

# 2nd Annual Formulation & Drug Delivery Congress

18 - 19 May 2016, London, UK

#### Day 1 Stream 1 – Large Molecule Drugs Formulation

- Characteristics of peptide & protein formulations
   Overcoming protein & peptide formulation challenges
- Ensuring the quality and stability of biologic formulation
- Formulation challenges of highly potent molecules
- Formulation strategies in early & pre-commercial development
- Suitable solution conditions & excipients
- Solids, liquids or advanced protein formulations

#### Day 1 Stream 2 – Small Molecule Drug Delivery

- Recent advancements in small molecule drug delivery
- Nanoparticles as drug delivery systems
- Oral-delivery vs lipid-based systems
- Enhancing bioavailability with drug delivery systems
- Versatile technology for small molecule drug delivery
  - biodegradable silica-based technology
  - gel–liposome-mediated co-delivery

#### Day 2 Stream 1 – Small Molecule Drugs Formulation

- Successful formulation strategies for small molecules
- Nano-formulations: predicting physical stability
- Oral suspensions: solubility & stability
- Improving chemical and physical stability in liquid formulations
- Improving the bioavailability of compounds
- Amorphous solid dispersions: overcoming poor solubility and dissolution rate

#### Day 2 Stream 2 – Large Molecule Drug Delivery

- New biologics drug delivery systems
- Increasing intracellular delivery of biologics
- Achieving long term release of antibodies
- Gene delivery systems: viral and non-viral
- Approaches for delivery of biologics across the bloodbrain barrier
- Challenges and opportunities in protein and peptide
   drug delivery

#### **Meet Senior Decision Makers**

Benefits to Attending

- Hear from and meet with the key innovators involved in formulation and drug delivery. Attendees include: Vice President and CTO, Global R&D, Teva; CTO, Connected Product Systems Engineering, Eli Lilly and Company; Senior Vice President, Peptides, Ipsen
- Discover collaborative solutions to biologics and small molecules formulation challenges. The congress brings together key opinion leaders to discuss topics areas ranging from protein & peptide formulation challenges through to the formulation of highly potent molecules and nano-formulations
- Discuss the latest innovations in biologics and small molecule drug delivery. Case studies include: novel drug and gene delivery systems, nanoparticles for drug delivery and enhancing bioavailability
- ✓ Unparalleled networking opportunities. The two-day congress offers dedicated networking breaks creating an interactive platform for scientific discussions and 1-1 meetings. The exhibition hall and poster presentation spaces offer a relaxed and professional environment for discussion
- A high quality programme devised with the help of our esteemed advisory board. Presentations will cover areas including ensuring the quality and stability of biologic formulations, amorphous solid dispersions and technologies for small molecule drug delivery
- Co-located with our inaugural Inhalation & Respiratory Drug Delivery Congress

### 2016 Speakers Include:



David Elder GlaxoSmithKline



Christoph Saal Merck KGaA

GlaxoSmithKline University College London Me

Over 150 VPs, Directors and Senior Managers from leading pharmaceutical organisations, biotech companies and academic institutions will attend the event. Delegate job titles include:

Formulation Sciences Drug Delivery Product Development

Technology Assessment Bioformulations Development Delivery Device Development Product Characterisation Pre-Formulation Biologics Development Drug Delivery Design Preclinical Development Nanotechnology

#### **Discover New Solutions**

Formal and informal meeting opportunities offer delegates the chance to discuss key solutions with leading service providers. Services to be discussed include:

Oral Formulations Inhalation Formulations Sterile Formulations Parenteral Formulations Stability Testing Hot Melt Extrusion Bioavailability Optimisation Solubility Measurement Solid & Oral Dosage Forms Drug Delivery Platforms Preformulation Testing Oral & Inhaled Products

For booking details & registration fees please refer to the last page or visit: http://www.formulation-congress.com/marketing

