The CLSI Consensus Process: Making a Difference in Health Care

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Director, Standards Development, CLSI

Today's Topics and Goals

- Introduction to CLSI
- The consensus process: a primer
- Creating a consensus document
- Standards: how they impact the professions
- CLSI guidelines for POCT
- Current standards development tracts
  - Getting Involved

Who Is CLSI?

Not-for-profit

Volunteer Membership Organization

Vision

Quality practices for better health

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

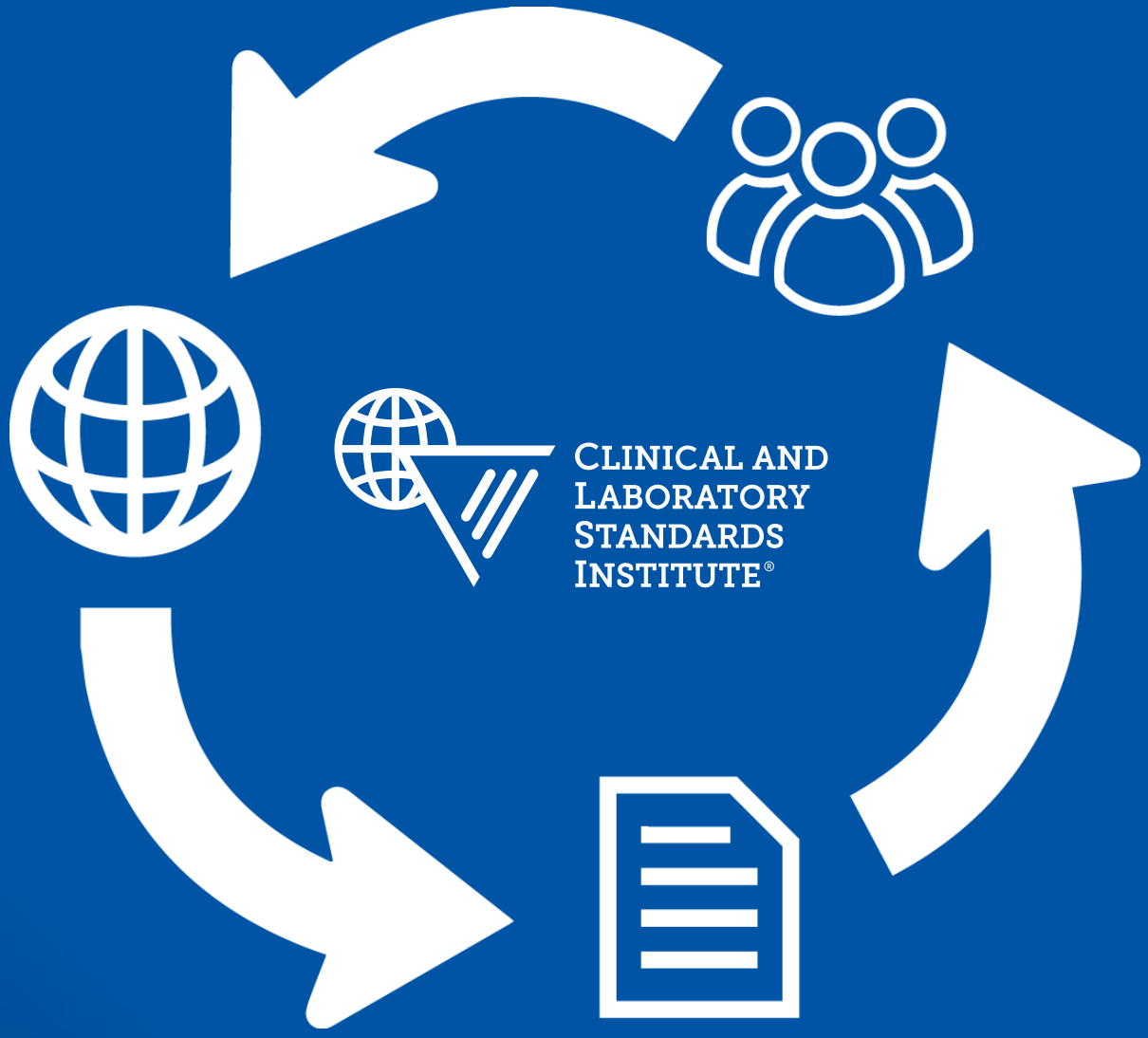
Mission

Develop clinical and laboratory practices and promote their use worldwide

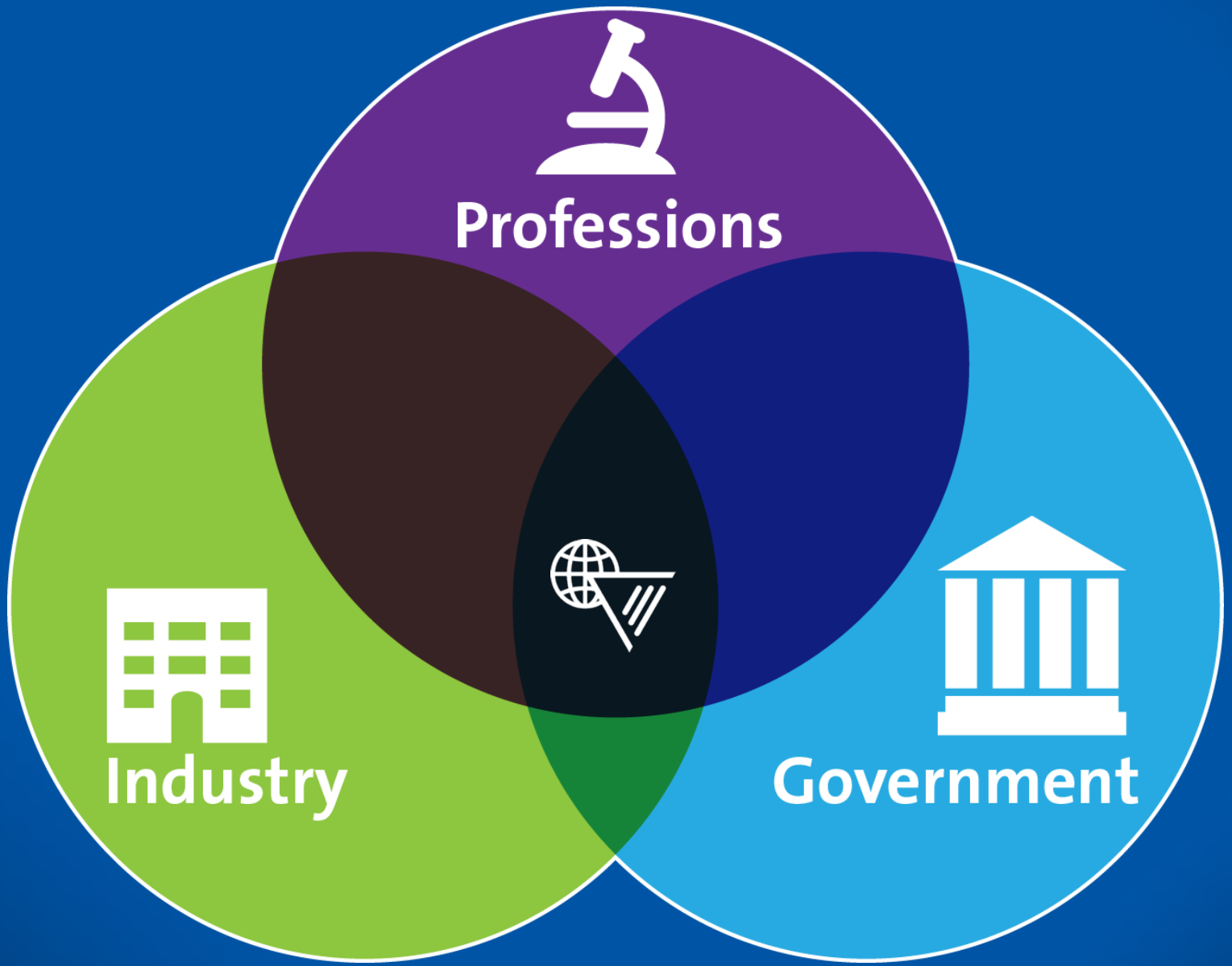
Values

- **Inclusiveness**
  We include the viewpoints of industry, government, and the health care professions in a consensus-driven process.
- **Excellence**
  We continuously improve upon our tradition of technical excellence and superior quality.
- **Responsiveness**
  We proactively identify and respond to the needs of our stakeholders in an open and timely manner.
- **Integrity**
  We act ethically and with fairness, trust, respect, and openness.
- **Teamwork**
  We are committed to effective collaboration among members, volunteers, staff, and other partners.

What Do We Do?



