach
- Exploring the involvement of the Stem Cell Bank in current EU projects and how they will impact the utility of Stem Cells in safety testing
- Understanding what the Stem Cell Bank can do to support the development effective, efficient and accurate stem cell assays

Dr Glyn Stacey, Director, *UK Stem Cell Bank*

16:40 Outlook to the Future: Exploring the Realistic Prospects and Pitfalls of Stem Cell Models for Predictive Toxicology

Topics and questions for debate will include:

- Where are science and the industry going with Embryonic Stem Cells and Induced Pluripotent Stem Cells: How do they complement each other and what are the opportunities?
- How do stem cell models fit in with 3Rs: What does industry actually stand to save and what are the pitfalls to achieving this?
- Much focus has been placed on models to predict liver and cardiac toxicity. Are we concentrating on the most vital areas or should industries attention be focused elsewhere to enhance results?
- Will current developments realistically lead to screens which influence the "make-test cycle" of pharmaceutical discovery?
- How do we optimize the role of public-private partnerships, in order to avoid duplication of effort?

Facilitated by Prof. Ian Cotgreave, Director of Toxicology and Safety Assessment, *AstraZeneca and focus day speakers*

17:40 Chairperson's Closing Remarks and Close of Focus Day

"Excellent Cross Section of Topics"
Danni Harris, Toxmet

CONFERENCE DAY ONE: WEDNESDAY 23RD FEBRUARY 2011**08:00 Registration and Coffee****08:50 PharmaIQ Welcome and Chairperson's Opening Address****Introduction to the Current Strategies to Avoid Toxicological Risk****09:00 A Medicinal Chemist's View of Predictive Toxicology and Strategies to Avoid Toxicological Risk**

- Medicinal chemists are increasingly attempting to avoid toxicological risk at the point of new compound design or in early screening and SAR studies
- In some areas such as hERG there is good knowledge of the chemical features which lead to activity and ways to reduce this liability
- There is also an increasing awareness of structural properties that lead to increases in the general risk of toxicological findings
- However while we have made progress there are still many gaps in our ability to avoid toxicological risk
- The talk will discuss the current situation with regard to the above points, how these are being addressed in AstraZeneca, and likely future developments

Dr Richard Luke, Principal Scientist, **AstraZeneca****09:45 Outlook to the Future of Regulatory Guidelines for Safety Testing: A UK Regulatory Overview of Predictive Toxicology in 2011**

- Understanding the role of the MHRA in safety testing
- Update on current safety testing guidelines in the UK
- Implementing scientific advice and MHRA recommendations
- Future perspectives: what does the future of scientific and regulatory predictive toxicology look like?

Dr David Jones, Expert Pharmaco-Toxicologist, **MHRA****10:30 Networking Coffee Break****Insights and Case Studies into Methods and Approaches for Accurate and Comprehensive Safety Assessment****11:00 Understanding Metabolite Mediated Cell Toxicity to Enhance Hazard Identification and Risk Assessment**

- Current understanding of the role of metabolism in toxicity, focusing on adverse drug reactions
- Overview of available *in vitro* and *in vivo* preclinical models that can be implemented in your predictive toxicology approach
- Case studies highlighting the value and limitations of individual models for hazard identification and risk assessment to boost the accuracy of toxicity testing

Dr Gerry Kenna, Principal Scientist in Molecular Toxicology **AstraZeneca****11:45 Nephrogenic Systemic Fibrosis (NSF): Lessons Learnt with Regard to the Predictive Capabilities of Preclinical Studies**

- The clinical picture of NSF - a rare disease associated with the administration of Gadolinium-containing contrast agents (GBCAs)
- Insights into preclinical findings after administrations of GBCAs
- Exploring hypotheses on the pathomechanisms based on preclinical results
- Can the preclinical results contribute to risk assessment and management of NSF?

Dr Thomas Steger-Hartmann, Head of the Department Laboratory Diagnostics, Genetic Toxicology, Early and Mechanistic Toxicology, **Bayer Healthcare****12:30 Networking Lunch Break****14:00 Re-evaluation of the National Toxicology Program (NTP) Mouse Lymphoma Tk Assay (MLA) Database Using Current Standards**

- According to the NTP the mouse lymphoma assay has a large number of positive responses for chemicals that are not rodent carcinogens
- Standards for interpreting MLA data have changed substantially since the NTP database was created
- Using current standards the majority of chemicals called positive by NTP are not actually positive
- A large portion of the NTP MLA experiments do not meet current acceptability criteria
- A large portion of the NTP MLA chemicals cannot be evaluated as positive, negative or equivocal using current standards
- Understanding what the conclusions of the re-evaluation of the NTP means for your predictive toxicology approach

