Ashland Pharmaceutical Technology Symposium

Enabling Technologies for Modern Drug Delivery

September 14th, 2017

Embassy Suites by Hilton San Francisco Airport Waterfront
150 Anza Blvd, Burlingame, CA 94010

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Presentation Abstract and Speaker Bios:

Reducing Formulation Risk with Science-based Excipient Selection

Abstract: The increasing number of challenging new chemical entities in development coupled with the pressure to reduce R&D and production costs have created the perfect storm in the pharmaceutical industry. Using a science-based approach to excipient selection will allow you to overcome challenges such as poor bioavailability and stability while optimizing the formulation using the manufacturing process that is most effective and efficient.

Thomas Dürig, PhD

Dr. Tom Dürig is a Senior R&D Director leads global research and development and technical services for Pharmaceutical and Nutrition Specialities. These groups, located in North America, Europe, Middle East, Latin America, and Asia provide technical service and are focused on research and development of highly functional materials that enable overcoming drug delivery challenges such as bioavailability enhancement, drug stabilization and controlled drug delivery as well as process technologies to achieve advanced drug delivery and continuous manufacturing.

Tom is a registered pharmacist, with over 20 years' experience in the industry. He received the Degree of Doctor of Philosophy in Pharmaceutical Sciences from Temple University, Philadelphia. He has worked in a variety of settings, including R&D, GMP manufacturing at major multi-national corporations and in academia. Dr. Dürig holds several patents pertaining to polymeric excipients and advanced dosage form design and has co-authored numerous publications, book chapters and conference presentations on these topics.

Presentation Abstract and Speaker Bios:

Rational Polymer and Process Selection for Amorphous Solid Dispersions

Abstract: As poorly soluble compounds became one of the major challenges in drug development, solubilization technologies, such as solid dispersions, complexation, size reduction and lipid-based formulations, have been significantly advanced in recent years. The selection the right solubilization technologies not only requires a thorough understanding on the APIs itself, but also required extensive knowledge on the interplay of solubility and permeability when different technologies are used. In addition, thorough understanding on excipients and processes are essential. In this presentation, rational formulation design for poorly soluble compounds will be discussed by covering the following topics:

- How to choose suitable formulation technologies for poorly soluble APIs: Interplay of solubility and permeability
- What should be considered when selecting excipient to maximize formulation performance: Physicochemical properties, processability, regulatory considerations and beyond
- When should formulation process be considered and how does this impact formulation selection: Understand advantages and limitations of different process technologies
- Art of formulating poorly soluble compounds: Case studies

Vivian Bi, PhD

Dr. Vivian Bi is the Technical Director of Phramceutical Solubilization and Contract Service at Ashland Specialty Ingredient (ASI). She has held various positions in Pfizer Global R&D, Vertex Pharmaceuticals and AstraZeneca Pharmaceuticals before joining ASI. Her research interests are oral and parenteral drug delivery systems. Dr. Bi has published over 50 research papers, abstracts and patents. She also serves as a reviewer for research journals such as Pharmaceutical Research and Journal of Pharmaceutical Sciences. Dr. Bi obtained her B.S. degree from Shenyang Pharmaceutical University in China, and completed her Ph.D. in Pharmaceutical Science from Meijo University in Japan.

Presentation Abstract and Speaker Bios:

Development of Poorly Soluble Compounds from FIH and Later Clinical Development Phases

Abstract: According to recent reports, the great majority of new drug candidate molecules in development are poorly soluble and to achieve exposure needed in pre-clinical and clinical settings, Pharmaceutical Scientists need to employ appropriate bioavailability enhancing approaches. Selection of the appropriate approach could have significant impact on success and development timeline of each project. Following a review of solubilization approaches in pre-clinical settings, various techniques for developing poorly soluble compounds for FIH, and further clinical development based on BCS and DCS Classification System will be reviewed.

Hamid Rezaei, PhD

Dr. Rezaei earned his Ph.D. in Pharmaceutics from University of Cincinnati after obtaining a M.S. degree in Pharmacology from The Ohio State University, and B.S. Degree in Chemistry from Ohio Wesleyan University. Hamid has worked at Plexxikon Inc. (a subsidiary of Daiichi Sankyo Inc.) for more than four years, initially as Director of Pharmaceutics and more recently as Sr. Director. Prior to Plexxikon, Hamid worked as a Scientist at Genentech, and starting in Jan-2001, as a Senior Scientist at AstraZeneca Pharmaceuticals.

Dr. Rezaei has over 16 years of experience in drug development initially working in "Big-Pharma" and more recently in smaller innovative pharma companies. During his work at Plexxikon Inc., Hamid has developed and managed the Pharmaceutics department, expanded capabilities to develop poorly soluble compounds, and managed the clinical supply chain for all current projects. He currently manages several projects from discovery support to pre-NDA stage, has contributed to several IND submissions, and has selected and managed multiple CMOs to manufacture clinical supplies. At Genentech, Hamid established and managed its first small molecule development laboratory, worked on several Oncology projects, and utilized a QbD-based approach to rapidly develop and transfer the formulation of a currently marketed oncology compound (Cobimetinib) for NDA submission. At AstraZeneca, Hamid developed two new formulations of Seroquel® (Quetapine), contributed to regulatory submissions of Crestor® (Rosuvastatin), and several other IND submissions.