Tripartite Constituencies

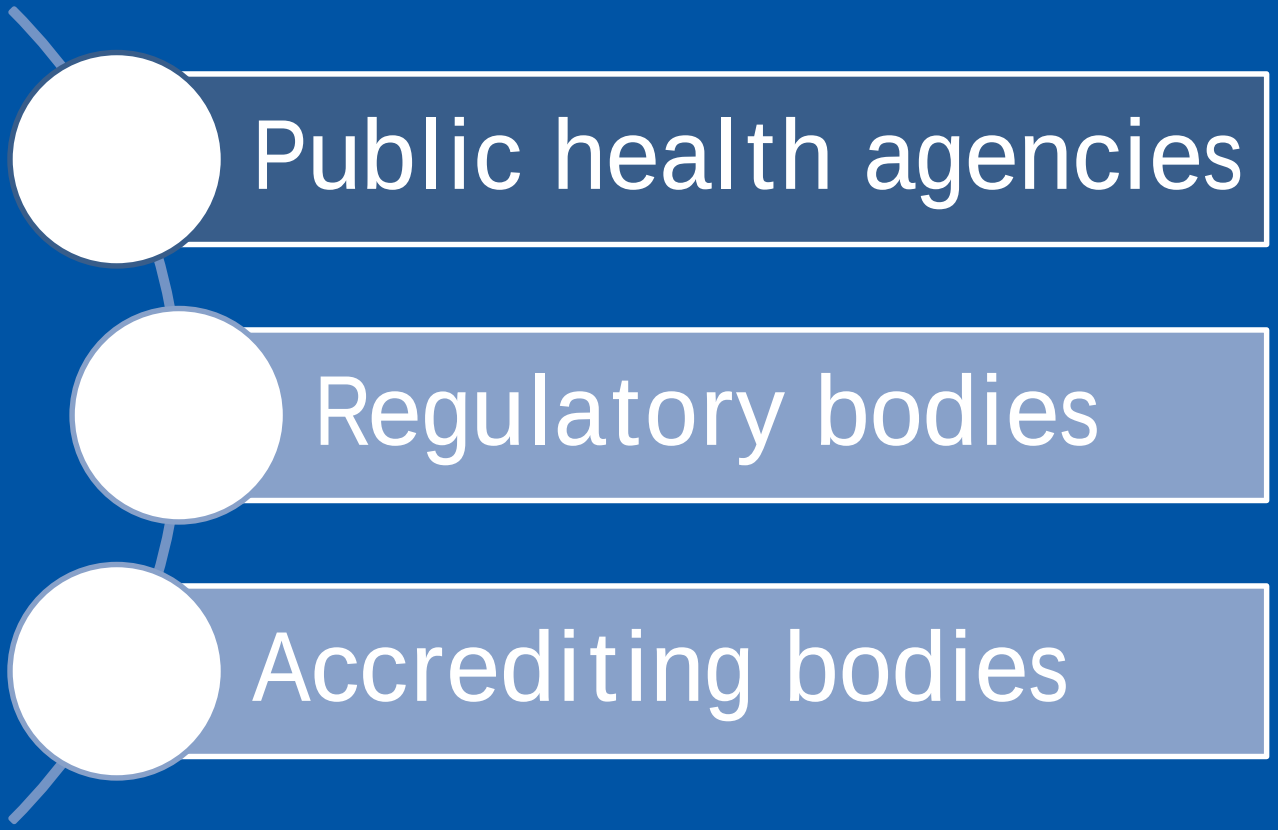


Professions Constituency

Industry Constituency

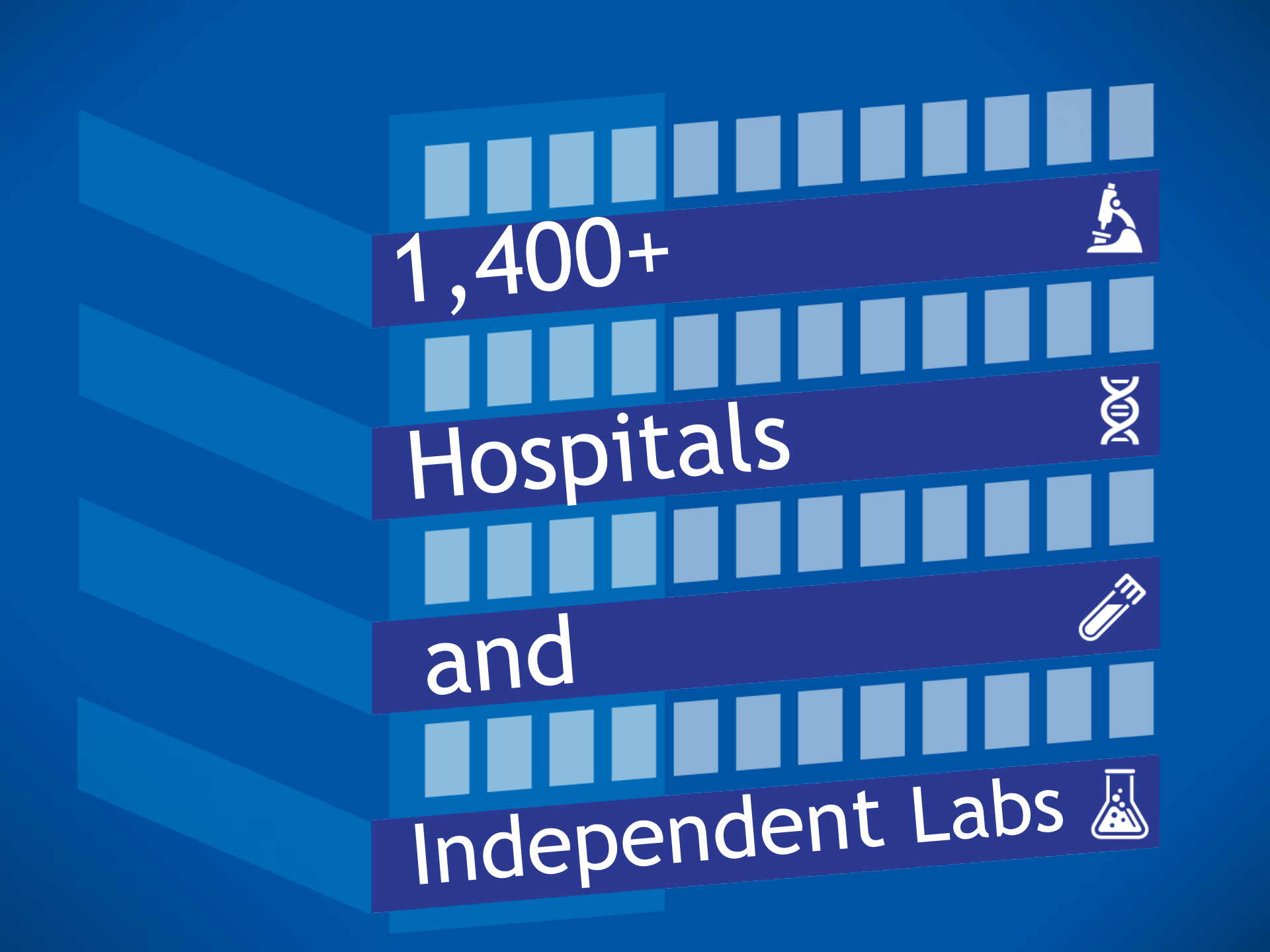
Abbreviations: IVD, *in vitro* diagnostic; LIS, laboratory information systems.

Government Constituency

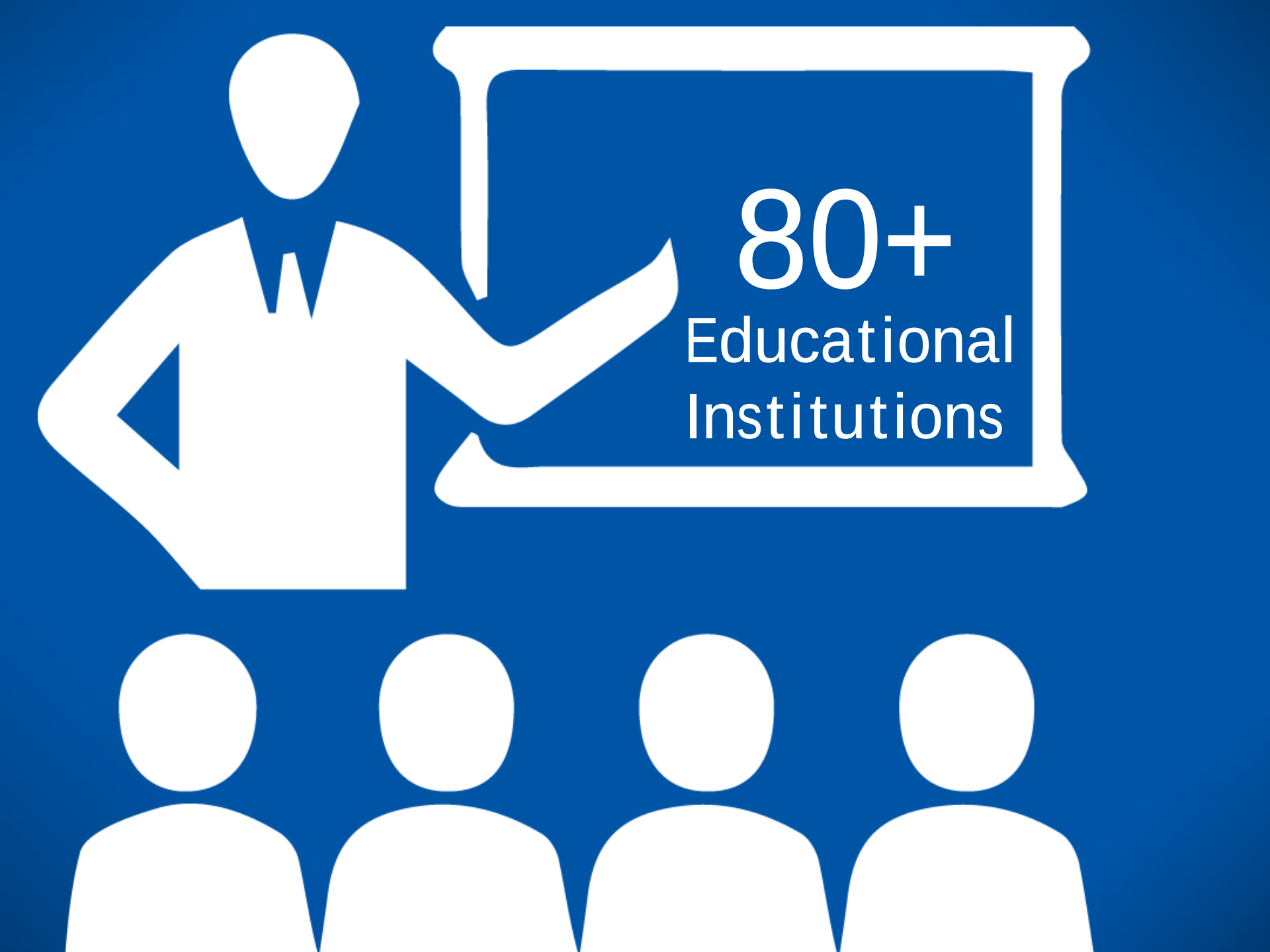


Who Are Our Members?

