

**FDA PUBLIC WORKSHOP: Leveraging Human-Relevant Cardiomyocytes  
in Nonclinical Studies to Provide Mechanistic Insights into Cardiovascular Safety Liabilities  
March 29, 2019 Great Room, FDA Headquarters, White Oak, Silver Spring MD**

<b>Time</b>	<b>Tentative Topic and Duration</b>	<b>Speakers</b>
8:30 – 8:35	Welcome	Xi Yang (FDA)
8:35 – 8:55	Overview of Gaps and Challenges	Gary Gintant (Abbvie)
8:55 – 9:15	A Novel Framework for Human-Relevant and Failure Mode-focused Assessment of Cardiovascular Safety in Nonclinical Drug Development	Brian Berridge (NIH)
9:15 – 9:35	Morphologies, Motions and Markers of <i>In Vitro</i> Cardiovascular Screening Assessments	Blake Anson (Stemonix)
9:35 – 9:55	Video-optical Analysis of Contractile Force in hiPSC-derived Engineered Heart Tissues	Arne Hansen (Univ. Med. Cntr Hamburg-Eppendorf)
9:55 – 10:10	Break (15 min)	
10:10 – 10:30	High-Throughput Imaging of Cardiac Microtissues for the Assessment of Cardiac Contraction During Drug Discovery	Amy Pointon (AstraZeneca)
10:30 – 10:50	Using Electrical Field Stimulation for Maturation of hiPSC Cardiomyocytes, Assessment of Inotropic Compounds and Cardiac Safety Assessment	Yama Abassi (ACEA)
10:50 – 11:10	Micropatterned Human iPSC-derived Cardiomyocytes	Alexandre Ribeiro (FDA)
11:10 – 11:30	Using Adult Human Primary Cardiomyocyte Models for Drug-induced Cardiotoxicity Detection	Najah Abi Gerges (Anabios)
11:30 – 11:50	PANEL DISCUSSION WITH AUDIENCE	Key Speakers
11:50 – 13:00	Lunch Break (70 min)	
13:00 – 13:20	Myocardial Biology of Kinase Inhibitor Cardiotoxicity: Predictable On-target and Surprising Off-target Effects	Brian Jensen (UNC Div Cardiology)
13:20 – 13:40	TBD - (Secondary Pharmacology and Off-target Profiling)	Jean-Pierre Valentin (UCB)
13:40 – 14:00	TBD - (Translational Biomarkers and Novel Technologies)*	Leposava Antonovic (FDA)
14:00 – 14:20	Chronic/Delayed Drug-Induced Cardiac Toxicity and Cardiac Biomarkers in hiPSC-CMs	Hua Rong Lu (Janssen)
14:20 – 14:30	Break (10 min)	
14:30 – 14:50	Tyrosine Kinase Inhibitor-induced Cardiotoxicity	Yasunari Kanda (NIHS)
14:50 – 15:10	The Pharmacogenomic Basis of Oncology Drug-Induced Cardiovascular Toxicity	Paul Burrige (Northwestern Univ)
15:10 – 15:30	TBD - (Integrated Response Markers)*	William B. Mattes (FDA)
15:30 – 16:30	PANEL DISCUSSION WITH AUDIENCE / Meeting Wrap-Up	Norman Stockbridge (FDA) & Key Speakers