#### 2016 Formulation & Drug Delivery Congress Confirmed Speakers:

- Menashe Levy, VP Chief Technology Officer, Global R&D, Teva Pharmaceutical Industries
- Matthew James Clemente, Chief Technology Officer, Connected Product Systems Engineering, Eli Lilly and Company
- Joël Richard, Senior Vice President, Peptides Development, Ipsen
- Justin M. Wright, VP Drug Delivery Innovation, Eli Lilly and Company
- Anand Subramony, Vice President, MedImmune
- Allen C. Templeton, Associate Vice President, Formulation Sciences, Merck & Co., Inc (MSD)
- Advait Badkar, Senior Director, Pfizer Inc
- Vijay H. Naringrekar, Director, Biologics Drug Products Development, Celgene Corporation
- Anthony Leone, Director Preformulation, Merck-MSD
- Ahmad Sheikh, Director Solid State Chemistry, AbbVie Inc
- Carol Thomson, Dose Form Quality Director, GlaxoSmithKline
- Nausheen Rahman, Director, Sanofi Pasteur
- Andy Lewis, Director, Novel Drug Delivery Technologies, Ipsen
- Marian Gindy, Director, Sterile Formulation Sciences Preclinical Development, Merck Sharp and Dohme (MSD)
- Christoph Saal, Director Analytics, Merck KGaA
- David Elder, Director, Product Development, GlaxoSmithKline
- Martinus Capelle, Associate Scientific Director, Janssen
- Brian Lobo, Associate Director and Group Leader, MedImmune
- Patrick Garidel, Head of Protein Science, Boehringer Ingelheim
- Cédric Yernaux, Head, Drug Product Belgium, GlaxoSmithKline
- Herbert Wachtel, Senior Principal Scientist, Boehringer Ingelheim Pharma GmbH & Co. KG
- Boris Shekunov, Senior Principal Scientist, Shire Pharmaceuticals
- Karsten Petersson, Senior Manager, Explorative Formulation & Technologies, LEO Pharma
- Carsten Worsøe, Principal Scientist, Novo Nordisk A/S
- Robert Kelley, Principal Scientist, Genentech
- Michael Keller, Senior Fellow, Novartis Pharma AG
- Vijay Sethuraman, Fellow, Novartis Pharmaceuticals
- Frank Bamberg, Senior Group Leader Pre-Fillable Syringe, F. Hoffmann La Roche
- Clare Rawlinson Malone, Senior Research Investigator II, Bristol-Myers Squibb
- Stephen T. Buckley, Head of Department, Novo Nordisk
- Avinash Nangia, Vice President, R&D, Lupin Pharmaceuticals, Inc.
- Ijeoma Uchegbu, Professor in Pharmaceutical Nanoscience, University College London
- Kamalinder Singh, Professor of Pharmaceutical Technology and Drug Delivery, University of Central Lancashire
- David Needham, Bohr Visiting Professor, University of Southern Denmark, Odense Denmark and Professor, Duke University, Durham, NC, USA

#### 2016 Co-located Inhalation & Respiratory Drug Delivery Congress Confirmed Speakers:

- Peter Daley-Yates, Director, Clinical Pharmacology, GlaxoSmithKline
- Louise Sheridan, Head of Global Devices, Global Technical Services, AstraZeneca
- Frank Thielmann, Lead New Inhalation Solids, Novartis Pharma
- Holger Memmesheimer, Head of Quality Unit Chemical Production, Boehringer Ingelheim Pharma GmbH&KO.KG
- Andy West, Head Ex vivo Bioimaging UK, GSK
- Jan Olof Svensson, Principal Scientist Inhalation, AstraZeneca
- Mike Tobyn, Research Fellow, Bristol-Myers Squibb
- Yuji Kasuya, Senior Scientist, Kitasato Daiichi Sankyo Vaccine Co., Ltd.
- John Patton, CEO, Dance Biopharma
- Claudia Vincenzi, Director, Respiratory Regulatory CMC, Mylan Global Respiratory Group
- Beverley Patterson, Associate Director, Inhalation Clinical, Actavis
- Robert Price, Professor of Pharmaceutics, University of Bath
- Ben Forbes, Professor, King's College London
- Janis Shute, Professor of Respiratory Pharmacology, University of Portsmouth and Scientific Director, Ockham Biotech
- Joy Conway, Professor of Respiratory Sciences and Lung Imaging, Southampton University
- Jonathan Reid, Professor of Physical Chemistry, University of Bristol
- Per Gerde, Associate Professor, Inhalation Toxicology, Karolinska Institutet