1,700+ Members From 60+ Countries


1,400+
Hospitals
and
Independent Labs

125+ Industry Organizations


80+
Educational
Institutions


40+
Government Agencies

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Why Do CLSI Standards Matter?

Why CLSI Standards Matter

Why CLSI Standards Matter

- Increased quality, safety, and consistency
- A basis for legislation

Why CLSI Standards Matter

- Increased quality, safety, and consistency
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- Access to best practices

Why CLSI Standards Matter

- Increased quality, safety, and consistency
- A basis for legislation
- Access to best practices
- Economically improved outcomes

Application of CLSI Documents

Regulatory Compliance

- Compliance with recognized CLSI consensus documents to facilitate regulatory review of IVD devices

Professional Practice

- Implementation of CLSI best practices for accreditation preparedness

Education in Clinical Laboratory Sciences

- Building blocks for sound organizational programs
  - POCT selection and implementation
  - Quality Management Systems
  - Performance standards
  - Risk assessment

Abbreviations: IVD, *in vitro* diagnostic; POCT, point-of-care testing.

Quality System Essentials

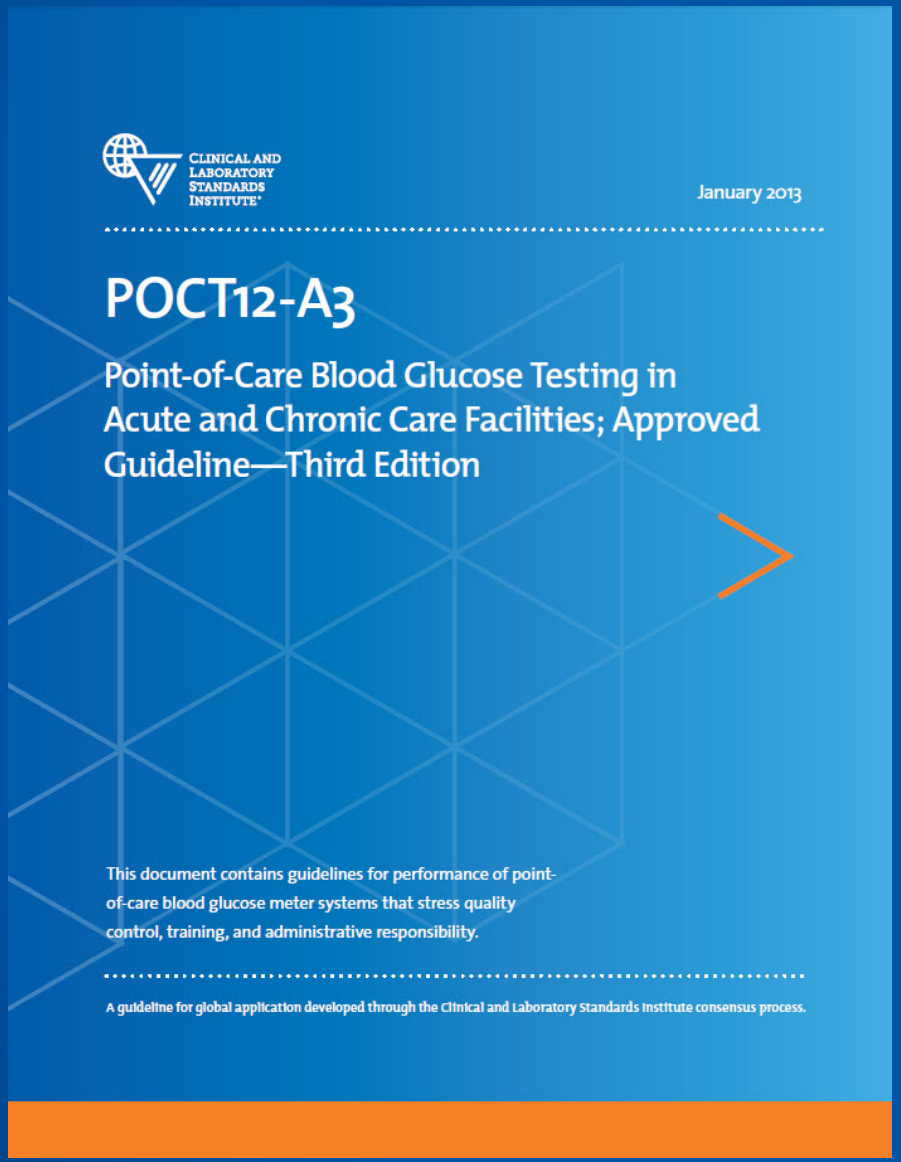
- QSEs are the fundamental building blocks in a Quality Management System.
- Each QSE encompasses policies, processes, and procedures necessary to manage and improve your facility's work practices.
- CLSI's QSEs were developed from the integration of ISO documents, hospital standards, accreditation standards, international and national (US) standards.

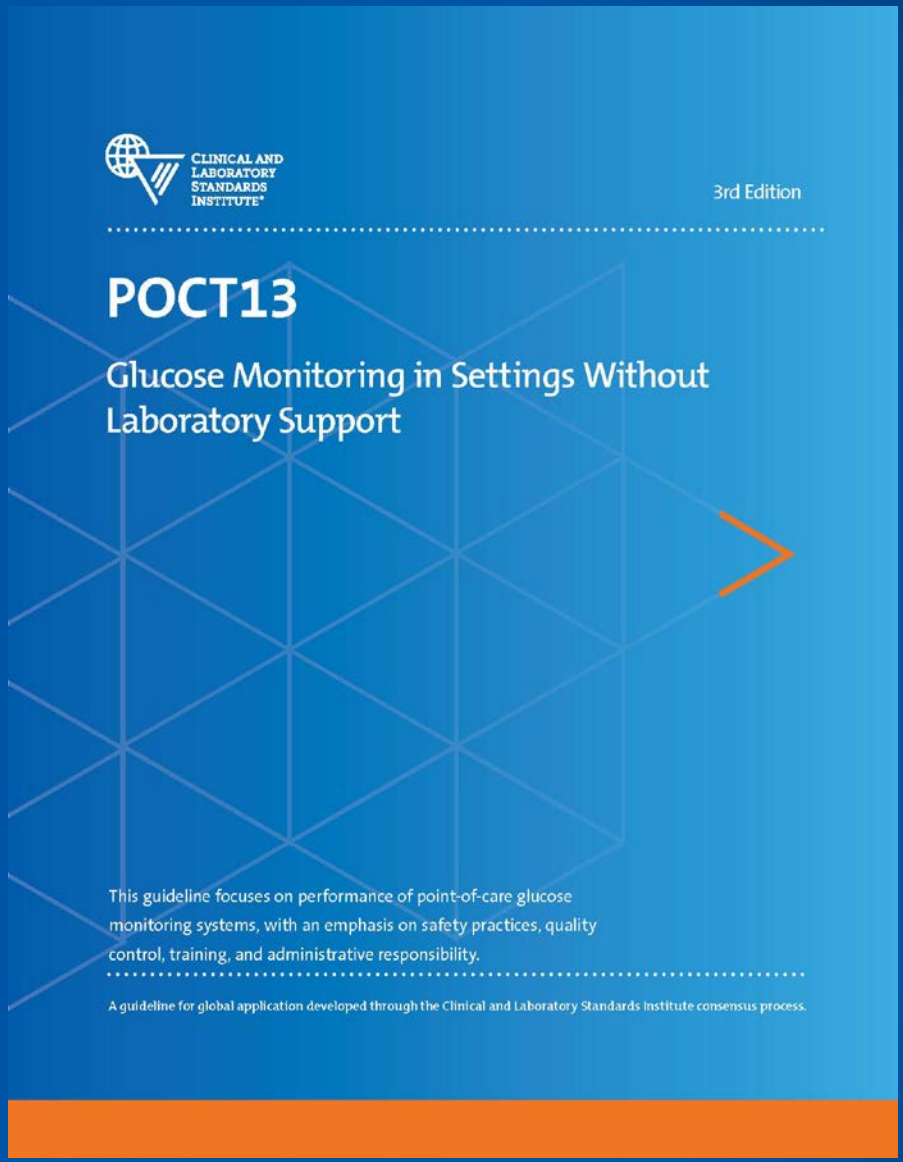
Abbreviations: ISO, International Organization for Standardization; QSE, Quality System Essential; US, United States.

