Workshop: Flight Simulator: Learning How to Develop Complex Generic Drug Products

The availability of generic drug products can mitigate the risk of drug shortages, help make prescription drugs more affordable, and enhance patient access to medicines. However, there may be substantial uncertainty about how to approach the development of complex generic drug products (CGDPs). The complexity of CGDPs may be associated with the active pharmaceutical ingredient (API), the formulation, the dosage form, the route of delivery, and/or the nature of the drug-device combination product. To encourage CGDP development, the Food and Drug Administration (FDA) is actively engaging with prospective developers of CGDPs to discuss specific issues of scientific or regulatory complexity, and to clarify the FDA's bioequivalence (BE) standards and recommendations.

This practical, active-participation workshop will help participants learn how to approach a demonstration of API sameness and BE for each type of CGDP and how to engage with the FDA about different types of questions during the development of a CGDP. Workshop participants will learn how to efficiently de-risk CGDP development, increase certainty about regulatory decision making, and enhance patient access to high-quality CGDPs. The unique focus of this workshop is that participants will gain hands-on experience, learning through mentoring and interactive practice how exactly to implement the concepts, information, and procedures covered in those other workshops. The program will consist of three sessions:

Session 1: Reviewing the Flight Plan: Learning to Navigate the Development Process for Different CGDPs

Presentations by FDA experts will guide workshop participants about how to efficiently navigate product development for different types of CGDPs, and how to get answers and feedback from FDA throughout that process. Case studies will be used to illustrate the scientific considerations impacting API sameness and BE for specific types of CGDPs, and to clarify the communication options that prospective ANDA applicants can use to discuss various types of questions with the FDA.

Session 2: Hands on the Controls: Practicing How to Structure Efficient Development Plans for Specific CGDPs

FDA experts will mentor workshop participants during multiple parallel breakout sessions, each focusing on different types of CGDPs. In each session, workshop participants will practice constructing product development plans for different types of hypothetical CGDPs by identifying the scientific issues relevant to that CGDP and proposing specific types of evidence (including modeling and simulation) that could support a demonstration of BE. As questions and uncertainties arise, participants will practice preparing

controlled correspondences and assembling pre-ANDA meeting packages, to discuss the questions with the FDA during the subsequent session of the workshop.

Session 3: Getting Cleared for Takeoff: Practicing How to Leverage FDA Feedback to Facilitate CGDP Development

Workshop participants will gain hands-on experience discussing CGDP development approaches with FDA experts in mock pre-ANDA meetings. The meetings will be structured as fun, simulated experiences where all workshop participants can interact directly with FDA experts. Each group from each breakout session will hold a mock pre-ANDA meeting for the hypothetical CGDP they will have developed with their mentors, and the participants from the other breakout sessions will observe as FDA experts answer questions and provide constructive, critical feedback.
Learning Objectives:

- Explain what drug product characterizations and studies are relevant for specific types of CGDPs.
- Demonstrate proficiency with knowing when and how to utilize various mechanisms for interactive communications with the FDA, including pre-ANDA meetings, to facilitate CGDP development.
- Identify one or more types of CGDPs that the participant's organization may be well-positioned to become engaged in developing.

Presentations

All presentations will be available on the workshop website, no later than 24 hours after the workshop. Presentations will remain online for registered attendees until August 7, 2019.

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Workshop Planning Committee

Sam Raney, Ph.D., U.S. Food and Drug Administration
Markham Luke, M.D., Ph.D., U.S. Food and Drug Administration

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aaps PharmSci 360 / NOV 4–7 2018 WASHINGTON, DC / Walter E. Washington Convention Center

