

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

Day 2 Session 3: Update on FDA Guidance and Recommendations for Assessing Formulation Stability and Approaches to Bioequivalence

Introductions:

Bing V. Li, PhD
Khondoker Alam, PhD

Associate Director of Science, OB, OGD, FDA
Senior Pharmacologist, DQMM, ORS, OGD, FDA

Presenters:

Dongmei Lu, PhD
Susan Zuk, MS
James Polli, PhD
Rong Wang, PharmD, PhD
Hansong Chen, PharmD, PhD
Sivacharan Kollipara, M Pharm
Qi Zhang, PhD
Fang Wu, PhD

Deputy Director (Acting), DTP II, ORS, OGD, FDA
Branch Chief, DRGS, OPPQ, OPQ, FDA
Professor, University of Maryland, Baltimore; Co-Director, CRCG
Associate Director, DB I, OB, OGD, FDA
Senior Interdisciplinary Scientist, DPQA XII, OPQA II, OPQ, FDA
Team Lead, Biopharmaceutics, Dr. Reddy's Laboratories Ltd.
Lead Pharmacologist, DTP II, ORS, OGD, FDA
Senior Pharmacologist, DQMM, ORS, OGD, FDA

Moderator:

Bing V. Li, PhD
Khondoker Alam, PhD

Associate Director of Science, OB, OGD, FDA
Senior Pharmacologist, DQMM, ORS, OGD, FDA

Panelists:

Dongmei Lu, PhD
Susan Zuk, MS
James Polli, PhD
Rong Wang, PharmD, PhD
Hansong Chen, PharmD, PhD
Sivacharan Kollipara, MPharm
Qi Zhang, PhD
Fang Wu, PhD
Bhagwant Rege, PhD
Liang Zhao, PhD
Sumit Madan, PhD

Deputy Director (Acting), DTP II, ORS, OGD, FDA
Branch Chief, DRGS, OPPQ, OPQ, FDA
Professor, University of Maryland, Baltimore; Co-Director, CRCG
Associate Director, DB I, OB, OGD, FDA
Senior Interdisciplinary Scientist, DPQA XII, OPQA II, OPQ, FDA
Team Lead, Biopharmaceutics, Dr. Reddy's Laboratories Ltd.
Lead Pharmacologist, DTP II, ORS, OGD, FDA
Senior Pharmacologist, DQMM, ORS, OGD, FDA
Director, DPQA VI, OPQA I, OPQ, FDA
Professor and Director, Center of Regulatory Science, SOP UCSF
VP, Formulation R&D, Sun Pharmaceutical Industries Ltd.