CLSI Educational Workshop Organization Introductions

Center for Drug Evaluation and Research (CDER)

The Center for Drug Evaluation and Research (CDER) is the branch of the United States Food and Drug Administration (FDA) responsible for regulation of over-the-counter and prescription drugs, including biological therapeutics and generic drugs.

Center for Devices and Radiological Health (CDRH)

The Center for Devices and Radiological Health is the branch of the United States FDA responsible for the premarket approval of all medical devices, as well as overseeing the manufacturing, performance, and safety of these devices.

Susceptibility Test Manufacturers Association (STMA)

STMA is an association that communicates directly with pharmaceutical companies regarding development of antimicrobial susceptibility testing (AST). They advocate for antimicrobial resistance legislation (eg, 21st Century Cures) and represent the AST industry on standardization committees, such as CLSI's Subcommittee on AST and working groups.

STMA Member Companies Include:

- Accelerate Diagnostics, Inc.
- Beckman-Coulter, Inc.
- BD Diagnostic Systems
- bioMérieux, Inc.
- Bio-Rad Laboratories
- Hardy Diagnostics
- Liofilchem Srl
- Mast Diagnostics, Ltd.
- Thermo Fisher Scientific

CMID Pharma Consulting

CMID Pharma provides advice to pharmaceutical and biotechnology companies on the microbiology components of antibacterial drug development. They also advise infectious disease diagnostic companies.

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CLSI Educational Workshop Agenda

Implementation of the 21st Century Cures Act for Breakpoints and Interpretive Categories

Date	Time	Location
Saturday, June 2	5:00-7:00 PM	The Westin Gaslamp Quarter California C San Diego, California

Topic	Speaker
Introduction and Goals	**Romney Humphries, PhD, D(ABMM)** *Chief Scientific Officer* *Accelerate Diagnostics Inc.*
Center for Drug Evaluation and Research (CDER) perspective	**John Farley, PhD** *Deputy Director* *Office of Antimicrobial Products* *FDA, CDER*
Center for Devices and Radiological Health (CDRH) perspective	**Patricia Conville, MS, MT(ASCP)** *Microbiologist, Scientific Reviewer* *Division of Microbiology Devices* *Office of In Vitro Diagnostics and Radiological Health* *FDA CDRH*
Susceptibility Test Manufacturers Association (STMA) perspective	**Sharon Cullen, BS, RAC** *Sr. Program Manager, Beckman Coulter* *Current President, STMA*
Pharmaceutical Industry perspective	**Linda Miller, PhD** *CMID Pharma Consulting*
Interactive panel discussion and Q&A moderated by Romney Humphries	

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