SESSIONS

DAY 1 - PEPTIDE DRUG DEVELOPMENT STRATEGIES - 14/11/2016

Registration

08:20 - 08:50
Main agenda

Chairperson's Opening Remarks

08:50 - 09:00
Main agenda

Thought Leaders Strategic Discussion Panel: Next Generation Peptide Discovery: Where is the Industry Going?

09:00 - 09:40
Main agenda

- Next generation peptide discovery: Where is the field going?
- Identifying drug able structures and modalities which make them therapeutically useful
- Evaluating how peptide developments fit in with other modalities developing in the biopharmaceutical and small molecule industry
- Overview of the expansions of peptides in:
  - Peptide vaccine market
  - New therapeutic areas beyond metabolic diseases e.g. immunology
  - Intracellular peptides
  - Conjugated peptides – small molecule and biopharmaceutical conjugates
  - Using peptide drug discovery platforms in new ways
  - Peptides as accessory vehicles
- Investor perspective: Trends in peptide investment and commercial attractiveness of peptides

Participants

Jesse Dong, Neon Therapeutics, USA

Bruce Morimoto, Celerion, USA

Waleed Danho, Danho Associates Inc, USA

From Peptide to Patient: How to Steer the Development of Peptide-Based Medicines and Turn Challenges into Success

09:40 - 10:20
Main agenda

The modification of endogenous peptides to turn them into medicines is both a simple and a complex task. While the synthetic steps involved in making new peptide analog are simple, multidisciplinary contributions are required to identify the best sequence motifs for the desired target product profile. The talk will present examples from Zealand Pharma peptide projects.

Participants

Marie Skovgaard, Zealand Pharma, Denmark

Morning Coffee

10:20 - 11:00
Main agenda

Strategies for the Development of Peptide Vaccines

11:00 - 11:40
Main agenda

- Focus on peptide epitopes enabling precise directionality of immune response
- Identification of protective epitopes from available structural information to uncover protective neutralising regions essential for the viral life cycle.
- Stabilization of conformational epitopes to mimic viral protein antigens
- Strategies to enhance immunogenicity with particular emphasis on Toll-like receptor signalling, on conjugations to carriers and on safety considerations for the development of injectables

Participants

Elisabetta Bianchi, IRBM Science Park S.p.A. Italy

Development Strategies of Neoantigen-Based Personalised Cancer Vaccines

11:40 - 12:20
Main agenda

Neoantigens arise as a result of somatic mutations during the development and progression of tumours. They are inherently non-self and are seen as foreign by the immune system. Mounting evidence suggests that immune rejection of tumours, for example which is seen with checkpoint inhibitors, may be mediated by recognition of neoantigens. Neon's personalised cancer vaccine targets neoantigens unlocking the immune system to attack tumours.

Participants

Jesse Dong, Neon Therapeutics, USA

Novel Peptidomimetic Antibiotics Targeting Gram-Negative Bacteria

12:20 - 13:00
Main agenda

Naturally occurring host-defence peptides with folded hairpin structures provide an excellent starting point for the design of peptidomimetics with novel mechanisms of antimicrobial action against pathogenic Gram-negative bacteria. Of particular interest are hairpin-shaped macrocyclic peptidomimetic antibiotics that target essential ß-barrel proteins on the bacterial outer membrane. For example, the peptidomimetic murepavidin (POL7080) is currently being tested in phase-II clinical trials in VAP patients, and holds great promise for the treatment of life-threatening Pseudomonas infections.

Participants

John Robinson, University of Zurich, Switzerland.

Lunch and Networking Time

13:00 - 14:00
Main agenda

Amino Acid and Peptide Conjugated Bioactive Compounds

14:00 - 14:40
Main agenda

Peptide or amino acid conjugated enzyme inhibitors and antioxidants have been developed for improving their biological activity, increasing resistance to degradation, and reducing cytotoxicity and side effects. We confirm that peptide or amino acid conjugation is a powerful tool to modulate or stabilise the activities of bioactive compounds and provide a new avenue in developing pharmaceutical and cosmeceutical agents.

