

## CLSI President's Message

AACC Annual Meeting 2008  
Monday, 28 July 2008  
10:30am – 12noon  
Renaissance Washington, DC Hotel

### *Perspectives on Quality: Laboratory practice (CLSI), laboratory certification (CMS) and IVD regulation (FDA)*

#### **Session Objectives**

You will learn:

- Perspectives on ensuring quality clinical laboratory performance from CLSI, CMS, and FDA experts.
- The scope and issues being addressed during the development of new CLSI guidelines focusing on QC based on risk management (EP22 and EP23).
- The potential value of future CLSI guidelines EP22 and EP23 to industry, government regulatory and medical laboratories.
- How to avoid the most commonly cited accreditation and compliance obstacles.
- Perspective on the role the FDA has on assuring the quality of *in vitro* diagnostic tests.

#### **Program Description**

The accomplishments, challenges and strategies for advancing quality performance in medical laboratories will be presented from the perspectives of the implementation of laboratory practices, accreditation of medical laboratories, and regulation of *in vitro* diagnostic tests.

#### **Program Schedule**

**10:30am – 10:40am**     **CLSI President's Message**

**Gerald A. Hoeltge, MD, President, Clinical and Laboratory Standards Institute**  
Co-Director, Transfusion Medicine, Cleveland Clinic

A report on CLSI's commitment to improve the quality of medical care and the critical role of expert volunteers in advancing this commitment by participating in the development of standards and guidelines for clinical and laboratory testing.

**10:40am – 11:00am**     **Status report on new guidelines for QC based on risk management (EP22 and EP23)**

**Greg Cooper, CLS, MHA**  
Manager, Clinical Standards and Practices, Bio-Rad Laboratories, Inc., Quality Systems Division

**James H. Nichols, PhD, DABCC, FACB**  
Director, Clinical Chemistry, Baystate Medical Center

A report on the challenges and progress in developing the CLSI consensus guidelines EP22-P, Presentation of Manufacturer's Risk Mitigation Information for Users of *in vitro* Diagnostic Devices - Proposed Guideline and EP23-P, Laboratory Quality Control Based on Risk Management; Proposed Guideline presented by the subcommittee chairholders.

**11:00am – 11:20am      Laboratory certification: How to avoid the most frequently cited deficiencies**

**Judith A. Yost, MA, MT(ASCP)**

Director, Division Laboratory Services, Centers for Medicare & Medicaid Services

A review of the deficiencies most frequently cited during laboratory accreditation inspections and practical approaches to implement best practices for ongoing accreditation preparedness.

**11:20am – 11:40am      FDA regulation of IVDs: Is quality assured?**

**Alberto Gutierrez, PhD**

Deputy Director, Premarket Program, Office of In Vitro Diagnostic Device Evaluation and Safety

A review of the regulatory tools available to the FDA and an analysis of their strengths and weaknesses in assuring product quality. This review will cover FDA roles in review of devices before they reach the market, and post-market programs to assure that those devices continue to meet their claims.

**11:40am – 12noon      Panel of Expert Speakers Q&A Session**

## **Speaker Bios**

### **Gerald A. Hoeltge, MD President, Clinical and Laboratory Standards Institute**

Gerald Hoeltge, MD is President of the Clinical and Laboratory Standards Institute. He has served CLSI as Treasurer, Director, Chair of the Area Committee on General Laboratory Practices, as chair of the subcommittees that authored the original editions of GP5 and GP17, and on numerous other writing and governance committees. At the Cleveland Clinic, where he is a Board Certified Pathologist, he has practiced clinical pathology for 30 years, his professional interests center around transfusion medicine and cytogenetics.

### **W. Greg Cooper, CLS, MHA**

Greg Cooper is the Manager of Clinical Standards and Practices for Bio-Rad Laboratories Inc. Quality Systems Division (Irvine, CA). He is a California-licensed Clinical Laboratory Scientist, former laboratory manager, holds a Masters degree in Healthcare Administration and is actively involved in development of laboratory standards with such organizations as the Clinical and Laboratory Standards Institute (Wayne, PA) and ISO Technical Committee 212. His work with Bio-Rad has offered him considerable opportunities to gain first-hand experience with domestic and international laboratory operations in most major markets.

### **James H. Nichols, Ph.D., DABCC, FACB**

James H. Nichols, Ph.D., DABCC, FACB is an Associate Professor of Pathology at Tufts University School of Medicine and Director, Clinical Chemistry for the Baystate Health System in Springfield, MA. Jim received his B.A. in General Biology/Premedicine from Revelle College, University of California at San Diego. He went on to complete a Masters and Doctorate in Biochemistry from the University of Illinois, Urbana-Champaign. Dr. Nichols was a fellow in the Postdoctoral Training Program in Clinical Chemistry at the Mayo Clinic, Rochester, MN. He is board certified in both Clinical Chemistry and Toxicological Chemistry by the American Board of Clinical Chemistry. Dr. Nichols spent several years as Associate Director of Clinical Chemistry, Director of Point-of-Care Testing, and an Associate Professor of Pathology at Johns Hopkins Medical Institutions prior to moving to Baystate Health System. The Baystate Health includes Franklin Medical Center, Mary Lane Hospital and Baystate Medical Center, a leading acute care center in New England. Jim is responsible for Clinical Chemistry including core automated chemistry, immunoassay, endocrinology, toxicology/therapeutic drug analysis, estoteric and point of care testing conducted through Baystate Reference Laboratories, one of America's largest hospital-based outreach programs. Dr. Nichols' research interests span evidence-based medicine, information management, laboratory automation, point-of-care testing and toxicology.

**Judith A. Yost, MA, MT(ASCP)**

Judy Yost received her BS Degree at Wilkes College and her MA at Central Michigan University. She is an American Society for Clinical Pathology certified Medical Technologist. She was the director of progressively larger laboratories and other clinical services prior to her employment at CMS. She is currently the Director of the Division of Laboratory Services, the division that is responsible for administering the CLIA program. These responsibilities include: oversight of the development of surveyor guidance and training, proficiency testing program and accrediting organization approvals, data system design and information analysis, lab enrollment and fee collection, execution of CLIA policy, collaboration with stakeholders, CDC, and FDA, and dissemination of educational materials to facilitate compliance. Judy is a member of professional societies, advisory committees, and boards, and has published several articles on laboratory quality oversight.

**Alberto Gutierrez, PhD**

Alberto Gutierrez is the Deputy Director for New Product Evaluation in FDA's Office of In Vitro Diagnostic Device Evaluation and Safety. Dr. Gutierrez received a bachelor's degree from Haverford College, master and doctorate degrees in Chemistry from Princeton University. Dr. Gutierrez has over 10 years of experience in research in the area of structural organic and organometallic chemistry. Dr. Gutierrez joined the FDA in 1992 as researcher and reviewer in FDA's Center for Biologics Evaluation and Research working on vaccine adjuvants and method development for determination of purity and structure of vaccine components. In 2000, he joined the Office of *In Vitro* Diagnostic Device Evaluation and Safety as a scientific reviewer, becoming a Team leader for Toxicology in 2003, Director of the Division of Chemistry and Toxicology Devices in 2005 and Deputy Director of the Office of *In Vitro* Diagnostic Devices in 2007.