Workshop Agenda

Sessions will take place in the Washington Convention Center, room 206

Saturday, November 3, 2018	
9:00 am – 9:05 am	**Welcome and Introductions** Sameersingh Raney, Ph.D., U.S. Food and Drug Administration Markham Luke, MD, Ph.D., U.S. Food and Drug Administration
9:05 am – 9:30 am	**CGDPs with a Complex Active Pharmaceutical Ingredient (API)** Xiaohui (Jeff) Jiang, Ph.D., U.S. Food and Drug Administration Adam Fisher, Ph.D., U.S. Food and Drug Administration Kris Andre, M.S., U.S. Food and Drug Administration Lei Zhang, Ph.D., U.S. Food and Drug Administration
9:30 am – 9:55 am	**CGDPs with a Locally-Acting Route of Delivery including Topical Dermatological Drug Products** Tannaz Ramezanli, Ph.D., U.S. Food and Drug Administration Pahala Simamora, Ph.D., U.S. Food and Drug Administration Andrew Babiskin, Ph.D., U.S. Food and Drug Administration Markham Luke, M.D., Ph.D., U.S. Food and Drug Administration
9:55 am – 10:20 am	**CGDPs with Drug and Device Constituents: Transdermal Delivery Systems (TDS)** Priyanka Gosh, Ph.D., U.S. Food and Drug Administration Robert Berendt, Ph.D., U.S. Food and Drug Administration Liang Zhao, Ph.D., U.S. Food and Drug Administration Sameersingh Raney, Ph.D., U.S. Food and Drug Administration
10:20 am – 10:45 am	**CGDPs with Drug and Device Constituents: Orally Inhaled and Nasal Drug Products (OINDPs)** Denise Conti, Ph.D., U.S. Food and Drug Administration Bhagwant Rege, Ph.D., U.S. Food and Drug Administration Robert Lionberger, Ph.D., U.S. Food and Drug Administration
10:45 am – 11:00 am	Coffee Break
11:00 am – 11:25 am	**CGDPs with Complex Formulations including Nanotechnology Products** Darby Kozak, Ph.D., U.S. Food and Drug Administration Katherine Tyner, Ph.D., U.S. Food and Drug Administration Lanyan (Lucy) Fang, Ph.D., U.S. Food and Drug Administration
11:25 am – 11:45 am	Participant Assignment to Breakout Sessions

11:45 am – 12:30 pm	**Group A: (Pre-Lunch Session) Development of CGDPs with a complex API** Xiaohui (Jeff) Jiang, Ph.D., U.S. Food and Drug Administration Adam Fisher, Ph.D., U.S. Food and Drug Administration Kris Andre, M.S., U.S. Food and Drug Administration Lei Zhang, Ph.D., U.S. Food and Drug Administration
11:45 am – 12:30 pm	**Group B: (Pre-Lunch Session) Development of CGDPs with a locally-acting (topical) route of delivery** Tannaz Ramezanli, Ph.D., U.S. Food and Drug Administration Pahala Simamora, Ph.D., U.S. Food and Drug Administration Andrew Babiskin, Ph.D., U.S. Food and Drug Administration Markham Luke, M.D., Ph.D., U.S. Food and Drug Administration
11:45 am – 12:30 pm	**Group C: (Pre-Lunch Session) Development of CGDPs involving a TDS** Priyanka Gosh, Ph.D., U.S. Food and Drug Administration Robert Berendt, Ph.D., U.S. Food and Drug Administration Liang Zhao, Ph.D., U.S. Food and Drug Administration Sameersingh Raney, Ph.D., U.S. Food and Drug Administration
11:45 am – 12:30 pm	**Group D: (Pre-Lunch Session) Development of CGDPs involving an OINDP** Denise Conti, Ph.D., U.S. Food and Drug Administration Bhagwant Rege, Ph.D., U.S. Food and Drug Administration Robert Lionberger, Ph.D., U.S. Food and Drug Administration
11:45 am – 12:30 pm	**Group E: (Pre-Lunch Session) Development of CGDPs with a complex (nanotechnology) formulation** Darby Kozak, Ph.D., U.S. Food and Drug Administration Katherine Tyner, Ph.D., U.S. Food and Drug Administration Lanyan (Lucy) Fang, Ph.D., U.S. Food and Drug Administration
12:30 pm – 1:30 pm	Lunch
1:30 pm – 2:30 pm	**Group A: (Post-Lunch Session) Development of CGDPs with a complex API** Xiaohui (Jeff) Jiang, Ph.D., U.S. Food and Drug Administration Adam Fisher, Ph.D., U.S. Food and Drug Administration Kris Andre, M.S., U.S. Food and Drug Administration Lei Zhang, Ph.D., U.S. Food and Drug Administration
1:30 pm – 2:30 pm	**Group B: (Post-Lunch Session) Development of CGDPs with a locally-acting (topical) route of delivery** Pahala Simamora, Ph.D., U.S. Food and Drug Administration