Dr. Martha M. Moore, Division of Genetic and Molecular Toxicology, **FDA****14:45 What is the real incidence of positive results in the mouse lymphoma TK assay (MLA) in pharmaceutical screening?**

- The mouse lymphoma assay (MLA) has been reported to have a false positive rate of more than 50%
- In pharmaceutical screening at AstraZeneca, only 15% of all drugs tested in the MLA are positive
- The vast majority of these positives are likely to be due to the pharmacological target of the drug, hence cannot be described as 'false positives'
- In reality, when used in a pharmaceutical screening paradigm, the 'false positive' rate of the MLA is as low as 5%
- Impact of the low 'false positive' rate of the MLA on your safety screening

Dr Mick Fellows, Safety Assessment, **AstraZeneca****15:30 Networking Coffee Break****16:00 Interactive Panel Discussion with the Drug Safety Executive Council****Predictive Toxicology Tools: Reducing the Risks Associated with the Adoption of Novel Technologies**

- Do you see the role of *in vitro* toxicity assays increasing in importance and frequency prior to animal toxicity testing? What *in vitro* assays are most often used now (other than ADME) prior to animal toxicity testing?
- Would you only implement a technology that you would run in-house?
- How does potential regulatory acceptance factor into a decision to adopt a new technology (--or-- does good science triumph over regulatory uncertainty)?
- To what extent are Stem Cells being used for *in vitro* cell-based assays to identify drugs with higher efficacy and minimal toxicity? What are the barriers that must be overcome for this approach to accelerate progress?
- To what extent do you need to quality/validate a novel technology so that your project team will accept it?
- At what level of management is the decision taken to evaluate and adopt a new technology?

Facilitated by: Dr. Ernie Bush, Director, Collaborative Projects, **Drug Safety Executive Council****Panel members: Dr Thomas Steger-Hartmann**, Head of the Department Laboratory Diagnostics, Genetic Toxicology, Early and Mechanistic Toxicology, **Bayer Healthcare**
Dr Gerry Kenna, Principal Scientist in Molecular Toxicology, **AstraZeneca****Dr Stephane Dhalluin**, Director, Investigative Non-Clinical Safety, **UCB Pharma****17:00 Chairperson's Closing Remarks and Close of Day One**

CONFERENCE DAY TWO: THURSDAY 24TH FEBRUARY 2011

08:00 Registration and Coffee

08:50 Pharma IQ Welcome and Chairperson's Opening Address

09:00 Understanding How to Mitigate Cardiac Toxicity During Lead Selection and Lead Optimization?

- Outline of major cardiac ion channel and non-ion channel targets associated with drug-related cardiotoxicities
- Application of assays and *in silico* tools for risk assessment and mitigation
- Predictive value of *in vitro* assays and associated follow-up tests for clinical adverse reactions
- Critical evaluation of the strategy and methodologies that can be employed to mitigate cardiac toxicity

Dr Laszlo Urban, Executive Director, **Novartis**

09:45 Achieving Accurate Prediction of Drug Induced Liver Injury in Man

- Socioeconomic impact of drug induced liver injury: ill health in man, lost pharmaceutical industry productivity
- Exploring the value of limitations of current preclinical safety testing strategies
- Analysis of new opportunities arising from mechanistic insights: *in silico*, *in vitro*, *in vivo* models
- Overview of the role of Innovative Medicines Initiative

Dr Gerry Kenna, Principal Scientist in Molecular Toxicology, **AstraZeneca**

10:30 Networking Coffee Break

Evaluation of Biomarkers as a Tool to Identify Toxicity and Help Accelerate Drug Development

11:00 Critical Evaluation: Is Nrf2 a Good Biomarker of Oxidative Stress and Reactive Metabolites and Evaluation of its Effectiveness in Safety Assessment

- Introduction to various models/experiments used to investigate toxicities related to reactive metabolites/oxidative stress
- Role of NRF2
- Experimental approach 1: cellular toxicogenomic analysis (genes controlled by NRF2) and potential biomarkers
- Experimental approach 2: predictivity of the AREc32 cell line: advantage and limitations
- Link between hepatotoxicity and reactive metabolites and applying this relationship to in your safety evaluation

Dr Helga Gerets, Senior Scientist *In Vitro* Toxicology, **UCB Pharma**

11:45 General and Fit-For-Purpose Toxicity Biomarkers: Applications in Predictive Toxicology and Acceleration of Drug Development

