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

DAY 1, SESSION 1: Safety & Risk Assessment Methods and Recommendations for Acceptable Intake Limit

Introductions:	**Robert Dorsam, PhD**	Director, DPTR, OSCE, OGD, FDA
Presenters:	**Naomi Kruhlak, PhD**	Scientific Lead, CTCS, DARS, OCP, OTS, FDA
	Jakub Kostal, PhD	Associate Professor and MS Program Advisor. Chemistry; Co-Director, MS Environmental Green Chem. Program, GWU.; Co-Founder and Principal, ToxFix
	Kevin Cross, PhD	Head of Science, Instem
	Robert Heflich, PhD	Director, DGMT, OR, NCTR, OCS, FDA
	Joel Bercu, PhD, MPH, DABT	Executive Director, Nonclinical Safety and Pathobiology, Gilead Sciences
	Maik Schuler, PhD	Head of Genetic Toxicology Group, Pfizer
	Anna Christodoulidou, PhD	Senior Scientific Officer, FEEDCO Unit, EFSA
Moderator:	**Robert Dorsam, PhD**	Director, DPTR, OSCE, OGD, FDA
	Xin Fu, PhD, DABT	Senior Pharmacologist, DPTR, OSCE, OGD, FDA
Panelists:	**Joel Bercu, PhD, MPH, DABT**	Executive Director, Nonclinical Safety and Pathobiology, Gilead Sciences
	Anna Christodoulidou, PhD	Senior Scientific Officer, FEEDCO Unit, EFSA
	Kevin Cross, PhD	Head of Science, Instem
	Robert Heflich, PhD	Director, DGMT, OR, NCTR, OCS, FDA
	Sruthi King, PhD	Deputy Director, DPTR, OSCE, OGD, FDA
	Jakub Kostal, PhD	Associate Professor and MS Program Advisor. Chemistry; Co-Director, MS Environmental Green Chem. Program, GWU.; Co-Founder and Principal, ToxFix
	Naomi Kruhlak, PhD	Scientific Lead, CTCS, DARS, OCP, OTS, FDA
	Govindaraj Kumaran, PhD	Chemist, DPQA XIX, OPQA III, OPQ, FDA
	Kristi Muldoon Jacobs, PhD	Director, OFCSDSI, FDA
	Maik Schuler, PhD	Head of Genetic Toxicology Group, Pfizer