	Andrew Babiskin, Ph.D., U.S. Food and Drug Administration Markham Luke, M.D., Ph.D., U.S. Food and Drug Administration
1:30 pm – 2:30 pm	**Group C: (Post-Lunch Session) Development of CGDPs involving a TDS** Priyanka Gosh, Ph.D., U.S. Food and Drug Administration Robert Berendt, Ph.D., U.S. Food and Drug Administration Liang Zhao, Ph.D., U.S. Food and Drug Administration Sameersingh Raney, Ph.D., U.S. Food and Drug Administration
1:30 pm – 2:30 pm	**Group D: (Post-Lunch Session) Development of CGDPs involving an OINDP** Denise Conti, Ph.D., U.S. Food and Drug Administration Bhagwant Rege, Ph.D., U.S. Food and Drug Administration Robert Lionberger, Ph.D., U.S. Food and Drug Administration
1:30 pm – 2:30 pm	**Group E: (Post-Lunch Session) Development of CGDPs with a complex (nanotechnology) formulation** Darby Kozak, Ph.D., U.S. Food and Drug Administration Katherine Tyner, Ph.D., U.S. Food and Drug Administration Lanyan (Lucy) Fang, Ph.D., U.S. Food and Drug Administration
2:30 pm – 2:45 pm	Coffee Break
2:45 pm – 3:10 pm	**Mock pre-ANDA meeting about a Hypothetical CGDP with a complex API** All Speakers
3:10 pm – 3:35 pm	**Mock pre-ANDA meeting about a Hypothetical CGDP involving a locally-acting route of delivery** All Speakers
3:35 pm – 4:00 pm	**Mock pre-ANDA meeting about a Hypothetical CGDP involving a TDS product** All Speakers
4:00 pm – 4:25 pm	**Mock pre-ANDA meeting about a Hypothetical CGDP involving an OINDP** All Speakers
4:25 pm – 4:50 pm	**Mock pre-ANDA meeting about a Hypothetical CGDP with a complex formulation** All Speakers
4:50 pm – 5:00 pm	**Closing Comments**

Robert Lionberger, Ph.D., U.S. Food and Drug Administration

5:00 pm **Adjournments**
Sameersingh Raney, Ph.D., U.S. Food and Drug Administration
Markham Luke, M.D., Ph.D., U.S. Food and Drug Administration

Speaker Biographies and Abstracts

CGDPs with a Complex Active Pharmaceutical Ingredient (API)

This presentation will include an introduction to the types of communications and meetings with FDA that are available during product development, prior to submission of an Abbreviated New Drug Application (ANDA), and after submission. This presentation will also discuss how to efficiently navigate product development for CGDPs with a complex active ingredient and discuss advanced analytical methods for characterizing complex mixtures.

Xiaohui (Jeff) Jiang, Ph.D., U.S. Food and Drug Administration

Biography unavailable.

Adam Fisher, Ph.D., U.S. Food and Drug Administration

Biography unavailable.

Kris Andre, M.S., U.S. Food and Drug Administration

Biography unavailable.

Lei Zhang, Ph.D., U.S. Food and Drug Administration

Biography unavailable.