Presentation Abstract and Speaker Bios:

Exploring new technologies for continuous tablet manufacturing:

A case study on application of integrated hot melt extrusion and njection molding process technology

Abstract: Commercial drug manufacturing is increasingly witnessing the transition of batch processes to continuous manufacturing. This development opens avenues to establish processes novel to the pharmaceutical industry as continuous manufacturing platforms. The combination of hot melt extrusion and injection molding (HME-IM) is one such process. Until now, it has been

used as a non-continuous, two-step approach to develop molded tablets. Furthermore, application of this process has been largely limited to slow release systems and amorphous drugs. We demonstrate the development of immediate release tablets using an integrated twin-screw HME-IM continuous manufacturing platform. We obtained tablets with acceptable appearance, strength, drug release, and stability. We also discuss effects of formulation attributes and critical process parameters on the performance and dimensional stability of molded tablets. Results of our study further support viability of the continuous HME-IM process as an alternate drug product manufacturing method.

Vibha Puri, PhD

Vibha Puri is a Scientist in the Small Molecule Pharmaceutical Sciences division at Genentech, Inc. Previously she was a Post-Doctoral Associate at the Novartis-MIT Center for Continuous Manufacturing in Cambridge, MA. She holds a PhD in Pharmaceutics from NIPER (Mohali) in India. She has a cumulative of seven years of industry experience with Ranbaxy Labs and Genentech in drug product development. She has published in the areas of amorphous drugs and solid dispersions, surface characterization of pharmaceuticals, and continuous drug product manufacturing. Her current research interests include characterization of inter-particulate interactions in powders and use of predictive tools for improving drug manufacturing processes.

Presentation Abstract and Speaker Bios:

Cyclodextrins: Versatile and Functional Formulating Agents for Large and Small Molecules

Abstract: Discussion will focus on what are cyclodextrins, inclusion complex methodology, analysis and case study for choosing the correct Cyclodextrin and inclusion complex methodology. Also, an overview on Cyclodextrin use in Large Molecule formulations will be discussed.

Scott Starr

Scott is a Sr. Sales and Business Development Manager of Wacker Americas. Scott has over 30 years of experience working in both the laboratory and technical sales for a variety of industries with a focus on Pharmaceuticals and Agricultural Chemicals. Started Career in 1985 in solid dosage formulation for Wyeth-Ayerst (now Pfizer), and then Transdermal Product Development for Ciba-Geigy (now Novartis). Scott also held positions at Glaxo-Wellcome in Analytical Method development. Scott moved into a technical sales role for various companies since 1998, an started working for Wacker in 2014 as a sales manager for the Pharma and Agro business and is now focusing on utilization of commercialization of Cyclodextrins in the Agriculture and Pharmaceutical Industries in North and South America. Scott obtained his Chemistry degree and MBA.

Presentation Abstract and Speaker Bios:

Binder Selection: What to Consider for Direct Compression, Wet Granulation and Dry Granulation

Abstract: Not all tablet binders are created equal. Pharmaceutical binders are chemically and physically diverse. Given the physical and chemical diversity, a systematic approach to binder selection is warranted to achieve an optimal balance of tablet strength and tablet disintegration time/drug dissolution rate. This delicate balance is achieved through rational selection of binders whose mechanical properties, and surface energetics are properly paired with the mechanical properties and surface energetics of the active pharmaceutical ingredient (API).

The presentation highlights the basic mechanical, size, and surface energetic properties of Ashland binders. Through case studies using model APIs of varying hydrophilicity/hydrophobicity (log Ps), comparisons of tablet performance for direct compression, roller compaction and wet granulation processes are reviewed. Finally, a simple decision tree for rational binder selection, based upon the case studies and physical/chemical properties of the binder/API combination, is proposed.

Joseph P. Reo, RPh, PhD

Joe is a Technical Director at the Pharmaceutical R&D Center of Excellence in Wilmington, DE. He has worked in the Pharmaceutical Industry for over 35 years, in consumer and prescription drug product development. In his current role, he is leading applications research, new functional ingredient development, and technical service support for Ashland functional excipients.

Over the last 30 years, he has worked at Bayer, Merck, Schering-Plough, Pfizer and J&J, in various drug delivery innovation, drug product development and leadership roles, including Science Lead for prescription to non-prescription re-classification, pharmaceutical science team leadership and operations oversight. His research areas span various disciplines, including a focus on particle engineering, control release, taste masking, granulation processes, and mechanical behavior of pharmaceutical polymers.

Joe is active in the American Association of Pharmaceutical Sciences organization, most recently as the Chair of the Formulation Design and Development (FDD) Section, and in the past, as Chair of FDD Forums, Chair of the Modified Release Focus Group, and FDD Abstract Screening Chair.

Joe is also a licensed Pharmacist, currently practicing in the Pennsylvania PENN Medicine Health System.