

# AAPS Formulation, Design and Development (FDD) Programming

## AT A GLANCE

Sunday	Monday	Tuesday	Wednesday	Thursday
	<p><b>8:00 am – 10:00 am</b> MONDAY MORNING ROUNDTABLES FUNDED BY A GRANT FROM</p> <p> <b>Algorithmme</b> Pharma</p>	<p><b>7:00 am – 8:15 am</b> <b>SUNRISE SESSION</b> Practical Considerations in Using Excipients for Drug Testing in Early Toxicology Studies</p>	<p><b>7:00 am – 8:15 am</b> <b>SUNRISE SESSION</b> Innovative Colonic Drug Delivery Systems with a Case Study in Formulation and Temporal Gastrointestinal Transit Analysis</p>	<p><b>7:00 am – 8:15 am</b> <b>SUNRISE SESSION</b> Modeling Ophthalmic Drug Delivery and Disposition</p>
<p><b>8:30 am – 4:00 pm</b> <b>SHORT COURSE #4</b> Recent Advances in Oral Drug Delivery</p> <p><i>An additional fee is required to attend this short course</i></p>	<p><b>ROUNDTABLE</b> Role of Excipient Impurities in Drug-excipient Interactions</p>	<p><b>8:30 am – 11:00 am</b> <b>SYMPOSIUM</b> AAPS Graduate Student Symposium in Formulation Design and Development (FDD)</p> <p>SPONSORED BY</p> <p> <b>Bristol-Myers Squibb Company</b></p>	<p><b>8:30 am – 11:00 am</b> WEDNESDAY MORNING SYMPOSIA FUNDED BY A GRANT FROM</p> <p> <b>AstraZeneca</b> life inspiring ideas</p> <p><b>SYMPOSIA</b> Pharmacokinetic-pharmacodynamic Aspects of Inhaled Lung-targeted Agents</p> <p>The Influence of Excipient Functionality on Quality by Design for Drug Product</p>	<p><b>8:30 am – 11:00 am</b> <b>SYMPOSIA</b> Hot-melt Extrusion: A Novel Oral Solids Processing Technology</p> <p>Advances in the Injectable Combination Products</p>
	<p><b>2:00 pm – 4:00 pm</b> <b>ROUNDTABLE</b> Nanoparticles – Are They Ever Going to Amount to Anything?</p>		<p><b>9:00 am – 11:00 am</b> <b>MINI-SYMPOSIUM</b> Intestinal Delivery of Lipidic Drug Complexes and Conjugates: Case Studies</p>	
	<p><b>2:00 pm – 4:30 pm</b> MONDAY AFTERNOON SYMPOSIA FUNDED BY A GRANT FROM</p> <p> <b>Catalent</b></p> <p><b>SYMPOSIUM</b> Novel Sustained Release Formulation Techniques with Lipid Excipients</p>			
	<p><b>5:00 pm – 7:30 pm</b> Formulation, Design and Development (FDD) Section Joint Membership Meeting and Reception</p>			

# AAPS Formulation, Design and Development (FDD) Programming

## New INTERACTIVE FEATURE for all Roundtable Sessions!

Click on roundtable moderator names to submit questions that you would like to be addressed at the roundtable session in Los Angeles.

### Sunday, November 8, 2009

8:30 am – 4:00 pm

#### Recent Advances in Oral Drug Delivery

##### Short Course #4

An additional fee is required to attend this short course

The program focus is on new technologies and various aspects of formulation development for oral drug delivery, especially for sustained and controlled release applications. Topics of interest include, but are not limited to the following areas: sustained release dosage form/process design as driven by pharmacokinetic attributes of drug substances; improvements in solubility characteristics of poorly soluble active ingredients through the use of sustained release formulation/processing approaches; opportunities for alteration of *in vivo* profiles of active ingredients (such as minimization of food effects) through the use of sustained release technology in dosage form design; *in vivo* and *in vitro* correlation challenges for sustained release products; and targeted delivery of drug substances through dosage form design. This course is suitable for scientists in pharmaceutical product development.

##### MODERATORS

Orapin P. Rubino, Ph.D.  
Glatt Air Techniques, Inc.

Robert A. Femia, Ph.D.  
Glatt Air Techniques, Inc.

#### Development of Oral Controlled Release Dosage Forms

Orapin P. Rubino, Ph.D.  
Glatt Air Techniques, Inc.

