



# Weaving a web of excellence through staff development and training

By David Loughmiller, MBA, MT(ASCP) SC,  
and Douglas Godwin, PhD

David Hornbeck, in sharing a challenge faced by his laboratory at Suburban Hospital in Bethesda, MD, addresses a problem confronting many labs today — internal attrition as baby boomers enter retirement. The challenge led Suburban to acquire expensive equipment to further automate the testing process. Yet, with the purchases, there remains a substantial shortfall in professional expertise to meet the demands placed on that laboratory. Hornbeck indicates, “While Suburban Hospital’s laboratory has invested and will continue to invest in technology to aid in meeting testing demand, administration sees continuous staff development as the next horizon. As baby boomers retire, an experience and knowledge void is being created. To help fill the voids left by the boomers, Suburban has added two positions to assist in keeping the staff trained on a continuous basis. The newest administrative positions are the quality coordinator and educational trainer/professional staff development coordinator .... Suburban’s hope is that these new positions will deliver the education level needed to continue to provide the tech-savvy technologists that the hospital and lab require as well as retain those who have already reached that level.”<sup>1</sup>

## A broader problem

Suburban Hospital’s challenges represent a microcosm of those being confronted throughout laboratory medicine. Laura Landro of *The Wall Street Journal*, in explaining the nature of the deficit, quotes Michael Laposata, Vanderbilt’s head pathologist in Nashville, TN. He indicates that labs of smaller hospitals around the nation are insufficiently staffed to meet any serious epidemic, let alone a threat of a potential pandemic like the influenza A/H1N1. Vanderbilt itself has periodically required double shifts and shuffled hospital staff to meet lab responsibilities. Landro expands on the problem by

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## LEARNING OBJECTIVES

Upon completion of this article, the reader will be able to:

1. Discuss traditional assumptions that have served as barriers in learning and teaching.
2. List and discuss the three phases of educational experience.
3. Describe the cognitive web and its implication for training.
4. Differentiate among four domains in educational planning and implementation.
5. Discuss setting and training formats to include implementing a learning strategy and ways of achieving a corporate web of excellence.

pointing out, “While the United States is currently experiencing a shortage of medical technologists, as well as virtually all other healthcare professionals, student enrollment in MT programs is steadily declining. Universities — University of Wisconsin-Madison being the latest — have cut budgets for Clinical Lab Science programs or closed them.<sup>2</sup>

The problem is two-dimensional — addressing attrition while maintaining competency among the entire staff as new complex technologies emerge in medical testing. Growing an atmosphere of excellence remains an ongoing challenge for laboratories across the country and training has served as a vital strategy for addressing this in many quarters.<sup>3</sup> This article focuses on training that occurs to meet educational demands in the laboratory setting.

### Understanding the training process

Everyone assumes that we all understand that recurrent term — training. In the world of training, the product we

obtain depends on the delivery system we employ. Uninformed choices often result in distorted, costly results, different from our intended target. Part of the dilemma is that most laboratory trainers understandably come from within the field, profiting from education and experience of trainers steeped in the science of laboratory technology.

Assigning a trainer involves a fresh field of inquiry — understanding learning and educational theory. It addresses two questions:

- How do individuals learn?
- What teaching strategies best bring about learning?

Research in brain development and the ensuing principles of learning conducted over the past 40 years invalidated many old assumptions about how individuals learn and develop. Discoveries in neurology, new pedagogical strategies (teaching methodologies), and revisions of traditional methodology have helped reveal the processes by which ideas are linked together in the development of hu-

man understanding. Without knowledge of these emerging insights, laboratory trainers are left with antiquated training approaches with which to face the growing complexity of technology in the field. Here is a brief introduction to new training knowledge and a number of approaches for implementing it.

### Traditional assumptions as barriers

The first problem in training lies in the assumptions about learning and teaching, most of which come from the way the trainers were educated — many ways that did not work well. Such suppositions affect the educational events that trainers plan and often leave them wondering why their implementation fell short.