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Formulation & Drug Delivery and Inhalation & Respiratory Drug Delivery Confirmed Sponsors 2016:



## 2<sup>nd</sup> Annual Formulation & Drug Delivery Congress Day One – 18<sup>th</sup> May 2016

07.30 - 08.20	Registration	
08.20 - 08.25	Oxford Global's Welcome Address	
08.25 - 08.30	Chairperson's Opening Address: Russell Burge, Application Scientist, Unchained Labs.	
08.30 - 09.00	Co-located Keynote Address:	
	Developing Drug Delivery Devices For Large Molec	ules
	Matthew James Clemente, Chief Technology Officer, Connected Product Systems Engineering, Eli Lilly and Company	
	Large Molecule Drugs Formulation	Small Molecule Drug Delivery
	Stream Chair: Russell Burge, Applications	Stream Chair: Mathieu Colomb-Delsuc, Senior
	Scientist, Unchained Labs.	Scientist, Vironova
09.00 - 09.30	Stream Keynote Address:	Stream Keynote Address:
	Addressing Challenges With Peptide Formulation	Mouth-Throat Models And Their Role In The
	Development	Evaluation Of Inhaler Performance
	Peptide formulation development offers several unique	<ul> <li>From CT data to the bench model</li> </ul>
	challenges relative to other product types	Flow profiles matter
	Developing commercially favourable peptide products	Case studies
	requires balancing molecule stability and solubility characteristics	
	<ul> <li>The interplay between peptide formulation</li> </ul>	
	composition, chemical and physical stability must be	
	optimized	
	Allen C. Templeton, Associate Vice President, Formulation Sciences, Merck & Co., Inc (MSD)	Herbert Wachtel, Senior Principal Scientist, Boehringer Ingelheim Pharma GmbH & Co. KG

09.30 – 10.00	Automated Buffer Exchange: Can An Automated System Provide Comparable Results? Buffer prep, buffer exchange and protein concentration can take 2-4 days of a scientist's time and it's all manual. Not anymore! Now there is a way better process that will give you the same results. The GRUNT totally automates protein formulation prep in a single, easy-to-use system. With just a 20 minute setup, the GRUNT prepares up to 12 protein formulations, at a volume of 0.5–8mL with protein concentrations up to 200 mg/mL. In this presentation, we will provide an overview of the GRUNT and compare the system's novel micro UF/DF process to current techniques.	<ul> <li>Fast And Efficient Characterization Of Drug Carriers By Electron Microscopy</li> <li>The focus of the presentation will be analysis of drug carriers by Cryo transmission electron microscopy</li> <li>A particular emphasis will be made on liposomal drug carrier and viral vectors</li> <li>A full description of the analysis process and image data treatment will be exposed</li> </ul>
	Russell Burge, Applications Scientist, Unchained Labs.	Mathieu Colomb-Delsuc, Senior Scientist, Vironova
	freeslate <sup>®</sup>	<b>Vironova</b>
10.00 - 11.20	LABS Morning Coffee & Refreshments: Poster Presentati	on Sessions: One to One Meetings x3
11.20 – 11.50	<ul> <li>Using Patient Insights When Developing New Pharmaceutical Products <ul> <li>Insight Driven Innovation drives patent friendly solutions</li> <li>The use of Patient Panels and User Studies</li> <li>Holistic product portfolio to serve all patents needs</li> <li>Examples with be given in the area of topical treatment</li> </ul> </li> </ul>	<ul> <li>Impact Of Preclinical Formulation On Clinical And Early Phase Drug Development</li> <li>What is preclinical formulation</li> <li>The three key elements required for development of an IND</li> <li>How early profiling can influence later stage formulation decisions</li> </ul>
	Karsten Petersson, Senior Manager, Explorative Formulation & Technologies, LEO Pharma	Vijay Sethuraman, Fellow, Novartis Pharmaceuticals
11.50 – 12.20	<ul> <li>Mechanistic Understanding Of Peptide</li> <li>Fibrilization To Enable Commercialization Of An</li> <li>Injectable Peptide</li> <li>Tools to characterize Fibrilization and experimental considerations</li> <li>Key pharmaceutical factors that influence fibrilization kinetics</li> </ul>	<ul> <li>Interactions Between Drug Products And Prefilled Syringes Container Closure Systems</li> <li>Description of critical components in prefilled syringes with potential drug product interaction potential</li> <li>What is the optimal tool/study to predict leachables and drug product interactions in a prefilled syringe?</li> <li>How to perform a simulated study for a prefilled syringe</li> <li>Case studies on simulated studies in prefilled syringes</li> </ul>
	Anthony Leone, Director Preformulation, Merck- MSD	Carsten Worsøe, Principal Scientist, Novo Nordisk A/S
12.20 – 12.50	Solution Provider Presentation For sponsorship opportunities please contact <u>sponsorship@oxfordglobal.co.uk</u>	<ul> <li>Bioavailability, Release Controlled And Taste Masking New Solutions For Pharmaceutical And Nutraceutical Applications</li> <li>Patented blends of surfactants</li> <li>Prilling, Hot Melt Coating, Spray Drying technologies</li> <li>Accurate release of actives</li> <li>Versatile technologies for actives (hydrophobic or hydrophilic ingredients) that are powered</li> <li>Perfect technologies for new galenic forms (stick packs, candies, pediatric forms)</li> <li>Mathilde André, Market Manager, Seppic</li> </ul>
		SEPPIC