#### Oral Controlled Release Multi-particulate Systems: Development Perspectives

Wantanee Phuapradit, Ph.D.  
Teva Pharmaceuticals

#### Consideration in Designing Oral Drug Delivery Systems

Atul M. Mehta, Ph.D.  
Mehta Consulting

#### Strategies in the Development of Extended Release Drug Products and *IVIVC*

Vinod Shah, Ph.D.  
Consultant

#### Enhancement of the Solubility of Poorly-soluble Drug Substances Through the Use of Formulation Additives

Harry Brittain, Ph.D.  
Center for Pharmaceutical Physics

#### Drug Delivery Strategy for Intestinally Metabolized Drugs

Jae Seung Kim, Ph.D.  
TSRL Inc.

#### The *IVIVC* for Sustained Release Products: Principles and Applications

Harald Rettig, Ph.D.  
BioVista LLC

### Monday, November 9, 2009

#### MONDAY MORNING ROUNDTABLES

FUNDED BY A GRANT FROM



8:00 am – 10:00 am

#### Role of Excipient Impurities in Drug-excipient Interactions

##### Roundtable

Study of drug-excipient interactions provides the basis for the design of a stable dosage form. In addition to the possible physical and chemical interactions between the drug substance and the excipient itself, recent experiences suggest that interaction between the drug molecule and impurities in the excipient can have major impact on dosage form stability. Those interactions are more difficult to identify due to the low and variable level of the impurities in the excipient, depending on the specific excipient batch and excipient manufacturer. The low level of impurities in the excipient also makes it an analytical challenge to develop appropriate methods for the control of those impurities. This roundtable will provide an overview of the most common excipient impurities associated with drug product instability and the analytical methods and strategy used for their control.

##### MODERATORS

Sherif I. Badawy, Ph.D.  
Bristol-Myers Squibb

Otilia M. Koo, Ph.D.  
Bristol-Myers Squibb

#### Mechanisms of Drug Degradation in the Presence of Excipient Impurities

Bradley Anderson, Ph.D.  
University of Kentucky

#### Profiling of Reactive Impurities in Commonly Used Excipients

Venkatramana Rao, Ph.D.  
Bristol-Myers Squibb

#### Challenges in Controlling Reactive Impurities in Excipients

Timothy Bee, Ph.D.  
International Specialty Products

#### MONDAY AFTERNOON ROUNDTABLES

2:00 pm – 4:00 pm

#### Nanoparticles — Are They Ever Going to Amount to Anything?

##### Roundtable

“Nanoparticle” has been a drug delivery buzz word for years, yet the technology seems to be stuck in the concept phase. In fact, there isn’t even a consensus as to what a nanoparticle is. What is holding us back? When are we going to see products based on this technology? For practical reasons, will nanoparticles be only applicable to niche products, or will they gain broader utility? This session will try to separate the fantasy from the reality. In a roundtable format, speakers with experience in the area will discuss where the field is today, the likely applications of nanoparticle technologies, and what pitfalls arise as these technologies move from the concept phase into development.

##### MODERATOR

Brian Rohrs, Ph.D.  
Bausch & Lomb

##### Nanoparticle Roundtable

Russell J. Mumper, Ph.D.  
University of North Carolina at Chapel Hill

##### Nanoparticle Roundtable

Panayiotis P. Constantinides, Ph.D.  
Biopharmaceutical and Drug Delivery Consulting, LLC

