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

SESSION 1: Regulatory Concepts for Formulation Sameness and Assessment

Presenters: Melissa Mannion, PharmD, JD Regulatory Counsel, DPD, OGDP, OGD, FDA

Timothy H. Kim, PharmD Acting Director, DOBPRA, OGDP, OGD, FDA

Moderator: Colleen Lee, JD Acting Deputy Division Director, DLRS, OGDP, OGD, FDA

Panelists: Melissa Mannion, PharmD, JD Regulatory Counsel, DPD, OGDP, OGD, FDA

Timothy H. Kim, PharmD Acting Director, DOBPRA, OGDP, OGD, FDA

Priyanka Ghosh, PhD Senior Pharmacologist, DTP-I, ORS, OGD, FDA

Truong-Vinh (Vinh) Phung, PharmD Supervisory Pharmacist, DFR, ORO, OGD, FDA