12.50 - 13.50	Lunch	
13.50 - 14.20	Biologics Formulation Development – Balancing Risk And Speed Across The Development Phases Due to the unique differences between a biologic and conventional small molecule drug, formulation and process development of Biologics presents interesting challenges particularly as they relate to balancing the speed to clinic and market with risk to the product and patients. In contrast to the routine practice in small molecule development, Proteins are not isolated as a solid powder, but are made available as a solution at certain protein concentration. This blurs the demarcation of a drug substance vs. a drug product and, at least some parameters of the formulation composition (buffer type, pH and protein concentration) need to be defined very early in the development process. With limited information about desired target product profile during early clinical development, it is challenging to provide reliable input for these parameters, particularly the protein concentration without limiting future pharmaceutical development options. During clinical development, the desire is to develop a formulation which allows delivering a wide range of doses to support dose ranging studies before finalizing phase III and commercial dose/s. And fixing protein concentration early in the drug substance process development may make commercial development challenging as major changes in the formulation composition during clinical development are undesirable. Therefore, development of a formulation for first in human studies with eye on the ball for commercial requirement is necessary but challenging. CMC development cost for biologics is significantly high compared to a conventional small molecule. At the same time there is time pressure to get into clinical studies as soon as possible. Some general strategies to manage these conflicting priorities of resources and speed will be discussed in this presentation.	<ul> <li>Exploring Innovative Delivery Approaches For Parenteral And Topical Drug Delivery</li> <li>The importance of understanding the manufacturing process – structure/activity relationship of siRNA lipoplexes</li> <li>Exploring nanomedicinal approaches to deliver small molecules to the skin</li> <li>Transdermal approaches for the delivery of peptides &amp; proteins</li> </ul>
	Vijay H. Naringrekar, Director, Biologics Drug Products Development, Celgene Corporation	Michael Keller, Senior Fellow, Novartis Pharma AG
14.20 – 14.50	Formulation Development For Early And Lae- Stage Development Of Monoclonal Antibodies, Peptides And Novel Molecules	<ul> <li>NanoPharmaceuticals: Overcoming Drug Delivery Challenges</li> <li>Understanding biological barriers to drug delivery</li> <li>Penetration of nanoparticles across tissue and cell barriers</li> <li>Presentation of case studies</li> </ul>
	Brian Lobo, Associate Director and Team Leader, MedImmune	Kamalinder Singh, Professor of Pharmaceutical Technology and Drug Delivery, University of Central Lancashire
14.50 – 15.20	Solution Provider Presentation	Solution Provider Presentation
	For sponsorship opportunities please contact <u>sponsorship@oxfordglobal.co.uk</u>	The new name for Molecular Profiles -
15.20 - 16.20	Afternoon Refreshments: Poster Presentation Sess	sions: One to One Meetings x2