**Barrier 1:** One of the most common barriers to effective training involves the way goals are set. The tendency has been to focus on processes rather than outcomes. The purpose in all education is to *evoke change* in students, not merely *expose* them to experiences. Experiences are of value only to the degree that they

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create a transformation. An appraisal of the outcomes should be the criteria for measuring training effectiveness. The questions to be addressed are:

- What is the end product we desire in our trainees?
- What educational methods will best get them there?

Focusing on processes is more than a casual barrier and serves as one of the most deceptive practices in education, assuming several forms. Exposing participants to educational material does not serve as education. It is not uncommon for a trainee to be handed a manual or article with the commission to study it and prepare for an assessment. The assumption is that exposure equals growth. This spawns rote memorization of facts, which knowledge dissipates soon after the exam.

**Barrier 2:** The first barrier leads us to a second assumption: If we, as trainers, covered the material, education has occurred. We planned it and then taught it. We, therefore, have trained our people. This pretext satisfies our curriculum

planning and our record keeping but often leaves the professional development we desire lacking. Yet, professional growth — for which we have made a substantial financial investment — is what we wish to accomplish. We must think through our standards, phrasing them appropriately, and then create the kinds of experiences that guide trainees to effectively meet those standards.

**Barrier 3:** Current training procedures most frequently overlook a variable that parallels an old axiom: *How* you say it is more important than *what* you have to say. Curriculum covers what needs to be said; it speaks to the content of training. Pedagogy addresses *how* it will be both delivered and learned. Learning is the paramount variable in the formula and is dependent on *how* we say it. For transformation to occur, motivation must be factored into the equation. Active interest directly impacts the professional development we desire.

### The three phases of education

Four decades of neurological research of educational practice provided rich insights into how humans learn and develop. This information stimulated a re-examination of teaching and instructional theory, resulting in new and innovative ways of bringing about change in human experience. Many of these have direct application to the medical laboratory and serve as resources for leaders responsible for needed change.

Another old idea is to *inform* people is to *educate* them. To challenge this premise, Minzey points out that there are three phases of education that unfold somewhat in sequence; 1) conversion, 2) information, and 3) application.<sup>4</sup>

**Conversion:** Before an idea makes sense to us and we weave what is being taught into our value system, we must first understand it, buy into why it is important, and discover how it fits our needs. As we begin to identify with the concept, we go through a conversional process. Pure information does not ensure our conversion. We all are somewhat informed about ideas to which we do not subscribe. Knowledge alone has not persuaded us, and new information is ignored. Being informed alone seldom does the job. We must first be persuaded not by *manipulation* but by *application* of the principles of positive influence.

**Implications for training:** Training events in the conversional phase should spur interest and motivation by including convincing elements and language. Helping staff see the “whys” of practice and policy tends to ease the needed transitions. Activities that allow participants to express themselves and share their attitudes about and insights into the material are meaningful tools in generating interest and motivation. The professional term is “establishing a mindset” as educators help participants discover the value and importance of the concepts. Conversion morphs schooling into education.

**Information:** Once converted, personal motivation drives the experience, and participants are ready to be informed and have a felt need for added comprehension. This phase encompasses the conceptual and theoretical level of understanding and performance. Now, information makes sense, and the learner merges it into his present understanding.

**Implications for training:** Educational experiences need to be equally motivational. How information is to be gained requires careful consideration. Traditionally, lecture has been the method of choice to relay information. Remember those late night study sessions involving panicked memorization, creating mnemonic devices, and intensive cramming? Students then came to an exam with their heads full of facts and, once emptied, their minds were left void. The only “education” they got was honing their survival skills. Educational experiences that help participants link ideas together are quite different from teaching designed to fill the mind.

**Application:** Putting ideas into action often involves the development of a set of both skills and habits that are embedded in the theoretical knowledge just learned. As the conceptual level is laid down, participants become ready for skill acquisition and application.

**Implications for training:** Skills should not be taught in isolation but should be linked to the cognitive framework that precedes them. It should be noted that training in skill development requires focused, accurate repetition of techniques to guard against using bad habits. Skills tend to be enhanced most efficiently when outcomes are rewarded

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or recognized. Team training can be an effective arena for skill development.

