

MARCH / APRIL '08

# INSIGHTS

## PROVIDING A VITAL ROLE: COLA Technical Advisors

*By Karen Appold*

Are you unclear about an aspect of the COLA accreditation process? Do you have an issue related to proficiency testing (PT) that you need help resolving? Was your laboratory recently surveyed and you need assistance responding to the Plan of Required Improvement (PRI) process?

Regardless of what laboratory issue you may need help with, COLA technical advisors (TAs) are available via phone, e-mail, or fax to assist a COLA Member laboratory, and provide information and education on lab topics free of charge as part of the COLA Member benefits. On occasion, they also answer questions from non-COLA members. Like all COLA employees, the TAs are committed to COLA's mission of quality in the laboratory.

### Advantages of Using a TA

TAs are educated in laboratory science and at minimum must have an associate's degree in lab science, MLT certification, and laboratory experience. They receive extensive training from COLA, take continuing education courses, and participate in workshops and teleconferences. "Most of our TAs have BS degrees and many years of laboratory experience," noted TA Supervisor, Louise Jackman, MT(ASCP)SC. COLA has four TAs and a team leader on staff.

Because TAs have worked in different types and sizes of laboratories and have used many different instruments, they can relate to a variety of laboratory personnel including those with limited or no laboratory experience or education.

### What Does a TA Do?

A typical day for Anita Coleman, MT(ASCP), Technical Advisor, includes answering phone calls that run the gambit from "When will my survey take place?" and "How can I prepare for it?" to "I received survey results and I don't know what to do." Coleman said, "When a laboratory calls with a question, the TA team uses resources such as COLA educational products, information from manufacturers, the Internet, and each other to find the answer." "The TA team is versed in CLIA regulations, as well as COLA criteria, and can refer customers to the team leader for additional help," Jackman noted.

COLA surveyors often ask Marsha Mank, MT(ASCP), Technical Advisor, for assistance by faxing LabGuides, Help Packets, or sample documents, or they may ask her for a second opinion on questions they have while out on the road, especially when their team leader is unavailable.

Other COLA TAs, Geri Scheid, MLT(ASCP), and Michael Dallas, MLT(ASCP), review documentation sent in by laboratories for the PRI process. "I will call the laboratory, if needed, to provide education on documentation or I will inform them that more documentation is necessary," Scheid explained. "If the documentation is in compliance, then I print a 'PRI complete letter' and put the laboratory on a Certificate List."

*Continued on page 2*



## NEW OPPORTUNITIES FOR COMMITTING TO QUALITY

**FROM THE CHAIR** Spring is in the air - time to do a little house cleaning. Get rid of any clutter (physical and mental) that may be hindering you, and seek new opportunities to revitalize your commitment to quality in laboratory medicine.

In this issue of *Insights*, you will find the article, *What to Look for When Hiring a Consultant*. This article provides insights on how hiring a consultant can improve the quality of your laboratory.

With the 2008 presidential campaign underway, consider how the election of a new president might affect your laboratory. You may want to seek expert advice to ensure that you stay ahead of any issues that could impact your operations. Who is better to assist you with a strategic planning initiative than a well qualified technical consultant?

This issue of *Insights* features an article on the vital role COLA Technical Advisors (TAs) play in helping laboratories achieve compliance and provide quality care. Take a look into a day in the life of TAs at COLA as they assist laboratories in achieving COLA's mission to promote quality patient care in laboratory medicine.

**Donna E. Sweet, MD, MACP**  
Chair, COLA Board of Directors

*Providing a Vital Role: — continued from front cover*

### Helping Laboratories to Achieve Compliance

The TAs' main role in helping laboratories achieve compliance is providing education. "After laboratories receive a PRI letter, they usually call with questions on what is needed to be sent back to COLA. I explain the citations that need documentation, describe the documentation required to achieve compliance, and provide education on the other citations. I direct them to COLA's Web site as often as I can. However, some personnel do not like to use the Internet so I fax the information," Coleman said.

The TAs' job is finished when documents are received, reviewed, and compliant. "Sometimes it is rather simple to relay what documentation is missing, and within a week or two we receive compliant documentation. However, I have worked with a laboratory as long as two or three months to get compliant documentation because the personnel didn't understand what was needed," Coleman noted.

