Assuring Regulatory Compliance in an Era of Change: What's a Lab to Do?

Preconference Workshop, ID Lab Con 2025
March 24, 2025 • 9:00 am – 4:00 pm PDT
Pasadena Convention Center • Pasadena, CA
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APHL 2025 ID LAB CON

MARCH 25-27, 2025
PASADENA, CA

DESCRIPTION

In Vitro Diagnostics (IVDs) are regulated by the FDA using a classification system that ultimately determines the appropriate regulatory controls and premarket submission processes that apply to each device. Clinical and public health laboratories have typically relied upon IVD companies to navigate the FDA's processes to bring IVDs to market. Previously, laboratories could utilize FDA authorized IVDs and supplement their test menus with laboratory-developed tests (LDTs) validated to CLIA standards. However, the FDA's final published rule on LDTs may result in new oversight that could dramatically shift how clinical and PH laboratories can develop and offer LDTs going forward. This workshop will provide an overview of FDA regulations that pertain to IVDs, with a focus on how to prepare for compliance with Stage 1 of the LDT Rule.

OBJECTIVES

At the end of the workshop, the participant will be able to:

- Describe the status of the FDA LDT regulations and understand how to maintain compliance with Stage 1 requirements as applicable
- Define key requirements of a quality system for clinical and PH laboratories
- Understand how regulatory requirements apply to a variety of different LDTs

SPEAKERS

Sarah Buss, PhD, D(ABMM), Association of Public Health Laboratories

Jonathan R. Genzen, MD, PhD, ARUP Laboratories

Karen Harrington, PhD, HCLD(ABB), Hologic

Kara Levinson, PhD, MPH, D(ABMM), Tennessee Department of Health

Beth M. Marlowe, PhD, D(ABMM), SM(ASCP), Quest Diagnostics

Kimberlee A. Musser, PhD, Wadsworth Center

Susan E. Realegeno, PhD, D(ABMM), M(ASCP), Quest Diagnostics

PROPOSED AGENDA

9:00 am	Welcome and Introductions
9:40 am	An Update on the FDA LDT Rule
10:10 am	FDA Rule Impact to PHLs and Available Resources
10:45 am	Break
11:00 am	LDT Validation at the Wadsworth Center
11:30 am	Small Group Activity
12:15 pm	Lunch Break
1:15 pm	Laboratory Quality Systems
1:45 pm	Small Group Activity
2:45 pm	Break
3:00 pm	Lessons from IVD Manufacturing
3:55 pm	Wrap-up
4:00 pm	Adjournment