CGDPs with a Locally-Acting Route of Delivery including Topical Dermatological Drug Products

This presentation will utilize case studies to illustrate how to efficiently navigate product development for different CGDPs with a locally acting route of delivery, discuss what kinds of evidence can be used to demonstrate bioequivalence (BE) for different types of prospective generic topical products, and illustrate how the evidence for characterization-based BE standards is modular and scalable, as appropriate to the nature and complexity of the drug product.

Tannaz Ramezanli, Ph.D., U.S. Food and Drug Administration

Division of Therapeutic Performance, Office of Research and Standards, Office of Generic Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, Maryland, USA

Pahala Simamora, Ph.D., U.S. Food and Drug Administration

Biography unavailable.

Andrew Babiskin, Ph.D., U.S. Food and Drug Administration

Andrew Babiskin, Ph.D., currently holds the position of Team Leader for the Locally-Acting Physiologically Based Pharmacokinetic Modeling Team in the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards (ORS), Office of Generic Drugs, CDER. His current work focuses on advancing mechanistic-based absorption modeling of local-acting complex products to develop/support novel in vitro and in vivo pharmacokinetic-based methods to establish bioequivalence in lieu of a bioequivalence study with clinical endpoints. Dr. Babiskin received his B.S. degree from the University of Maryland (College Park) in Chemical Engineering and his M.S. and Ph.D. degrees from the California Institute of Technology in Chemical Engineering. He joined the FDA in 2012 as an ORISE postdoctoral fellow in the OGD Science Staff (now ORS) and became an employee within DQMM in 2014.

Markham Luke, M.D., Ph.D., U.S. Food and Drug Administration

Biography unavailable.

CGDPs with Drug and Device Constituents: Transdermal Delivery Systems (TDS)

This presentation will utilize case studies to illustrate how to efficiently navigate product development for TDS products, discuss the specific in vitro and in vivo studies that are recommended to support a demonstration of BE for prospective generic TDS products, and clarify unique product quality issues impacting certain types of TDS products.

Priyanka Gosh, Ph.D., U.S. Food and Drug Administration

Priyanka Ghosh is a pharmacologist within the Division of Therapeutic Performance, Office of Research and Standards, OGD. Her specialization is drug products in the topical and transdermal drug delivery area. In her current role, Dr. Ghosh is responsible for the development of product-specific guidances for generic drug development, reviewing and responding to controlled correspondences, citizen petitions and Pre-ANDA meeting packages. Dr. Ghosh is also the project officer on multiple regulatory science research initiatives related to topical and transdermal drug products, under the GDUFA regulatory science research program. Prior to joining the FDA, Dr. Ghosh completed her B.Tech in Biotechnology from West Bengal University of Technology (India) and a Ph.D. in Pharmaceutics and Drug design from the University of Kentucky. Dr. Ghosh is the author on numerous research manuscripts and review articles in the topical and transdermal area.

Robert Berendt, Ph.D., U.S. Food and Drug Administration

Biography unavailable.

Liang Zhao, Ph.D., U.S. Food and Drug Administration

Liang Zhao has been serving as Director of the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards (ORS) in Office of Generic Drugs, CDER since 2015. He initially joined FDA as a clinical pharmacology reviewer in the Office of Clinical Pharmacology in 2009 and worked as a team leader in the Division of Pharmacometrics in 2013-2015. In the agency, he has covered therapeutic areas of Oncology, Pulmonary, Allergy, and Rheumatology including biosimilar development as clinical pharmacologist, and has later dedicated his work to regulatory research and standards for generics. Prior to joining FDA, he worked at MedImmune (the Biotechnology Unit of AstraZeneca) as an Associate Director and was a key contributor to establishing the clinical pharmacology function at the headquarter site. Prior to joining MedImmune, he started his professional career as an Associate Consultant for Strategic Consulting Service, Pharsight and a Research Investigator for Clinical Discovery, Bristol Myers Squibb.