For more information please contact marketing@oxfordglobal.co.uk

16.20 - 16.50 16.50 - 17.20	Overcoming Large Molecule Formulation Challenges Cédric Yernaux, Head, Drug Product Belgium, GlaxoSmithKline Exploiting Nanotechnology To Create New Medici	<ul> <li>Endogenous-Inspired Hydrophobic Drug Delivery To Cancers: LDL-like Nano Particles Designed To "Put The Drug In The Cancer's Food"</li> <li>Reverse-engineer the LDL as inspiration for nano- particle anti-cancer drug delivery especially for metastatic disease.</li> <li>New method for making nanoparticles by rapid solvent injection</li> <li>Evaluation of cell cytotoxicity of formulated drug nanoparticles</li> <li>Use of micropipet technique to explore and inform nanoscale design</li> <li>David Needham, Bohr Visiting Professor, University of Southern Denmark, Odense Denmark and Professor, Duke University, Durham, NC, USA</li> </ul>
	<ul> <li>The design and synthesis of nanoparticle forming compounds</li> <li>The fabrication of nano medicines</li> <li>Creating differentiated medicinal products from nanomedicines</li> <li>Ijeoma Uchegbu, Professor in Pharmaceutical Nanoscience, University College London</li> </ul>	
17.20 – 17.50	Vaccine Formulation Development         • Generic physical and chemical screening technologies to support formulation development         • Overview of nano (micro) particulate technologies for vaccines         • Early manufacturability assessments to de-risk development         • Case study: thermostable adenovirus vaccines         Martinus Capelle, Associate Scientific Director, Janssen	
15.50 - 18.20	Delegates are welcome to attend the co-located presentation	
18.20	Networking Drinks End of Day One	

# 2<sup>nd</sup> Annual Formulation & Drug Delivery Congress Day Two – 19<sup>th</sup> May 2016

	Conference Room: Stream Chair:	
08.30 – 09.00	<ul> <li>Keynote Address: Harnessing Novel Enabling Technologies For New Therapeutic Entities – NTE</li> <li>NTEs, are existing approved drugs that are either reformulated or repurposed to fill major patients unmet needs</li> <li>Teva has industrialized the process of developing NTEs by establish a global and harmonized systematic approach f seeking and evaluation of new enabling technologies</li> <li>Menashe Levy, VP Chief Technology Officer, Global R&amp;D, Teva Pharmaceutical Industries</li> </ul>	
	Small Molecule Drugs Formulation	Large Molecule Drug Delivery
	Stream Chair:	Stream Chair:
09.00 – 09.30	<ul> <li>Stream Keynote Address:</li> <li>Oral Suspensions: Solubility, Stability</li> <li>Why suspensions?</li> <li>What are the stability challenges? <ul> <li>chemical, physical, orientation and microbiological</li> <li>In-use stability</li> </ul> </li> <li>Leachables/extractables <ul> <li>Definitions</li> <li>Testing requirements</li> <li>Limits</li> </ul> </li> <li>Shelf-life considerations</li> <li>Conclusions</li> </ul>	<ul> <li>Stream Keynote Address:</li> <li>Designing Novel Drug Delivery Solutions For Biologics <ul> <li>Overcoming systemic tox</li> <li>Targeted delivery</li> <li>Sustained release</li> <li>Oral delivery of macromolecules</li> </ul> </li> </ul>
	David Elder, Director, Product Development, GlaxoSmithKline	Anand Subramony, Vice President, MedImmune