##### Nanoparticle Roundtable

Mansoor Khan, Ph.D., M.S., R.Ph.  
U.S. Food and Drug Administration

# AAPS Formulation, Design and Development (FDD) Programming

## MONDAY AFTERNOON SYMPOSIA

FUNDED BY A GRANT FROM



2:00 pm – 4:30 pm

### Novel Sustained Release Formulation Techniques with Lipid Excipients

#### Symposium

Sustained-release (SR) oral drug delivery is of great interest for a number of reasons, including reduced dosing frequency, improved efficacy and reduced frequency of adverse effects, all of which lead to improved patient compliance and greater product acceptance. The profile of drug release is determined by the relatively complex excipient matrix in which the drug is dispersed. Thus, a comprehensive arsenal of excipient materials and novel methods of preparation are needed to meet the unique needs of each drug. Much like cellulosic polymers, acrylates and polyacrylamide copolymers, lipid excipients have been successfully applied in SR delivery. References in currently marketed dosage forms prove their utility, especially in conventional direct compression and capsule filling methods. Owing to their thermo-plastic properties, lipid excipients have enormous and largely un-exploited potential in sustained release drug delivery. More recently, lipids have been applied in melt granulation/pelletization, spray cooling and hot melt coating techniques. There are also a number of publications on preparation of solid lipid nanoparticles (SLN) and nano structured lipid carriers (NLC) through high pressure homogenization. These novel approaches allow solvent-free preparations of SR matrices adaptable to the needs of each drug. This session will bring the latest SR formulation techniques employing lipid excipients. The presentations are aimed at understanding the nature of lipid matrices and their influence on drug release profile. As such, considerations in selecting materials and methods for optimal and yet stable release profiles will be discussed.

#### MODERATOR

Avinash Thrombre, Ph.D.  
Pfizer Global Research & Development

#### Contribution of Lipid Based Ingredients to Advanced Oral Modified Release Formulations

Guy G. Vergnault, Ph.D.  
Skye Pharma AG

#### Spray Cooling with Lipids: Considerations in Development of Sustained Release Lipid Particles

Duncan Q. Craig, Ph.D.  
University of East Anglia

#### Novel Sustained-release Multiparticulates: A Case Study Demonstrating Performance, Manufacturability, and Stability

Jim Nightingale, Ph.D.  
Bend Research Inc.

## JOINT MEMBERSHIP MEETING AND RECEPTION

5:30 pm – 7:30 pm

Formulation, Design and Development (FDD) Section  
Joint Membership Meeting and Reception

## Tuesday, November 10, 2009

### TUESDAY SUNRISE SESSIONS

7:00 am – 8:15 am

#### Practical Considerations in Using Excipients for Drug Testing in Early Toxicology Studies

##### Sunrise Session

Drug candidates are becoming more challenging to formulate in early toxicology studies; low aqueous solubility, poor oral bioavailability, and transporters substrates. There are a number of different practices currently adopted in the industry to overcome these challenges; in terms of excipients selection and the safety levels chosen. Frequently, there is a balance of applying the excipients at high enough dose to facilitate toxicology testing without causing unwanted effects. In this sunrise session, current formulation, considerations, and practices in industry will be reviewed. In addition, we will explore if standardized approaches can be a reality.

#### MODERATOR

Otilia M. Koo, Ph.D.  
Bristol-Myers Squibb

#### Current Practices in Formulation Selection for Early Toxicology Studies

Yunxia (Vivian) Bi, Ph.D.  
AstraZeneca

#### Excipients in Early Toxicology Testing — Will Standardization Help or Hinder Drug Discovery?

Michael J. Hageman, Ph.D.  
Bristol-Myers Squibb

## Graduate Student Symposium

8:30 am – 11:00 am

AAPS Graduate Student Symposium in Formulation Design and Development (FDD)

SPONSORED BY



Bristol-Myers Squibb  
Company

# AAPS Formulation, Design and Development (FDD) Programming

**Wednesday, November 11, 2009**

## WEDNESDAY SUNRISE SESSIONS

**7:00 am – 8:15 am**

### Innovative Colonic Drug Delivery Systems with a Case Study in Formulation and Temporal Gastrointestinal Transit Analysis

#### Sunrise Session

Inflammatory bowel disease can affect both the small and large intestines. Mesalamine is an anti-inflammatory drug used to treat inflammation of the digestive tract (Crohn's disease) and mild to moderate ulcerative colitis. This presentation will share with the audience the knowledge in gastrointestinal physiology and different formulation strategies so that a product targeted to the colon to provide superior patient care may be achieved. The total aims are five fold. First, available commercial dosage forms (enema, rectal suppository, extended release oral capsule and delayed release oral tablet and parenteral preparations) and their ingredients will be thoroughly reviewed. Second, *in vitro* drug release patterns of two commercial oral products, Pentasa extended release capsule coated with ethylcellulose and Asacol delayed release tablet coated with Eudragit S conducted by the presenter and coauthors will be presented. Third, the current innovative technologies such as Oros-CT, Pulsicap™, Capsule within Capsule, Targit™, Eudrapulse™, Eudramode™, Eudracol™, Port™, Eaglet™, Code™, COLAL™, will be discussed according to the mechanisms of release such as swelling, erosion, bacterial degradation or combination. Fourth, a product of delayed release Mesalamine beads formulated by the presenter and coauthors will be instituted to show step by step procedure including how to make core beads by using Caleva™ Bench Top Extruder/Granulator (Model 10/25), Caleva™ Spheronizer, how to prepare the aqueous Eudragit™ S coating solution, how to spray coat core beads with Wurster™ spray coater, and how to quantify percent of coating thickness, determine total weight of coated pellets to achieve the desired strength and select the right size of hard gelatin capsule for loading. Five, use of temporal G.I. transit simulations to formulate and predict sustained input of target-site directed, single and multiple dose orally administered in fasting state, light versus heavy meals, exclusively into the colon will be demonstrated.