TAs stay abreast of new regulations to help laboratories achieve and maintain compliance. "When we hear about changes or issues that may affect our laboratories, we work as a team to properly convey the new information," Dallas said.

### Obtaining Expertise from a TA

"Sometimes we have laboratories with multiple issues that require extra attention and mentoring," Coleman shared. "Occasionally a laboratory is required to hire a technical consultant for training and oversight for quality control, proficiency testing, quality assessment, and general laboratory operations. It is rewarding when a laboratory such as this is able to turn around and make the improvements necessary to do significantly better on their next survey. We feel good knowing the patients benefit."

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## COLA INSIGHTS

COLA is sponsored by the American Academy of Family Physicians (AAFP), the American Medical Association (AMA), the American Osteopathic Association (AOA), and the American College of Physicians (ACP); and is endorsed by 29 national and state medical organizations. Letters to the editor are welcome.

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*Providing a Vital Role: — continued from page 2*

The TAs work as a team, rotating work tasks so all TAs are able to assist any laboratory, Jackman explained. "All contacts and information sent to and received from laboratories are in our computer in each laboratory's file. We can quickly familiarize ourselves with where the laboratory is in our processes and assist with questions or problems."

### Personal Rewards on the Job

TAs find their work fulfilling and enjoyable. Scheid describes herself as a people person who constantly smiles through the phone. With 14 years of COLA experience behind her smile, she feels that laboratories benefit from it. "I don't always know all the answers, but I will research a subject until an appropriate answer is found and report back to the lab," she said. "I try to return calls quickly. I realize that when someone is alone in the laboratory and requires assistance, they need our expertise promptly."

Coleman shares similar sentiments. "I enjoy educating laboratory personnel through the accreditation process. When laboratories improve or are already performing good laboratory medicine, I feel that the patients they serve are safe and secure," she said. "Some labs are very challenging. They keep you on your toes to find more innovative ways to educate long distance. I feel that COLA performs a great service to laboratories through consulting, educating, and accrediting. Laboratories that are not a member of COLA are missing out on a wonderful relationship with a caring organization."

To obtain expertise from a TA, a laboratory should call 800-981-9883 and ask to speak with a TA or e-mail questions to COLA at [info@colas.org](mailto:info@colas.org).

### A Day in the Life of a TA

- Assist laboratories with technical questions about lab processes, CLIA regulations, and COLA criteria in terms that laboratory staff can readily understand.
- Verify the accuracy of laboratory information in COLA's participant database.
- Advise new laboratories on how to get started, keeping COLA requirements and CLIA regulations in mind.
- Provide assistance to laboratories for all types of PT issues.
- Review documentation from laboratories that have been surveyed and are in the PRI process. If paperwork is incomplete, follow-up with a call to the laboratory.
- Provide sample procedures, forms, and other educational aids.

*Karen Appold is an editorial consultant based in Royersford, PA.*

## NEW COLA EDUCATIONAL PRODUCT!



Get more benefit from your quality improvement efforts with COLA's *Quality Assessment Plan: A Simplified Approach*.

This new quality assessment plan reflects the updated CLIA requirements of 2003 which emphasize the need to assess quality across the entire laboratory path of workflow. This plan allows you to efficiently and effectively evaluate your general, pre-analytic, analytic, and post-analytic activities. This approach incorporates QA into the daily routine of your laboratory to get a better picture of *ongoing* performance, rather than just at one point in time. This QA plan is organized in a 3-ring binder and includes:

- Detailed instructions
- A ready-to-implement QA Plan
- Data Collection Forms
- QA Review Forms

## CHOOSE WISELY

### What to look for when hiring a consultant

By Karen Appold

Sometimes you require expertise beyond what is available from your own laboratory staff. When such situations occur, you may find yourself calling upon a consultant.

As a result of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), moderate complexity labs must have a qualified lab director, clinical consultant, technical consultant, and testing personnel. Some laboratories need to employ an outside technical consultant if they don't have a qualified, trained laboratorian who understands CLIA requirements. "Ultimately, these labs need additional expertise," said M. Ann Bachman, MT(ASCP), CLC(AMT), Director, Regulatory Compliance, DoctorsManagement.

