

EXCIPIENTS AND FORMULATION ASSESSMENTS OF COMPLEX GENERIC PRODUCTS: BEST PRACTICES AND LESSONS LEARNED

Session 4: Scientific Challenges and Considerations During Formulation Development

Presenters:

Nitin Bhattad, MPharm

Babita Mallick, PhD

Xinran Li, PhD

Global Head of Regulatory Science, Viatris Inc.

Team Lead, Analytical Development, Sandoz Inc.

Pharmacologist, DB-II, OB, OGD, FDA

Moderator:

Pamela Garner Dorsey, PhD

Senior Pharmacologist, DB-III, OB, OGD, FDA

Panelists:

Nitin Bhattad, MPharm

Global Head of Regulatory Science, Viatris Inc.

Babita Mallick, PhD

Team Lead, Analytical Development, Sandoz Inc.

Melissa Kim Mannion, PharmD, JD

Regulatory Counsel, OGD, FDA

Hiren Patel, PhD

Staff Fellow, DB-II, OB, OGD, FDA

Yan Wang, PhD

Team Lead DTP-I, ORS, OGD, FDA