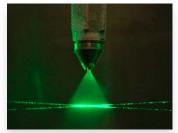
## CAPSUGEL FORMULATION ACADEMY 'ADDRESSING THE BIOAVAILABILITY CHALLENGE'

October 19<sup>TH</sup>, 2016 - Hotel Radisson Blu, Basel, Switzerland









Dear customer,

We are pleased to invite you to the 1st Annual Capsugel Formulation Academy looking at addressing Bioavailability challenges. The exclusive 1-day symposium will take place on October 19th at the Radisson Blue hotel in Basel, Switzerland.

Formulators face a myriad of challenges in designing and developing successful formulations. Drug products are increasingly specialized and designed for specific patient populations. Drug substances are increasingly complex and often have dissolution rate or solubility challenges and hence poor bioavailability. Today's target product profiles require more innovative solutions to achieve the desired pharmacokinetics and effective drug delivery.

Join us for a symposium focused on improving Bioavailability and modulating Pharmacokinetic profiles of drug candidates. Capsugel scientists, academics and industry speakers will discuss a range of technologies and formulations, and considerations for advancing "enabled" compounds from preclinical to commercial products. Methodologies for identifying optimal approaches will be presented, along with representative case studies addressing a range of problem statements.

### Space is limited so register now!

For any questions regarding the program or the registration, please contact your usual Capsugel representative or send an e-mail to AcademiesEMEA@capsugel.com.

We look forward to meeting you at this exclusive symposium!! With very best regards,

Catherine Lehmann
Senior Marketing Manager EMEA

## **Themes**

- Bioavailability Enhancement Technology Selection Methodologies
- Amorphous dispersions including spray-dried dispersion and hot-melt extrusion technologies
- Lipid-based formulation approaches
- Lipid multiparticulate technology
- Encapsulation approaches for effective targeted delivery within the GI tract

## Registration

Exclusive event by invitation only. No fees applying.

Registration open until October 7th.

### Hotel & Location

Hotel Radisson Blu Steinentorstrasse 25 4051 Basel, Switzerland Tel. +41 61 227 27 27 www.radissonblu.com/basel

#### Your Questions

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09.30	Registration and Welcome Coffee
10.00	Welcome to the Formulation Academy <b>Eduardo Jule</b> , Director, Pharmaceutical Business Development - Capsugel
10.15	Trends in Solubilizing Technologies  Pr Clive Wilson, Visiting Professor at the Strathclyde Institute Of Pharmacy And Biomedical Sciences; Member of Steering Group, European Federation for Pharmaceutical Sciences - University of Strathclyde, UK
11.00	Coffee Break
11.20	Methodologies for Choosing a Bioavailability Enhancing Technology  Dr. David K. Lyon, Director, Research - Capsugel, Bend site
	With a significant fraction of new compounds in pharmaceutical pipelines demonstrating limited dissolution rate or low solubility and corresponding poor bioavailability, bioavailability enhancing technologies have become a centerpiece for many development programs.  While empirical approaches can successfully be used to define the technology and formulation for a low-solubility compound, rationally choosing the technology early in the development process can significantly shorten timelines and decrease costs. Technology selection methodologies based on predictive modeling will be discussed.
11.50	Scientific rationale for the development of Lipid based systems for Bioavailability Enhancement  Dr. Jen Mains, Director, Formulation Development - Capsugel, Livingston site
	Lipid / liquid-based formulations are often an optimal approach for addressing poor bioavailability. An exploration of lipid based systems as oral bioavailability enhancers will be presented along with the biopharmaceutical mechanisms for absorption, and molecule parameters conducive for LBF technology. Formulation characterization, effective development strategies, excipient selection, and best practices for successful lipid-based formulation design and scale-up will be discussed.
12.20	Spray-Dried Dispersions: A Mature Technology for Bioavailability Enhancement  Dr. David K. Lyon, Director, Research - Capsugel, Bend site
	The design and spray-drying of amorphous formulations for improving bioavailability of poorly soluble compounds has become a mature technology. Today, several commercial products utilizing spray-dried dispersion technology are commercially marketed in human and animal health. This presentation will discuss fundamental formulation considerations for obtaining a high-performing amorphous formulation. In addition, the interaction of the spray-drying process and amorphous solid dispersions and the resultant dosage forms will be discussed.
13.00	Lunch
14.00	Case Study: Development and scale up studies required to support the commercialisation of liquid filled hard formulations <b>Dr. Wei Tian</b> , Director, Formulation - Capsugel, Linvingston site
	Liquid-Filled Hard Capsule (LFHC) is a popular finished dosage format for lipid-based formulations. Considerations for robust process design and characterization will be discussed to ensure successful scale-up. Equipment considerations will also be presented related to the commercial manufacturing of filled, banded and enterically coated LFHC products.
14.30	Soft Gelatin Capsule fast track technology transfer : success factors  Marc-Antoine Perrissin-Fabert, Senior technical manager - Mylan, France
15.00	Innovative technologies for Targeted Delivery in the GI tract  Dr. Keith Hutchison, Vice President, Research & Development - Capsugel
	Several innovative encapsulation technologies have been developed for targeted delivery of crystalline or solubilized compounds within the GI tract. Intrinsically enteric capsule technologies that provide enteric protection and/or targeted deliver to the duodenum without the use of functional coatings, and which enable the oral delivery of sensitive molecules such as

vaccines will be discussed. Effective colonic delivery inclusive of emerging microbiome applications will also be presented.



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#### 15.30 Lipid Multiparticulate Technology and its Applications

Dr. Jan Vertommen, Senior Director, Product Development & Manufacturing - Capsugel, Ploërmel site

Lipid Multiparticulate (LMP) technology offers a range of functionality applicable to many formulation challenges while also harnessing the benefits of the multiparticulate dosage format. Dependent upon the lipid excipients utilized to form the matrix multiparticulates, LMP formulations may be designed to provide bioavailability enhancement and/or controlled release and/or taste-masking. The improved palatability offered with LMP formulations can also provide an optimal approach for dosing pediatrics, geriatrics and other specialized patient populations. LMP technology will be presented, covering excipient options, the manufacturing process and representative case studies.

#### 16.00 Round Table Discussion and Q&A

16.30 Closure of the day