Sameersingh Raney, Ph.D., U.S. Food and Drug Administration

Sam Raney is a thought leader in topical and transdermal drug products, with over 25 years of experience producing numerous research manuscripts, review articles, book chapters and patents in pharmaceutical product development. Dr. Raney has been a researcher and adjunct professor within academia, a principal or sub investigator on over 400 pharmaceutical product studies, has held senior management roles in industry, serves as an expert panel member in the U.S. Pharmacopeia, and is the Lead for Topical and Transdermal Drug Products in the FDA Office of Generic Drugs. Dr. Raney holds a Bachelors in Molecular Biophysics & Biochemistry from Yale University, and a Ph.D. in Biochemistry & Molecular Biology from the University of British Columbia in Canada.

CGDPs with Drug and Device Constituents: Orally Inhaled and Nasal Drug Products (OINDPs)

This presentation will utilize case studies to illustrate how to efficiently navigate product development for Orally Inhaled and Nasal Drug Products (OINDPs), will outline the regulatory considerations related to BE for generic OINDPs, and discuss FDA's corresponding recommendations. The unique challenges of bioequivalence for OINDPs, as well as FDA's current thinking on the in vitro testing and product quality evaluation will be discussed.

Denise Conti, Ph.D., U.S. Food and Drug Administration

Denise Conti's specialization is drug products in the nasal and oral inhalation drug delivery area. In her current role, Dr. Conti is responsible for the development of product-specific guidances for generic drug development, reviewing and responding to controlled correspondences, pre-ANDA meeting requests, citizen petitions and internal consults. Dr. Conti is also the project officer on multiple regulatory science research initiatives related to nasal and oral inhalation drug products, under the GDUFA regulatory science research program. Prior to joining the FDA, Dr. Conti completed her B.Sc. in Chemical Engineering from Regional University of Blumenau (Brazil), her M.Sc. in Materials Science and Engineering from Santa Catarina State University (Brazil), and her Ph.D. in Chemical Engineering from the Wayne State University (Detroit, Michigan). Dr. Conti is the author and co-author on numerous research manuscripts in the oral inhalation drug delivery area.

Bhagwant Rege, Ph.D., U.S. Food and Drug Administration

Biography unavailable.

Robert Lionberger, Ph.D., U.S. Food and Drug Administration

Robert Lionberger, Ph.D., serves as Director of the Office of Research and Standards (ORS) in the Office of Generic Drugs (OGD). Dr. Lionberger leads OGD's implementation of the GDUFA science and research commitments including internal research activities and external research grants and collaborations to ensure the therapeutic equivalence of generic drug products. ORS also provides pre-submission advice on complex generics through pre-ANDA meetings, product specific guidance and correspondence responses. He received his undergraduate degree from Stanford University in Chemical Engineering, and a PhD from Princeton University in Chemical Engineering. After his Ph.D., he conducted post-doctoral research in Australia in the Department of Mathematics and Statistics at the University of Melbourne. Prior to joining the FDA 15 years ago, he was an Assistant Professor of Chemical Engineering at the University of Michigan.

CGDPs with Complex Formulations including Nanotechnology Products

This presentation will utilize case studies to illustrate how to efficiently navigate product development for CGDPs with complex formulations and will outline the recommended scientific and regulatory considerations for the development of parenteral, otic, and ophthalmic CGDP formulations that incorporate nanotechnology. The unique challenges of demonstrating the physicochemical similarity and BE of these CGDPs, as well as current thinking on the in vitro and/or in vivo testing that FDA recommends for equivalence determinations will be discussed.

Darby Kozak, Ph.D., U.S. Food and Drug Administration

Darby Kozak is Chemist and Team Lead for the Complex Drug Substances and Formulations team in the Division of Therapeutic Performance (DTP), Office of Research and Standards (ORS), Office of Generic Drugs (OGD). In this role, Dr. Kozak leads a team of interdisciplinary scientists and oversees research projects on the development of new analytical methods and equivalence evaluation methodologies for complex parenteral, ophthalmic, and otic drug products and formulations that incorporate nanotechnology. Prior to joining the FDA in 2015, Dr. Kozak was the Chief Scientist for Izon Science, a Research Fellow at the Australian Institute for Bioengineering and Nanotechnology, Lecturer at the University of Queensland, and Visiting Fellow at the Fred Hutchinson Cancer Research Center. Dr. Kozak has a B.Sc. in Chemical Engineering from the University of Washington (Seattle, WA) and Ph.D. in Physical Chemical from the University of Bristol (United Kingdom).