Participants

Yoon-Sik Lee, Seoul National University, Korea

Spotlight Presentation

14:40 - 15:20
Main agenda

This slot is reserved for technology and service providers; please contact perri.lucatello@informa.com for more info.

Afternoon Coffee and Networking Time

15:20 - 15:50
Main agenda

Smart Fusions of Cytotoxic Peptides and Cligonucleotide Analogues

15:50 - 16:30
Main agenda

Participants

Oliver Seitz, Humboldt-Universität zu Berlin, Germany

SESSIONS

DAY 1 - PEPTIDE DRUG DEVELOPMENT STRATEGIES - 14/11/2016

Strategic Discussion Panel: Evaluating Alternative Approaches to PEGylation for Extending the Half Life and Stability of Peptide Products

16:30 - 17:30
Main agenda

- Comparison of alternative approaches to PEGylation for extending the half-life and maintaining the in vivo potency of peptides
- Modification of peptides to improve target selectivity
- Technologies to chemically modify peptide
- How to approaches impact bio distribution and half-life?
- Preclinical developments: How are novel half-life extension techniques scaling up
- Case study on application and development on use of approach in peptide therapeutics

Participants

Waleed Danho, Danho Associates Inc, USA

Chairperson's Closing Remarks and End of Day One

17:30 - 17:30
Main agenda

SCHEDULE

DAY 1 - PEPTIDE DRUG DEVELOPMENT STRATEGIES - 14/11/2016

TIME	MAIN AGENDA
08:00	**08:20** - Registration **08:50** - Chairperson's Opening Remarks
09:00	**09:00** - Thought Leaders Strategic Discussion Panel: Next Generation Peptide Discovery: Where is the Industry Going? **09:40** - From Peptide to Patient: How to Steer the Development of Peptide-Based Medicines and Turn Challenges into Success
10:00	**10:20** - Morning Coffee
11:00	**11:00** - Strategies for the Development of Peptide Vaccines **11:40** - Development Strategies of Neoantigen-Based Personalised Cancer Vaccines
12:00	**12:20** - Novel Peptidomimetic Antibiotics Targeting Gram-Negative Bacteria
13:00	**13:00** - Lunch and Networking Time
14:00	**14:00** - Amino Acid and Peptide Conjugated Bioactive Compounds **14:40** - Spotlight Presentation
15:00	**15:20** - Afternoon Coffee and Networking Time **15:50** - Smart Fusions of Cytotoxic Peptides and Cligonucleotide Analogues
16:00	**16:30** - Strategic Discussion Panel: Evaluating Alternative Approaches to PEGylation for Extending the Half Life and Stability of Peptide Products
17:00	**17:30** - Chairperson's Closing Remarks and End of Day One

SESSIONS

DAY 2 - CLINICAL DEVELOPMENT & DELIVERY STRATEGIES - 15/11/2016

Registration and Morning Coffee

08:00 - 08:50
Main agenda

Chairperson's Opening Remarks

08:50 - 09:00
Main agenda

Participants

Waleed Danho, Danho Associates Inc, USA

Oral Peptide Delivery Products: Learnings from Clinical Advances and Future Challenges

09:00 - 09:40
Main agenda

Large molecules like peptides are administered chronically through the parenteral route, sometimes for long periods of treatment. For this reason, there is a real interest in developing and bringing to the market formulations that can be administered through a non-invasive route, like the oral route. As peptides generally show a very low ability to cross the membranes, one of the main challenges is the development of new technologies that improve permeability of these molecules across the epithelial membranes. The purpose of this talk is to review and discuss the key oral peptide delivery technologies significantly progressing in the Clinic, as well as the key challenges related to the very low oral bioavailability and the safety/efficacy profile.