09.30 - 10.00	Solution Provider Presentation	Novel Biodegradable Polymeric Drug Delivery
	Catalent.	<ul> <li>System For Protein Therapeutics</li> <li>Challenges in development of sustained release formulations of protein therapeutics</li> <li>SynBiosys Pro – a hydrophilic biodegradable polymer platform for delivery of peptides, proteins and monoclonal antibodies and its advantages over poly(DL-lactide-glycolide) copolymers with respect to release kinetics and preservation of protein bioactivity</li> <li>Membrane emulsification for development of well injectable and highly concentrated microparticle suspensions</li> <li>Case studies: development of injectable sustained release formulations for various systemic and site-specific diseases</li> <li>Rob Steendam, Chief Technology Officer, InnoCore Pharmaceuticals</li> </ul>
10.00 - 11.00	Morning Coffee & Refreshments: Poster Presentati	
11.00 – 11.30	<ul> <li>Novel Delivery Systems For Small Molecules</li> <li>"Microsieve Technology" for designing microspheres and nanoparticles</li> <li>Advantages over conventional technologies</li> <li>Case studies involving small molecules and macromolecules</li> <li>Repurposing technology for creating differentiated pharmaceutical products</li> </ul>	<ul> <li>Anticipating Aggregation Propensity Of Proteins At Early Formulation Development Stage: How To Support A Data-Based Approach For Immunogenicity Risk Assessment</li> <li>Stability challenges of protein formulations - What are aggregates and their attributes? Why do we care about aggregates?</li> <li>Anticipating Protein Aggregation Propensity: biophysical methods to detect Higher Order Structure (HOS) alterations and to monitor loss of colloidal stability</li> <li>Combining analytical methods for definition of the Formulation Design Space</li> <li>Identification and characterization of aggregates and particulates in a risk-based approach for immunogenicity</li> <li>Case Studies: Combination of Biophysical Methods in Formulation Development for high concentration liquid formulations of proteins (growth factors, fusion proteins, mAbs,)</li> </ul>
	Avinash Nangia, Vice President, R&D, Lupin Pharmaceuticals, Inc.	Joël Richard, Senior Vice President, Peptides Development, Ipsen
11.30 – 12.00	Scientific Strategies To Develop Poorly Soluble Small Molecules <ul> <li>Use of Drug Substance data and modelling to predict the path forward</li> <li>Screening approaches for lipid formulations</li> <li>Screening approaches for amorphous dispersions</li> </ul> Jon Sutch, Senior Manager, Formulation Development, Patheon UK CPatheon UK	Solution Provider Presentation For sponsorship opportunities please contact <u>sponsorship@oxfordglobal.co.uk</u>
	A HEALTHIER WORLD. DELIVERED.	

