DIA

DIA/FDA Complex Generic Drug-Device Combination Products Conference

October 19-20 | Virtual Event

Co-sponsored with the FDA.

Overview

Complex Generic Drugs are a large and diverse group of products with complex active ingredients or formulations, complex routes of delivery (such as locally acting drugs in dermatological products and complex ophthalmological products), or complex dosage forms (e.g., transdermals or extended release injectables). They also include complex drug-device combination products (such as auto injectors and metered dose inhalers) and other products where complexity or uncertainty concerning the approval pathway or possible alternative development approaches would benefit from early scientific engagement. Though the products in this diverse collection provide important therapies to patients, their complex elements make them difficult to produce, thus impeding access to the more affordable generic versions of these life-saving medicines.

Since the 2017 announcement of the Drug Competition Action Plan, the FDA has been working to improve the efficiency of the generic drug approval process and make it easier to bring generic competition and improve consumer access to this important category of drugs. In addition to improving regulatory clarity with respect to complex generic products, research collaborations funded through the Generic Drug User Fee Amendments (GDUFA) in 2018 and 2019 have provided data to support assessment and approval of these products.

DIA's *Complex Generic Drug-Device Combination Products Conference* will examine current knowledge and ongoing scientific research of the FDA Office of Generic Drugs (OGD) supporting evidence-based development, assessment, and approval of complex generic combination products. Join FDA staff and industry experts to discuss these topics, as well as common review issues and challenges, expectations for industry after product approval, and future directions for the development of the generic versions of these important therapeutic products.

Highlights

- Hear from FDA staff from CDER, Office of Generic Drugs, Office of Pharmaceutical Quality, CDRH, Office of Combination Products, and other industry experts
- Gain a better understanding of the current regulatory landscape for generic combination drug-device products
- Examine scientific concerns and recent research advances associated with the development of generic drug-device combination products

Target Audience

Professionals involved in:

- Biopharmaceutical, Device, and Combination Product R&D and Development
- Generics Development
- Clinical Research
- Pharmacology
- Regulatory Affairs
- Safety/Pharmacovigilance
- Quality Assurance and Control
- CMC/GMP
- Policy
- Consulting, Legal, Government Affairs
- Business Development

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Acting Deputy Director, Office of Bioequivalence, Office of Generic Drugs, CDER
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Rumi Young, MS
Acting Team Lead, Combination Products, CDRH
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Schedule At-A-Glance

All times listed are Eastern Standard Time.

DAY ONE | MONDAY, OCTOBER 19

10:00-10:15AM	**Welcome and Opening Remarks**
10:15-10:45AM	**Session 1:** Keynote Address
10:55AM-12:40PM	**Session 2:** Overview of Complex Generic Drug-Device Combination Product Regulation
12:40-1:00PM	Break
1:00-2:45PM	**Session 3:** Bioequivalence and Quality Considerations for Inhalation and Nasal Drug-Device Combination Products
2:45-3:15PM	Break
3:15-5:15PM	**Session 4:** Considerations for Development and Regulatory Review for Injection Devices

DAY TWO | TUESDAY, OCTOBER 20

10:00-10:05AM	Welcome to Day 2
10:05-11:35AM	**Session 5A:** Considerations for Demonstrating Bioequivalence for Generic Intravaginal Rings and Intrauterine Systems
11:35AM-12:00PM	Break
12:00-1:30PM	**Session 5B:** Intravaginal-Ring and Intrauterine-System Product Development and Quality Considerations
1:30-2:00PM	Break
2:00-4:00PM	**Session 6:** Complex Topical and Transdermal Drug-Device Combination Products
4:00-4:30PM	Break
4:30-6:15PM	**Session 7:** Challenges and Opportunities in Post Marketing Pharmacovigilance and Lifecycle Management for Complex Generic Drug-Device Combination Products
6:15-6:45PM	**Session 8:** Closing Remarks
6:45PM	Conference Adjourns

Learning Objectives

At the conclusion of this meeting, participants should be able to:

- Explore the statutory framework, and associated regulatory and policy considerations, for drug-device combination products submitted in an ANDA
- Identify and address scientific considerations for establishing bioequivalence for different complex generic drug-device combination delivery methods
- Identify specific product quality considerations and challenges in developing different approaches to complex generic drug-device combination product manufacturing
- Discuss ideas for improving communication and collaboration between industry, academia and the agency in developing novel methods and standards for assessing the sameness of complex generic drug-device combination products
- Explore the challenges and opportunities in post-marketing pharmacovigilance and lifecycle management for complex generic drug-device combination products

Continuing Education Credits

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This session is designated for up to 13.25 contact hours or 1.325 continuing education units (CEUs).