**Conclusions:** These three phases of experience — conversion, information, and application — create a sound foundation upon which other training strategies are fashioned. Effective training procedures address all three levels of learning and development to serve as an important base for the curriculum to follow.

### Current brain theory and the nature of thought

**The cognitive web:** Ideas do not exist in isolation but are linked together in mental structures “cognitive webs” in psychology. Any idea externally or internally generated gets woven together, as in a web, in the mind with already existing related concepts. Chose a common laboratory test as the central concept — troponin analysis (see Figure 1A). The concept of a lab test is a function requiring specific actions. Usually when the thought involves an activity, the mind begins to classify events that follow. So, the first generation of sub-concepts becomes the three stages of the analysis (see Figure 2B). Depending on the individual learner, a mental image of the molecule, the setting in which the test is conducted, the function of troponin in cardiovascular contractions, a specific piece of equipment needed, or related chemicals would be among the first level of supporting concepts. A second level of concepts cluster around the main idea (i.e., for *Preanalytical* from left to right:

orders, collection, patient compliance, clinical history, timing [see Figure 1C]). Each level adds more sub-concepts that help form a learner’s understanding as it relates to the central idea of troponin analysis, but all levels relate to the original concept. Each second-, third-, and fourth-generation idea, in turn, can become a “web” of related concepts of its own. Each item at any level in the map ties to other ideas within the infrastructure and outside of this cognitive web.

**Implications for training:** To develop mental structures in training sessions, the trainer guides a discussion in which members of the group make contributions to the formation of a web. The process unfolds under the direction of a trainer, and learners are exposed to the instructor’s cognitive web, which overlays their experience (see Figure 1D).

### Planning and implementing experiences for growth

What is the end product we desire in our trainees? How does a laboratory trainer get a handle on the development desired in the staff? How does a lab trainer transcend passing on the mere documentation of the profession that so often leads to “minimums” in meeting standards? There are four domains that should be considered in planning and implementation:

- 1) knowledge — the conceptual framework of understanding to be developed;
- 2) affect — the affective domain;
- 3) developmental requirements; and

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4) the skill base to be mastered (see Figure 1D).

Each domain should build upon the three phases of education.

**The conceptual framework of understanding:** The curriculum content of the first domain involves an understanding of theory, concepts, patterns, analyses, and contexts related to the subject. These are woven together within cognitive webs created around that content. While curricular essentials are most often laid out by the standards of the profession and in the pre-service preparation of the professional, usually every student has some understanding of the material prior to a session. Each participant brings his own cognitive web to the training setting, and the instructor will enrich that knowledge base.

**Implications for training:** Learning experiences should include both individual and team activities. The instructor's role is to both mentor and facilitate the learning process. The methodology through which knowledge is gained is critical. The instructor should carefully plan questions to ask his students. Excellent phrases for formulating appropriate questions include:

- What is the implication of \_\_\_\_?
- How does \_\_\_\_ relate to \_\_\_\_?
- What is the connection between \_\_\_\_ and \_\_\_\_.
- How does it work?
- Relate what you have said to \_\_\_\_.
- Explain the dynamics of \_\_\_\_.

As with previous strategies, providing trainee's opportunities for expression, processing information, and analyzing scenarios under supervision are important developmental activities.

**The affective domain:** This dimension explores values, attitudes, perceptions, habits, norms, and related social relationships, which form the essence of who we are, thus making this second domain of critical value in training. Trainers explore these attributes as they relate to professional roles their trainees play out in the lab. These attributes combine to drive motivation in participants, again a key ingredient in professionalism. Once motivation becomes intrinsic, the laboratorian will work from personal and professional ambition rather than from the standpoint of simply "having a job."

**Implications for training:** Since the affective domain addresses dimensions of personality, interpersonal instructional strategies are important. Because the dynamics of the affective domain function in the workplace by design or default, the effectiveness of the lab is enhanced when these forces are accounted for in planning and training. Training-event planning begins by considering those dimensions: attitudes, values, perceptions, and other elements found in a productive, successful laboratory environment.

