Day 1 - April, 14 2015 - Tuesday

7:00-8:00 AM

Delegate registration and light breakfast

8:00-8:10 AM

Chairman's Opening Remarks

Boehringer Ingelheim

Chairman: Keith Horspool, Ph.D., VP, Pharmaceutical Sciences, Boehringer Ingelheim

NOVARTIS

Co-chair: Riccardo Panicucci, Ph.D., Global Head, Chemical and Pharmaceutical Profiling, Novartis

Keith Horspool, Ph.D.
VP, Pharmaceutical Development
Boehringer Ingelheim

Riccardo Panicucci, Ph.D.
Global Head, Chemical and Pharmaceutical Profiling
Novartis

8:10-8:45 AM

Keynote

Inspiring Next Generation Products: Assessing the Latest Innovations in Drug Development and Delivery Technologies to Determine the Path of the Future

MedImmune

- What theraputing spaces will drive innovation into 2020 and beyond?
- Striving toward more patient-enabled therapies and self-administration systems
- Looking beyond the vial and pill for the drug delivery technology of the future
- Exploring recent advances in naontechnologies, patch-pump infusers, smart pills and drug device combinations

Anand Subramony, Ph.D, VP, Drug Delivery and Device Development, MedImmune

Anand Subramony, Ph.D.
Principal Fellow and Head, Novel Drug Delivery Technologies & Therapeutics Group
MedImmune

8:45-9:20 AM

PLENARY

Developing Wearable Systems and Drug Device Combination Products: How Will These Technologies Change the Drug Delivery Landscape?

SANOFI

- Exploring the latest approached and systems to desin and target experimental molecules
- Detirmining the best data aggregation and analytical systems to demonstrate proof-of-concept during regulatory submission and filing for NDA
- Assessing emerging technologies to improve statistics and modeling
- How will these systems improve early drug discovery and new product development

Anke Liewald, Head, Operations and Project Management, Medical Device Development, Sanofi

Anke Liewald
VP Drug Delivery and Device Development
Sanofi

9:20-9:55 AM

Thought Leadership

Bringing State-of-the-Art Innovations in Ophthalmic Drug Delivery from the Bench to Market

Alcon
a Novartis company

- Developing patient-centric delivery and devices for the eye
- Exploring other experimental treatments for macular degeneration and diabetic macular edema
- Developing novel platforms for drug delivery and monitoring:
- Non-invasive opthalmic devices
- Drug-eluding contact lenses
- Microchips and other feedback systems
- Steps for detirmining if a platform device strategy makes business sense
- Improving development cycle times and reducing costs
- Developing innovative drug delivery devices through external partnerships and collaborations

Laman Alani, Ph.D, V.P., Pharmaceutical Producats and Technology Development, Alcon

> **Laman Alani, Ph.D.**
> VP, Pharmaceutical Products and Technology Development
> **Alcon Laboratories**

9:55-10:00 AM

Please move to your next session

10:00-11:15 AM

Pre-arranged one-to-one meetings & refreshments

10:00-10:45 AM

Plenary Workshop

This workshop is to be attended by all delegates in Group 1

10:45-11:15 AM

Meet the speakers and Refreshment Break

11:15-11:20 AM

Please move to your next session

11:20-11:55 AM

STREAM 1	STREAM 2	STREAM 3
BIOLOGICS	SMALL MOLECULES	TECHNOLOGY

Case Study: Examining Clinical Results and Models for Oral Peptides in Development

- Discussing the pros and cons of the oral peptide technologies in regards to:
  - Peptide stability
  - Bioavailability
  - Saftey and efficacy
- Formulating oral peptides to cross epithelial membranes
- Assessing opportunities to apply oral peptides technology to target GI tract diseases
- Exploring the potential for manufacturability

Joel Richard, Ph.D, SVP, Peptides, Ipsen

> **Joel Richard**
> SVP, Peptides
> **Ipsen**

Discussing the Advantages and Acceptability of Mini-Tablets for Pediatric Formulations

- Assesing hter WHO's preference for solid dosage forms over liquids
- Exploring opportunities for taste masking and modified drug release
- developing physical and analytical methods for characterizarion and quality control of mini-tablets
- Detirmining tablet size and dose strength
- Overcoming challenges in the manufacture and packaging of mini-tablets
- Case-study: Reviewing the successful launch of the Novartis US Lamisil Oral Granules