"We have several clients whose physicians became qualified as laboratory directors by earning the relevant 20 CME credits, but they didn't have the one year of laboratory experience to become their own technical consultants," reported Mary Blount, MT(ASCP), Compliance Specialist/HazMat, DoctorsManagement. "We can fill the position of technical consultant for new directors and partner with them for the one year as a mentor to ready them for that position. Often, they still feel inadequate for that role and we remain the technical consultant. As point-of-care testing becomes more and more important to physician office laboratories (POLs), this need has escalated."

Michelle M. Hill, MS, MT(ASCP)SLS, CLC(AMT), President, Technology Consulting Services, found that the greatest need for consultation services has been in POLs. "I have also found that larger, hospital-based and referral laboratories need consultants for other regulatory issues such as OSHA, HIPAA, or OIG compliance" she said.

The COLA Patient Safety Goal for 2008 is:

*PRE 16: Prior to collection of a patient's specimen, is the patient's identity verified using two separate identifiers?*

## Getting Started

When a laboratory calls Tim Dumas, CLS, Medical Laboratory Consultant, Tim - "The Lab Guy" - Consulting, he begins with a simple fact finding telephone interview at no charge. Then, a site visit is scheduled to meet the staff and determine their needs. "I do a short version of a laboratory inspection to assess the time it will take to correct any issues," said Dumas. "My salary is based on the laboratory's profit, so I also perform a detailed laboratory financial assessment."

Most of Hill's clients are referrals from vendors, professional colleagues, reference laboratories, and CLIA inspectors. When asked what she can do for a lab, her response is, "I will take the responsibility that CLIA has outlined for the technical consultant and assume some of your laboratory director's responsibilities so you can take care of your patients and not worry about your laboratory."

## Common Jobs and Tasks of Laboratory Consultants

What exactly do consultants do? Bachman, Blount, Dumas, and Hill summarize their capabilities.

- Set up a complete laboratory from the start.
- Develop a laboratory procedure manual.
- Develop a quality assessment (QA) manual, implement a QA program, and perform QA monitoring.
- Review monthly quality control (QC) data, temperature charts, maintenance records, etc.
- Review proficiency testing reports and recommend corrective actions.
- Perform personnel competency assessment.
- Do a pre-inspection audit to help prepare for a certification survey.
- Accompany the surveyor during an inspection.
- Assist with required corrective actions to maintain certification.
- Provide financial assessment and maximize laboratory revenue.
- Update analyzers and LIS/EMR systems; recommend equipment.
- Optimize laboratory work flow, effectiveness, and performance.
- Help to hire new laboratory testing personnel.

### Consider Qualifications and Expertise

Choose a consultant based on your needs and type of laboratory. A candidate should provide documentation of several years of experience in different settings or in your laboratory's specialty, and proper CLIA qualifications, Bachman advised.

Although supervisory and bench experience is important, experience in a hospital is not necessarily a good background for providing assistance in a POL, Bachman said. It may be difficult for a hospital or reference laboratory tech to stick to the CLIA regulations that apply to a POL. "Hospital laboratory professionals sometimes tell POLs they must do certain things that are not required by CLIA, but may be required by Joint Commission, College of American Pathologists, state regulations, or their own policies," Bachman said.

Certification as a laboratory consultant is meaningful, but isn't required. American Medical Technologists was the first to offer certification (CLC), but now other agencies offer certification as well.

### The Hiring Process

Just like when hiring any other employee, you should obtain a potential consultant's resume, advised Dumas. Check credentials and history. The laboratory director, office manager, and lab person should all be present at the interview and prepared with their own set of questions.

"Don't forget the 'gut' factor when assessing a consultant's integrity," Dumas added. "Changes will probably be coming and you need someone who can effectively communicate and execute these changes with your staff."

Ask if the consultant has any exclusive affiliations or represents any distributors or manufacturers of laboratory equipment. "This could lead to a bias in equipment selection," Dumas cautioned.

Find out about their background and how many other laboratories they are involved with, advised Blount. It is important that a consultant has good communication skills, is energetic, organized, and qualified.

Also inquire about expectations, Blount added. How many visits and how much on-site attention should you expect? What knowledge does he have in assessing ongoing profitability and feasibility? Is he willing to train over the phone?