#### MODERATOR

Dave Wallick, Ph.D.  
The Dow Chemical Company

### Tutorial Overview of Colonic Drug Delivery

Brahma N. Singh, Ph.D, F.C.P.  
Forest Laboratories, Inc.

### Innovative Colonic Drug Delivery Systems with a Case Study in Formulation and Temporal Gastrointestinal Transit Analysis

Monica C. Chuong, Ph.D.  
Massachusetts College of Pharmacy and Health Sciences

## WEDNESDAY MORNING SYMPOSIA

FUNDED BY A GRANT FROM



**8:30 am – 11:00 am**

### Pharmacokinetic-pharmacodynamic Aspects of Inhaled Lung-targeted Agents

#### Symposium

Discovery and development of inhaled lung-targeted therapeutic agents such as bronchodilators and corticosteroids present substantial PKPD challenges; lung PK is not easily measurable in preclinical models and may not be measurable in clinical studies. Systemic PK is relevant for systemic effects but may not be so for airway effects such as bronchodilation. Sufficient understanding of the lung as an absorption barrier for small molecules is not currently available to allow for inference of lung PK from systemic observations. Quantitative dose-exposure-response analysis is rarely possible because of lack of relevant exposure data. Therefore, basic research is needed in order to characterize the ADME profile of lung-targeted inhaled agents. This symposium will provide specific information on the gaps that exist in our understanding of the lung as an ADME barrier, and in the absence of requisite clinical information, what quantitative tools exist to help develop PKPD understanding of lung-targeted agents.

#### MODERATORS

Dennis K. O'Connor, B.S.  
Boehringer Ingelheim Pharmaceuticals, Inc.

Balaji M. Agoram, Ph.D.  
Pfizer Global Research & Development

#### Lung ADME

Ann Tronde, Ph.D.  
AstraZeneca

#### Inhalation by Design

Rhys Jones, M.S.  
Pfizer Global Research & Development

### PK-PD Considerations of Inhaled Agents — Corticosteroids as an Example

Gunther Hochhaus, Ph.D.  
University of Florida

### Bioequivalence Testing for Inhaled Lung-targeted Agents

Wallace Adams, Ph.D.  
U.S. Food and Drug Administration

**8:30 am – 11:00 am**

### The Influence of Excipient Functionality on Quality by Design for Drug Product

#### Symposium

Excipients facilitate manufacturing, enhance or support stability, and/or aid *in vivo* performance of a product. Certificates of analysis provide little information about what the industry has termed excipient functionality. This demands thorough understanding of material characteristics such as particle size and morphology, solid-state characterization and processing to name a few. Functionality has become a hot topic since the European Pharmacopoeia (EP) listed specific functionality-related characteristics (FRCs) in some of its excipient monographs. USP has looked into including a General Chapter on Excipient Performance Testing suggesting it could be part of the labeling section and non-mandatory. Excipient manufacturers are voicing concerns because in their view functionality may mean different things to different people. The characterization of functionality is very simply process understanding in accordance with the philosophy of the U.S. Food and Drug Administration (FDA), PAT and 21st century GMP initiatives. QbD is an approach to product development that seeks to find the limits within which acceptable product can be manufactured (edge of failure) and thereby the approvable design space. Standardized testing for excipients could play a critical role in the definition of design space and any quality-by-design endeavor must define the materials properly. There is a growing need for a systematic process to evaluate the interaction between components of a product to increase scientific understanding and correlation between physical and mechanical properties of materials and their functionality and ways in which the design space can be expanded by development of relevant functionality tests. This symposium will address the role the functionality tests of excipients will play in the QbD world through how we perform the functionality tests, how this test helps in establishing the design space, and the appropriate control strategies. A regulatory perspective will provide in-sight into this concept. In addition, the challenges and opportunities facing the excipient manufacturers and also the role of the pharmacopoeia as it pertains to supporting such changes will also be discussed as part of this symposium.

