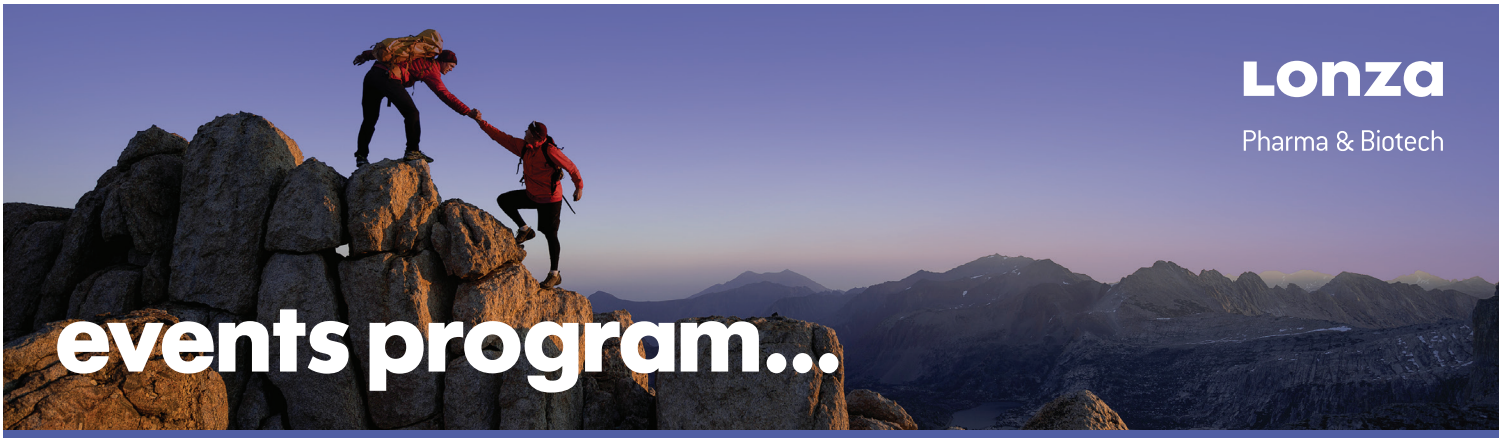

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Pharma & Biotech

events program...

Saturday and Sunday, November 3 – 4, 2018

Short Course (2 Day):

Surfactants and biopharmaceuticals – a love-hate relationship

- Saturday, Nov. 3, 2018 – 9:00am – 5:00pm and Sunday, Nov. 4, 2018 – 9:00am – 1:00pm
- Workshop Organizer: Satish K. Singh, PhD, FAAPS – Lonza and Atanas Koulov, PhD – Lonza

Short Course – Saturday:

Behavior of surfactant during processing (UF/DF, filter adsorption)

- Saturday, Nov. 3, 2018 – 3:30 – 4:00pm
- Location: 207 A, WEWCC
- Workshop presenter: Hanns-Christian Mahler, PhD, FAPPS – Lonza

Short Course – Sunday:

Analytical toolbox for characterization and control of surfactants in biopharmaceuticals

- Sunday, Nov. 4, 2018 – 9:00 – 9:30am
- Location: 207 A, WEWCC
- Workshop presenter: Michael Jahn, PhD – Lonza

Monday, November 5, 2018

Prologue:

Nanoparticles – small size, enormous potential

- Monday, Nov. 5, 2018 – 8:30am – 9:00am
- Location: 147 AB
- Speaker: Stefan Siegrist, PhD – Novartis
- Moderator: Prof. Sven Stegemann, PhD – Lonza
- Moderator: Dawn Downey, PhD – Eli Lilly & Company

Prologue:

Formulation of biologics from molecule selection to clinical studies

- Monday, Nov. 5, 2018 – 8:30am – 9:00am
- Location: 146 A
- Speaker: Prof. Hanns-Christian Mahler, Ph.D. FAPPS – Lonza
- Moderator: Satish K. Singh, PhD, FAAPS – Lonza
- Moderator: Lisa A. Kueltzo, PhD – Vaccine Production Program – National Institute of Health