Type of Activity: Knowledge

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October 19 Day 1: DIA/FDA Complex Generic Drug-Device Combination Products Conference: 6 Contact Hours or .6 CEUs, Type of Activity: Knowledge, UAN: 0286-0000-20-149-L04-P

October 20 Day 2: DIA/FDA Complex Generic Drug-Device Combination Products Conference: Pharmacy 7.25 Contact Hours or .725 CEUs, Type of Activity: Knowledge, UAN: 0286-0000-18-072-L04-P

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All times listed are Eastern Time.

DAY ONE | MONDAY, OCTOBER 19

10:00-10:15AM

Welcome and Opening Remarks

Robin Weinick, PhD, Senior Vice President and Managing Director, Americas and Global Program Officer, DIA

William Chong, MD, Associate Director for Clinical Affairs, Office of Generic Drugs, CDER, FDA

10:15-10:45AM

Session 1: Keynote Address

Thinh Nguyen, Director, Office of Combination Products, OCPP, FDA

10:55AM-12:40PM

Session 2: Overview of Complex Generic Drug-Device Combination Product Regulation

Session Co-Chairs
Lisa Bercu, JD, Regulatory Counsel, Office of Generic Drugs Policy, CDER, FDA

Roisin Wallace, Vice President, Head of Global Device Development, Mylan

This session will explore what is a combination product under FDA regulations and how to determine a product's classification if uncertain, review combination product regulations, and highlight recent guidance's FDA has published on combination products. This session also will address FDA's recommendations on how to assess the user interface of a generic drug-device combination product and will identify commonly issued deficiencies for combination products. Finally, intellectual property considerations when developing a combination product will be addressed

At the conclusion of this session, participants should be able to:

- Define what is a combination product and understand what steps to take if there is uncertainty
- Describe the regulatory requirements for combination products for approval
- Explain how to assess the user interface of a combination product submitted in an ANDA and identify commonly issued deficiencies
- Discuss intellectual property considerations when developing a combination product

The Combination Product Regulatory Framework: Products Addressed, Substantive Principles, and Procedural Considerations
John Barlow Weiner, JD, Associate Director for Policy, Office of Combination Products, CDER, FDA

Combination Product Review Responsibilities and Overview of User Interface Assessment
Jennifer Hammer, MD, Physician/Primary Reviewer, FDA

Drug-Device Combination Products – Quality Considerations
Kimberly Peters, MS, Biomedical Engineer/Senior Policy Advisor, OPQ, CDER, FDA

IP Considerations for Device Development of Complex Drug-Device Combination Products
Samir Patel, JD, Associate General Counsel, Global IP, Mylan

Panel Discussion
All Speakers to be joined by:

Elizabeth Bielski, PhD, Chemist, DTP, ORS, OGD, FDA

Irene Chan, PharmD, BCPS, Deputy Director, Div of Medication Error Prevention & Analysis, OSE, CDER, FDA

12:40-1:00PM

Break

1:00-2:45PM

Session 3: Bioequivalence and Quality Considerations for Inhalation and Nasal Drug-Device Combination Products

Session Co-Chairs
Denise Conti, PhD, Senior Staff Fellow, Division of Therapeutic Performance, ORS, OGD, CDER, FDA

Changning Guo, PhD, Research Chemist, Division of Complex Drug Analysis, Office of Testing and Research, Office of Pharmaceutical Quality, CDER, FDA

This session will present an overview of oral inhalation and nasal drug-device combination products. We will discuss the current recommendations for establishing bioequivalence as described in product-specific guidances (PSGs), the remaining scientific gaps, and the use of new tools and approaches that can help to inform product development and support regulatory assessment. This session will also discuss relevant quality and manufacturing considerations for complex oral inhalation drug-device combination products, and the generic industry perspective on development and regulatory assessment.