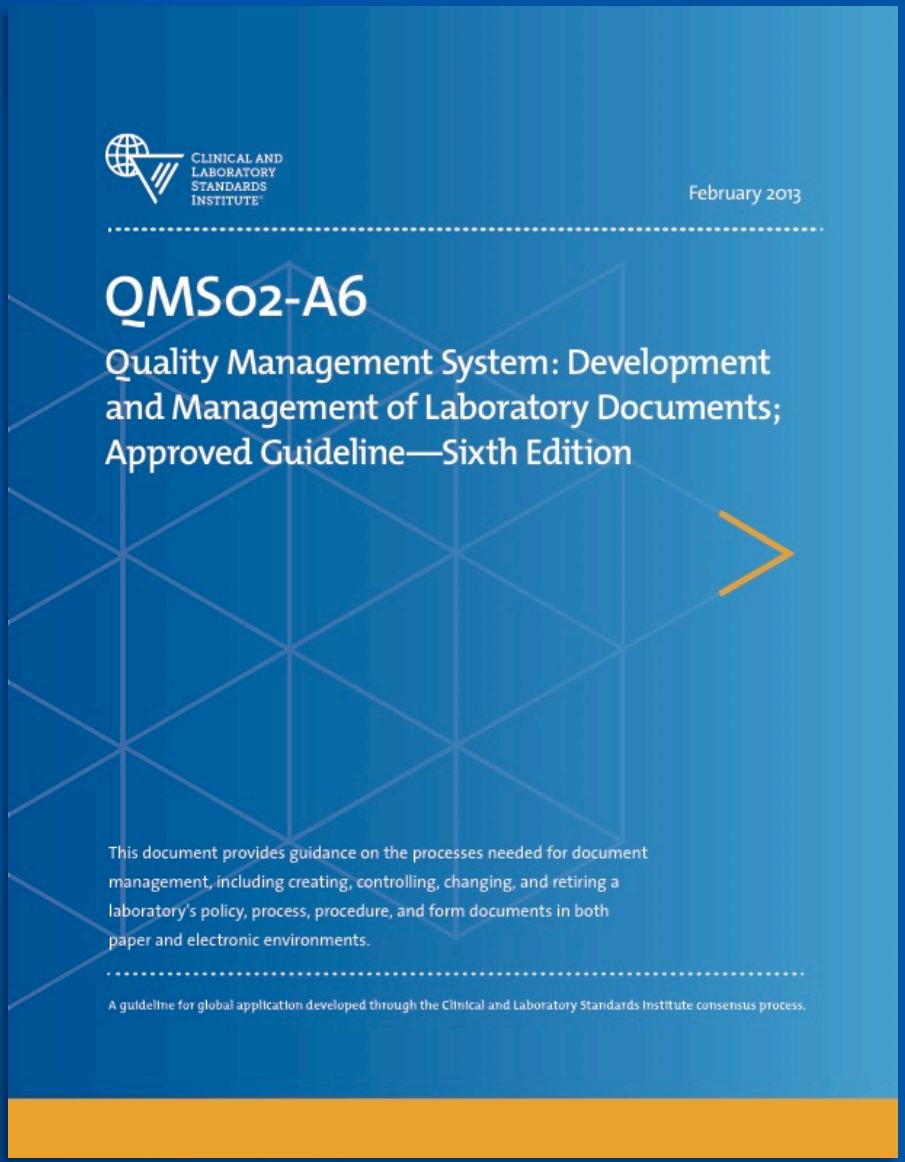
The Systematic Approach

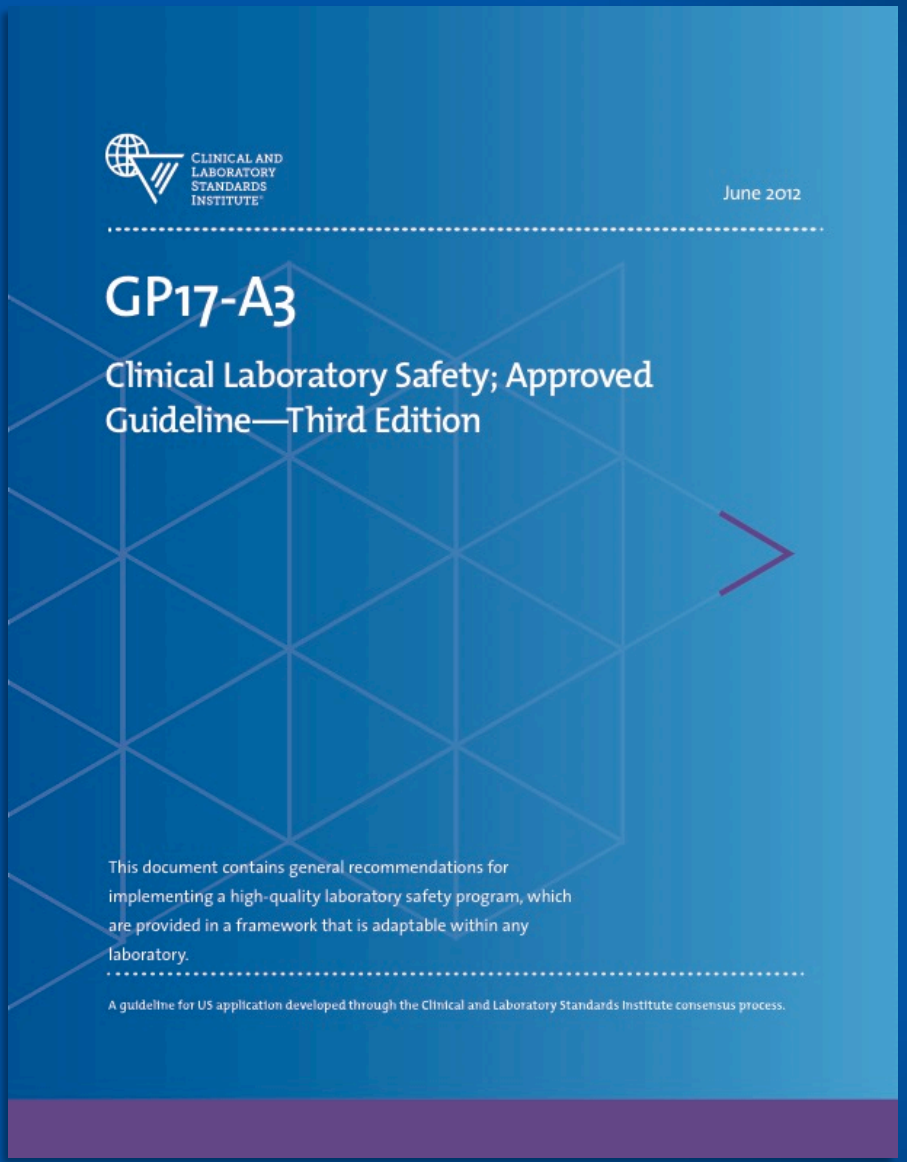
- Policy: “What must we do?”
- Process: “How does it happen in our facility?”
- Procedure: “How do I do this activity?”

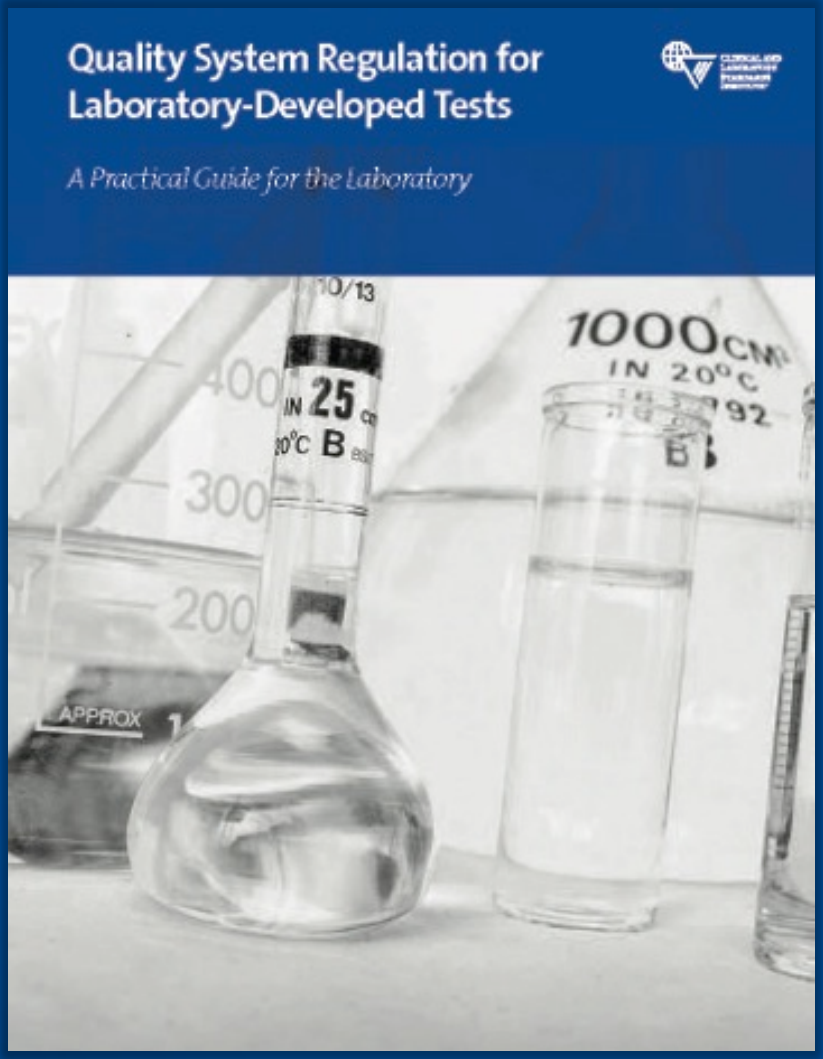
Library of Over 200 Standards


CLINICAL AND LABORATORY STANDARDS INSTITUTE®
January 2013
POCT12-A3
Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Third Edition
This document contains guidelines for performance of point-of-care blood glucose meter systems that stress quality control, training, and administrative responsibility.
A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.


CLINICAL AND LABORATORY STANDARDS INSTITUTE®
3rd Edition
POCT13
Glucose Monitoring in Settings Without Laboratory Support
This guideline focuses on performance of point-of-care glucose monitoring systems, with an emphasis on safety practices, quality control, training, and administrative responsibility.
A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.


Clinical and Laboratory Standards Institute
February 2013
QMS02-A6
Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition
This document provides guidance on the processes needed for document management, including creating, controlling, changing, and retiring a laboratory's policy, process, procedure, and form documents in both paper and electronic environments.
A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.


Clinical and Laboratory Standards Institute
June 2012
GP17-A3
Clinical Laboratory Safety; Approved Guideline—Third Edition
This document contains general recommendations for implementing a high-quality laboratory safety program, which are provided in a framework that is adaptable within any laboratory.
A guideline for US application developed through the Clinical and Laboratory Standards Institute consensus process.


