Agenda

Implementing FDA's Predictive Toxicology Roadmap: An Update of FDA Activities

8 a.m.-4 p.m., September 18, 2019

(WO31, the Great Room 1503A)

Time	Title	Presenter
8:00-8:30 a.m.	Registration	
8:30-8:40 a.m.	Welcome and Introduction	Tracy Chen, Ph.D., DABT (OCS)
8:40-8:50 a.m.	Opening remarks	RADM Denise Hinton (OCS)
		Morning Session Moderator: Antonia Mattia, Ph.D. (CFSAN)
8:50-9:10 a.m.	In Vitro Systems Working Group	Donna Mendrick, Ph.D. (NCTR)
9:10-9:30 a.m.	FDA's collaborative research efforts toward developing practical microscale platforms to evaluate the safety and efficacy of FDA-regulated products	Kyung E. Sung, Ph.D. (CBER)
9:30-9:50 a.m.	Using (Q)SAR Models to Support Drug Safety Assessment	Naomi L. Kruhlak, Ph.D. (CDER)
9:50-10:10 a.m.	Using *C. elegans* for human predictive safety and risk assessment: strengths and limitations of an invertebrate model	Piper Reid Hunt, Ph.D. (CFSAN)
10:10-10:30 a.m.	Break	
10:30-10:50 a.m.	Application of an Expanded Decision Tree and TTC Approach for Safety Assessment	Szabina Stice, Ph.D. (CFSAN)
10:50-11:10 a.m.	Botanical Safety Consortium (BSC)	Sibyl Swift, Ph.D. (CFSAN)
11:10-11:30 a.m.	Alternatives to Animal Testing at CVM	Victor Long, Pharm.D., Ph.D. (CVM)
11:30 a.m.-12:00 p.m.	Panel Discussion	
12:00-1:00 p.m.	Lunch	
		Afternoon Session Moderator: Ronald L. Wange, Ph.D. (CDER)
1:00-1:20 p.m.	Drug Development Tools (DDT)	Christopher Leptak, MD, PhD (CDER)
1:20-1:40 p.m.	CDRH's Medical Device Development Tools (MDDT) program and its use for biocompatibility evaluation of medical devices	CAPT Hilda Scharen, MS (CDRH) Molly Ghosh, PhD, DABT (CDRH)
1:40-2:00 p.m.	Developing and Implementing a Mechanistic Model-Based Approach to Assess Cardiac Safety of New Drugs	David Strauss, MD, Ph.D. (CDER)
2:00-2:20 p.m.	Predictive Toxicology at CTP	Luis G. Valerio, Jr., Ph.D., ATS (CTP)
2:20-2:40 p.m.	Break	
2:40-3:00 p.m.	ICCVAM	Jennifer Goode (CDRH)
3:00-3:20 p.m.	The CBER INTERACT (INitial Targeted Engagement for Regulatory Advice on CBER producTs) Program	Mercedes Serabian, MS, DABT (CBER)
3:20-3:40 p.m.	Additional collaborations and partnerships with FDA in toxicology	Paul Brown, Ph.D. (CDER)
3:40-4:00 p.m.	Panel Discussion	
4:00 p.m.	Meeting Adjourn	