LabGuide 5



This LabGuide pertains to QSE Personnel and the General Phase of the Path of Workflow.

Finding a Laboratory Consultant

Technical laboratory consultants can provide expertise to help you provide quality patient care; maintain Good Laboratory Practices; and identify, investigate and correct problem areas in your laboratory.

Consultant Services

Your laboratory may need the expertise that a qualified and experienced laboratory consultant can provide, or you may be required to engage the services of a qualified technical consultant as part of your correction plan following an onsite inspection, or you may not have someone on staff that qualifies to hold the CLIA-required position of technical consultant (for moderate complexity laboratories) or technical supervisor (for high complexity labs). If any of these situations apply to your laboratory, you can hire an outside laboratory consultant.

The right laboratory consultant can provide many services, such as:

- Assisting with new lab start-up or a change from waived to non-waived testing
- Creating written policy and procedure manuals
- Providing staff training, competency assessment, and continuing education
- Aiding in evaluation and selection of instrumentation
- Determining test menu feasibility and cost analysis
- Offering training in proper billing practices and CPT coding
- Establishing a written quality control (QC) program
- Establishing and implementing a written quality assessment (QA) plan
- Assisting with OSHA training, safety audits, and the creation of a safety manual
- Aiding in selection and implementation of a laboratory information system (LIS)
- Helping with the evaluation and selection of a proficiency testing (PT) program
- Troubleshooting QC problems, PT failures, or technical issues
- Assisting with preparation for onsite inspection and being present to provide support during the inspection
- Correcting deficiencies noted at an onsite survey / inspection in order to achieve compliance

Finding the Right Consultant

To qualify as a technical consultant or a technical supervisor, the individual must meet the CLIA education and experience requirements, and must also be able to fulfill all the responsibilities of the position. These requirements and responsibilities are described in LabGuide 4, titled *Personnel for Non-waived Testing*.

This LabGuide provides suggestions to help you find the right laboratory consultant for your laboratory.

(p1) Consultant Services

(p1) Finding the Right Consultant

- (p2) Professional Organizations
- (p3) Qualifications
- (p3) Fee Negotiations
- (p3) Follow-up

To find a qualified consultant, you could always look for a recommendation from a trusted colleague, but this type of personal referral may not be available to you. Consider exploring the following resources to find a qualified laboratory consultant in your area:

- Your local hospital's laboratory manager or supervisor
- Your reference laboratory (they may provide consulting services)
- Laboratories associated with physician's offices in your area
- The internet

Professional organizations are another possible source of qualified leads. They may have members in your area who have expressed an interest in providing laboratory consultation. Your state or regional CMS office may also keep a list of qualified laboratory consultants. The following list provides contact information for a few of the professional organizations.

- AAB American Association of Bioanalysts (www.aab.org)
 906 Olive Street, Suite 1200 | St. Louis, MO 63101-1448
 Phone: (314) 241-1445
 - AABB (www.aabb.org) 8101 Glenbrook Road | Bethesda, MD 20814-2749 Phone: (301) 907-6977
- AACC American Association for Clinical Chemistry (www.aacc.org) 1850 K Street NW, Suite 625 | Washington, DC 20006 Phone: (800) 892-1400
- AMT American Medical Technologists (www.amt1.com) 10700 West Higgins, Suite 150 | Rosemont, IL 60018 Phone: (847) 823-5169 or (800) 275-1268
- ASCLS American Society for Clinical Laboratory Science (www.ascls.org) 2025 M Street NW, Suite 800 | Washington, DC 20036 Phone: (202) 367-1174
- ASCP American Society for Clinical Pathology (www.ascp.org) 33 West Monroe Street, Suite 1600 | Chicago, IL 60603 Phone: (312) 541-4999
- ASH American Society of Hematology (www.hematology.org) 2021 L Street NW, Suite 900 | Washington, DC 20036 Phone: (202) 776-0544
- ASM American Society for Microbiology (www.asm.org) 1752 N Street NW | Washington, DC 20036-2904 Phone: (202) 737-3600

There are several nationally known clinical laboratory professional organizations.

Qualifications

Look for candidates that have the education and experience necessary to qualify under CLIA as a technical consultant or a technical supervisor. This will help ensure that the candidate has the expected level of knowledge of laboratory regulations, processes and procedures. You may also wish to add national certification to your list of desired qualifications. Conduct interviews with qualified potential candidates to determine their:

- Familiarity with your type and size of laboratory
- Ability to communicate with personnel that have the education and experience level of your employees
- Problem-solving and customer service skills
- Experience with your instruments and test procedures
- Experience with laboratory information systems (LIS), if applicable
- Availability to your staff
- Schedule and other work commitments
- Relationships with manufacturers or suppliers
- Services offered and areas of expertise

Tell the consultant about your laboratory operations, your personnel, your test menu, and your reasons for seeking an outside consultant. Always ask for personal and professional references, and take the time to call them. Feedback from current clients will be of great help in determining if this is the right consultant for you.

Fee Negotiations

Consultants use various methods to charge for their services. Be sure to discuss fees and payment methods with your chosen consultant. Various considerations include: fee per service or per specialty of testing; hourly fees; retainer fees; and travel Fees and expenses.

Always ask for a written proposal for consulting services that includes a full description of each service provided, the time commitment involved, and the itemized fees for each service.

Follow-up

It is as essential to assess the competency of Technical Consultants as it is other laboratory staff. One way to do this is to monitor their effectiveness in fulfilling their contractual obligations. The following steps will help:

- Inform all lab staff of the role you want the consultant to play.
- Ensure that the consultant clearly understands your expectations.
- Monitor the ongoing interaction between your staff and the consultant. Good rapport between them will help ensure cooperation and a successful return on your investment.
- Stay informed about the consultant's activities and progress in achieving the desired outcomes.

The complete CLIA personnel requirements (Subpart M) can be found at: <u>www.cdc.gov/clia/regs/subpart_m.aspx</u>