At the conclusion of this session, participants should be able to:

- Understand the scientific questions for development of complex oral inhalation and nasal drug-device generic combination products
- Discuss the recommendations and challenges to demonstrate pharmaceutical equivalence
- Understand the industry current practices and challenges for development

Overview of Complex Generic Inhalation and Nasal Drug-Device Combination Products
Bryan Newman, PhD, Pharmacologist, Office of Generic Drugs, CDER, FDA

Quality Considerations for Complex Generic Inhalation Drug-Device Combination Products
Nashwa El-Gendy, PhD, Staff Fellow, OPQ, OLDP, DIMRPIII, CDER, FDA

Manufacturing Considerations for Complex Generic Inhalation Drug-Device Combination Products
Joanne Wang, PhD, Acting Branch Chief, OPMA, OPQ, CDER, FDA

Complex Generic Drug-Device Inhalation Products and User Interface Sameness: Successful Outcomes
Kimberly Witzmann, MD, Acting Deputy Director, Office of Bioequivalence, Office of Generic Drugs, CDER, FDA

Pharmacokinetic Comparison of Locally Acting Nasal Suspension Spray Products
Guenther Hochhaus, PhD, Professor, University of Florida

Juergen Bulitta, Associate Professor, Department of Pharmaceutics at the College of Pharmacy, University of Florida

Industry Perspective on Complex Generic Inhalation Drug-Device Combination Products
Xian-Ming Zeng, Executive Vice President and Head of Global Inhalation and Complex Injectable R&D, Lupin Research, Inc.

Panel Discussion
All Speakers

2:45-3:15PM

Break

3:15-5:15PM

Session 4: Considerations for Development and Regulatory Review for Injection Devices

Session Co-Chairs
Sarah Mollo, PhD, RAC, Combination Product Policy Analyst, OPEQ, CDRH, FDA

Rosario LoBrutto, PhD, Head of Scientific Affairs, Sandoz

ANDAs present unique review considerations as compared to NDAs for BLAs. The combination product in an ANDA needs to both meet the needs of a user as well as meet the requirements for a generic drug product. This session will provide an FDA perspective on the expectations and common pitfalls of two key areas of an ANDA; the drug product quality review and device performance review. Additionally, industry representatives who have developed and marketed combination products for an ANDA will highlight some of the current advances in this space as well as some of the challenges they have encountered.

At the conclusion of this session, participants should be able to:

- Apply lessons learned from case studies during the development of injectable primary pack (e.g. PFS, pen injector, auto injector) technologies
- Identify drug product quality and device performance expectations for a generic application for products including injection devices
- Proactively identify potential issues that could be encountered during review of a generic application with injection devices

Quality Assessment of Generic Combination Parenteral Drug Products
Farnoosh Fazlollahi, PhD, Product Quality Assessor, OLDP, OPQ, CDER, FDA

Current Advances in Ready to Use/Ready to Administer Products
Paolo Mangiagalli, PhD, Senior Director, Device Development Unit, Sanofi, France

Challenges and Consideration in Auto Injector Development for Generic Combination Products
Mark DeStefano, Director, Combination Products and Device R&D, Teva Pharmaceuticals

Evolving Component Technologies to Meet the Needs of Cartridge Delivery Applications
Royce Brockett, Director of Product Management, Prefilled Systems and Delivery, West Pharmaceutical Services

Device Performance Considerations for Injection Devices
Rumi Young, MS, Acting Team Lead, Combination Products, CDRH, FDA

Panel Discussion
All Speakers to be joined by:

Alan Stevens, MS, Acting Division Director, Division of Drug Delivery, General Hospital and Human, CDRH, FDA

Irene Chan, PharmD, BCPS, Deputy Director, Div of Medication Error Prevention and Analysis, OSE, CDER, FDA

DAY TWO | TUESDAY, OCTOBER 20

10:00-10:05AM

Welcome to Day 2

Markham Luke, MD, PhD, Director for Therapeutic Performance, Office of Generic Drugs, CDER, FDA

10:05-11:35AM

Session 5A: Considerations for Demonstrating Bioequivalence for Generic Intravaginal Rings and Intrauterine Systems

Session Co-Chairs
Yan Wang, PhD, Acting Team Lead, Division of Therapeutic Performance, Office of Research and Standards, Office of Generic Drugs, CDER, FDA

Robert Berendt, PhD, Branch Chief, Division of Immediate & Modified Release Products III, OLDP, OPQ, CDER, FDA

Due to the relatively nascent state of generic intravaginal-ring and intrauterine-system products in the US marketplace and regulatory pipeline, the structure and content of this session are intended to promote information sharing and discussion to facilitate development of these complex drug-device products. Two main themes – Bioequivalence and Quality – will be explored. Overall, the presentations will provide insight into the current state of regulatory science, product development, and quality assessment of IVRs and IUSs from regulatory, academic, and industry perspectives.