12.00 – 12.30	<ul> <li>Challenges And Opportunities In Drug Delivery For Biologics</li> <li>This talk will be focused on emerging trends in the industry and a changing perspective of the term "drug delivery".</li> <li>Product differentiation is going to play a very important role for success within the BioPharma industry</li> <li>The traditional connotation of term "drug delivery" is evolving from a life-cycle management exercise to more of a product enabling paradigm</li> <li>Efficacy, safety and affordability are "non-negotiable" elements in the drug delivery paradigm and will not be compromised for a superior delivery experience</li> </ul>	Updates In Parenteral Delivery Systems & Technology
	Advait Badkar, Senior Director, Pfizer Inc	Justin M. Wright, VP Drug Delivery Innovation, Eli Lilly and Company
12.30 - 13.30	Lunch	
13.30 – 14.00	<ul> <li>Selection Of Solid State Forms And Formulation Development – Aspects And Integral Approaches</li> <li>Solid-State Selection – Being fit for the purpose of formulation development</li> <li>Improving formulation development by using the most appropriate solid-state form for this formulation</li> <li>Using optimized solid-state selection for fast formulation development for early clinical trials</li> </ul>	Challenges And Opportunities Presented By New Technologies In Secondary Production Continuous processing as an example: Advantages over batch processes Drawbacks Opportunities around process control Challenges: Regulatory Quality Organisation
	Christoph Saal, Director – Analytics, Merck KGaA	Carol Thomson, Dose Form Quality Director, GlaxoSmithKline
14.00 – 14.30	<ul> <li>Analysis Of Drug Dissolution</li> <li>Intrinsic dissolution rate of ionazable molecules</li> <li>Dissolution in biorelevant media</li> <li>Relationship between pharmacopeial QC methods</li> <li>Prediction of dissolution profile for different dosage forms</li> </ul>	<ul> <li>Structure-Based Drug Delivery Design For Biopharmaceuticals And Vaccines</li> <li>Macromolecule drugs, such as peptides, proteins and oligonucleotides, often act on intracellular targets that impose additional barriers to efficient drug delivery relative to small molecules</li> <li>Interdisciplinary research in cell biology, materials science, and engineering has the potential to advance new drug delivery technologies specific to macromolecule drugs</li> <li>Research high lighting structure-based drug delivery design for the development of sub-unit vaccines, oligonucleotide drugs, and immunotherapeutics will be shared</li> </ul>
	Boris Shekunov, Senior Principal Scientist, Shire Pharmaceuticals	Marian Gindy, Director, Sterile Formulation Sciences - Preclinical Development, Merck Sharp and Dohme (MSD)
14.30 – 15.00	<ul> <li>Integrated Solid Form Development – A</li> <li>"Managed Risk" Based Approach</li> <li>From thermodynamically stable form to most developable solid form</li> <li>Integration of solid form development with DS isolation process development and DP process development</li> <li>Risk assessment and risk management framework/strategies</li> </ul>	Oral Protein And Peptide Drug Delivery
45.00 45.20	Ahmad Sheikh, Director Solid State Chemistry, AbbVie Inc	Andy Lewis, Director, Novel Drug Delivery Technologies, Ipsen
<u>15.00 – 15.30</u> 15.30 – 16.00	<ul> <li>Afternoon Refreshments: Poster Presentation Sess</li> <li>Current Challenges And Opportunities For</li> <li>Formulation QbD In Vaccines</li> <li>Internal guidelines and organizational structure to support QbD for projects</li> <li>Case study for one of our projects</li> <li>Challenges in vaccines to overcome for QbD work</li> </ul>	Sions         Protein Stabilisation As An Inter- And Multi- Disciplinary Task: From In Silico Modelling To Protein Science         • Current status and applications of in silico tools to predict protein stability         • Consideration of predictive tools as an integrative development strategy         • Presentation of case studies
	Nausheen Rahman, Director, Sanofi Pasteur	Patrick Garidel, Head of Protein Science, Boehringer Ingelheim

16.00 - 16.30	<ul> <li>Understanding Potentially Rate Controlling Mechanisms Of Dissolution For Amorphous Polymer Stabilised Drug Dispersions</li> <li>Selection and development of enabling formulations</li> <li>Novel methods for understanding and categorising product performance</li> <li>Chemical and physical properties affecting dissolution and product development</li> </ul>	<ul> <li>Latest Device Technologies For Drug Delivery</li> <li>And Technical Development Challenges</li> <li>When and How you define the right device for your biotech drugs:         <ul> <li>A rough device development timeline for a known disposable injection system would be 3-5 years. Depends on the patient population, home use or hospital use and also heavily linked to market/competitor research and on the sensitivity of the molecule</li> </ul> </li> <li>Case Studies and issue management:         <ul> <li>Evaluation of primary packaging Supplier: Who is your right supplier and how do you define and challenge this partnership</li> <li>Drug interaction with primary packaging and solutions</li> </ul> </li> </ul>
	Clare Rawlinson Malone, Senior Research Investigator II, Bristol-Myers Squibb	Frank Bamberg, Senior Group Leader Pre-Fillable Syringe, F. Hoffmann - La Roche
16.30 – 17.00	<ul> <li>Delivery Of Protein Therapeutics To The Back Of The Eye For Treatment Of Ophthalmic Disease</li> <li>Considerations for delivery to the eye:</li> <li>Volume and excipient limitations</li> <li>Compatibility of formulation with ocular tissue</li> <li>Stability to vitreous humor conditions of therapeutics intended to have long duration</li> <li>Robert Kelley, Principal Scientist, Genentech</li> </ul>	
17.00 – 17.30	Strategies For The Oral Delivery Of Macromolecules: An Industrial Perspective         • Formulation technologies         • Device-based approaches         • Considerations from an industry perspective         Stephen T. Buckley, Head of Department, Novo Nordisk	
17.30	End of Conference	