Quality System Regulation for
Laboratory-Developed Tests
A Practical Guide for the Laboratory
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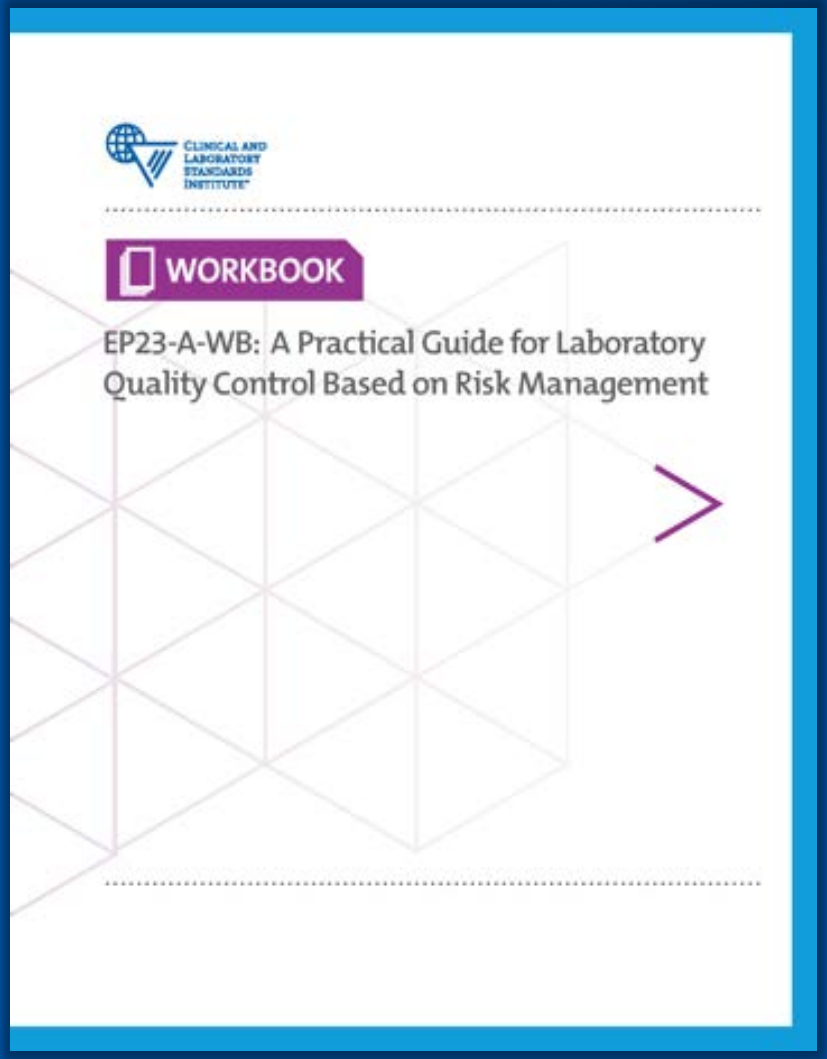
CLINICAL AND LABORATORY STANDARDS INSTITUTE
WORKBOOK
EP23-A-WB: A Practical Guide for Laboratory Quality Control Based on Risk Management

QMS01 — *Redesigned*

4 The Quality Management System Model

A QMS can be described as a set of essential building blocks needed for a laboratory's work operations to fulfill stated quality objectives. Such a system provides the means to direct and control the organization with regard to quality.[17]

The QMS model in this guideline describes the management foundation of quality building blocks (ie, the QSEs) and demonstrates how the foundation supports the laboratory's path of workflow as depicted in Figure 1.

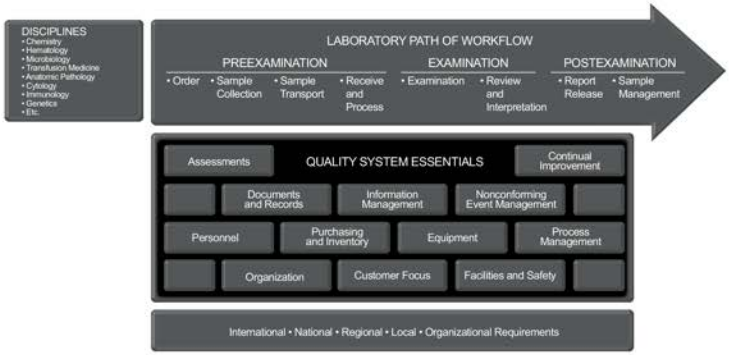

Figure 1. The Quality Management System Model for Laboratory Services. The 12 QSEs function as building blocks that are necessary to support any laboratory's path of workflow and laboratory disciplines. This example represents how the 12 QSEs support a clinical laboratory's disciplines.

NOTE:

The QSEs are simply published requirements for medical laboratories sorted into 12 generic topics.

QSEs are the foundational building blocks that function effectively to support the laboratory's path of workflow. If a QSE is missing or not well implemented, problems will occur in preexamination, examination, and postexamination laboratory activities. For example, when the laboratory lacks defined processes for properly installing, calibrating, and maintaining its analyzers so that they are working effectively, there will be problems in examination processes.

4.1 The Quality System Essentials

For the purposes of the QMS model described in this guideline, the QSEs are:

- Organization
- Process Management
- Customer Focus
- Documents and Records
- Facilities and Safety
- Information Management
- Personnel
- Nonconforming Event Management
- Purchasing and Inventory
- Assessments
- Equipment
- Continual Improvement

REMINDER:

Laboratories can use the QSEs as a generic outline for the quality management systems required in ISO standards.

QMS01 — *Redesigned*

Policy	Process	Procedure
State intent and direction for:	*Activities that transform the intent into action:*	*Examples of documented instructions for:*
Hazardous waste management	• Hazardous waste disposal plan • Hazardous waste management training program	• Identifying waste stream disposing of various types of the laboratory's hazardous waste
Fire prevention	• Fire prevention and control plan • Fire extinguisher training program	• Reporting a fire • Taking follow-up action • Recording staff participation
Emergency management: preparedness, response, mitigation, and recovery	• Internal and external preparedness plans, including response to bioterrorism and chemical terrorism • Evacuation plan • Emergency preparedness training program	• Assigning roles and responsibilities to laboratory staff in a declared disaster • Evacuating the laboratory in specific situations • Conducting and recording regular evacuation drills • Posting evacuation routes • Executing the business recovery plan
Radiation safety, as applicable	• Radiation safety program • Radiation safety training program	• Using radiation safety badges properly • Posting radiation signage • Monitoring radiation • Taking action when acceptable levels are exceeded

The requirements for QSE Facilities and Safety are:

- Allocate appropriate space for laboratory activities.
- Secure access to laboratory areas, as appropriate.
- Maintain cleanliness and monitor the environment.
- Maintain physical means of staff communications.
- Provide safety protocols and training for all of the following:
  - Biosafety
  - Occupational health, accidents, and illnesses
  - Fire protection
  - Radiation safety, as appropriate
  - Chemical hygiene
  - Hazardous waste management
  - Emergency management

Each laboratory needs to establish and maintain a facility that provides adequate space, workflow, and environmental conditions to support the quality of work and safety for all staff, in compliance with requirements. This includes the environment in which services are delivered to patients as well as nonpatient work areas.

5.3.1 Facility Design and Modification

The laboratory should work with its organization's facility planning department to develop processes for laboratory building and renovation projects. The projects should ensure the best possible design for work process flow, environmental conditions, and ergonomics. The laboratory needs a means to ensure that international, national, accreditation, local, and organizational requirements for current and planned space are met.

5.3.1.1 Space Allocation, Facility Design, and Access

The laboratory's allocated space needs to be organized such that its workload can be performed without compromising the quality of work and the safety of personnel or patient care services.

The laboratory design needs to support efficient operation and quality examinations, optimize the comfort of its occupants, provide for adequate storage space, and minimize the risk of injury and occupational illness. CLSI document QMS04[35] provides useful information on laboratory design. CLSI document GP17[36] provides information on laboratory safety.

Consideration is needed for the following:

- ☐ Accommodations and access for disabled persons, comfort, privacy, and safety, as well as optimization of collection conditions
- ☐ Maintaining confidentiality of protected health information in areas accessible to patients and visitors
- ☐ Protection of patients, staff, and visitors from recognized hazards including engineering controls required for the type of examinations performed in the laboratory
- ☐ Separation of work areas when cross-contamination is possible between adjacent laboratory sections, or effective separation where there are incompatibilities. Examples include nucleic acid amplification testing, a quiet workspace without interruptions for cytopathology screening, and a temperature-controlled environment for the computer system
- ☐ Adequate emergency systems
- ☐ Laboratory-specific environmental requirements (eg, energy sources, lighting, ventilation, water, refuse disposal, microbial control)
- ☐ Adequate storage space with the required environmental conditions
- ☐ Controlled access to areas requiring biosecurity including access to supplies and patient samples
- ☐ Adequate communication system appropriate to the size and needs of the laboratory

NOTE:

Each laboratory needs to establish and maintain a facility that provides adequate space, workflow, and environmental conditions to support the quality of work and safety for all staff, in compliance with requirements.

NOTE:

The laboratory's allocated space needs to be organized such that its workload can be performed without compromising the quality of work and the safety of personnel or patient care services.

REMINDER:

CLSI document QMS04[35] provides useful information on laboratory design. CLSI document GP17[36] provides information on laboratory safety.