At the conclusion of this session, participants should be able to:

- State the current landscape of IVRs and IUSs in the US market
- Describe current regulatory science and thinking associated with demonstrating bioequivalence for generic IVRs and IUSs
- Explain Q1/Q2 sameness considerations for IVRs and IUSs
- Identify critical quality and design attributes of IVRs and IUSs that should be considered during product development to ensure clinical performance according to the reference listed drug labeling

Current Landscape of Approved IVRs and IUSs on the US Market: Overview of Product Designs, Formulations, and Manufacturing Processes
Pinaki Desai, PhD, Quality Assessor, Office of Lifecycle Products, OPQ, CDER, FDA

Bioequivalence of IVRs and IUSs: Current Perspective and Future Directions
Yan Wang, PhD, Acting Team Lead, Division of Therapeutic Performance, Office of Research and Standards, Office of Generic Drugs, CDER, FDA

In Vitro Drug Release Testing of IUSs: Challenges to Solutions
Diane Burgess, PhD, Board of Trustees Distinguished Professor of Pharmaceutics, University of Connecticut Department of Pharmaceutical Sciences

Development & In Vitro Release Testing of Intravaginal Rings
Bruce Frank, PhD, Vice President, Operations and Client Services, Lubrizol

Panel Discussion
All Speakers to be joined by:

Karyn Berry, MD, MPH, Medical Officer, Division of Clinical Review, Office of Bioequivalence, OGD, CDER, FDA

11:35AM-12:00PM **Break**

12:00-1:30PM **Session 5B:** Intravaginal-Ring and Intrauterine-System Product Development and Quality Considerations

Session Co-Chairs
Yan Wang, PhD, Acting Team Lead, Division of Therapeutic Performance, Office of Research and Standards, Office of Generic Drugs, CDER, FDA

Robert Berendt, PhD, Branch Chief, Division of Immediate & Modified Release Products III, OLDP, OPQ, CDER, FDA

This session will continue the conversation of Intravaginal-Ring and Intrauterine Systems

Manufacturing Quality Considerations for IVRs and IUSs
Yubing Tang, PhD, Chemist, CDER, FDA

Device Mechanical Testing and Compatibility Considerations for IVRs and IUSs
Monica Garcia, PhD, Acting Assistant Director, Division of Reproductive, Gynecology, and Urology Devices, Office of Health Technology 3, Office of Product Evaluation and Quality, CDRH, FDA

Intravaginal-Ring Product Development and Quality Considerations
Brendan Muldoon, PhD, Senior Director, Generics R&D, Teva Pharmaceuticals

Panel Discussion
All Speakers to be joined by:

Karyn Berry, MD, MPH, Medical Officer, Division of Clinical Review, Office of Bioequivalence, OGD, CDER, FDA

1:30-2:00PM **Break**

2:00-4:00PM **Session 6:** Complex Topical and Transdermal Drug-Device Combination Products

Session Co-Chairs
Karthik Balasubramanian, PhD, MS, Director, Combination Products and Semisolids, Generic CPD, Teva Pharmaceuticals

Sam Raney, PhD, MS, Lead for Topical and Transdermal Drug Products, Office of Generic Drugs, CDER, FDA

A good understanding of how critical material attributes (CMAs), critical quality attributes (CQAs), and critical design attributes (CDAs) can impact a pharmaceutical product is essential to adequately control the quality, safety and effectiveness of the product. Yet, for complex topical and transdermal

drug-device combination products, it may not always be clear what attributes may be critical to product quality and/or performance. This session will explore how to adequately mitigate known and unknown product risks while enabling the availability of high quality, safe and effective topical and transdermal drug-device combination products.

Specific topics to be explored will focus on recommendations in two recent FDA Guidances for Industry:

1. Draft guidance for Industry, Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA (Jan 2017)
2. Draft guidance for industry on Transdermal and Topical Delivery Systems – Product Development and Quality Considerations (Nov 2019)

At the conclusion of this session, participants should be able to:

- Identify CMAs, CQAs and/or CDAs of topical and transdermal drug-device combination products
- Explain key elements of comparative analyses for topical and transdermal drug-device combination products
- Implement recommendations in FDA guidance's that are consistent with the intent behind the recommendation
- Recognize challenges for industry to develop generic topical and transdermal drug-device combination products

An FDA Perspective on the Comparative Analyses of Critical Material, Quality and Design Attributes for Topical, Transdermal, Rectal & Vaginal Drug-Device Combination Products
Megan Kelchen, PhD, Reviewer (Chemist), OGD, ORS, CDER, FDA

Industry Experience with Comparative Analyses of Topical and Transdermal Delivery Systems
Sal Rifaat, Senior Director, R&D, Teva Pharmaceuticals