Participants

Joël Richard, Ipsen, France

Controlled Release Delivery of Peptides

09:40 - 10:20
Main agenda

Participants

Mike De Leeuw, InGell Labs BV, The Netherlands

Morning Coffee and Networking

10:20 - 11:00
Main agenda

Cellular Uptake of Two p53/MDM2 Stapled Peptide Inhibitor Variants

11:00 - 11:40
Main agenda

Olefin metathesis has been shown to enhance intracellular uptake for a-helices interrupting the p53/MDM2 interaction (Brown (2013), Chang (2013)). The shorter version (Brown (2013)) and a longer variant (Chang (2013)) of these stapled peptides were prepared to compare activity in biochemical and cellular assays. In addition, co-localization experiments of the corresponding FAM-labeled stapled variants with induced down-stream targets are presented.

Participants

Thomas Vorherr , Novartis Institutes for BioMedical Research, Switzerland

Functional Penetrating Phylomers (FPPs) for More Efficient Delivery of Biologics In Vivo

11:40 - 12:20
Main agenda

Structure-rich Phylomer peptide libraries1 derived from from biodiverse genomes were screened for new cell penetrating peptides (CPPs) for more efficient delivery of macromolecules into cells. A novel genetic screen known as the 'endosome escape trap' was employed to isolate rare CPP's which deliver 60nM phage nanoparticle cargoes to the cytoplasm. These new cell penetrating Phylomers known as 'FPPs' show no evidence of toxicity and can be targeted to particular cell types using receptor binding domains. A variety of functional assays were used to determine the extent of delivery of peptide and protein cargoes to the cytoplasm or nucleus. One such assay based on split GFP complementation has shown Phylomer FPPs to be 37-160 times more efficient at cytoplasmic delivery than conventional CPPs such as TAT or R9. Phylomer FPPs have also been shown to effectively deliver a 90 amino acid MYC inhibitor in a mouse model of breast cancer. This new delivery approach is being applied in Phylomer peptide screens targeting transcription factor oncoproteins such as cMyc, MycN and STAT5, for more efficient cell targeted intracellular delivery of protein conjugates of more than 50 kDa in size and also for delivery of nucleic acids.

Participants

Paul Watt, Phylogica Ltd, Australia

Spotlight Presentation

12:20 - 12:50
Main agenda

This slot is reserved for technology and service providers; please contact perri.lucatello@informa.com for more info.

Lunch and Networking Time

12:50 - 14:20
Main agenda

The Molecular Basis for the Prolonged Blood Circulation of Lipidated Incretin Peptides: An In-Vitro Study of their Oligomerization and Interaction with Serum Albumin

14:20 - 15:00
Main agenda

We have studied the oligomerisation and albumin-binding of an unconjugated and a lipidated incretin peptide. Above 1mg/ml, peptides form stable oligomers. This concentration range is relevant to formulation and storage of the peptides. At the expected therapeutic concentration range (~10-100 ng/mL), the oligomers dissociate into monomers and binds to albumin. Our findings suggest that only monomers are present in vivo and the lipidated peptides bind to HSA mainly by the fatty acid chain.

Participants

Sonoko Kanai, F. Hoffmann-La Roche Ltd, Switzerland

Translating Macrocyclic and Constrained Peptide Therapeutics into the Clinic

15:00 - 15:40
Main agenda

The presentation will cover two case studies which both resulted in clinical stage programs for diseases with a great unmet medical need: POL6014, a highly potent and selective macrocyclic inhibitor of human neutrophil elastase (HNE) POL6014, administered by aerosol inhalation, is currently in Phase I clinical, development with focus on Cystic Fibrosis and other rare lung diseases. Polyphor's macrocycle pipeline also includes a novel breakthrough antibiotics against Gram-negative bacteria, including a pre-clinical, broad spectrum program as well as the Phase II compound POL7080 for the highly-selective treatment of serious infections caused by Pseudomonas aeruginosa.

