2nd Annual
BIOEQUIVALENCE SUMMIT
Innovative Approaches Toward Developing Bioequivalent Drugs While Comprehensively Maintaining Regulatory Compliance

October 5-6, 2015 Hilton Boston Back Bay | Boston, MA

CHAIRPERSON

FEATURED SPEAKERS

AUDRA STINCHCOMB
Chief Scientific Officer and Founder
F6 PHARMA

HEATHER HUET
Senior Investigator II, Oncology Biotherapeutics
NOVARTIS

ZAHRA SHAHROKH
Chief Development Officer
STC BIOLOGICS

SIBEL UCPINAR
Director
IMPAX LABORATORIES

HENRY WU
Director, Biopharmaceutics
MERCK

Hear the latest innovations, solutions and topical issues:

STC BIOLOGICS addresses the challenges of developing biosimilars

F6 PHARMA designs highly variable topical bioequivalent drugs

MERCK explores the use of biowaiver methodologies to determine bioequivalence and bioavailability

BANNER LIFE SCIENCES streamlines bioequivalent study designs to be submitted in ANDAs

“A difficult subject made easier.”
—Principal Analytical Scientist, SUNOVION PHARMACEUTICAL

“Complex mathematical issues [were] presented simply and that made them attractive.”
—Senior Biostatistician, ORION PHARMA

TO REGISTER Call 866-207-6528 or Visit www.exlevents.com/bioequivalence
Dear Colleague,

Recent changes in the healthcare system have put a greater focus on the development and availability of generic drugs. The pharmaceutical industry has responded by exploring alternative delivery methods, creating new test designs and, most notably, developing the first American biosimilar. These advances have been met with acclaim, but they do bring new challenges. Regulatory ambiguity in testing procedures causes delays for generic developers, and legal action from originator drug companies restricts those focusing on biosimilars from moving quickly. This summit will further explore the scientific necessity of this subject while guiding experts through their collective difficulties.

Exl Events’ 2nd Annual Bioequivalence Summit is the industry’s premier event offering all-inclusive technical and regulatory solutions for demonstrating bioequivalence in generics and biosimilars. Additionally, this event will feature comprehensive presentations on novel drug therapies, cost-effective and timely testing procedures, accurate modeling techniques for forecasting patient reaction, and much more. Throughout the event, you will exchange knowledge of generic drug development with your fellow professionals, and you will be prepared for your next steps toward successful implementation by its conclusion.

The expert speaking faculty of the 2nd Annual Bioequivalence Summit provides in-depth examinations of:

- Innovative testing and modeling procedures that cut costs and provide more accurate results
- Advances in FDA regulations and requirements, and insight into the FDA’s recent overhaul and funding increase
- Highly demanded alternative delivery methods, such as long-acting injectables and topical applications
- Legal challenges from originator drug companies that impact the development of biosimilars

We look forward to seeing you in Boston this fall!

Sincerely,

Derek O’Connor
Conference Production Director
doconnor@exlevents.com

WHO SHOULD ATTEND:
This conference is designed for representatives from pharmaceutical and biotechnology companies as well as generic drug developers with responsibilities in the following areas:

- Bioequivalence
- Pharmacokinetics/Pharmacodynamics
- Drug Metabolism
- Regulatory Affairs
- Statistics/Biostatistics
- Drug Research and Development
- Clinical Sciences
- Preformulation
- Scientific Affairs
- Drug Delivery
- Drug Discovery
- Life Cycle Management

THIS CONFERENCE WILL ALSO BE OF INTEREST TO:

- Branded Drug Developers
- Clinical Research Labs
- CROs/CMOs
- Drug After-Market Manufacturers/Suppliers
- Regulatory Consultants
- Statistical Service Providers
- API Suppliers
- Managed Care Professionals

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TO REGISTER Call 866-207-6528 or Visit www.exlevents.com/bioequivalence
Monday, October 5, 2015 / Day One

8:00 Registration and Continental Breakfast

8:45 Chairperson’s Opening Remarks

Audra Stinchcomb, Chief Scientific Officer and Founder, F6 PHARMA

9:00 CASE STUDY: Regulatory Approval Process of Biosimilars

At biosimilars have emerged in the United States, regulatory agencies have had to develop a stringent review and approval process. In March of this year, the FDA called upon biostatistician Dr. Bernard Cole to assess and assist in the review of Zanxio, now the United States’ first biosimilar.

