



Public Workshop--Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices

Sheraton, Silver Spring MD

September 29, 2016

Time	Topic	Presenter(s)
8:00 AM-9:00 AM	Registration	
9:00 AM-9:15 AM	Introductory Remarks	Sumathi Nambiar, CDER, FDA
9:15 AM-9:30 AM	FDA Perspective on Antimicrobial Susceptibility Test Development	Ribhi Shawar, CDRH, FDA
9:30 AM-10:00 AM	Clinical and Laboratory Perspective	Amy Mathers, University of Virginia Romney Humphries, UCLA
10:00 AM-10:45 AM	Pharmaceutical Company Experience and Perspective	Mary Motyl, Merck Kevin Krause, Achaogen
10:45 AM-11:00 AM	Break	
11:00 AM-11:45 AM	Diagnostic Device Manufacturer Experience and Perspective	Bill Brasso, BD Diagnostic Systems Darcie (Roe) Carpenter, Beckman Coulter
11:45 AM-12:30 PM	Clarifying Questions from Audience/Panelists	
12:30 PM-1:30 PM	Lunch	
1:30 PM-2:00 PM	Roles and Resources in Coordinated Development	Melissa Miller, UNC School of Medicine Jean Patel, CDC
2:00 PM-2:30 PM	Clarifying Questions from Audience/Panelists	
2:30 PM-2:45 PM	Public Comments	



2:45 PM-3:45 PM	Panel Discussion	
3:45 PM-4:00 PM	Concluding Remarks	Ed Cox, CDER, FDA Steve Gitterman, CDRH, FDA

Workshop Chair/Co-Chair: Sumathi Nambiar and Jean Patel

Panelists:

FDA: Ed Cox, Sumathi Nambiar, Ribhi Shawar, Steve Gitterman

Romney Humphries (UCLA); Ian Critchley (Allergan); Bill Brasso (BD Diagnostic Systems); Mary Motyl (Merck); Jean Patel (CDC); John Rex (Astra Zeneca); Melissa Miller (UNC School of Medicine); Fred Tenover (Cepheid); Sam Bozzette (bioMerieux); Olga Lomovskaya (The Medicines Company); Kevin Krause (Achaogen); Darcie (Roe) Carpenter (Beckman Coulter); Helen Boucher (Tufts University School of Medicine); Amy Mathers (University of Virginia School of Medicine); Charlene Reed (Foundation to Combat Antimicrobial Resistance)