

ADVANCING GENERIC AND BIOSIMILAR DEVELOPMENT

November 2, 2026 | 1:15pm – 2:15pm

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Advancing Generic and Biosimilar Product Development

November 2, 2026, 1:15 - 2:15 p.m.

Moderator
Kimberly Maxfield, PhD, MPH
Director, U.S. Regulatory Affairs, Biocon

Panelists
Cory Wohlbach
Global Vice President,
Biosimilar Regulatory Affairs, Teva
Kalpana Vanam, MBA
Senior Vice President,
Gx, Biosimilars and Specialty, Lupin
Janet Vaughn
Senior Vice President,
Regulatory Affairs – North America, Sandoz



Breakout Session Description

This session will explore recent and emerging Administration and FDA initiatives intended to support generic and biosimilar development, review, approval, and market entry.

Discussion will focus on how these initiatives may affect regulatory strategy, development timelines, approval predictability, and patient access to affordable medicines.

Session Outline

Cory – Advancing biosimilar product development	Recent FDA guidances
Kalpana – Advancing generic product development	GDUFA IV
Janet – Advancing manufacturing of biosimilar and generic products	ANDA Prioritization Pilot
Q&A	