### Selecting the Right Consultant

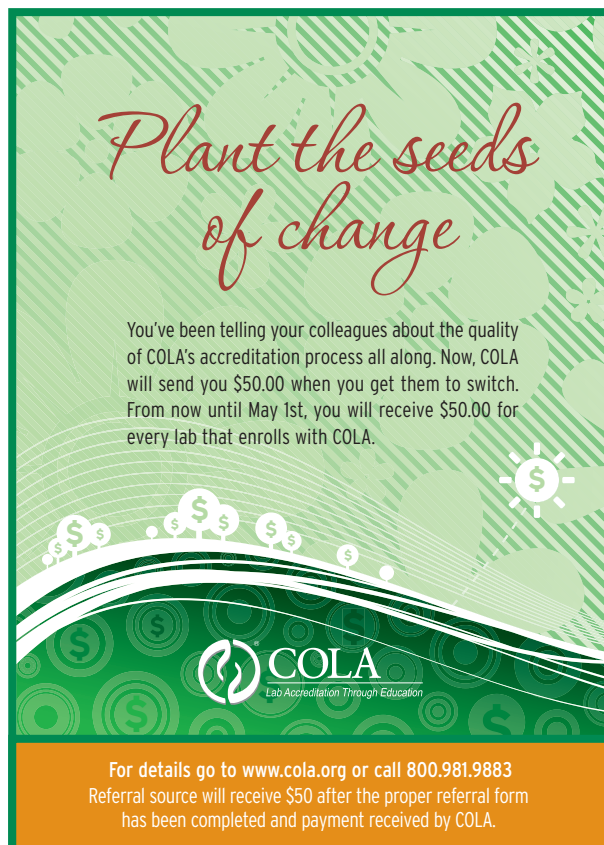
According to Dumas, consider the following aspects when choosing a consultant.

#### People Skills:

- Ability to effectively communicate with your level of personnel.
- A consultant will become a manager to your staff, and you will put significant trust in this person. Make sure everyone will get along.


#### Technical Skills:

- Experience managing and performing testing in a laboratory like yours.
- Certification and experience working as an MT or MLT is important.
- Familiarity with all CLIA regulations and experience with laboratory inspections.
- Able to provide a detailed list of recommended laboratory improvements that includes their



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For details go to [www.cola.org](http://www.cola.org) or call 800.981.9883  
Referral source will receive \$50 after the proper referral form has been completed and payment received by COLA.

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*Choose Wisely – continued from page 5*

- benefits, costs, and time frame for completion.
- Able to estimate a laboratory's revenue and address profitability and budget concerns.

#### **Fees and Reputation:**

- Able to provide references.
- Willingness to customize the fee structure based on a laboratory's size, revenue, and budget. Their fee shouldn't take all the profit.
- Willing to provide a guarantee.

When checking references, make sure your questions are specific enough to determine if this person is right for your setting and needs.

According to Bachman, the most important question to ask a reference is: "Was this person able to deliver the assistance you needed in a timely manner? Why or why not?"

Dumas advised asking these basic questions: "Was the consultant easy to work with?" Did he complete the job on time? If not, why not? Were you satisfied and did lab performance improve? Would you recommend him?"

Additionally, Blount recommended digging deeper with these questions: Is he knowledgeable enough to be of service to the laboratory and supervisor? Is he accessible for phone consultation and is that a part of his program? Does he offer survey preparation and come on-site for the survey? Does he treat laboratory personnel with respect and partner with them on compliance issues and concerns? Can he help with profitability issues that arise?

#### **A Word of Caution**

Before your laboratory starts looking for outside help, determine your level of commitment, Bachman noted. "It is a waste of time and money to get help if you are not going to comply with the advice from the consultant," she concluded.

*Karen Appold is an editorial consultant based in Royersford, PA.*

#### **Working with a Consultant: Laboratorians share their experiences**

Amber Allen, CMA, Laboratory Supervisor, Table Rock Family Medicine, and Jessica Sullivan, Lab Tech, University Internal Medicine, discuss using consultants in their laboratories.

#### **Q: What are some common tasks that you ask consultants to do?**

**Allen:** Our consultant performs QA/QC reviews, and completes paperwork for all of our manuals, personnel files, and proficiency testing. She's onsite for our COLA inspection every 2 years.

**Sullivan:** She ensures we are within regulatory guidelines and assists in our continuing education requirements. She was instrumental in adapting new equipment to synchronize and communicate with current equipment. She also trained staff on how to use it. In fact, she was more knowledgeable than the vendor selling the product.