Gesine Winzenburg, Ph.D, Fellow, Technical Research and Development, Novartis Pharma AG

> **Gensine Winzenburg**
> Fellow of Technical Research and Development
> **Novartis**

Spray-Drying Technology

Utilising St to prepare amorphous compounds with enhanced soluability

- Understanding the advantages of SDt when handelling temperature sensitive compounds
- Utilising SDt as a cost effective method of power production
- Is SDt still the best option?-Comparing SDt to emerging technologies

11:55-12:00 PM

Please move to your next session

12:00-12:35 PM

WORKSHOP	WORKSHOP	WORKSHOP

Examining highly automated procedures for the assessment of protein formulation

- Demonstrating how automated systems can solve key challenges in development laboratories, including through-put and data management
- Enhancing productivity and reproducibility of your current activities
- Automating of laborious manual methods and procedures using proprietary instruments

Engineered Particles for Enhanced Oral and Inhaled Bioavailability

- Improving oral pharmokinetics through amorphous spray-dried and solid lipid particles
- Spray-dried particles for improved ling and nasal pharmokinetics and dynamics
- Case studies for each technology and delivery route

EMULSION TECHNOLOGY FOR MICRO ENCAPSULATION (ET4ME)

Innovative technology platform for controlled particle engineering

- Product differentiation by applying uniform and reproducible PLGA microsphere formulations for sustained release of APIs
- Non-invasive therapeutic and preventive vaccination by chitosan mucosal delivery systems

12:35-1:35 PM

Themed Lunch

1:35-2:10 PM

Innovation Spotlight

Electronic Drug Delivery: Pioneering the Next Generation of Drug Delivery and Biosensing

- Bringing digital drug delivery platforms of the future into practice today
- Discussing advancements in smart devices and how they can be used for therapeutic benefits
- Programming microCHIPS technology to deliver and administer multiple drugs and doses:
  - Comination products
  - Dosage amount and timing
  - Sustained release formulations
- Exploring applications for contraception and osteoporosis
- Examining data laws and regulation in the U.S.
- Looking forward: What is ths scalability of the technology

Robert Farra, President and Chief Operating Officer, MicroCHIPS

> **Robert Farra**
> President and Chief Operating Officer
> **MicroCHIPS**

2:10-2:15 PM

Please move to your next session

2:15-2:50 PM

STREAM 1

BIOLOGICS

Examining the Latest Progress in Microneedle Patch Technology

- Discussing the effectiveness of drug-coated microneedle patch as an alternative to injections
- Evaluating microneedle coating, packaged storage stability and preclinical delivery performance
- Case Study: Reviewing current data of ZP-Glucagon
- Advancing microneedle patch technology to commercialisation
- What next-generation technologies will propel innovation in the dermal and transdermal space for the next 5 - 10 years?

Peter Daddona, Ph.D, Chief Scientific OFficer and EVP, Research & Development, Zosano Pharma

> **Peter Daddona**
> Chief Scientific Officer and EVP R&D
> **Zosano**

STREAM 2

SMALL MOLECULES

Case Study: Project Triumphs and Setbacks on the Road to Developing Inhaled Insulin Technology

- Integrating formulation and device technologies early-on for an effective oral inhalation system
- Assesing the development powder formulations for delivery of peptides, protein and small molecule theraputics
- Examining toxicology studies required for regulatory submission
- Expanding future applications of the technology to therapies beyond insulin

Andrea Leone-Bay, Ph.D., VP, Pharmaceutical Development, MannKind Corporation

> **Andrea Leone-Bay, Ph.D.**
> VP, Pharmaceutical R&D
> **MannKind Corporation**

STREAM 3

TECHNOLOGY

Delivery Technology

In what direction is the drug delivery technology space moving?

- Evaluating how fast the delivery technology field has evolved until now - are there limiting factors to its continued development?
- What is the potential of less-traditional delivery routes such as nasal and ocular delivery?
- Discussing the future of evolving areas including polymer technologies, auto injectors, microneedles etc.
- Looking retrospectively, has the industry done all it can until now to maintain the R&D paradigm?