QUICK GUIDE

GP42-A6 QG

Technique for Skin Puncture in Adults

Skin Puncture Proc

NOTE: Standard Precautions should

1. Prepare the accession order (test request).
2. Identify the patient.
3. Position the patient.
4. Verify the patient diet restrictions, as appropriate.
5. Verify that the patient is free of latex allergies.
6. Wash hands and put on gloves.
7. Verify the paperwork, select the microcollection device, and assemble the supplies.
8. Choose the puncture site.
9. Warm the puncture site (as applicable).
10. Clean the puncture site and allow to air dry.
11. Open a new, sterile skin puncture device within sight of the patient or guardian. Inspect the skin puncture device and other equipment.
12. Notify older children and adults of the imminent puncture.
13.
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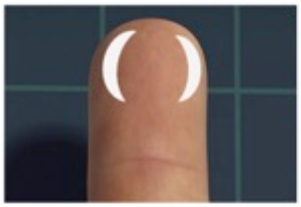

Source Documents: *Procedures and Devices for the Collection of Diagnostic Capillary B* (GP42-A6 [replaces H04-A6])

WALL CHART

POCT10/GP16-WC

Microscopic Components in Urine Sediment and Vaginal Fluid

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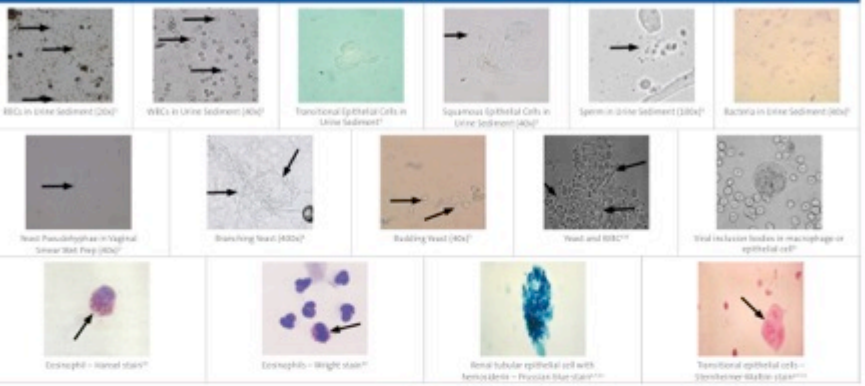
CELLS



CRYSTALS

NONCELLULAR MATERIAL

Source Documents: *Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline—Second Edition* (POCT10-A2); and *Urinalysis; Approved Guideline—Third Edition* (GP16-A3)

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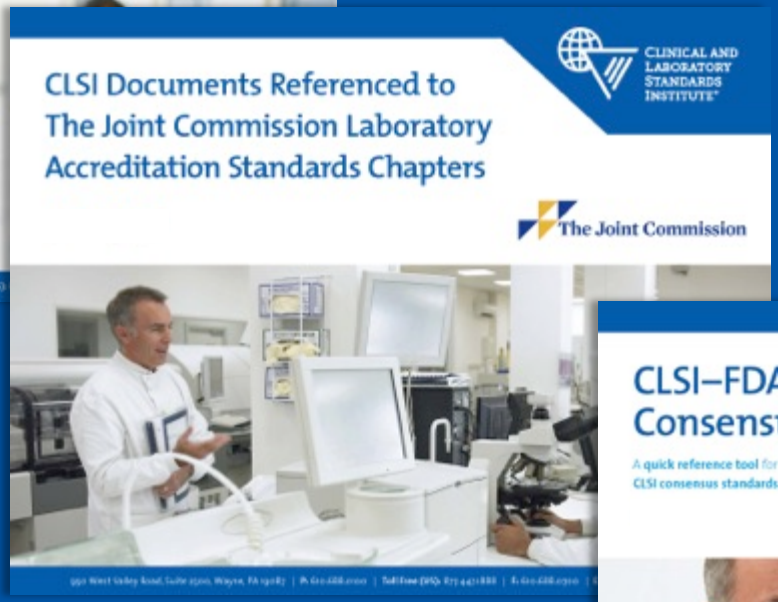
Implementing Standards

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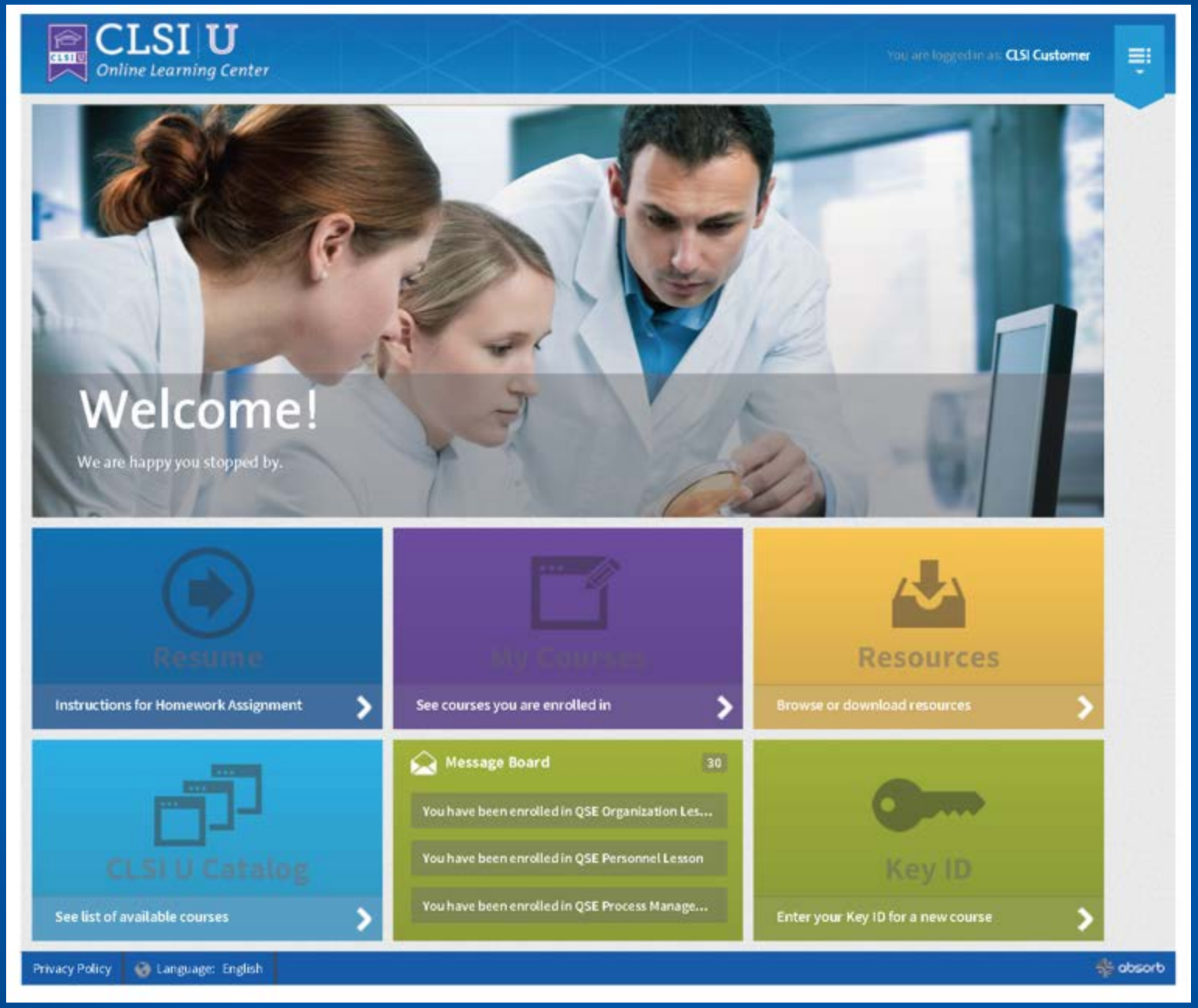
CLSI U
Online Learning Center
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Welcome!
We are happy you stopped by.
Resume
Instructions for Homework Assignment
My Courses
See courses you are enrolled in
Resources
Browse or download resources
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Message Board
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You have been enrolled in QSE Organization Les...
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CLSI As a Global Organization

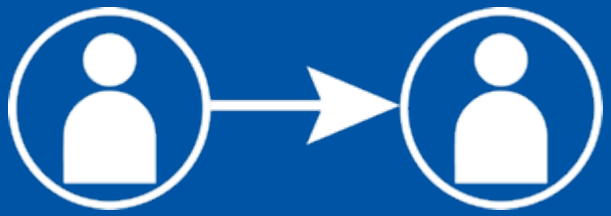
CLSI's Role in Global Standards

Secretariat for ISO Technical Committee (TC) 212

Administrator of ANSI-accredited US Technical Advisory Group to ISO/TC 212

Abbreviations: ANSI, American National Standards Institute, ISO, International Organization for Standardization.

ISO: Broad, standard requirements



CLSI: Detailed help and practical guidance

Complementary, not conflicting, roles


Global Health
Partnerships


HANDOVER OF CERTIFICATE OF INTERNATIONAL ACCREDITATION FOR THE NATIONAL HEALTH LABORATORY QUALITY ASSURANCE AND TRAINING CENTER, BUGANDO MEDICAL CENTER LABORATORY AND MBEYA REFERAL HOSPITAL LABORATORY CENTER, BUGANDO MEDICAL CENTER LABORATORY AND MBEYA REFERAL HOSPITAL LABORATORY IN TANZANIA.
21ST JUNE 2014