#### **Q: What qualities should you look for when hiring a consultant?**

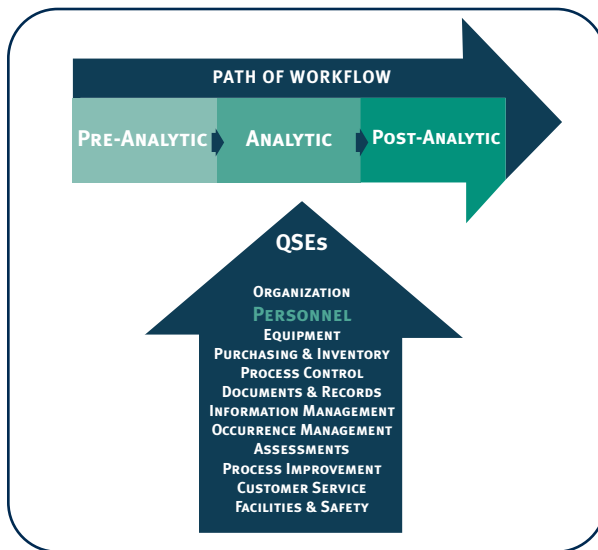
**Allen:** Experience with your type of laboratory whether COLA or CLIA, current regulations, education, having an MT degree, and being certified with a current accreditation agency.

For us, it is important that the consultant can visit our laboratory several times annually. The consultant or an affiliate should be reachable daily. The consultant should be able to provide good references and a fee schedule.

**Sullivan:** Check references and speak with laboratory staff for their impression, not just management's. Determine the consultant's ability to communicate effectively, promptly respond to questions and problems, their accessibility, and knowledge of equipment. Find someone who is familiar with your laboratory's specific issues.

## QSE: PERSONNEL

Quality Management Systems (QMS) is a systematic approach to quality management with a focus on error prevention and efficiency. The goal is to take quality and effectiveness to a higher level of performance. The Quality System Essentials (QSEs) work together to comprise a quality management system, supporting the path of workflow and forming the foundation of the laboratory's operations.



QSE: Personnel is about people. People perform your laboratory's work, and they are your laboratory's most valuable and costly asset. It is vitally important for patient care that your laboratory hires people who are qualified for the jobs they will perform, are trained to do their work processes and procedures correctly, and continue to remain competent in their job tasks.

QSE: Personnel guides your laboratory to:

- Determine and document job qualifications and job descriptions
- Provide adequate orientation and training
- Assess personnel competency
- Provide continuing education
- Create and keep proper personnel records

You may also be interested in the LabUniversity® course QSE: Personnel. Visit the COLA Store at [www.cola.org](http://www.cola.org) for more information on this and other QMS courses.

Another way to learn more about QMS is to attend the Symposium for Clinical Laboratories:

- St. Louis, MO      May 14–17, 2008
- Scottsdale, AZ      September 25–26, 2008

These spirited events offer everyone from experienced laboratory professionals to novice quality managers the opportunity to select topics to enhance their knowledge and skills in QMS.

Lucia Berte, a Quality Systems Consultant, President of Laboratories Made Better, LLC will be among the presenters at The Symposium for Clinical Laboratories which is being held from May 14–17, 2008 in St. Louis, MO. Luci will be presenting a breakout session related to QSE: Personnel – “Telling Ain’t Training.”

## New! COLA LabUniversity® online course QUALITY CONTROL IN THE LABORATORY

This new and up-to-date course addresses the current laboratory quality control requirements as stipulated by the CLIA '88 regulations. The course includes the following lessons:

- |                                   |                              |                            |
|-----------------------------------|------------------------------|----------------------------|
| • Introduction to Quality Control | • QC Policies and Procedures | • Corrective Actions       |
| • QC Materials                    | • Statistics of QC           | • QC Documentation         |
| • Related Processes               | • Performing QC              | • Quality Assessment of QC |
| • CLIA QC Requirements            | • Reviewing QC               |                            |



This course replaces *Quality Control in the Clinical Laboratory, Part 2: The Basics of Quality Control* in the Laboratory Director Program. The content is completely revised to reflect the current CLIA requirements, and many additional resources and useful forms are offered. This course has been approved for CME and P.A.C.E.® credit. Check it out by visiting the COLA Store at [www.cola.org](http://www.cola.org).

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