2:50-2:55 PM

Please move to your next session

2:55-4:10 PM

Pre-arranged one-to-one meetings & refreshments

2:55-3:40 PM

Plenary Workshop

This workshop is to be attended by all delegates in Group 2

3:40-4:10 PM

Meet the speakers and Refreshment Break

4:10-4:15 PM

Please move to your next session

4:15-4:50 PM

WORKSHOP

Using RapidFACT and pharmaceutical design spaces to optimize drug products across the development life cycle

- Adaptive manufacturing and clinical testing provide real-time data to drive formulation selection.
- Case studies spanning early to late stage development and life-cycle management.
  - Selecting and optimizing solid oral formulations to achieve the Target Product Profile.
  - Managing an oral to subcutaneous route switch with a low bioavailability peptide.
  - Design freeze for an oral CR formulation prior to pivotal Phase III studies.
  - Enhancing asset value via a next generation oral MR formulation.

Kieran Crowley
Senior Director of Translational Pharmaceutics
Quotient Clinical Ltd.

WORKSHOP

Case Study: Utilizing Nanonization of API to Enhance Solubility

- Exploring opportunities, challenges and applications of poorly soluble drugs and NCEs
- Using top-down methods for particle size reduction to enhance solubility
- Examining the process parameters and fundamental limits of using bead mills for particle reduction
- Selecting the correct machine desing and materials for specific applications
- Overview of the clinical benefits and commercialised drugs utilising nanotechnology

WORKSHOP

Transdermal Drug Delivery Systems

Breakthrough device for transdermal drug delivery

- Novel diode pumped laser microporation devices
- Precise deposition of large molecular weight drugs into selected skin layers
- Preclinical and clinical applications of P.L.E.A.S.E. based drug delivery

4:50-4:55 PM

Please move to your next session

4:55-5:30 PM

Thought Leadership

Overcoming Regulatory Hurdles When Developing New Formulations

- Creating an essential regulatory check list for new formulations
- Understanding fundamental requirements on the use of new and experimental dosage forms
- Evaluating what excipients should be used or avoided based on safety and toxicology studies
- Keeping up to date with emerging FDA and EMEA legislations

5:30-6:05 PM

Innovation Spotlight

Pharmaceuticals 2050: Exploring the potential of 3D printing individualised medicines

- Commercialising 3D printing technologies and 'chemputer' platforms
- Discussing the scalability of the technology and new opportunities for specialty products
- Examining the Univesity of Glasgow's printer that is able to print molecules
- Navigating the regulatory pathway and the roadblocks to success

Lee Cronin, Ph. D., Regius Chair of Chemistry, Chemistry Department, University of Glasgow

> **Lee Cronin**
> Regius Chair of Chemistry
> **University of Glasgow**

6:05-6:15 PM

Chairman's Closing Remarks

6:15-7:30 PM

Networking Drinks Reception

Day 2 - April, 15 2015 - Wednesday

8:00-8:30 AM

Delegate registration and light breakfast

8:30-8:40 AM

Chairman's Opening Remarks

Keith Horspool, Ph.D., VP, Pharmaceutical Sciences, Boehringer Ingelheim

Riccardo Panicucci, Ph.D., Global Head, Chemical and Pharmaceutical Profiling, Novartis

> **Keith Horspool, Ph.D.**
> VP, Pharmaceutical Development
> **Boehringer Ingelheim**

> **Riccardo Panicucci, Ph.D.**
> Global Head, Chemical and Pharmaceutical Profiling
> **Novartis**

8:40-9:15 AM

State of the Industry Address

Discussing the potential for innovative partnerships to address healthcare R&D challenges

- Is collaboration the key to improve medical innovation and bring new therapies to the market?
- Generating a solid contractual framework to bridge gaps between two different companies
- Communicating with your partners efficiently in order to set clear business objectives
- Case studies in drug discovery: What are the best examples and how can we learn from them?

Christoph Huwe, Ph.D., Global Head, External Innovation and Alliances, Bayer Pharma AG

> **Christoph Huwe**
> Global Head of External Innovation and Alliances
> **Bayer**

9:15-9:50 AM

Keynote

Evaluating Formulation Technology Trends to Enable Next Generation Biological Drug Pipelines

- What infrastructure is needed to support new technologies and drug candidates?
- Looking beyond traditional monoclonal antibodies for new modalities
- What opportunities open with different concentration spectrums?
- Improving understanding of degradation and stabilizing mechanisms
- Assessing the latest tools for rapid formulation development
- Reinventing the science between discovery and development to be more efficient

Ping Yeh, Ph.D., Executive Direction, Process and Product Development, Amgen

> **Ping Yeh**
> Executive Director, Process and Product Development
> **Amgen**

9:50-10:25 AM

Case Study

Reviewing the Latest Advancements in Human Abuse-Deterrent Oral Formulations

- Discussing the need for developing abuse deterrent formulations for opioid and other controlled products
- Applying new and existing excipients, polymeric materials and processing technology to formulations Demonstrating the reduction of the abuse potential in abuse deterrent formulations
- Determining the business reasons and societal benefits for developing abuse-deterrent
- Adapting to regulatory changes and guidance from the FDA – What is there positioning?