Katherine Tyner, Ph.D., U.S. Food and Drug Administration

Katherine Tyner is the Associate Director of Science (acting) in the Immediate Office of the Office of Pharmaceutical Quality (OPQ), Center for Drug Evaluation and Research at the United States Food and Drug Administration (FDA). As Associate Director, Dr. Tyner leads the OPQ Science Staff in coordinating the intersection between science, review, and policy in OPQ as well as facilitating interactions between other CDER offices and FDA Centers. She received her PhD in Chemistry from Cornell University and joined the Food and Drug Administration in 2007 as a chemist specializing in nanotechnology. While at the FDA, Dr. Tyner has investigated the quality, safety, and efficacy of drug products containing nanomaterials and other complex drug products, and she currently leads the CDER nanotechnology working group and is active in other CDER and FDA nanotechnology initiatives. Dr. Tyner is the author of multiple book chapters and journal articles concerning the appropriate characterization and biological impact of complex drug products.

Lanyan (Lucy) Fang, Ph.D., U.S. Food and Drug Administration

Biography unavailable.

Group A: (Pre-Lunch Session) Development of CGDPs with a complex API

FDA experts will mentor workshop participants during multiple parallel breakout sessions, each focusing on different types of CGDPs. In each session, workshop participants will practice constructing product development plans for different types of hypothetical CGDPs by identifying the scientific issues relevant to that CGDP and proposing specific types of evidence (including modeling and simulation) that could support a demonstration of BE. As questions and uncertainties arise, participants will practice preparing controlled correspondences and assembling pre-ANDA meeting packages, to discuss the questions with the FDA during the subsequent session of the workshop.

Xiaohui (Jeff) Jiang, Ph.D., U.S. Food and Drug Administration

Biography unavailable.

Adam Fisher, Ph.D., U.S. Food and Drug Administration

Biography unavailable.

Kris Andre, M.S., U.S. Food and Drug Administration

Biography unavailable.

Lei Zhang, Ph.D., U.S. Food and Drug Administration

Biography unavailable.

Group B: (Pre-Lunch Session) Development of CGDPs with a locally-acting (topical) route of delivery

FDA experts will mentor workshop participants during five parallel breakout sessions, each focusing on different types of CGDPs. Each breakout sessions will run for 45 minutes before lunch and continue for 1 hour after lunch. In each session, workshop participants will practice constructing product development plans for different types of hypothetical CGDPs by identifying the scientific issues relevant to that CGDP and proposing specific types of evidence (including modeling and simulation) that could support a demonstration of BE. As questions and uncertainties arise, participants will practice preparing controlled correspondences and assembling pre-ANDA meeting packages, to discuss the questions with the FDA during the subsequent session of the workshop.

Tannaz Ramezanli, Ph.D., U.S. Food and Drug Administration

Biography listed above.

Pahala Simamora, Ph.D., U.S. Food and Drug Administration

Biography unavailable.

Andrew Babiskin, Ph.D., U.S. Food and Drug Administration

Biography listed above.

Markham Luke, M.D., Ph.D., U.S. Food and Drug Administration

Biography unavailable.

Group C: (Pre-Lunch Session) Development of CGDPs involving a TDS

FDA experts will mentor workshop participants during five parallel breakout sessions, each focusing on different types of CGDPs. Each breakout sessions will run for 45 minutes before lunch and continue for 1 hour after lunch. In each session, workshop participants will practice constructing product development plans for different types of hypothetical CGDPs by identifying the scientific issues relevant to that CGDP and proposing specific types of evidence (including modeling and simulation) that could support a demonstration of BE. As questions and uncertainties arise, participants will practice preparing controlled correspondences and assembling pre-ANDA meeting packages, to discuss the questions with the FDA during the subsequent session of the workshop.

