UPDATES ON APPROACHES TO ACCEPTABLE INTAKES OF NITROSAMINE DRUG SUBSTANCE RELATED IMPURITIES (NDSRIS) AND BIOEQUIVALENCE ASSESSMENT FOR REFORMULATED DRUG PRODUCTS

Day 2 Session 2B: NDSRIs: Risk Factors of Formation, Confirmatory Testing, and Risk Mitigation

Introductions: Andre Raw, PhD Associate Director, Science and Communication, OPQA I, OPQ, FDA

Dan Snider, PhD Head of Global Quality Compliance, Viatris

Presenters: Naiffer Romero, MSc, MPH Principal Scientist, Science Division, United State Pharmacopeia

Guozhang Zou, PhDResearch Scientist, DPQR V, OPQ, FDA

Jingyue (Jan) Yang, PhD Senior Research Scientist, DPQR I, OPQR, OPQ, FDA

Xiang Yu, PhD Senior Biologist, OPQA I, OPQ, FDA

Nitish Sharma, PhD Assistant Professor, Dept of Pharmaceutical Analysis, NIPER-Ahmedabad

Moderator: Andre Raw, PhD Associate Director, Science and Communication, OPQA I, OPQ, FDA

Dan Snider, PhD Head of Global Quality Compliance, Viatris

Panelists: Naiffer Romero, MSc, MPH Principal Scientist, Science Division, United State Pharmacopeia

Guozhang Zou, PhD Research Scientist, DPQR V, OPQ, FDA

Jingyue (Jan) Yang, PhD Senior Research Scientist, DPQR I, OPQR, OPQ, FDA

Xiang Yu, PhD Senior Biologist, OPQA I, OPQ, FDA

Nitish Sharma, PhD Assistant Professor, Dept of Pharmaceutical Analysis, NIPER-Ahmedabad