Sensitive and predictive toxicity biomarkers can be valuable tools for accelerated drug discovery and development. The presentation will illustrate with case studies the development and incorporation of novel biomarkers for early detection of drug-induced toxicities, with special focus on:

- Genomics and urinary biomarkers for drug-induced nephrotoxicity
- *In vivo* and *in vitro* biomarkers for PPAR agonist-associated side effects
- Biomarkers for bile duct injury

Dr Yi Yang, Research Investigator, **Abbott**

12:30 Networking Lunch Break

Exploring Testing Approaches for Specific Toxicities and New Approaches to Improve the Predictive Capabilities of Your Strategy

14:00 Exploring Effective Non-Clinical Safety Testing for Dermal Drug Development

- Introduction to models for local dermal tolerance and their predictive ability
- Considerations for dermal drug development - what is special?
- How to best interpret the guidelines for dermal drug development to ensure effective non-clinical safety testing

Dr Sandra Johanssen, Toxicologist, Global Preclinical Development, **Intendis / Bayer Healthcare**

14:45 Employing High Content Analysis (HCA) to Enhance Toxicity Prediction Capabilities and Ultimately Reduce Late Stage Drug Attrition

- Introduction to high content analysis: measuring multiple parameters over a period of time to obtain realistic pictures of the toxic effects of your compounds
- Exploring the advantages afforded through the implementation of HCA
- Case studies: examples of how high content analysis could have aided toxicity prediction of failed drugs
- Future perspectives: maximising the potential benefits of HCA to reduce late stage drug failure

Dr Peter O'Brien, Veterinary Clinical Pathologist, **University College Dublin**

15:30 Networking Coffee Break

16:00 Insights into An Interoperable Approach to Collaborative Drug Design and Predictive Toxicology and How it Can Help Enhance Your Safety Assessment Strategy

- Introduction to an interoperable infrastructure for collaborative drug design
- Overview of the OpenTox Framework
- Optimally integrating predictive toxicology predictions into drug design
- Incorporation of ontology supporting interoperability
- Collaboration pools and virtual organisations
- Case study: "Scientists Against Malaria"

Dr Barry Hardy, Director, Community of Practice & Research Activities and Project Coordinator, **OpenTox**

16:45 Round Table Discussion Session: Preparing for the Future of Predictive Toxicology

This will be a unique opportunity for all participants to discuss and share ideas about the issues raised during the course of the conference. Conclusions and take home lessons will be drawn to apply back in the workplace in order to improve predictive capabilities and to ultimately reduce late stage failure and development costs. Specific topics and papers for discussion are welcomed for submission prior to the conference. Simply send to rachel.kenworthy@iqpc.co.uk before Friday 11th February. **Facilitated by from day 1 and day 2 speakers**

17:45 Chairperson's Closing Remarks and Close of Day Two

"Good networking event"
Dr Roy Edward, Biostatistics

WHY GET INVOLVED?

Maximise Your Involvement: Sponsorship and Exhibition Opportunities

The 3rd Annual Predictive Toxicology conference will be attended by senior figures and decision-makers from industry, bringing buyers and suppliers together in one location.

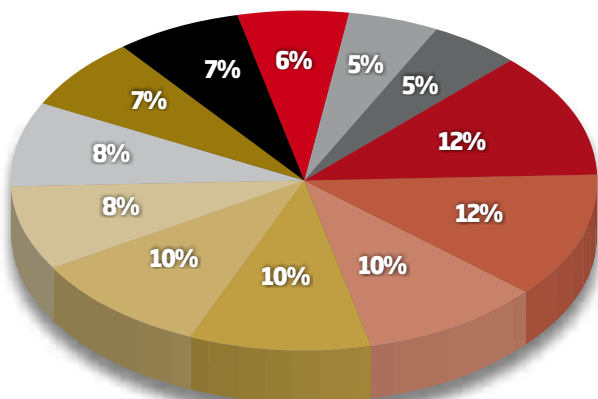
On-message and on target, the event will provide an excellent platform from which to launch new business relationships. With our tailored networking sessions, sponsors can achieve the kind of face-to-face contact that overcrowded trade shows cannot.