Priyanka Gosh, Ph.D., U.S. Food and Drug Administration

Biography listed above.

Robert Berendt, Ph.D., U.S. Food and Drug Administration

Biography unavailable.

Liang Zhao, Ph.D., U.S. Food and Drug Administration

Biography listed above.

Sameersingh Raney, Ph.D., U.S. Food and Drug Administration

Biography listed above.

Group D: (Pre-Lunch Session) Development of CGDPs involving an OINDP

FDA experts will mentor workshop participants during five parallel breakout sessions, each focusing on different types of CGDPs. Each breakout sessions will run for 45 minutes before lunch and continue for 1 hour after lunch. In each session, workshop participants will practice constructing product development plans for different types of hypothetical CGDPs by identifying the scientific issues relevant to that CGDP and proposing specific types of evidence (including modeling and simulation) that could support a demonstration of BE. As questions and uncertainties arise, participants will practice preparing controlled correspondences and assembling pre-ANDA meeting packages, to discuss the questions with the FDA during the subsequent session of the workshop.

Denise Conti, Ph.D., U.S. Food and Drug Administration

Biography listed above.

Bhagwant Rege, Ph.D., U.S. Food and Drug Administration

Biography unavailable.

Robert Lionberger, Ph.D., U.S. Food and Drug Administration

Biography listed above.

Group E: (Pre-Lunch Session) Development of CGDPs with a complex (nanotechnology) formulation

FDA experts will mentor workshop participants during multiple parallel breakout sessions, each focusing on different types of CGDPs. In each session, workshop participants will practice constructing product development plans for different types of hypothetical CGDPs by identifying the scientific issues relevant to that CGDP and proposing specific types of evidence (including modeling and simulation) that could support a demonstration of BE. As questions and uncertainties arise, participants will practice preparing controlled correspondences and assembling pre-ANDA meeting packages, to discuss the questions with the FDA during the subsequent session of the workshop.

Darby Kozak, Ph.D., U.S. Food and Drug Administration

Biography listed above.

Katherine Tyner, Ph.D., U.S. Food and Drug Administration

Biography listed above.

Lanyan (Lucy) Fang, Ph.D., U.S. Food and Drug Administration

Biography unavailable.

Group A: (Post-Lunch Session) Development of CGDPs with a complex API

FDA experts will mentor workshop participants during multiple parallel breakout sessions, each focusing on different types of CGDPs. In each session, workshop participants will practice constructing product development plans for different types of hypothetical CGDPs by identifying the scientific issues relevant to that CGDP and proposing specific types of evidence (including modeling and simulation) that could support a demonstration of BE. As questions and uncertainties arise, participants will practice preparing controlled correspondences and assembling pre-ANDA meeting packages, to discuss the questions with the FDA during the subsequent session of the workshop.

Xiaohui (Jeff) Jiang, Ph.D., U.S. Food and Drug Administration

Biography unavailable.

Adam Fisher, Ph.D., U.S. Food and Drug Administration

Biography unavailable.

Kris Andre, M.S., U.S. Food and Drug Administration

Biography unavailable.

Lei Zhang, Ph.D., U.S. Food and Drug Administration

Biography unavailable.

Group B: (Post-Lunch Session) Development of CGDPs with a locally-acting (topical) route of delivery

FDA experts will mentor workshop participants during multiple parallel breakout sessions, each focusing on different types of CGDPs. In each session, workshop participants will practice constructing product development plans for different types of hypothetical CGDPs by identifying the scientific issues relevant to that CGDP and proposing specific types of evidence (including modeling and simulation) that could support a demonstration of BE. As questions and uncertainties arise, participants will practice preparing controlled correspondences and assembling pre-ANDA meeting packages, to discuss the questions with the FDA during the subsequent session of the workshop.

