

## LLS Class of 2016 Laboratory Quality Survey

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The Laboratory Leadership Service Class of 2016 (LLS 2016) is collaborating with OADLSS to develop a framework for quality training tailored to research laboratories. As part of this project, LLS 2016 is seeking feedback from the CDC Laboratory community on their knowledge and perception of Laboratory Quality Management Systems (LQMS), capabilities and barriers to LQMS implementation, and preferred training delivery methods. This information may help inform the development of an LQMS training curriculum.

We are asking you to participate in this survey. Your participation in this survey is completely voluntary and will not in any way affect your employment. No personally identifying information will be collected and responses to the survey will be anonymous. You may end your participation at any time during the survey by stopping and exiting the survey.


If you have any questions or concerns about this survey, please contact Dr. Justine Pompey at [czo3@cdc.gov](mailto:czo3@cdc.gov).

### INFORMED CONSENT STATEMENT

I have read the information provided above, and I know who to contact to ask questions about this survey. By launching the electronic survey, I agree to take part.

Public reporting burden of this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB Control Number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA 0920-1071

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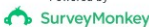
## LLS Class of 2016 Laboratory Quality Survey

**What is research?** For the purposes of this survey, research is defined as any activity directed towards expanding knowledge and/or understanding of a scientific question. Any activity that supports those goals is also considered research. Some examples of research include but are not limited to assay development, surveillance, product and/or reagent development, product testing, and animal care.

**Who is part of the CDC research community?** Anyone who is directly involved in research activities, as well as, those who work to support research operations at CDC. Some examples include laboratory scientists, bioinformaticians, engineers, animal care staff, core facility (e.g., Biologics and Biotechnology Core Facility) operations staff, quality specialists, safety officers, administrative staff, and management.

**What is your "group"?** There are several questions that ask about activities that occur in your group. For the purposes of this survey, your group is defined as the smallest collection of people in which you work (e.g., Drug Development Unit, Genetics Team, Laboratory Branch, Health Effects and Laboratory Division).

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## LLS Class of 2016 Laboratory Quality Survey

### 1. In what Center, Institute, or Office do you work?

- Center for Global Health (CGH)
- National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
- National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)
- National Center for Immunization and Respiratory Diseases (NCIRD)
- National Institute for Occupational Safety and Health (NIOSH)
- National Center on Birth Defects and Developmental Disabilities (NCBDDD)
- National Center for Environmental Health (NCEH)
- Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)

### 2. What percentage of your time is spent fulfilling each of the following roles?

- **ADS/ADLS/Division/Branch Laboratory Director** (Branch, Division, or Center level)
- **Laboratory Manager/Supervisor** (Team lead, Unit lead, Project officers, and/or Principal investigators)
- **Laboratory Support Specialist** (e.g., responsible for ordering laboratory supplies, managing service contracts, onboarding personnel, project management)
- **Frontline Staff** (e.g., Laboratory scientists, engineers, bioinformaticians, animal care staff, and research and product support staff)
- **Quality Management** (Quality managers and quality specialists in official or unofficial capacity and anyone participating in quality related activities)
- **Safety Officer/Representative** (in official or unofficial capacity)



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- **Safety Officer/Representative** (in official or unofficial capacity)

	0%	25%	50%	75%	100%
ADS/ADLS/Division/Branch Laboratory Director	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Laboratory Manager/Supervisor	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Laboratory Support Specialist	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Frontline Staff	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Quality Management	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Safety Officer/Representative	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other (please specify)

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### LLS Class of 2016 Laboratory Quality Survey

#### 3. What type of activities occur in your group? (Choose all that apply)

- Basic research (a systematic study to expand knowledge and/or understanding of a scientific question without specific application towards processes or products)
- Applied research (a systematic study to meet a recognized and specific need, including a product or assay development)
- Surveillance work
- Production of reagents or supplies for research activities in the CDC community
- Animal support for research activities
- None of the above

#### 4. What percentage of your time is spent participating in research or research support activities?

- 1% to 60%
- 5% to 100%
- I don't participate in research or research support activities

#### 5. Is your group accredited (e.g., CAP, ISO, CLIA, AAALAC) or pursuing accreditation?

- Yes
- No
- I don't know

#### 6. An LQMS can be defined in a number of ways. With which definition do you most agree? (Choose one)

- A system used by laboratory management to improve the efficiency of overall operations (ensure the consistent quality of the tests performed, the products created, the data generated from laboratory research, and the results reported)
- A system that establishes the guidelines for accuracy, reliability, and timeliness of scientific data.
- A system that ensures the organization achieves quality objectives, maintaining compliance with regulatory requirements, meeting applicable quality standards, and promoting continuous quality improvement.
- A management system to direct and control an organization with regards to quality.
- None of these statements describe an LQMS.
- I am unsure if any of these statements describe an LQMS.