Exhibiting and sponsorship options are extensive and bespoke packages can be developed to suit your individual company's needs. Most packages include complimentary entry passes, marketing solutions targeted at industry officials and executives and specifically tailored networking opportunities. Other features of sponsorship include:

- Prominent exhibition space in the main conference networking area
- Participation in comprehensive pre-event marketing campaigns
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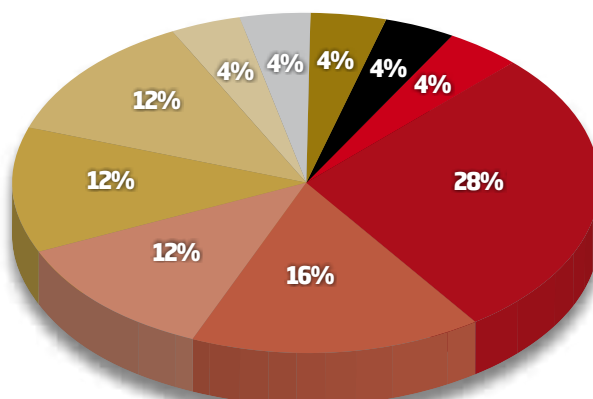
For more information and to discuss the right opportunity, contact us on +44 (0)207 368 9300 or sponsorship@iqpc.co.uk

Who Will Attend?



Predictive Toxicology Attendee Job Titles

- | | |
|--|---|
| <ul style="list-style-type: none"> Division Dir Genetic and Predictive Toxicology Associate Director of Drug Safety Genetic Toxicologist Senior Scientist Principle Scientist Tox Vice President Drug Metabolism Pharmacokinetics, Toxicology | <ul style="list-style-type: none"> Toxicology Scientist Head of Genetic Tox Department Director Special Toxicology Head Business Development Head of Medicinal Chemistry Professor of Predictive Tox Director of Center for Risk |
|--|---|



Predictive Toxicology Attendees by Geo

- | | |
|---|--|
| <ul style="list-style-type: none"> United Kingdom Denmark France Germany Spain | <ul style="list-style-type: none"> Canada Finland Switzerland The Netherlands United States |
|---|--|

Why Attend Predictive Toxicology this Year?

1. Brand new focus day dedicated to assessing exactly how robust, reliable and predictive stem cells are and how to implement them as part of your predictive toxicology strategy.

2. DSEC panel discussion: get your questions answered and explore how to **reduce the risks when implementing novel technologies** with Bayer Healthcare, AstraZeneca and UCB Pharma

3. 19+ speakers new for this year: hear a range of novel approaches and case studies to ensure you are **employing the most cutting edge approaches as part of an effective and accurate safety assessment strategy**

What Your Peers think of the Past Predictive Toxicology Events:

"...at the Predictive Toxicology Conference 2010, the aim is to provide attendees with practical knowledge which translates to better patient outcomes and better returns on investment"

Dr Mitchell Friedman - Director of Toxicology, Takeda Pharmaceuticals (2010)

"Late stage attrition of nascent drugs causes substantial losses, both financially and in terms of effort...Recent advances on several fronts are providing in silico, cellular and animal models that more faithfully predict clinical reality. I am speaking at Predictive Toxicology again this year to help keep attention focused on mitochondrial dysfunction as a key safety issue, but also to hear about the latest developments on other fronts."

Dr James Dykens - Associate Research Fellow, Drug Safety R&D, Pfizer (2010)

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Predictive Toxicology

Main Conference: 23rd-24th February 2011
Pre-conference Focus Day: 22nd February 2011
Venue: America Square Conference Centre, London, UK

To speed registration, please provide the priority code located on the mailing label or in the box below.

My registration code **PDFW**

Please contact our database manager on +44(0) 207 368 9300 or database@iqpc.co.uk quoting the registration code above to inform us of any changes or to remove your details.

Packages	Tick	Register and pay by 19th Nov*	Register and pay by 17th Dec*	Register and pay by 14th Jan*	Standard Price
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Conference + Focus Day		Save £250 £2098 + VAT	Save £150 £2198 + VAT	Save £50 £2298 + VAT	£2348 + VAT
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Please photocopy for each additional delegate

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Name of person completing form if different from delegate: _____

Signature _____

I agree to IQPC's cancellation, substitution and payment terms.

Special dietary requirements: Vegetarian Non-dairy Other (please specify) _____

Please indicate if you have already registered by Phone Fax Email Web

Please note: if you have not received an acknowledgement before the conference, please call us to confirm your booking.

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Total price for your Organisation: (Add total of all individuals attending):

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Name On Card: _____ Signature: _____

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VENUE & ACCOMMODATION

VENUE:

America Square Conference Centre
 One America Square, 17 Crosswall, London EC3N 2LB

ACCOMMODATION:

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