# AAPS Formulation, Design and Development (FDD) Programming

## MODERATOR

Umang Shah, Ph.D.  
Solvay

## FDA's Perspective

Moheb Nasr, Ph.D., invited  
U.S. Food and Drug Administration

## USP Perspective on Performance Related Tests for Excipients

Kevin Moore, Ph.D.  
United States Pharmacopeia (USP)

## Excipient User's Perspective

Mohan Ganapathy, Ph.D.  
Merck and Co., Inc.

## Excipient Manufacturer's Perspective

Richard C. Moreton, Ph.D.  
Finnbrit Consulting

## WEDNESDAY MORNING MINI-SYMPOSIA

9:00 am – 11:00 am

### Intestinal Delivery of Lipidic Drug Complexes and Conjugates: Case Studies

#### Mini-symposium

Lipid-drug complexes arise from non-covalent association of a drug with a lipidic carrier usually mediated by electrostatic and/or hydrogen bonding interactions. In contrast, lipid-drug conjugates comprise covalent conjugates of drug and a lipidic moiety, such as a fatty acid, a glyceride, other neutral lipid, or a phospholipid. The development of lipidic drug complexes and conjugates for pharmaceutical applications is driven primarily by the need to target drugs to specific sites in the body and/or to improve their biopharmaceutical or physicochemical properties. Lipidic drug conjugates are generally designed to exhibit characteristics which mimic those of dietary lipids, a key consideration in their utilization for oral delivery. These conjugates may provide enhanced intestinal permeability, improved GI stability, tolerability, and increased potential for intestinal lymphatic transport. In the latter case, for drugs with high first pass metabolism, recruitment of lymphatic transport via a prodrug strategy can provide for very significant increases in oral bioavailability. Alternatively, drug lipid/phospholipid conjugates can significantly alleviate the GI-injury induced by NSAIDs, such as aspirin and indomethacin. In contrast, the generation of drug:lipid complexes via drug complexation with excipients in lipid-based drug delivery systems, such as SEDDS, can reduce drug solubility, absorption, and is an often overlooked but critical aspect of formulation design. The objective of this symposium is to discuss recent advances in understanding and present case studies in the use of drug-lipid conjugates and drug-lipid

complexes. Product development challenges and considerations particularly in reference to the impact of complexation and conjugation on pharmacokinetic and pharmacodynamic endpoints and the implications in terms of regulatory approval will be highlighted throughout the symposium.

## MODERATOR

Panayiotis P. Constantinides, Ph.D.  
Biopharmaceutical and Drug Delivery Consulting, LLC

### Targeting Lipidic Prodrugs to the Lymphatics

Christopher J. H. Porter, Ph.D.  
Monash Institute of Pharmaceutical Sciences,  
Monash University

### Drug-excipient Complexation in Self-emulsifying Drug Delivery Systems and Implications for Excipient Selection in Lipid-based Drug Delivery Systems

Shirlynn Chen, Ph.D.  
Boehringer Ingelheim Pharmaceuticals, Inc.

### Improving Gastrointestinal Safety of Non-steroidal Anti-inflammatory Drugs with Phospholipids

Upendra Marathi, Ph.D.  
PLx Pharma

## Thursday, November 12, 2009

## THURSDAY SUNRISE SESSIONS

7:00 am – 8:15 am

### Modeling Ophthalmic Drug Delivery and Disposition

#### Sunrise Session

Sophisticated models for ocular drug disposition are becoming available, but there is little literature information on how accurate the models are, and to what problems they have been applied. This session will offer case studies in how these models have been applied, what insights have been gained, and what limitations have been experienced. Since sophisticated modeling and simulation of drug delivery is a relatively young field, this session is of broader interest not only for those scientists trying to build PK models, but also for the pharmacokinetic and drug delivery scientists trying to utilize those models to speed up drug development.

## MODERATOR

Brian Rohrs, Ph.D.  
Bausch & Lomb

### Modeling for Ophthalmic Drug Development

John Crison, Ph.D.  
Simulations Plus, Inc.