An FDA Perspective on TDS Product Development and Quality Considerations
Meenal Chavan, PhD, Reviewer (Chemist), OPQ, OLDP, FDA

Case Study: Industry Experience with TDS Product Development and Quality Considerations
Michael Kimball, MS, Vice President, Generics R&D, Teva Pharmaceuticals

Case Study: Industry Experience with TDS Product Development and Quality Considerations
Kuljit Bhatia, PhD, Head of Global Dermatologics R&D and Scientific Affairs, Mylan

Panel Discussion
All Speakers to be joined by:

Robert Berendt, PhD, Branch Chief, Division of Immediate & Modified Release Products III, OLDP, OPQ, CDER, FDA

Irene Chan, PharmD, BCPS, Deputy Director, Div of Medication Error Prevention & Analysis, OSE, CDER, FDA

Andrew Fine, PharmD, BCPS, Clinical Team Leader, Office of Generic Drugs, CDER, FDA

Priyanka Ghosh, PhD, Pharmacologist, Division of Therapeutic Performance, Office of Generic Drugs, CDER, FDA

Kaushalkumar Dave, PhD, Reviewer Scientist, Office of New Drugs, FDA

4:00-4:30PM — **Break**

4:30-6:15PM — **Session 7:** Challenges and Opportunities in Post Marketing Pharmacovigilance and Lifecycle Management for Complex Generic Drug-Device Combination Products

Session Co-Chairs
Karen Feibus, DrMed, MD, Lead Medical Officer, CSSS, Office of Generic Drugs, CDER, FDA

James Wabby, MHS, Executive Director, Regulatory Affairs, Combination Products and Device, AbbVie

Complex generic drug/device combination products offer new therapeutic access and opportunity but also bring new challenges. Issues related to lifecycle management of product safety and therapeutic equivalence affect drug developers, drug regulators, healthcare providers, and patients. During this session, CDER representatives will discuss methods to monitor combination generic drug pharmacovigilance and to identify post-market safety issues through evaluation of medication errors and human factors considerations. The Office of Combination Products will discuss implementation of recent regulatory changes in post-marketing safety reporting requirements for combination products. Post-marketing changes to the drug or device constituent parts or manufacturing processes can pose unique review challenges. A generic drug industry representative will explore the importance of promoting a culture of safety reporting compliance and building a product safety lifecycle management infrastructure. Time is included for open discussion and dialogue.

At the conclusion of this session, participants should be able to:

- Differentiate among the roles played by OGD, OCP, and OSE's Division of Medication Errors and Prevention Analysis in evaluating post-marketing safety concerns
- Describe human factors and medication error considerations in evaluating post-market safety issues throughout the product lifecycle
- Explain how FDA determines whether post-marketing changes impacts quality attributes

Combination Product Post-marketing Safety Reporting Requirements and Implementation Update
Melissa Burns, MS, Senior Program Manager, Office of Combination Products, OCPP, OC, FDA

Complex Generic Drug-Device Product Safety Surveillance and Data Analytics
Jung Lee, RPh, MPH, Safety Officer, Clinical Safety Surveillance Staff, OGD, CDER, FDA

Human Factors and Medication Error Considerations in Evaluating Post-Market Safety Issues for Generic Drug/Device Combination Products
Millie Shah, PharmD, Human Factors Team Leader, DMEPA, OSE, CDER, FDA

Post-market ANDA Quality Supplement Review for Drug-Device Combination Products
Jianxin (Jason) Yang, PhD, Chemist/Quality Assessor, Office of Life Cycle Drug Products, OPQ, CDER, FDA

Industry Collaboration to Ensure Lifecycle Management Best Practices for Complex Generic Combination Products
Karthik Balasubramanian, PhD, MS, Director, Combination Products and Semisolids, Generic CPD, Teva Pharmaceuticals

James Wabby, MHMS, Executive Director, Regulatory Affairs, Combination Products and Device, AbbVie

Panel Discussion
All Speakers

6:15-6:45PM

Session 8: Closing Remarks

Session Chair
Robert Lionberger, PhD, Director, Office of Research and Standards, Office of Generic Drugs, CDER, FDA

This session will serve to provide a summary of key points and highlights of the conference. Thoughts on future challenges and directions will be discussed.

At the conclusion of this session, participants should be able to:

- Summarize key takeaways from the conference
- Discuss future challenges and directions for complex generic drug-device combination products

6:45PM

Conference Adjourns