- Learn metrics and standards used by regulatory bodies
- Understand how to properly structure your studies to fit testing guidelines
- Listen to a walk-through of the approval process

Bernard Cole, Interim Dean and Professor of Statistics, UNIVERSITY OF VERMONT

9:45 Technical, Logistic and Legal Challenges of Establishing Bioequivalence for Biosimilar Products

Over the past year, drug developers have submitted license applications for biosimilars in the US. Many have faced legal opposition, citing patent protection, while others have had to fight for access to the originator biologics. The FDA has also been ambiguous regarding the level of nonclinical and clinical data for approval, as the process is still young.

- Define methodologies for developing biosimilars
- Understand lessons learned from the commercialization of generics that affect biosimilar development
- Engage the debate over patent and know-how protection as it relates to the US BPCIA

Zahra Shahrak, Chief Development Officer, STC BIOLOGICS

Magdalena Leszczynecka, President and CEO, STC BIOLOGICS

10:30 Networking Break

11:00 Challenges in Oncology Drug Discovery and Development

Oncology drugs continue to be some of the most high-profile treatments. However, several challenges exist, including cytotoxicity of drugs, lack of test subject availability and safety, and high costs. To exemplify these challenges, a case study of the creation of a nanobody targeting DR5 will be presented.

- Delve into the challenges in the development of novel biologics
- Understand considerations for the interpretation of preclinical activity data of antibody therapeutics
- Use the presented case study to fine-tune your future oncology studies

Heather Huet, Senior Investigator II, Oncology Biotherapeutics, NOVARTIS

11:45 In Vitro Release Testing Methods and the Development of IVIVC for Complex Drug Products

Complex drug products, such as microspheres, are considered high risk. In vitro release testing can be used for both safety and quality control purposes.

- Pinpoint how the FDA classifies “complex” active ingredients, formulations, deliveries and device combinations
- Hear methods for complex parenterals
- Learn about the use of microspheres

Diane Burgess, Board of Trustees, Distinguished Professor of Pharmaceutics, UNIVERSITY OF CONNECTICUT

12:15 Luncheon

1:15 In Vitro Alternatives to Clinical Endpoint Studies to Optimize Organizational Performance

In vivo testing can be both a financial and logistical challenge. The FDA has announced that one of their initiatives for 2015 is to investigate substituting in vitro studies for clinical endpoints, thereby reducing the number of human subjects exposed to a new drug and expediting development.

- Study in vitro methods as a mechanism for assessing the in vivo product bioequivalence of locally acting drugs
- Grapple with the current logistic and precision challenges of clinical endpoint studies
- Utilize in vitro studies in the development of topical drug delivery

Chandra Vattikonda, Senior Director, North America Generics, DR. REDDY’S LABORATORIES

2:00 Advances in Absorption Modeling and Drug Dissolution for Sustained-Release Drugs

Determining the bioequivalence of a new drug depends on the rate of the absorption of the active pharmaceutical ingredient into the bloodstream. Forecasting has proven difficult for sustained-release drugs because of the need to target the release rate.

- Address the challenges of poorly water-soluble, orally administered drugs
- Support particle size specification for sustained-release drugs
- Use in vitro models to correlate with in vivo absorption/bioavailability

Shirlynn Chen, Senior Research Fellow, BOEHRINGER INGELHEIM

2:45 Networking Break

3:15 Define Biowaiver Strategies and Approaches to Account for Challenging Factors

Successful biowaiver of BE studies can reduce the cost of product development and accelerate product approvals. That said, gaps between science and regulation, as well as a lack of harmonization among agencies, present significant challenges for sponsors to use this approach effectively.