Participants

Steffen Weinbrenner, Polyphor Ltd, Switzerland

Afternoon Coffee and Networking Time

15:40 - 16:10
Main agenda

Feedback from Bicycle Therapeutics: Translating Macrocyclic and Constrained Peptide Therapeutics into the Clinic

16:10 - 16:50
Main agenda

Participants

Christophe Bonny, Bicycle Therapeutics, UK

SESSIONS

DAY 2 - CLINICAL DEVELOPMENT & DELIVERY STRATEGIES - 15/11/2016

Cutting Edge Peptide Therapeutics in the Clinic

16:50 - 17:30
Main agenda

This session will highlight cutting edge peptide therapeutics in phase I, III and III clinical developments being developed. Details on the discovery, development and scientific concepts behind the products in the clinic will be discussed and how half-life, delivery and formulation issues are being resolved.

If you are interested in presenting on this topic please contact catherine.marshall@informa.com

End of Conference Day Two and Evening Entertainment

17:30 - 20:30
Main agenda

SCHEDULE

DAY 2 - CLINICAL DEVELOPMENT & DELIVERY STRATEGIES - 15/11/2016

TIME	MAIN AGENDA
08:00	**08:00** - Registration and Morning Coffee **08:50** - Chairperson's Opening Remarks
09:00	**09:00** - Oral Peptide Delivery Products: Learnings from Clinical Advances and Future Challenges **09:40** - Controlled Release Delivery of Peptides
10:00	**10:20** - Morning Coffee and Networking
11:00	**11:00** - Cellular Uptake of Two p53/MDM2 Stapled Peptide Inhibitor Variants **11:40** - Functional Penetrating Phylomers (FPPs) for More Efficient Delivery of Biologics In Vivo
12:00	**12:20** - Spotlight Presentation **12:50** - Lunch and Networking Time
13:00	
14:00	**14:20** - The Molecular Basis for the Prolonged Blood Circulation of Lipidated Incretin Peptides: An In-Vitro Study of their Oligomerization and Interaction with Serum Albumin
15:00	**15:00** - Translating Macrocyclic and Constrained Peptide Therapeutics into the Clinic **15:40** - Afternoon Coffee and Networking Time
16:00	**16:10** - Feedback from Bicycle Therapeutics: Translating Macrocyclic and Constrained Peptide Therapeutics into the Clinic **16:50** - Cutting Edge Peptide Therapeutics in the Clinic
17:00	**17:30** - End of Conference Day Two and Evening Entertainment

SESSIONS

DAY 3 - PROCESS DEVELOPMENT, MANUFACTURING AND ANALYSIS - 16/11/2016

Chairperson's Opening Remarks

08:50 - 09:00
Main agenda

Participants

Jesper Lau, Novo Nordisk, Denmark

Automated Flow Peptide Synthesis: Toward Amide Bonds at Nature's Pace

09:00 - 09:40
Main agenda

Here we describe a rapid flow solid phase peptide synthesis methodology that enables incorporation of an amino acid residue in 40 seconds with amide-bond formation taking only 5 seconds. To demonstrate the broad applicability of this method, it was employed to synthesize hundreds of peptides and proteins.

Participants

Bradley Pentelute, MIT, USA

Downstream Process Development of Aggregation-Prone Peptides

09:40 - 10:20
Main agenda

Aggregation-prone peptides represent additional challenges for process development and commercial manufacturing of peptide drug substances. Several strategies and methods are developed, optimised and applied at BACHEM to elucidate, control and prevent the formation of aggregates. The presentation will focus on downstream process steps i.e. TFA cleavage, preparative HPLC and preparative SEC purification. These unit operations greatly impact the formation and removal of aggregates. BACHEM's approach for identifying appropriate process parameters will be explained and illustrated with case study examples.