Tannaz Ramezanli, Ph.D., U.S. Food and Drug Administration

Biography listed above.

Pahala Simamora, Ph.D., U.S. Food and Drug Administration

Biography unavailable.

Andrew Babiskin, Ph.D., U.S. Food and Drug Administration

Biography listed above.

Markham Luke, M.D., Ph.D., U.S. Food and Drug Administration

Biography unavailable.

Group C: (Post-Lunch Session) Development of CGDPs involving a TDS

FDA experts will mentor workshop participants during five parallel breakout sessions, each focusing on different types of CGDPs. Each breakout sessions will run for 45 minutes before lunch and continue for 1 hour after lunch. In each session, workshop participants will practice constructing product development plans for different types of hypothetical CGDPs by identifying the scientific issues relevant to that CGDP and proposing specific types of evidence (including modeling and simulation) that could support a demonstration of BE. As questions and uncertainties arise, participants will practice preparing controlled correspondences and assembling pre-ANDA meeting packages, to discuss the questions with the FDA during the subsequent session of the workshop.

Priyanka Gosh, Ph.D., U.S. Food and Drug Administration

Biography listed above.

Robert Berendt, Ph.D., U.S. Food and Drug Administration

Biography unavailable.

Liang Zhao, Ph.D., U.S. Food and Drug Administration

Biography listed above.

Sameersingh Raney, Ph.D., U.S. Food and Drug Administration

Biography listed above.

Group D: (Post-Lunch Session) Development of CGDPs involving an OINDP

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Denise Conti, Ph.D., U.S. Food and Drug Administration

Biography listed above.

Bhagwant Rege, Ph.D., U.S. Food and Drug Administration

Biography unavailable.

Robert Lionberger, Ph.D., U.S. Food and Drug Administration

Biography listed above.

Group E: (Post-Lunch Session) Development of CGDPs with a complex (nanotechnology) formulation

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Darby Kozak, Ph.D., U.S. Food and Drug Administration

Biography listed above.

Katherine Tyner, Ph.D., U.S. Food and Drug Administration

Biography listed above.

Lanyan (Lucy) Fang, Ph.D., U.S. Food and Drug Administration

Biography unavailable.

Mock pre-ANDA meeting about a Hypothetical CGDP with a complex API

Mock pre-ANDA meeting about a Hypothetical CGDP involving a locally-acting route of delivery

Mock pre-ANDA meeting about a Hypothetical CGDP involving a TDS product

Mock pre-ANDA meeting about a Hypothetical CGDP involving an OINDP

Mock pre-ANDA meeting about a Hypothetical CGDP with a complex formulation

Workshop participants will gain hands-on experience discussing CGDP development approaches with FDA experts in mock pre-ANDA meetings. The meetings will be structured as fun, simulated experiences where all workshop participants can interact directly with FDA experts. Each group from each breakout session will hold a mock Pre-ANDA meeting for the hypothetical CGDP they will have developed with their mentors, and the participants from the other breakout sessions will observe as FDA experts answer questions and provide constructive, critical feedback.

Organizing Committee Biographies

Sam Raney, Ph.D., U.S. Food and Drug Administration

Sam Raney is a thought leader in topical and transdermal drug products, with over 25 years of experience producing numerous research manuscripts, review articles, book chapters and patents in pharmaceutical product development. Dr. Raney has been a researcher and adjunct professor within academia, a principal or sub investigator on over 400 pharmaceutical product studies, has held senior management roles in industry, serves as an expert panel member in the U.S. Pharmacopeia, and is the Lead for Topical and Transdermal Drug Products in the FDA Office of Generic Drugs. Dr. Raney holds a Bachelors in Molecular Biophysics & Biochemistry from Yale University, and a Ph.D. in Biochemistry & Molecular Biology from the University of British Columbia in Canada.

Markham Luke, M.D., Ph.D., U.S. Food and Drug Administration

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