Tanzania

Azerbaijan

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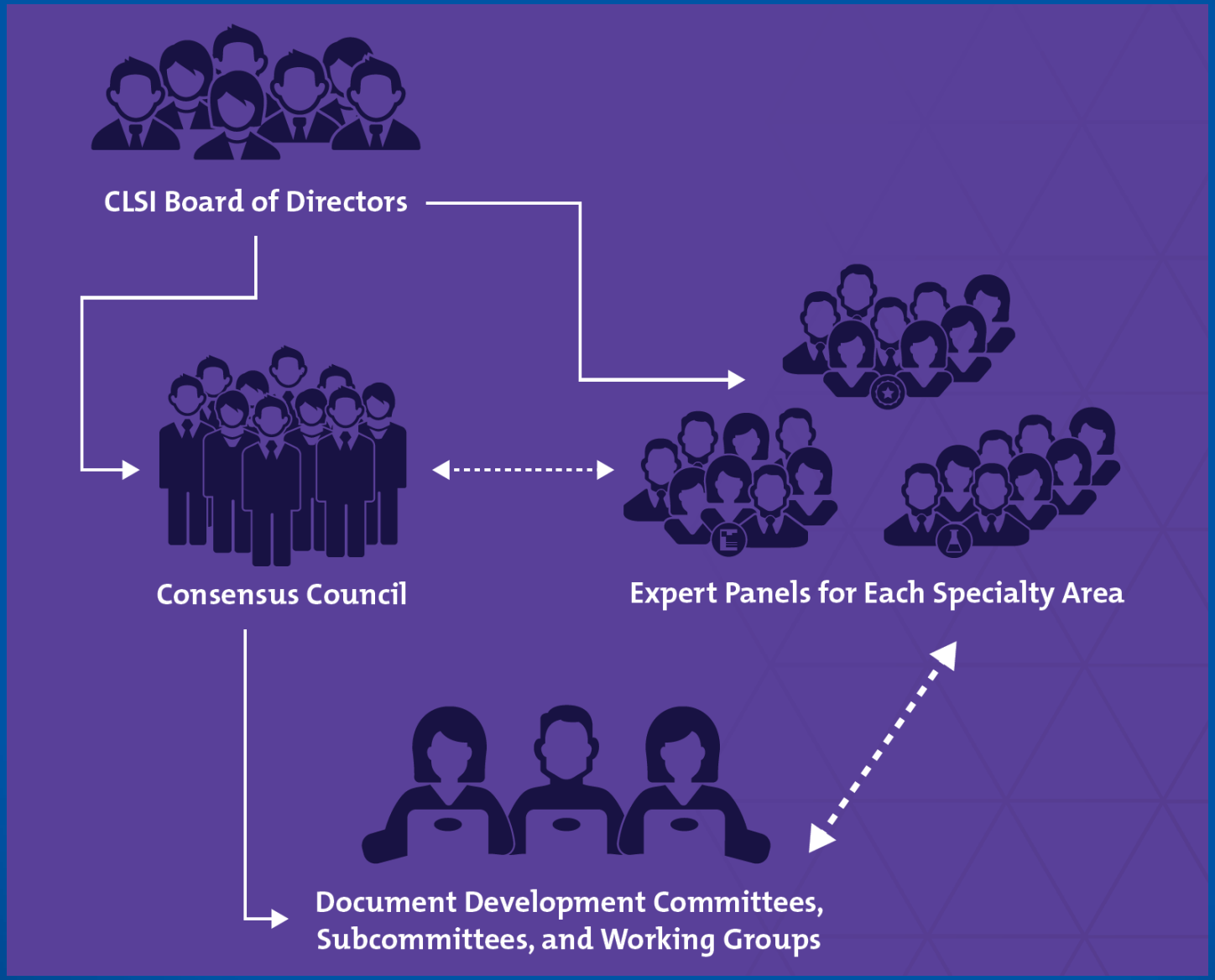
How Do We Create Standards?

>2,000

Active Volunteers

>75 Standards in Development

Standards Development Structure



Overview of the Process

- Proposals are generated by individuals or at the request of an Expert Panel (Project Proposal Form).
- The Expert Panel evaluates the Project Proposal and decides to move it to Consensus Council.
- Consensus Council Reviews and Authorizes Project Proposals (need and alignment across Expert Panels).
- A Call for Volunteers is issued to form a Document Development Committee.
- The Document Development Committee writes the document.
- The document moves through review and approval process.
- There are two voting stages (14- or 19-month track).
- The consensus standard or guideline is published.

Document Development Process

Abbreviation: DDC, document development committee.

Volunteer Value Proposition

- Maximizes the impact of your participation
- Expands opportunities for you
- Enables volunteers to work together
- Timely response to the critical need for standardized best medical practices worldwide

Standards vs Guidelines

- Standard
  - Specific, essential requirements
  - Used without modification
- Guideline
  - General operating practice, method, or material
  - Used as written or modified for a specific need

Point-of-Care Documents

- In Development:
  - POCT15, *Point-of-Care Testing for Infectious Diseases;* Report
  - POCT16, *Emergency and Disaster Point-of-Care Testing;* Guideline

Point-of-Care Documents

- For Revision:
  - POCT14, *Point-of-Care Monitoring of Anticoagulant Therapy; Approved Guideline* (formerly H49)
  - POCT05, *Continuous Glucose Monitoring; Approved Guideline*

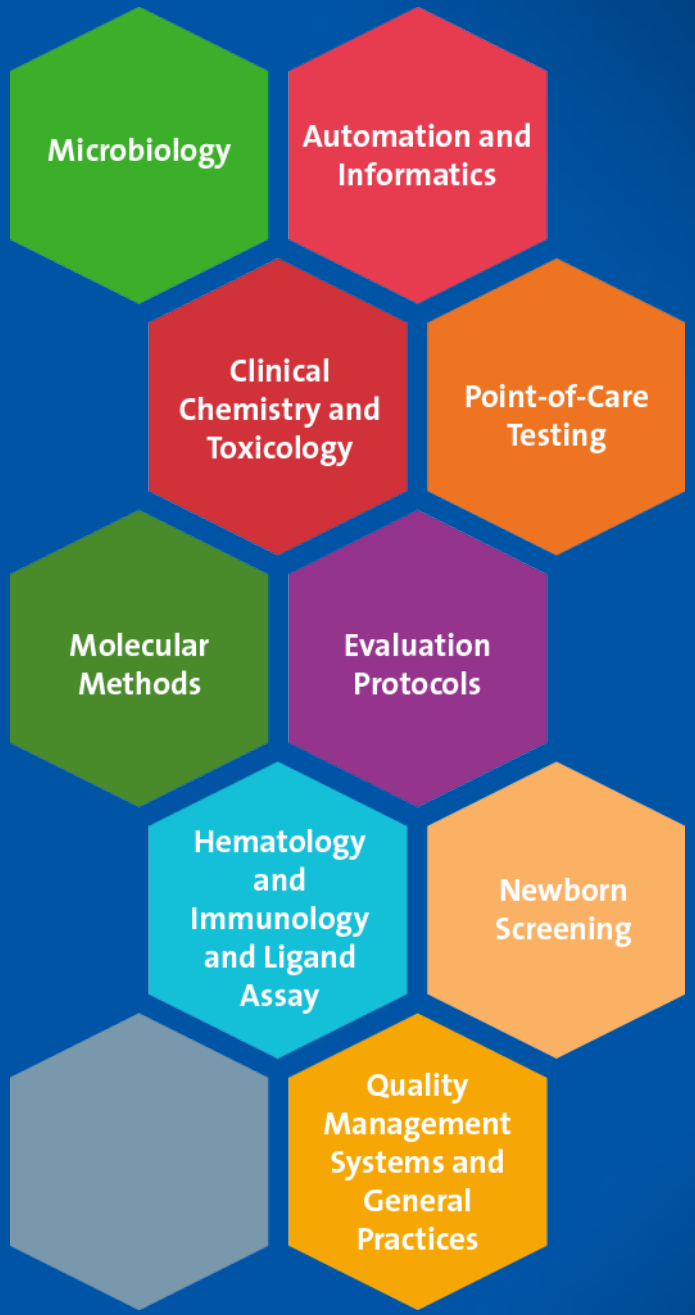
Point-of-Care Documents

- Published:
  - POCT01-A2—*Point-of-Care Connectivity; Approved Standard*
  - POCT02-A—*Implementation Guide of POCT01 for Health Care Providers; Approved Guideline*
  - POCT04-A2—*Point-of-Care* In Vitro *Diagnostic Testing; Approved Guideline*
  - POCT06—*Effects of Different Sample Types on Glucose Measurements*
  - POCT07—*Quality Management Approaches to Reducing Errors at the Point-of-Care*

Point-of-Care Documents

- Published:
  - POCT08-A—Quality Practices in Noninstrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers; Approved Guideline
  - POCT09-A—Selection Criteria for Point-of-Care Testing Devices; Approved Guideline
  - POCT10—Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline
  - POCT12—Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline
  - POCT13—Glucose Monitoring in Settings Without Laboratory Support; Approved Guideline

Standards Specialty Areas



Submit New Project Ideas

clsi.org/volunteer/propose-a-project/

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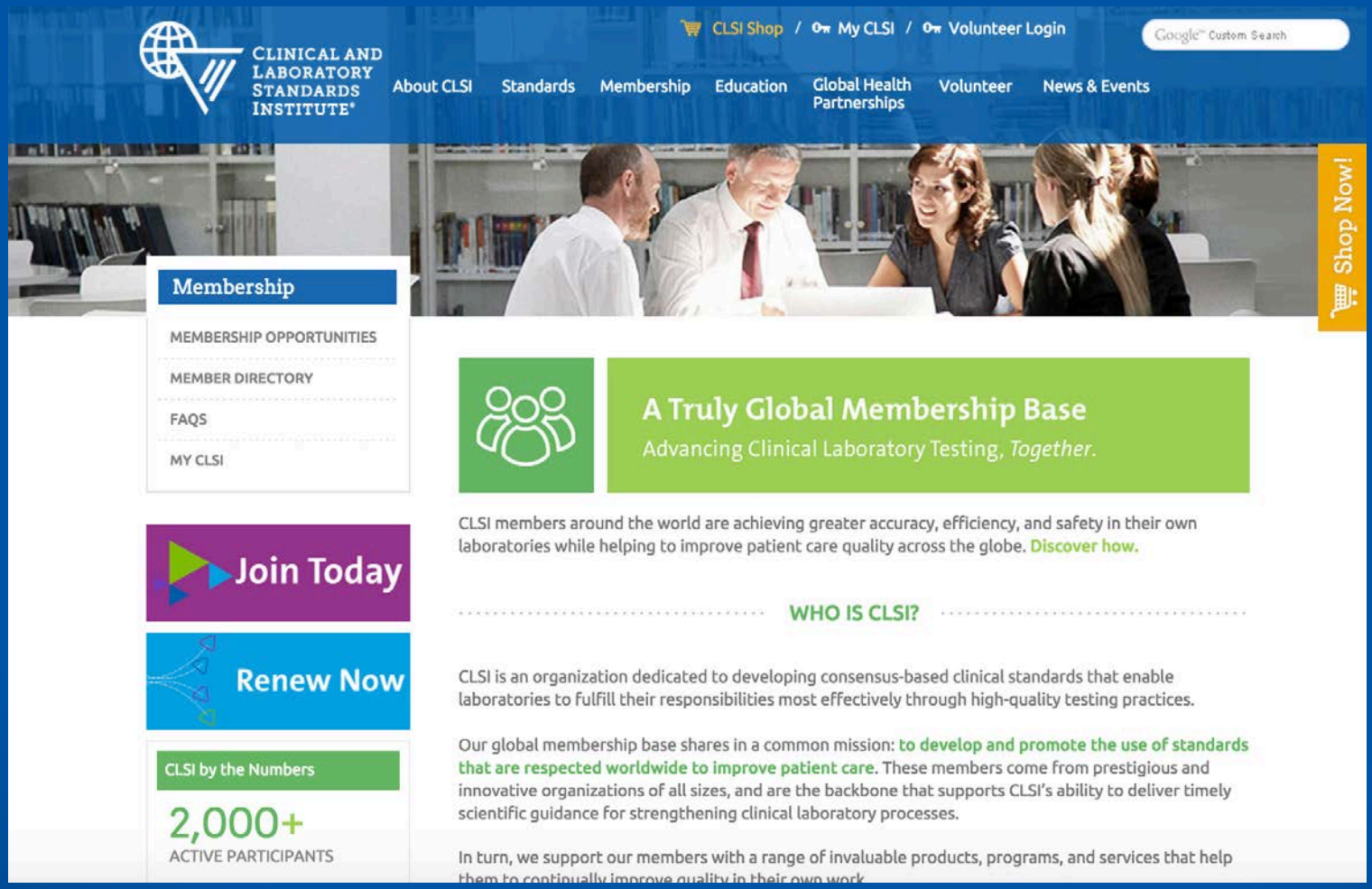
Staying Connected With CLSI