Ralph Heasley, Ph.D., VP, Platform Development and Technology, Mallinkrodt Pharmaceuticals

> **Ralph Heasley**
> VP Platform Development and Technology
> **Mallinckrodt**

10:25-10:30 AM

Please move to your next session

10:30-11:30 AM

Delegate-to-Delegate Meetings and Meet the Speakers

11:30-11:35 AM

Please move to your next session

11:35-12:10 PM

WORKSHOP

Micronization of Active Pharmaceutical Ingredients with Agitator Bead Mills

- Reviewing opportunities of nanoscale API presented to pharma companies
- Discussing the fundamentals of agitator bead mills for micronization:
  - Real comminution vs. dispersing
  - Machine characteristics of agitator bead mills
  - Design criteria
  - Materials of construction
- Case Study: Examining nano-enabled drugs on the market

WORKSHOP

Enabling Better Treatments Through Oral Drug Delivery

- Discussing Catalent's global network of soft gel manufacturing sites
- Applying soft gel capsules to enhance solubility and to get to market faster
- Ensuring reliable supply by using Catalent's expertise to avoid costly development iteration

WORKSHOP

Outsourcing to a CRO

- Utilizing Collaborative Relations to Ensure Long-term Agreements and Developmental Success
- Promoting cultural relations in evolving external partnerships
- Limiting barriers to collaboration by communicating with one voice
- Prioritising an open and transparent framework in cementing relations and building trust
- Analysing the three tiers of an appropriate partner - Technologies, quality and finances
- Putting initiatives in place to support such a long-term relationship
- Ensuring data integrity & quality is achieved and sustained

12:10-12:15 PM

Please move to your next session

12:15-12:50 PM

BIOLOGICS

Examining Applications of Biocompatible Polymers to Deliver Drugs for Lung Cancer and Asthma

- Using polymers to take advantage of the biological system
- Overcoming the barrier to deliver your drug to the tumor site and achieve targeted effects
- How to improve the effectiveness of theraputic nanoparticles
  - Biodegradablitity and biocompatability
  - Drug leakage
  - Tumor cell internalisation
- Reviewing cutting-edge imaging technology for nanoparticles

Mahavir B. Chougule, Ph.D., Assistant Professor, Department of Pharmaceutical Sciences, University of Hawaii at Hilo

> **Mahavair Chougule**
> Assistant Professor, Dept. of Pharmaceutical Sciences
> **University of Hawaii at Hilo**

SMALL MOLECULES

Discussing Oral Drug Delivery Technologies to Overcome Poorly Soluble Compounds

- Assessing the benefits of dosage forms for modified release
- Exploring systems and technologies that are proven to be effective:
  - Multiparticulate systems
  - Gastro-retentive technologies
- Examining data and findings from CMC and PK perspectives to support claims
- Reviewing recent applications of the technology in drug candidates and approved product

Sree Nadkarni, Ph.D., Senior Director, Technical Development, Depomed

> **Sree Nadkarni, Ph.D**
> Senior Director, Technical Development
> **Depomed**

STREAM 3

PARTNERSHIP

Engaging with Leading Industrial & Academic Partners

Sourcing a partner based on the needs of your company, your existing suppliers and your consumer base

- Negotiating a win-win arrangement and drafting appropriate legal & IP contracts
- Ensuring efficient data and technology transfers to third parties
- Collaborating to ensure maintained quality, productivity and efficiency

12:50-1:50 PM

Lunch & Learn Roundtable Discussions

Assessing emerging technologies to improve product targeting

1:50-2:25 PM

WORKSHOP

Discussing the Latest in Subcutaneous Needle-Free Injection Drug Delivery

- Overcoming the challenges delivering viscous biologic formulations
- Determining the right gap compression for delivery at high driving pressures
- Comparing needle-free technologies with other pre-filled and single-use systems
- Assessing the safety and tolerability of needle-free drug delivery systems
- Examining needle-free options to delivery more than 0.5-1 mL – What are the regulatory concerns?

