

**Public Workshop:
Antimicrobial Susceptibility and
Resistance: Addressing Challenges
of Diagnostic Devices**

Welcome!

Disclaimer

- **Rome wasn't built in a day, but they were laying bricks every hour...**



Progress

- **Exceptional progress has been made yet challenges exist; it is because of these new challenges that we are here today**
 - **FDA-CDC Antimicrobial Resistance Isolate Bank**
 - **21st Century Cures**
 - **Coordinated Development**
 - **PACCARB Proposals**
 - **Scientific advances**

Goals

- The focus of the workshop is to inform FDA and others regarding the scientific and regulatory challenges associated with developing AST devices and molecular or novel devices that detect antimicrobial resistance markers
- Think of this as another brick, as another step forward: we won't solve everything, but we should expect progress.
- We all need to move forward together as partners.

AM Agenda

Traditional AST Devices		
Time	Topics	Presenter(s)
8:30 - 8:40AM	Welcome and Meeting Goals	Steve Gitterman FDA, CDRH
8:40 - 9:00 AM	FDA Perspective on 21 st Century Cures Legislation	John Farley FDA, CDER
9:00 – 9:20 AM	Perspective on Current Reference Methods	Romney Humphries UCLA
9:20 - 9:40 AM	Industry Perspective on the Challenges of AST Methods and the Role of STMA	Bill Brasso BD Diagnostic Systems
9:40 – 10:00 AM	FDA Perspective and Experience with Review of AST devices	Ribhi Shawar FDA, CDRH
10:00 - 10:15 AM	Break	
10:15 - 10:30 AM	Industry Perspective on the Advantages and Challenges of Novel AST Methods	Steve Metzger Accelerate Diagnostics
10:30 - 12:00 PM	Panel Discussion	
12:00 - 1:00 PM	Lunch	

Your Role

- Think about the questions!
- Network
- DOCKET!