How Do I Get Involved?

clsi.org/volunteer

How Do I Become a Member?

clsi.org/membership



How Do I Buy Standards?

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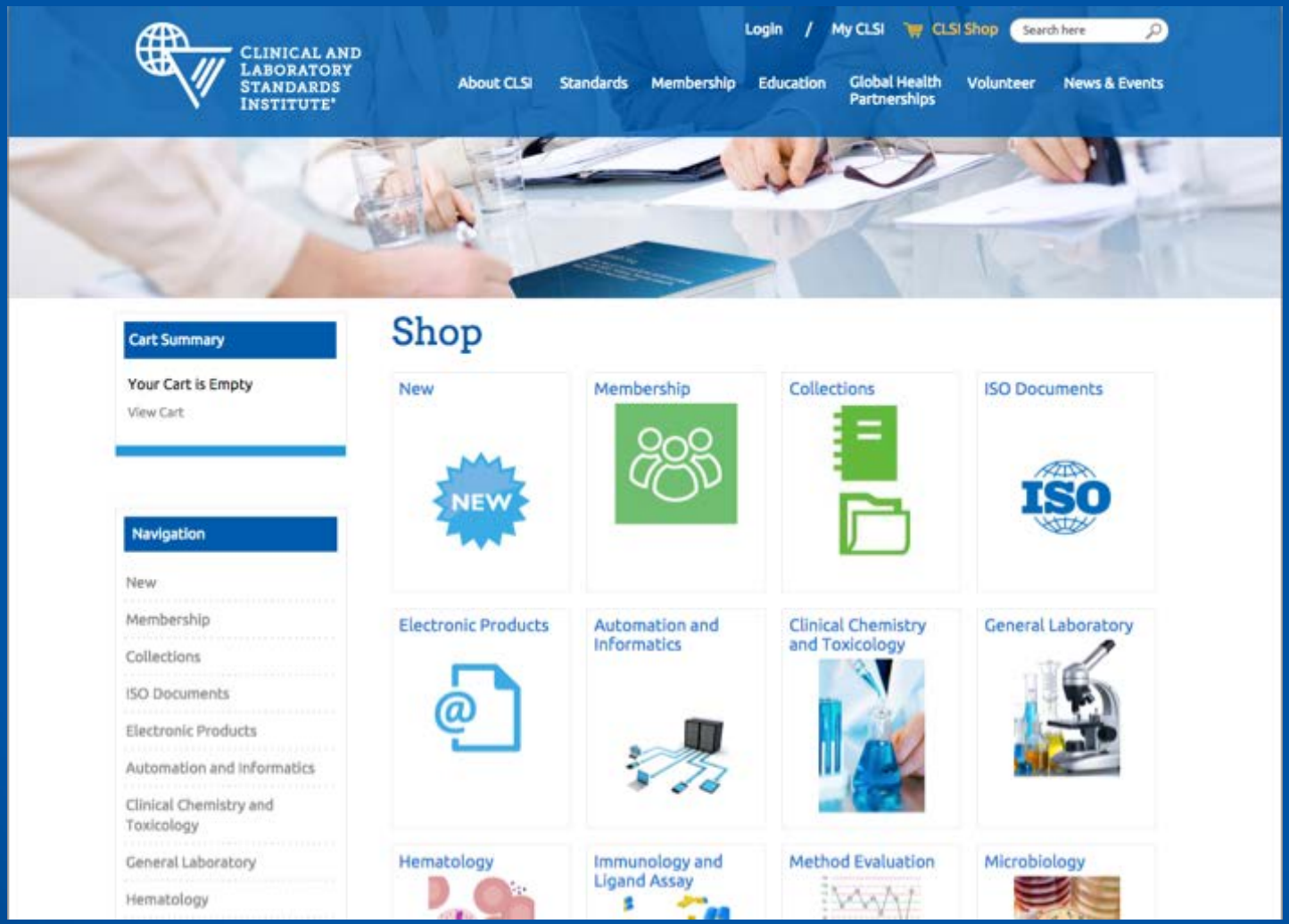

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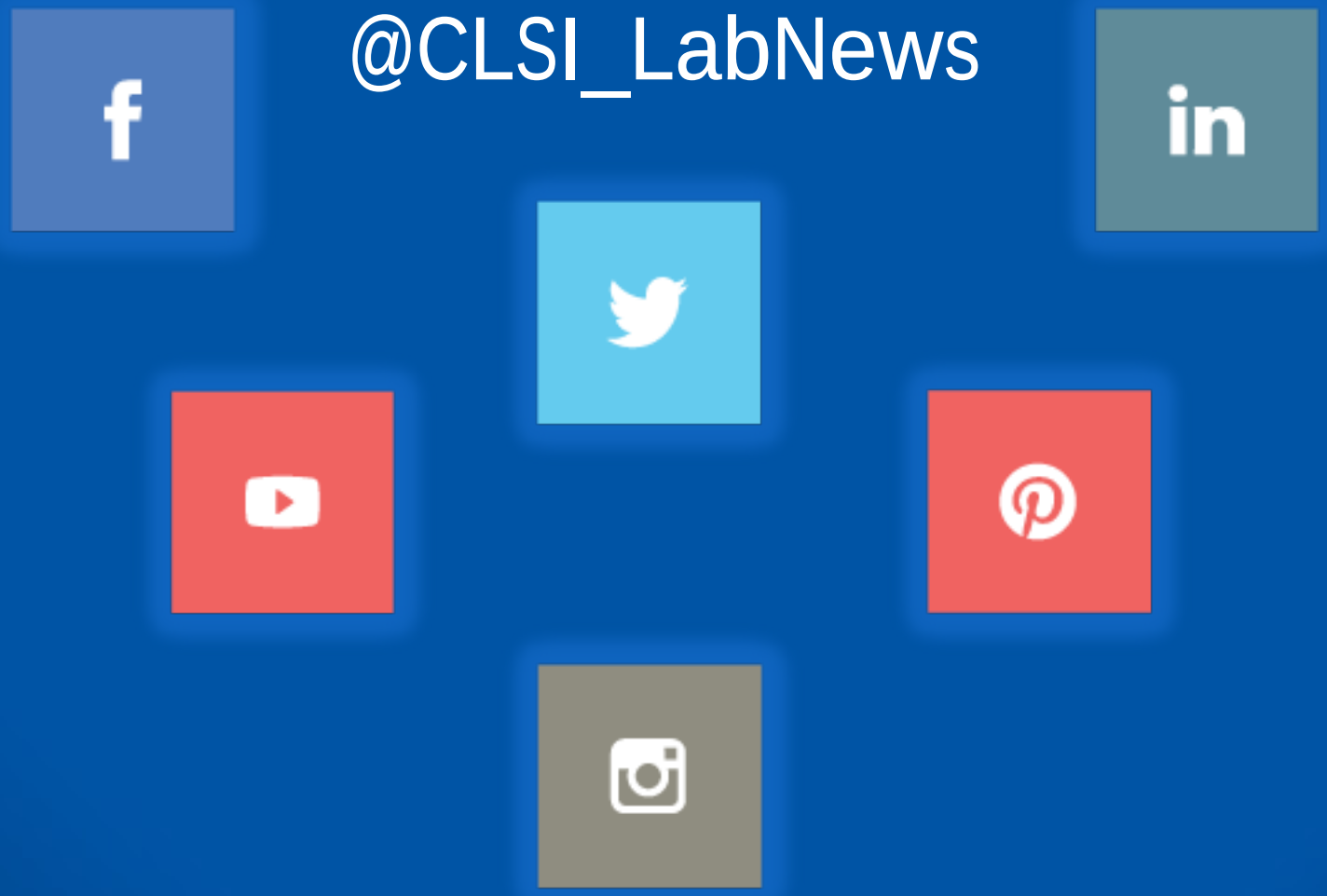

Summary

- CLSI provides the venue for consensus standards development.
- CLSI has global reach and is aligned with US and International standards.
- Point-of-care testing has relevant specific standards as well as general guidelines.
- The standards process requires active participation from all sectors.
- These documents provide guidance for practical implementation of POCT.
- These documents provide applicable performance and quality requirements for POC devices.
- Whether employed in the health care delivery, regulatory, or industry sector, CLSI standards are integral to your daily responsibilities.
- Get Involved in the process—don't be a bystander.

Questions?

Contact Us!

customerservice@clsi.org | +1.610.688.0100