WORKSHOP

Making Transformational Improvements to Solubility and Permeability for Poorly Soluble Compounds

- Examining the latest processing tools and technologies to improve solubility and bioavailability
- Using novel and known excipients that are available in the market
- Selecting conventional vs. non-conventional formulation approaches to enhance APIs
- Evaluating regulatory implications new technologies can present to existing and future therapies

WORKSHOP

Regulations

Striking a balance between what is expected and what the industry/consumer is willing to support

- Surviving the regulatory Catch-22 - balancing cost reductions with increasing regulatory demands for more measurements and analysis
- Better medicines vs. reduced costs - which do we want more?
- Deploying strategies that satisfy industry, regulatory & consumer demands
- End of the 'Perfect Therapy' - should society be expected to support an ever-ageing population or is the investment better spent elsewhere?

2:25-2:30 PM

Please move to your next session

2:30-3:05 PM

STREAM 1

BIOLOGICS

Discussing New Peptide Vectors to Deliver Therapeutic Compounds Across the BloodBrain Barrier

- Examining different delivery approaches to the brain (i.e. - invasive, biochemical, physiological and convection-enhanced)
- Targeting specific cells in the brain, such as neurons, astrocytes and tumor cells
- Exploring opportunities for conjugating therapeutic compounds that include:
  - Antibodies
  - Enzymes
  - Biologics
  - Small molecules
- Assessing the benefit of new fusion proteins for the treatment of brain diseases
- Case study: Developing the second generation of biOasis's Transcend brain delivery platform

Reinhard Gabathuler, Ph.D., Chief Scientist, biOasis Technologies

Reinhard Gabathuler
Chief Scientist
biOasis Technologies

STREAM 2

SMALL MOLECULES

Implementing Quality by Design Principles and Concepts to Drug Delivery and Formulation Development

- What are the business reasons for launching a QbD initiative in product development?
- Tips for achieving buy-in across your organization
- Examining tools and technologies to drive performance: oIntranets and templates
  - Risk assessments
  - Statistical process controls
  - Quality Risk Management (QRM)
- Discussing staged approaches and roadmaps to launch a QbD program

Sarah Betterman, Senior Scientist, QbD, Pharmaceutical Development, Upsher-Smith Laboratories

Sarah Betterman
Senior Scientist QbD Pharmaceutical Development
Upsher-Smith

STREAM 3

PARTNERSHIP

Using open innovation to deliver optimum results for development industry

Obtaining regulatory approval for new products by using the open innovation model and collaborating with academics, small and medium size companies

- Selecting financially stable partners by using sophisticated R&D models
- Ensuring that the stakeholders are completely aware of the risks associated with the different collaborations
- Efficiently using the knowledge of smaller pharma companies and gaining investment from larger pharma companies
- Bridging the gaps between different organisations to achieve common goals and to have clear business objectives

3:05-3:10 PM

Please move to your next session

3:10-3:45 PM

Case Study

Creating an effective technology transfer strategy between exploratory and regulatory development

- Best strategies for involving formulation and process development teams at in the right time
- Determining critical manufacturing process components
- Avoiding tech transfer vulnerabilities:
  - Loss of knowledge or experience
  - "Reinvention of the wheel"
  - Confused ownership and responsibilities
  - Delayed approvals
- Reviewing FDA perspectives on tech transfer between sites - What is the current guidance?
- Discussing scale-up from small- to large-scale manufacturing

3:45-4:20 PM

Plenary

Optimizing Conventional Formulations for Continuous Manufacturing

- Improving material science, API and process robustness for continuous manufacturing
- Ensuring you have fully automated controls to realize true end-to-end pharma production
- Debating the benefits of using pods versus stationary set-ups
- Best techniques for small volumes and easier change overs
- Breakthrough technologies poised to revolutionize formulation and manufacturing
- What new products are utilizing continuous manufacturing?

4:20-4:55 PM

Panel Discussion

Creating Proactive Models for Technical Lifecycle Management: Simplifying SOPs and Improving Operational Performance by Increasing Process Controls and Automation

- Reconfiguring bioproduction systems to produce biologics faster and at a lower cost
- Examining complex process architecture for areas of improvement and new operations technology
- Rethinking routine operations and attitudes to create a roadmap for change
- Knowing when to invest in new bioreactors, purification equipment and facility upgrades

4:55-5:00 PM

Chairman's Closing Remarks