Prologue:

Prior knowledge and smart risks – manufacturing and bioprocessing

- Monday, Nov. 5, 2018 – 8:30am – 9:00am
- Location: 145 AB
- Speaker: Reed Harris – Genentech Roche
- Moderator: Atanas Koulov, PhD – Lonza
- Moderator: Sambit R. Kar, PhD – Bristol-Myers Squibb

Process controls, manufacturing, and engineering challenges – chemical

- Monday, Nov. 5, 2018 – 9:00am – 11:00am
- Location: 145 AB
- Moderator: Dawn Downey, PhD – Eli Lilly & Company
- Moderator: Sven Stegemann, PhD – Lonza

Rapid Fire Presentation:

Manufacturing of liposomal antibiotic formulations using high-throughput microfluidics technology

- Monday, Nov. 5, 2018 – 9:00am – 11:00am
- Location: 146 B
- Speaker: Swapnil Khadke, MSc, PhD

Symposium:

Formulation development challenges and strategies – biomolecular

- Monday, Nov. 5, 2018 – 9:00am – 11:00am
- Location: 146 A
- Moderator/Speaker: Satish K. Singh, PhD, FAAPS – Lonza
- Moderator: Lisa A. Kueltzo, PhD – Vaccine Production Program – National Institute of Health

Process controls, manufacturing, and engineering challenges – biomolecular

- Monday, Nov. 5, 2018 – 9:00am – 11:00am
- Location: 145 AB
- Moderator: Atanas Koulov, PhD – Lonza AG
- Moderator: Sambit R. Kar, PhD – Bristol-Myers Squibb

Tuesday, November 6, 2018

Panel:

Discussion and Q&A on CSTDs

- Tuesday, Nov. 6, 2018 – 10:30am – 11:00am
- Location: 146 A
- Panelist: Sumit Goswami, M.tech, PhD, – Pfizer
- Panelist: Bharat Jagannathan, PhD – Amgen
- Panelist: Camellia Zamiri, PhD – Genentech
- Panelist: Prof. Hanns-Christian Mahler Ph.D., FAPPS – Lonza

Immuno-oncology: advancement from infancy to products – manufacturing and bioprocessing

- Tuesday, Nov. 6, 2018 – 3:00pm – 5:00pm
- Location: 207 A
- Moderator: Sandeep Nema
- Moderator: Satish K. Singh, PhD, FAAPS – Lonza AG

Additional events listed on reverse side

Partner presentations

Technology selection methodologies for addressing bioavailability challenges

Tuesday, Nov. 6, 2018 – 9:00am–10:00am
Location: Partner Presentation Room 2, Exhibit Hall A/B

Compounds that require bioavailability enhancement to achieve target absorption are increasingly common in current pipelines. This presentation focuses on the rationale for selecting technologies that enable progression of such compounds, based on compound's physical properties (e.g. melt and glass-transition temperatures, Log P) and product specifications (e.g., dose, pharmacokinetics, permeability). Predictive modelling and rapid screening best practices will also be discussed along with representative case studies demonstrating the parameters for choosing solid dispersion or and lipid-based approaches.

Learning objectives:

- Rational technology selection based on API physio chemical properties
- Solid dispersion design and development for bioavailability enhancement
- Lipid formulation design and development for bioavailability enhancement

Presented by:

- Michael Grass, Ph.D., Principal Scientist Product Development, Lonza
- Jenifer Mains, Ph.D., Manager Formulation R&D, Lonza

Best Practices for Highly Potent API development and manufacturing

Tuesday, Nov. 6, 2018 – 10:00am–11:00am
Location: Partner Presentation Room 2, Exhibit Hall A/B

Drug product development for highly potent APIs (HPAPIs) can be challenging. Complications with the interface between operations in drug substance and drug product handling can result in increased program complexity and cost. This presentation focuses on best practices for developing and manufacturing highly potent compounds, contained particle engineering, and overall infrastructure requirements to meet accelerated timelines to clinic and market. Case studies which illustrate efficient and rapid development, scaling and commercial production of HPAPI will be discussed.