# 2nd Annual Formulation & Drug Delivery Congress 2016

Conference: 18-19 May 2016, Kensington Close Hotel, London, UK

www.formulation-congress.com

HOW TO REGISTER:

FAX your booking form to +44(0)1865 250985 | PHONE on +44(0)1865 248455 | EMAIL: marketing@oxfordglobal.co.uk

Delegate Details	Registration Fees
Please complete fully and clearly. Please photocopy for additional	I would like to attend: (Please tick as appropriate)
delegates Title:Forename:Surname: Job Title: Company/Organisation:	Industry Delegates (Biopharma, Pharma or Biotech         Companies)         □ Congress       £799       plus VAT         1 day pass       £499       plus VAT         □ Day 1       □       Day 2
Email: Address:	Academic Delegates         Congress       £499 plus VAT         1 day pass       £299 plus VAT         Day 1         Day 2
Postcode: Country: Direct Telephone Direct Fax: Mobile: Switchboard: Signature: Date:	Vendor Delegates         (CROs, Consultants, Technology and Service Providers)         Congress Only       £1350 plus VAT         1 day pass       £799 plus VAT         Day 1         Day 2         Poster Presentation       £250 plus VAT         PROMOTIONAL LITERATURE DISTRIBUTION         Distribution of your company's promotional literature to all
Terms & Conditions of Booking	conference attendees     £999 plus VAT       Documentation
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Delegate Booking Fee The Delegate Booking Fee includes: lunches and refreshments throughout the Congress event, conference presentations, workshop and panel sessions, scheduled one-to-one meetings and networking/social events, conference and speaker notes. Delegates may attend, free of charge, all sessions arranged by the Organiser. An admin surcharge of £50 + VAT will be applied to payments settled following the receipt of an invoice. This charge will not be applied to pay- ments settled online. Vendor Delegates will not be eligible for one to one meetings unless they purchase a sponsorship meetings package. These can only be purchased directly from Oxford Global Marketing Ltd and not via the online booking facility.	VAT is charged at 20% on the attendance fees for all delegates. VAT is also charged on online and paper copy documentation and promotional literature distribution for all UK customers and for those EU customers not supplying a registration number for their own country here. How to Pay (choose one of the following payment options)
<b>Poster Presentations</b> Those who have booked a poster presentation at the event must provide the poster title, abstract (200 words or less), principal author, organisation, mailing address, email, telephone, fax and additional authors, within a month of registration. All poster spaces will be for A0 (841mm x 1189mm) portrait size.	Number of delegates:         Industry del(s)       Academic dels(s)         Special Offer: 3 for 2         Offer is only valid on the congress and for those registering at Industry or Academic rates
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The data controller is the Organiser. The Organiser may disclose such personal information to Registered Event Sellers (Solution Providers) and other Delegates but solely for the purposes of the Event. The Delegate consents to the use of his/ her personal and company information on the terms set out herein.	Valid from:
Miscellaneous This Agreement may not be transferred or assigned by either the Delegate or the Delegate's Company. The Organiser will determine the scope and content of Congress conference events, seminars, workshops and activities throughout the Event. The Organiser reserves the right to cancel the Event without liability to Delegate's Company or individual Delegate. If for any reason the Organiser has to cancel or postpone this Event, the Organiser reserves the right to transfer this Booking to another Congress within the same sector to be held within twelve months. Should another Congress in the same sector not be available within this period, the Booking Fee will be refunded.	Security code:   Cardholders name:  Signature: Date:  PLEASE INVOICE ME: Invoice Address (if different from above)
☐ I agree to the above Terms and Conditions	*Please note there is a £50 plus VAT handling charge for payment via invoice *All card payments will be subject to a 3% bank charge or 4% AMEX charge

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If you have any further queries please call the marketing team on +44(0)1865 248455 or email marketing@oxfordglobal.co.uk