Participants

Thomas Meier, BACHEM AG, Switzerland

Morning Coffee and Networking

10:20 - 11:00
Main agenda

Peptide Production using Microwave Assisted SPPS

11:00 - 11:30
Main agenda

Enhancing the efficiency of peptide synthesis at larger scales is of significant value. In this presentation, we report the most recent advances in microwave assisted SPPS and demonstrate the application of a large scale microwave solid phase peptide synthesizer utilizing reaction vessels up to 15L toward the synthesis of a series of peptides. This process allowed for the incorporation of 48 amino acids per 24 hour day at batch sizes up to 500 grams of purified peptide. The synthesis results yielded similar or in some cases improved purity compared to high purities obtained from microwave SPPS at research scale. Key side reactions such as epimerization and aspartimide formation were easily controlled making this approach of high potential value for peptide production.

Participants

Keith Porter, CEM Corporation

Optimisation of Physicochemical and Biophysical Properties of Peptide Drugs

11:30 - 12:10
Main agenda

The development of a preclinical peptide candidate to a commercial drug is a challenging and time consuming process. Due to very poor oral bioavailability, peptides are generally are injected as aqueous formulations. Main challenges are sufficient solubility of the peptide as well as chemical and physical stability of the peptide formulation. The selection of a proper peptide candidate and development of peptide formulations will be discussed.

Participants

Martin Will, Sanofi, Germany

Spotlight Presentation

12:10 - 12:40
Main agenda

This slot is reserved for technology and service providers; please contact perri.lucatello@informa.com for more info.

Lunch and Networking Time

12:40 - 13:40
Main agenda

Research Roadshow

13:40 - 14:10
Main agenda

Tour of poster presentations within the exhibition hall. Each presenter has 5 minutes to present their work.

Core-Shell Type Resins for Peptide Synthesis

14:10 - 14:30
Main agenda

Core-shell (CS) type resins were developed for peptide, and possibly oligo synthesis. The CS structure was designed to overcome the diffusion problem and for easy access of reagents. The swelling of the CS type resin can be easily controlled. The performance of CS type resins was verified by synthesising "difficult" sequence peptides and the results were compared with those of non CS type resin and PEG-based resins.

Participants

Yoon-Sik Lee, Seoul National University, Korea

Industry Case Study: Process Development of Barusiban

14:30 - 14:45
Main agenda

Barusiban is a competitive oxytocin receptor antagonist that displays a high affinity for the human wild type uterine oxytocin receptor. It is a oxytocin analogue consisting of both natural and non-natural amino acids. In this study we will illustrate how yield was improved throughout development in order to obtain a more reliable process as well as an example of reducing cost of goods.

Participants

Leila Malik, Ferring Pharmaceuticals, Denmark

Thought Leaders Discussion: Overcoming the Current and Future Challenges in Peptide Manufacturing – Development of Robust, Innovative Processes to Reduce Costs of Goods in Peptide Synthesis and Manufacturing

14:45 - 15:20
Main agenda

- Evaluating innovations in large scale peptide manufacturing to reduce costs of goods and increase efficiency for manufacturing
- Process and manufacturing strategies to improve yield and reduce the environmental impact
- New synthesis technologies for solid phase synthesis and application to commercial scale
- Latest developments in coupling methods, resins and linkers
- Large scale manufacturing of complex and conjugated peptides products e.g. cyclic peptides and peptide vaccines

Afternoon Coffee and Networking Time

15:20 - 15:50
Main agenda

SESSIONS

DAY 3 - PROCESS DEVELOPMENT, MANUFACTURING AND ANALYSIS - 16/11/2016

2D-LC as an On-line Desalting Tool for Peptide Impurity Identification in MS Unfriendly HPLC Methods

15:50 - 16:30
Main agenda

A 2D-LC/MS system was built which allows for fast and direct collection of MS information for chromatographic peaks eluted in MS incompatible mobile phases, without requiring difficult, time consuming and error-prone translation of chromatographic methods from MS incompatible to MS compatible eluents, or off-line fraction collection and preparation. Several examples showing the application of the approach to complex mixtures containing peptides with impurities and positional isomers are presented.