- Interpret current regulatory guidance on biowaivers based on BCS and SUPAC
- Review recent examples of biowaivers for IR/MR products with mixed regulatory outcomes
- Identify alternative tools to facilitate and support biowaivers in complex product development

Henry Wu, Director, Biopharmaceutics, MERCK

4:00 CASE STUDY: Physiologically Based Pharmacokinetic (PBPK) Modeling to Simulate Changes in Particle Size and Dosage

PBPK modeling introduces a mathematical matrix into pharmacokinetics and is more precise than the trial and error method in drug development. Regulators often reject first-round drug submissions due to inaccurate and poor dosing recommendations, creating an immediate need for an accurate prediction tool.

- Understand methodology and use in predicting in vivo performance
- Assess the benefits of forecasting gastrointestinal absorption rate in controlled versus immediate release drugs
- Hear why the FDA is vehemently supporting PBPK models as a cheaper, safer tool for bioavailability studies

Wen Lin, Senior Investigator, NOVARTIS

4:45 Chairperson’s Closing Remarks

Audra Stinchcomb, Chief Scientific Officer and Founder, F6 PHARMA

5:00 Day One Concludes
8:00  Registration and Continental Breakfast

8:45  Chairperson’s Recap of Day One
Audra Stinchcomb, Chief Scientific Officer and Founder, F6 PHARMA

9:00  Streamline Bioavailability/Bioequivalence Study Designs for Various Dosage Forms to Be Submitted in IND and NDA

When submitting a new drug, the requirements and regulations branch from each selection is an IND, NDA or ANDA. Matching the dosage form, delivery method and bioequivalence trials required is a very complicated process.

- Differentiate between the information to be submitted in ANDA and IND/NDA
- Hear alternate approaches to support BA/BE
- Explore documenting BA and BE for various dosage forms for oral solid, liquid, transdermal and combination products

Rensi Sutaria, Regulatory Affairs, BANNER LIFE SCIENCES

9:45  Development of Abuse Deterrent Products — Benefits and Potential Consequences

Prescription opioids are essential medicines in pain management. However, opioid over-prescribing in the US has led to increased misuse and abuse of these products, resulting in significant public health issues and cost. The FDA and NIH (NDA) are both actively promoting the development of abuse deterrent products as a viable option to help stem the drug abuse epidemic.

- Become knowledgeable about the various abuse deterrent/resistant technologies
- Understand approaches to PK and PD clinical studies to achieve abuse deterrent labeling
- Learn about abuse deterrent/resistant approaches beyond opioids

Albert Brzecklo, Chief Scientist and Vice President Technical Affairs, ACURA PHARMACEUTICALS, INC.

10:30  Networking Break

11:00  Fine-Tune Tolerance Ranges for Narrow Therapeutic Index Drugs

The FDA has opined that typical bioequivalence standards and testing procedures may be inadequate for narrow therapeutic index (NTI) drugs, as the slightest variation in drug levels may have clinically significant negative effects on patient outcomes. In response, developers are exploring more extensive, accurate studies in accordance with stricter guidelines and limits.

- Study FDA recommendations for determining bioequivalence, and interpret their standards and metrics
- Assess the potential negative impact of switching from RLD to generic NTI drugs and from one generic NTI to another
- Describe the stricter EU and Canadian regulations and whether these standards could be applied to US generics

Nicole Maisch, Associate Clinical Professor, ST. JOHN’S UNIVERSITY

11:45  Luncheon

12:45  Anvisa Regulations in Bioequivalence and Biowaivers: Trends and Challenges

In Brazil, requirements regarding bioequivalence studies and biowaiving are under revision, considering new perspectives on therapeutic equivalence, scientific updates and global harmonization. A Regulatory Agenda 2015-2016 was approved by Anvisa directors in order to promote discussions among regulators, academia and industry about the requisites for complex drugs, narrow therapeutic index (NTI) drugs and BCS biowaiving.