"Teaming" methodology is critical to the affective domain. The give-and-take of group activity enhances "people skills" — when properly facilitated by the leadership — interweaving with the learners' technical competency to enrich professional performance. Group experiences should provide opportunities for sharing views and opinions, which leads to professional bonding that builds corporate culture. Such exchanges also allow participants to realign their values and perceptions.

Additionally, each individual's need for status should be facilitated in these sessions; therefore, the leadership methods needed for this sphere are mentoring, coaching, facilitating, analyzing, demonstrating, and modeling.

Figure 1A

**COGNITIVE WEB**

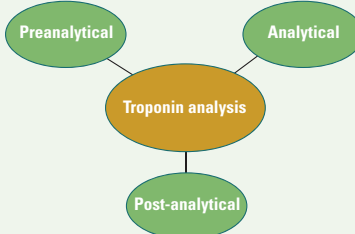
Lab application

Troponin analysis

THE CONCEPT

Figure 1B

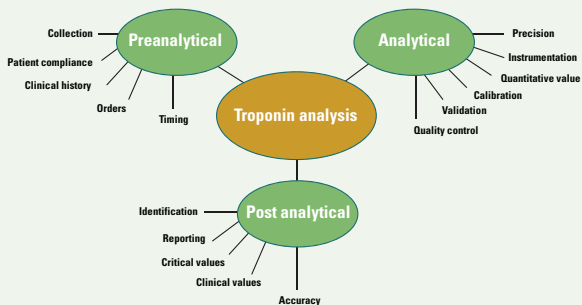
**COGNITIVE WEB**



FIRST LAYER OF RELATED CONCEPTS

Figure 1C

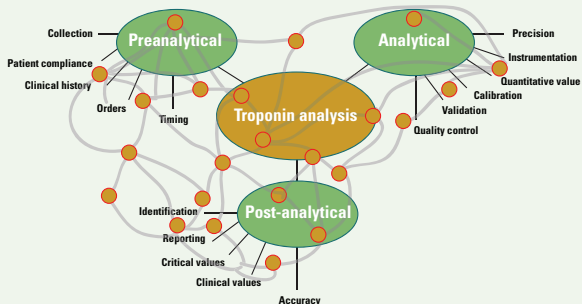
**COGNITIVE WEB**



SECOND LAYER OF RELATED CONCEPTS

Figure 1D

**COGNITIVE WEB**



OVERLAY OF INSTRUCTOR'S COGNITIVE WEB

Figure 1A-D: Demonstration of how the cognitive web stages work in laboratory science.

**The developmental (psychomotor) domain:** By definition, this domain involves those characteristics that are produced by natural physiological development: nature more than nurture. In the lab, the developmental domain means addressing activities involving hand-eye coordination. Pipetting, pouring, and other close manipulative work are among the skills that are required. Refining these traits often requires practice.

**The skill domain:** Skills emerge from the other three domains. Cognitive skills such as analysis, synthesis, observation, problem solving, and both inductive and deductive reasoning

are interwoven with inter- and intra-personal skills of the affective domain, along with those of the developmental domain, collectively meeting the demands of professional standards.

**Implications for training:** Skill development requires special attention in planning. Since skill acquisition is a personal achievement for each laboratorian, the one-on-one instructional strategies of mentoring, coaching, observing, demonstrating, modeling, and peer teaching tend to be most effective. Normal interaction in the lab usually provides many mentoring opportunities for leaders.

**Conclusions:** Utilizing these four domains for both curriculum and teaching planning provides a laboratory trainer with a framework for 1) clarifying and formulating the specific standards being addressed; 2) establishing the conceptual, affective, developmental, and skill acquisition desired; and 3) creating educational strategies by which students will gain these four dimensions of learning and change.

### Settings and training formats

For different elements of the training experience, trainers need an overlap in talent. While certain learning strategies are facilitated better in some formats more than others, there remains that “web” of mental activity among all formats of learning.

