FDA/CRCG Workshop on Navigating the GLP-1 Generic Drug Pathway

Public Workshop
September 23-24, 2026

Day 2: 10:35 AM – 12:30 PM Small Group Discussions (In-Person Only)

In this collaborative session, in-person participants from Industry, Academia, and the FDA will actively engage in structured activities and discussions that delve into selected challenges and opportunities within three topic areas. Guided by experienced moderators, workshop participants will explore the selected topics with a focus on achieving meaningful outcomes to facilitate GLP-1 generic product development and regulatory assessment. The topics areas will encompass:

BREAKOUT 1:
CONTROL STRATEGIES FOR GLP-1 PEPTIDES, RECOMBINANT AND SYNTHETIC

FDA moderators: Eric Pang, PhD, Acting Team Lead, Senior Pharmacokineticist
Cameron Smith, PhD, Supervisory Pharmaceutical Scientist
Josh Shipman, PhD, Chemist
Industry moderators: Suzanne Keating, MSc, Senior Director Regulatory Affairs, Injectables, Viatris Inc.
Kamal Upadhyay, PhD, Vice President, R&D Pharma, Head, Biological E. Ltd

Topic 1: Bioassay considerations for current and future GLP-1 products
When are bioassays necessary for demonstrating API sameness, and are they required for product release specifications? How should bioassay studies be designed to account for products containing multi-receptor agonists?

Topic 2: Formulation-dependent quality factors
What quality factors and information would be critical to consider when peptide formulations differ from the RLD's. What other quality factors are essential to consider when changing formulations and what are non-critical?

Peptide's higher-order structure (HOS) is stabilized by excipients and product pH. How to evaluate HOS comparison data when there are Q1/Q2 differences in product formulation or differences in pH? Is it acceptable to adjust the pH of the test product for the purposes of structural analysis, such as using NMR?

Topic 3: Control of product and process impurities
Robust control of impurities is a cornerstone requirement for both synthetically and recombinantly produced peptide products. How would the recent changes to the PSGs affect the method developments for detecting and quantifying peptide-related impurities? Additionally, control of host cell proteins (HCPs) in recombinant products will be discussed, topics include when different analytical technologies for HCP control can be applied at different stages of the development and manufacturing process.

BREAKOUT 2:
DEVICE USER INTERFACE AND HUMAN FACTORS FOR GLP-1 INJECTABLES

FDA moderators: Shinae Kim, PhD, Pharmacokineticist
Linda Assatourians, MD, Physician
Industry moderator: Brandon Wood, BSc, Sr. Director, Reg. Affairs, Complex Gx, Teva Pharmaceuticals USA, Inc.

Topic 1: Hands-On practice for design difference categorization

Participants will examine two autoinjectors with distinct design features and work through the process of categorizing their design differences using established frameworks. The goal is to apply categorization criteria in a practical setting and discuss how ambiguous or borderline design differences should be handled.

Topic 2: Demonstrating device substitutability when the RLD device design Is discontinued or replaced
When an RLD device design is discontinued or transitioned to a new design, generic applicants face challenges in demonstrating substitutability for "other design differences." This discussion will explore what evidence, study designs, or regulatory strategies could be used to establish that a proposed device remains substitutable under these circumstances.

Topic 3: Alternative approaches to comparative use human factors (CUHF) study design
The current CUHF study framework presents practical challenges for generic applicants, including user population recruitment, RLD device access, and study protocol design. This discussion will focus on identifying key gaps and challenges in the existing framework, and explore what alternative study designs, protocols, and surrogate strategies industry and academia are considering or have encountered in practice.

Breakout 3:
BIOEQUIVALENCE STUDY DESIGN AND REGULATORY STRATEGIES FOR ORAL SEMAGLUTIDE PRODUCTS

FDA moderators: Karen Li, PharmD, Staff Fellow
Yuqing Gong, PhD, Lead Pharmacologist
Justin Penzenstadler, PharmD, Acting Assoc. Director
Sami Nazzal, PhD, Senior Pharmacologist
Hongling Zhang, PhD, Division Director
Industry moderator: John D. Kirsch, RPh, PhD, MBA, Head of CMC R&D, Viatris

Topic 1: Addressing high PK variability and study design feasibility challenges
What BE study design strategies can address the extremely high intra-subject variability and prolonged study duration challenges in oral semaglutide? This discussion will explore innovative statistical approaches, single-dose versus multidose study designs, and the feasibility of multidose, multi-period studies. Participants will discuss how simulation and modeling can be leveraged to reduce the number of studies, subjects, or study periods while maintaining regulatory confidence, and consider the trade-offs between study feasibility, subject burden, safety monitoring, and regulatory acceptability.

Topic 2: Managing confounding factors in oral semaglutide BE studies
What are acceptable approaches for managing confounding factors in oral semaglutide BE studies, particularly antiemetic use? This discussion will address how antiemetic use should be standardized, documented, and justified to ensure it does not compromise the interpretability of pharmacokinetic data or BE assessments.

Topic 3: Bioequivalence strategies for formulations with qualitative/quantitative differences or alternative permeation enhancers
How should bioequivalence be established for oral semaglutide formulations that differ from the RLD? The PSG provides formulation consideration options for oral semaglutide products. This discussion will explore the practical challenges in implementing these options, particularly for formulations that are not-qualitatively the same/not-quantitatively similar or those that use alternative permeation enhancers (i.e., not SNAC). Participants will discuss how formulation impacts PK variability, and what alternative BE study designs, endpoints, or additional evidence could address these challenges.