Participants

Ping Zhuang, Merck & Co., Inc, USA

High and Low Resolution Mass Spectrometry, and its Application Throughout Peptide Drug Development

16:30 - 17:10
Main agenda

Mass spectrometry is an extremely powerful technique for the characterisation of biotherapeutics, and has become as equally useful for their quantitation in biological matrices. High resolution mass spectrometry is best suited for in-vivo metabolite identification, whilst low resolution triple quadrupole instruments are excellently placed for supporting PK studies. Examples of both approaches will be discussed.

Participants

Richard Kay, University of Cambridge, UK

Closing Remarks from the Chair and End of Conference Day Three

17:10 - 17:10
Main agenda

SCHEDULE

DAY 3 - PROCESS DEVELOPMENT, MANUFACTURING AND ANALYSIS - 16/11/2016

TIME	MAIN AGENDA
08:00	**08:50** - Chairperson's Opening Remarks
09:00	**09:00** - Automated Flow Peptide Synthesis: Toward Amide Bonds at Nature's Pace **09:40** - Downstream Process Development of Aggregation-Prone Peptides
10:00	**10:20** - Morning Coffee and Networking
11:00	**11:00** - Peptide Production using Microwave Assisted SPPS **11:30** - Optimisation of Physicochemical and Biophysical Properties of Peptide Drugs
12:00	**12:10** - Spotlight Presentation **12:40** - Lunch and Networking Time
13:00	**13:40** - Research Roadshow
14:00	**14:10** - Core-Shell Type Resins for Peptide Synthesis **14:30** - Industry Case Study: Process Development of Barusiban **14:45** - Thought Leaders Discussion: Overcoming the Current and Future Challenges in Peptide Manufacturing – Development of Robust, Innovative Processes to Reduce Costs of Goods in Peptide Synthesis and Manufacturing
15:00	**15:20** - Afternoon Coffee and Networking Time **15:50** - 2D-LC as an On-line Desalting Tool for Peptide Impurity Identification in MS Unfriendly HPLC Methods
16:00	**16:30** - High and Low Resolution Mass Spectrometry, and its Application Throughout Peptide Drug Development
17:00	**17:10** - Closing Remarks from the Chair and End of Conference Day Three

SESSIONS

DAY 4 - CMC AND REGULATORY IMPLICATIONS OF MANUFACTURING & SCALE UP OF PEPTIDES - 17/11/2016

Registration

08:30 - 09:00
Main agenda

CMC and Regulatory Implications of Manufacturing & Scale Up of Peptides

09:00 - 15:00
Main agenda

This workshop will present strategies and case studies on the latest techniques and regulatory implications for the manufacturing and scale up of peptide therapeutics.

Some of the key points to be addressed will include:

- Case study on considerations for early phase scale up manufacturing
- Commercial manufacturing scale up case study
- Evolution of impurity specifications during drug development. A regulatory perspective
- Qualification and validation of analytical methods from Phase 1 to commercial
- Considerations for peptide contract manufacturing: Lessons learned on outsource management
- CMO-sponsor collaboration: Aligning the manufacturing approach with the drug development stage
- Technical CMC for peptides

Participants

Bruce Morimoto, Celerion, USA

End of Workshop

15:00 - 15:00
Main agenda

SCHEDULE

DAY 4 - CMC AND REGULATORY IMPLICATIONS OF MANUFACTURING & SCALE UP OF PEPTIDES - 17/11/2016

TIME	MAIN AGENDA
08:00	**08:30** - Registration
09:00	**09:00** - CMC and Regulatory Implications of Manufacturing & Scale Up of Peptides
10:00	
11:00	
12:00	
13:00	
14:00	
15:00	**15:00** - End of Workshop