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### 7. Which of the following components does your group have? (Choose all that apply)

- Documented standard protocols or procedures (i.e., SOPs)
- Reagent records (e.g., documented lot numbers or expiration dates)
- Documented quality control plan (e.g., for reagent and/or equipment qualification and/or test method quality control requirements, etc.)
- Documented procedures for reporting safety incidents and near misses
- Reporting system for errors (e.g., for equipment failures, testing errors, etc.)
- Written personnel training requirements
- Documented equipment calibration records, maintenance schedules, and/or service contracts
- Testing and/or validation records
- Data management system
- Specimen inventory system
- Reagent inventory system
- My group does not have any of these components

### 8. Do you think an LQMS would (please answer each question):

	Yes	No	Unsure
Reduce error rates (e.g., during data generation, results reporting, inventory management, etc.)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Improve accuracy of

- Testing and/or validation records
- Data management system
- Specimen inventory system
- Reagent inventory system
- My group does not have any of these components

8. Do you think an LQMS would (please answer each question):

	Yes	No	Unsure
Reduce error rates (e.g., during data generation, results reporting, inventory management, etc.)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Improve accuracy of data/results?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Increase efficiency and productivity?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Save money/reduce financial assets?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Improve continuity of laboratory activities throughout personnel turnover (e.g., equipment maintenance, personnel training, etc.)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Improve continuity of research generation throughout personnel turnover (e.g., sample processing, product testing, etc.)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Improve continuity of laboratory activities throughout organization restructuring (e.g., equipment maintenance, personnel training, etc.)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Improve continuity of research generation throughout organization restructuring (e.g., sample processing, product testing, etc.)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

9. Below are potential barriers to implementing LQMS. Rank the following barriers to implementing an LQMS in your group from the greatest barrier (1) to the smallest barrier (6).

research generation  
throughout  
organization  
restructuring (e.g.,  
sample processing,  
product testing, etc.)?

9. Below are potential barriers to implementing LQMS. Rank the following barriers to implementing an LQMS in your group from the greatest barrier (1) to the smallest barrier (6).

- Personnel: There are not enough staff to implement an LQMS.
- Time: It takes too much time to implement an LQMS.
- Cost: It costs too much to implement an LQMS.
- Resources: We do not have enough tools to implement an LQMS (e.g., software and templates).
- Guidance: We do not know how to implement an LQMS.
- N/A: There are no barriers to implementing an LQMS.

10. Please feel free to list additional barriers or to expand on your answer here: (For example, we have enough tools to implement LQMS but they are not user friendly)

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11. If your group has already implemented an LQMS, what do you feel are the difficulties in maintaining it? (Choose all that apply)

- Personnel
- Knowledge and expertise
- Time
- Cost
- Insufficient resources
- There are no difficulties in maintaining our QMS
- My group has not implemented a QMS

12. I would prefer to receive initial training in Laboratory Quality Management through: (Rank the items below from the most preferred format (1) to the least preferred format (4))

☰	▾	In-person seminar
☰	▾	In-person workshops (includes hands-on activities)
☰	▾	Webinars (live seminars through the computer)
☰	▾	Online trainings

13. After receiving initial training in Laboratory Quality Management, I would prefer to

13. After receiving initial training in Laboratory Quality Management, I would prefer to receive subsequent Quality Management training through: (Rank the items below from the most preferred format (1) to the least preferred format (4)).

1	In-person seminar
2	In-person workshops (includes hands-on activities)
3	Webinars (live seminars through the computer)
4	Online training

14. Please feel free to list additional training formats here.

15. I would prefer for the Laboratory Quality Management training content to be presented as: (Rank the items below from the most preferred format (1) to the least preferred format (3))

1	Case studies (tangle a example relevant to my work)
2	Group exercises (hands-on examples)
3	Literature (read content and sign-off that you have read it)

16. Which of the following courses would you be interested in? (Choose all that apply)

- A broad, general overview of Quality Management in relation to laboratory/research operations
- Training in Laboratory Quality Management specific to job title (e.g., Laboratory Branch chief, Team lead)
- Training in Laboratory Quality Management specific to job activities (e.g., testing, safety, document review)
- Training tailored to a specific Quality Standard (e.g., ISO 17025, ISO 9001)
- Training tailored to a specific requirement (e.g., CLIA, FDA, QSR)
- Training modules for Quality System Essentials (QSEs, e.g., Documents & Records, Process Management, Non-conforming Items Management)
- Other (please specify)

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