Learning objectives:

- Successful management of Highly Potent material handling is not only about containment, but largely is defined by a focused working culture
- Integrated service offerings combining full value chain from drug substance to final dosage form largely contribute to accelerate product launch
- Lonza has proven track record in the full service offering, underlined by our strong support of programs in breakthrough therapy indications.

Presented by:

- Michael Reinhard, Ph.D., Chemical Division, Lonza

Encapsulation best practices for early clinical studies

Tuesday, Nov. 6, 2018 – 11:00am–12:00pm
Location: Partner Presentation Room 2, Exhibit Hall A/B

Specialized encapsulation techniques can greatly simplify early studies, and play a critical role in meeting drug program timelines. Xcelodose® Precision Powder Micro-dosing Systems facilitate powder-in-capsule (PIC) / micro-dosing studies can eliminate the need for preformulation steps and excipient compatibility testing in early clinical evaluations. A set of best practices have been developed based on extensive PIC studies over a range of API characteristics to help accelerate feasibility studies and first-in-human (FIH). Representative case studies demonstrating PIC study extremes will be discussed.

Learning objectives:

- Capsule technologies for micro-dosing applications
- Principles of micro-dosing technologies, including case studies and best practices for streamlining development
- Micro-dosing opportunities for large scale, high throughput to support late phase PiC initiatives

Presented by:

- Jeff Williamson, Director Product Development, Lonza
- Stephanie Sastre, Supervisor, Process Engineering, Lonza

Chalk talks

How to perform an extractables / leachables assessment

Monday, Nov. 5, 2018 – 12:30pm – 12:50pm
Learning Lounge 2

During the complex manufacturing, storage and administration process of biopharmaceuticals the drug product (DP) and constituents thereof are in contact with a multitude of materials, which inevitably leads to a contamination with leachables. For the sake of patients' safety and in order to comply with health authority expectations leaching has to be monitored and controlled within an extractables/leachables (EL) assessment. Within this talk the different steps of the EL assessment and potential challenges will be discussed.

Learning objective:

- The attendees will leave the session knowing on how to successfully implement an EL assessment.

Presented by:

- Michael Jahn, Ph.D., Head Forensic Chemistry, Lonza DPS

Subvisible particles – how to measure and control

Tuesday, Nov. 6, 2018 – 12:00pm – 12:20pm
Learning Lounge 2

The talk will review the current state of technology for sub-visible particle measurements, including pros and cons of different methods and their best use in development. The talk will focus on how to build an appropriate toolbox for control and characterization of sub-visible particles in the context of the current regulatory requirements, including special topics like setting product-specific limits for sub-visible particles.

Learning objective:

- What are the important differences between the various methods for sub-visible particle characterization? What is the best way to apply the different methods in development? How to build a sounds and robust control system for SvPs?

Presented by:

- Atanas Koulov, PhD., Head of Drug Product Analytical Development & QC, Drug Product Services, Lonza Pharma & Biotech

Challenges for High Concentration Protein Formulations

Tuesday, Nov. 6 – 2:00pm – 2:20pm
Learning Lounge 2

Therapeutic proteins are increasingly developed for somewhat more convenient parenteral administration, such as subcutaneous (SC) administration. Given typically large doses of protein therapeutics, and considering that injection volume is somewhat limited for SC administration, this requires sufficiently high protein concentrations. Yet, these products will have a variety of challenges including manufacturability, stability and injectability (usability). This talk will highlight some of the challenges and discuss mitigation options.

Learning objective:

- Things to consider for SC product development

Presented by:

- Prof. Hanns-Christian Mahler, Ph.D. FAPPS, Head of Drug Product Services

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