## THURSDAY SYMPOSIA

8:30 am – 11:00 am

### Hot-melt Extrusion: A Novel Oral Solids Processing Technology

#### Symposium

The advent of high throughput screening in the drug discovery has resulted in compounds with high lipophilicity and poor solubility. Various approaches have been adopted to address these solubility issues including preparation of solid dispersions/solid solutions. Any new chemical entities, as well as existing drugs that demonstrate poor bioavailability due to solubility issues are prime candidates for hot-melt extrusion (HME). The numerous advantages of HME technology include shorter and more efficient times to the final product, environmental advantages due to elimination of solvents in processing, and increased efficiency of drug delivery to the patient. HME has been demonstrated to provide rapid, sustained, modified, and targeted drug delivery. A variety of hot-melt polymers (both hydrophilic as well as hydrophobic) and lipid-based matrices have been used in different applications to obtain tailored release profiles for selected active pharmaceutical ingredients (APIs). Improvements in bioavailability utilizing HME techniques demonstrate the value of the technology as a potential drug delivery-processing tool. Amorphous forms of drugs with high amounts of energy produced from the HME process aid in enhancement of solubility of such drugs. The interest in HME technology for pharmaceutical applications is evident from the increasing number of patents and publications in the scientific literature. Although some aspects of HME dosage forms were presented in earlier AAPS meetings, there was no comprehensive discussion of various applications and advancements in this technology. The proposed objective of this symposium is to present the latest developments and myriad of applications of HME technology for pharmaceutical dosage forms including granules, pellets, tablets, implants, and transmucosal systems. For example, low temperature HME techniques will be discussed. Topics will cover case studies including HME applied to the formulation design of highly water insoluble and thermo-degradable drugs. It will also deal with the specific problems associated with these techniques and its plausible solutions (technology and formulation design related) so that the span of this technology widens. The challenges related to HME dosage forms will be discussed from the regulatory perspective for the improvement of our understanding of the regulatory issues faced by these techniques and the products produced by this innovative technology. This symposium is targeted to reveal the novel applications of HME technology for constantly evolving oral solid dosage form technology, which is continuing to shift the paradigm of pharmaceutical processing and drug delivery systems.

# AAPS Formulation, Design and Development (FDD) Programming

## MODERATORS

Dave Miller, Ph.D.  
Hoffmann-La Roche Inc.

Sampada B. Upadhye, M.S.  
University of Mississippi

### Hot-melt Extruded Films, Pellets and Tablets: Affording Flexibility to the Process via Polymer Blends

Michael A. Repka, D.D.S., Ph.D.  
University of Mississippi

### Physical-chemical Characterization of Polymers and Actives to Modulate Successful Melt Extrusion

Andreas Gryczke, Ph.D.  
Evonik Pharma Polymers

### Melt Extrusion — Future of an Exciting Technology

Jörg Breitenbach, Ph.D.  
Soliqs

### Quality by Design for Pharmaceutical Hot-melt Extrusion

Scott Martin, Ph.D.  
Thermodfisher

8:30 am – 11:00 am

## Advances in the Injectable Combination Products

### Symposium

It has been increasingly evident that cancer probably be initiated from and maintained by a small sub-population of undifferentiated, tumorigenic cells called cancer stem cells (CSCs). Production of the main mass of the tumor may be attributed to this minor population of CSCs through a particular process of continuous self-renewal and differentiation. Thus, CSCs have come into sight as a potential target of cancer therapy. To date, many types of cancer stem cells have been identified in various cancers including breast, colorectal, pancreatic, head and neck cancers. Since cancer stem cells are resistant to current available chemotherapeutic regimen, it is important to explore new molecular target to eliminate these drug resistant cancer stem cells. This roundtable will provide a forum to debate cancer stem cell concept, targeted drug delivery, and drug targeting strategy to eliminate cancer stem cells.

### MODERATORS

Sandeep Nema, Ph.D.  
Pfizer Global Biologics Pharmaceutical R&D

Yatin Gokarn, Ph.D.  
Genentech, Inc.

### Case Study 1: Developing a mAb-autoinjector Device

Speaker to be Determined

### Case Study 2: Lessons Learned from Drug- injector Products

Jessica M. Ballinger, Ph.D.  
Pfizer Global Research & Development

### Case Study 3: Challenges During Development of a Single-use Needle-free Drug Product

Stephen Farr, Ph.D.  
Zogenix, Inc.

### Regulatory Requirements for Injection Drug-device Combination: An Update

Scott A. Colburn, Ph.D., invited  
U.S. Food and Drug Administration