

# *CLSI President's Message*

AACC meeting

28 July 2008

Gerald A. Hoeltge, MD  
President

The Clinical and Laboratory  
Standards Institute



# Perspectives on Quality

Laboratory Practice (CLSI)  
Laboratory Certification (CMS)  
IVD Regulation (FDA)



# CLSI Today

- \$7M annual budget
- 30 employees
- 2,000 member organizations in 24 countries
- nearly 2,000 active volunteers
- 191 consensus standards and guidelines
- >75,000 documents each year distributed



# CLSI Document Portfolio

	Publications				<u>Develop</u>
	Proposed	Approved	Archived	<u>Total</u>	
• Auto	0	13	7	<b>20</b>	0
• CC	1	15	9	<b>25</b>	3
• EP	1	10	2	<b>13</b>	5
• Hem	2	21	4	<b>27</b>	0
• ILA	1	11	8	<b>20</b>	3
• Micro	2	24	6	<b>32</b>	3
• MM	0	14	2	<b>16</b>	1
• POCT	5	3	1	<b>9</b>	6
• QSLP	1	20	8	<b>29</b>	3
<b>Total CLSI</b>	<b>13</b>	<b>131</b>	<b>47</b>	<b>191</b>	<b>24</b>

Access sample pages at: [www.clsi.org](http://www.clsi.org)



# Volunteers Needed

- What?
  - Development of Standards and Guidelines
  - Global Health Partnerships
- Why?
- How?

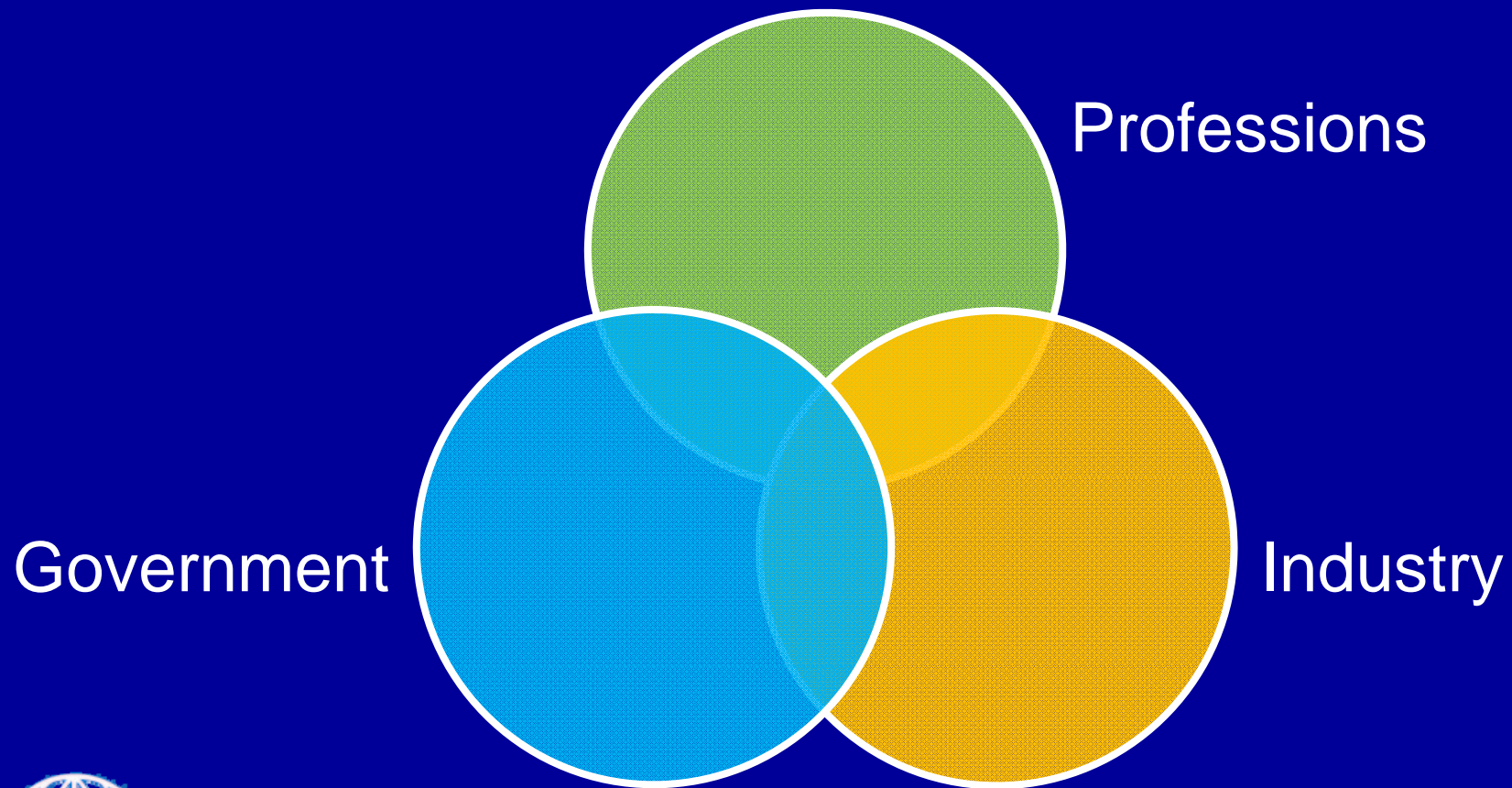


# CLSI Standards and Guidelines

- Identified need/project idea
- Project proposal
- Assessment
- Call for nominations
- Subcommittee membership
- Project authorization  
(14 new projects in 2008)



# The CLSI Consensus Process



# Global Health Partnerships

## *CLSI Lab Strengthening Program Services:*

- Assessment/Gap Analysis
- Training and Education
- Mentoring
- Laboratory Self-assessment
- Continuous Quality Improvement



# Why?

## *CLSI's Mission:*

To develop best practices in clinical and laboratory testing and promote their use throughout the world, using a consensus-driven process that balances the viewpoints of industry, government, and the healthcare professions



# How to Get Involved

- Watch for “Call for nominations”.
- Nominate yourself!
- Recruit/Mentor others.
- Comment upon P-level documents.
- Join CLSI teleconferences and meetings.



The only point of view that matters  
is that of the patient.



# Perspectives on Quality

- ***Status Reports: CLSI EP22 and EP23***

Greg Cooper, CLS, MHA

James Nichols, PhD, DABCC, FACB

- ***Laboratory Certification (CMS)***

Judith A. Yost, MA, MT(ASCP)

- ***FDA Regulation of IVDs***

Alberto Gutierrez, PhD