- Hear the challenges and trends in Anvisa’s process of revision of BE and biowaiving requirements
- Learn Anvisa current thinking about complex drugs (therapeutic proteins, liposomal drugs, oral inhaled drugs), narrow therapeutic index drugs and BCS biowaiving
- Understand the procedures for participation in Anvisa discussions about those themes

Gustavo Mendes Lima Santos, Coordinator of Therapeutic Equivalence Coordination, ANVISA

1:30  New Paths to Capitalize on Regulatory Paradigms in Oncology Development

Oncology development is experiencing a very dynamic time and there are opportunities to streamline clinical development programs and obtain approvals more quickly. Based on recent US regulatory paradigms, the traditional path from Phase 1 to 2 to 3 is no longer the only (or fastest) path to patients, as evidenced by Phase 1 or pivotal phase 2 trials having led to approval. The result is that drug developers can now consider a broader range of possibilities and apply innovative design principles much earlier in the process. The use of biomarkers to determine patient selection, cohort studies, basket, and umbrella studies and other unique approaches are now considered viable for regulatory approval if the compound displays a substantial benefit and a balanced risk. Moreover, an accelerated approach to clinical development should also contemplate formulation needs, companion diagnostics, early patient access, and potential post-marketing requirements much sooner than traditional development programs of years past.

- Hear how the traditional clinical phase path is no longer the only way
- Learn the role of biomarkers and alternative studies to be used to gain regulatory approval
- Understand how these advances can accelerate studies

Leena Das-Young, Vice President, Late Phase Oncology Strategy, Development, Submissions & Lifecycle Management Group, PFIZER

2:15  Test Subject Variability Challenges in the Development of Topical Bioequivalent Drugs

The FDA has identified the need for clinical trials as a major hindrance in establishing bioequivalence in topical drugs. These trials are not just time-consuming — they are also extremely costly. In addition, the human user factor creates ambiguous results, due to variance in patient skin features and application methods.

- Address the high variability of skin properties, application methods and preferred absorption
- Interpret economic limitations of topical drugs before factoring in generic competition
- Explore the use of heat testing to enhance penetration

Audra Stinchcomb, Chief Scientific Officer and Founder, F6 PHARMA

3:00  Networking Break

3:30  Overview of Bioequivalence Determination of Inhalation Products

Bioequivalence of conventional oral dosage forms intended for systemic action is determined by comparing drug concentration in plasma or urine following the administration of test and reference products to healthy human subjects at the same dose and under similar conditions. However, this approach cannot directly demonstrate BE of orally inhaled and nasal drug products intended for local action, due to lack of relevance of drug concentration in blood to the drug available at the local site(s) of action.

- Hear an overview of the current challenges and opportunities in establishing bioequivalence for locally acting orally inhaled products (OIP) and Nasal Sprays (NS)
- Understand FDA requirements for demonstrating BE of inhalation products
- Discuss the complexities in the evaluation of in vitro, pharmacokinetic and pharmacoodynamic/clinical end point studies, and describe the challenges in the application of BE approaches for OIPs and NSs

Sibel Ucpinar, Director, IMPAX LABORATORIES

4:15  Recommendations for the Development of Long-Acting Injectable Drug Products

The FDA has announced it is spending approximately $1 million to study the effectiveness of long-acting injectables. These investigations have expanded to cover treatment options for schizophrenia. Due to that disease’s symptoms, application as a long-lasting injectable is more patient-friendly and effective to cover treatment options for schizophrenia. Due to that disease’s symptoms, application as a long-lasting injectable is more patient-friendly and effective than several oral tablets taken daily.

- Monitor PRPK and PK/PB modeling requirements to establish standards
- Develop statistical analysis for microparticle products
- Predict challenges of intersubject variability

Michael Palmieri, Senior Director, Analytical Development, ALKERMES

5:00  Chairperson’s Closing Remarks
Audra Stinchcomb, Chief Scientific Officer and Founder, F6 PHARMA

5:15  Summit Concludes
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