**The training arena:** Whether at the university or in the workplace, training environments may bring to mind the classroom, the conference room, and/or the lab, although the

first two, unfortunately, have been used more for lecture than any other strategy. The rule of thumb in teaching/learning is to plan the routines that achieves the type of transformation we seek in participants, then modify the environment accordingly. For example, when employing teaming tasks, a classroom may be divided into sections by round tables or clustering chairs in circles. These simple approaches enable individual participation, allow leadership to emerge within groups, and provide cross-fertilization of thought and insight.

**Implementing a learning strategy:** Brief lectures have contributions to make but should not play center stage in the training process. When used, lecture should be followed with a number of interactive strategies addressing concepts, vocabulary, and/or skills. For example, when employing a “cycle of learning” strategy, lecture and teaming methods are rotated. It begins when new concepts, attitudes and/or skills are shared with the entire group. Learners are then divided into clusters with specific assignments to complete.

The first task in each group is to choose a leader. The instructor might encourage discussion, demonstration, analyses and problem solving within each cluster. The instructor and assistants rotate among groups to facilitate the process. The full group is then reconvened, each team reporting on its discussion. This session is opened for comments from all participants. The teams are then reassembled for the next level of assigned tasks and ideas. At a designated time, the full group is gathered for a

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final analysis. This is known as spiral curriculum, as each phase of the cycle raises the sophistication of both performance and comprehension. As with each format, planning for this strategy is guided by an awareness of the educational principles appropriate to the venue.

**Informal settings:** By mating emphasis with redundancy, informal events are equally critical in effective training — many times, more so. Interpersonal coaching emerges in the teachable moments of the office, at lunch, during breaks, in lab activities, and during team experiences, building competency among lab associates one event at a time.

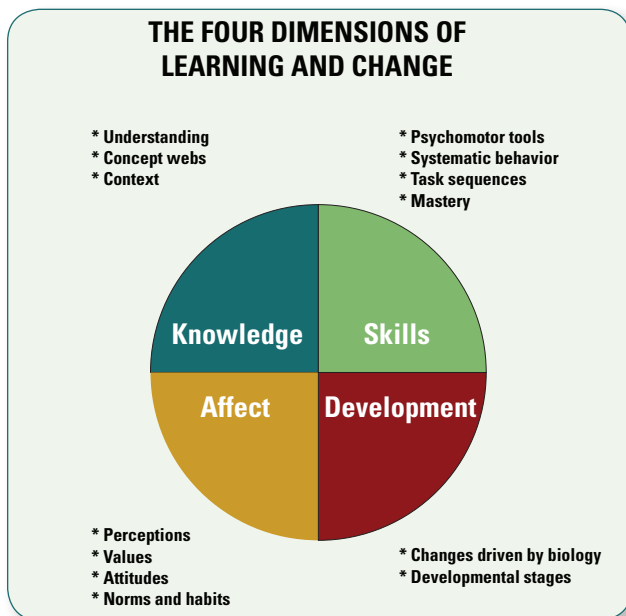


Figure 2: The four dimensions of educational planning and implementation.

**The training of trainers:** The acquisition of training skills for laboratory leadership can be obtained through educational and consulting experiences, which serve leaders in both line authority and directors of laboratory training. Each position plays a key role in the educational process in the laboratory, and receiving training as a pair is the optimum format. Once acquired, educational skills tend to be disseminated throughout the laboratory over time.

### Building and maintaining a corporate web of excellence

**Corporate culture as a training venue:** A number of settings and training formats can be part of the educational process in a laboratory. The ultimate training component for a highly proficient, successful laboratory, however, is more than a bevy of training experiences. It is the social structure of the laboratory environment itself. It is the standard of excellence the lab has set for itself and the means by which all staff become committed and trained toward that end.

Leadership from which high standards are suggested to the staff is where training for the corporate venue begins. These are not top-down mandates but rather points of introduction to a set of stakeholders who will, in turn, provide input, discussion, and recommendations. Standards set by a group are owned by the group. The use of conversational methodology assumes the

form of team-building and the establishment or enhancement of corporate culture producing meaningful input from both the bottom up and top down and unifying its people into a cohesive, integrated workforce.<sup>5</sup>

*This is conversion in action,  
which invites an investment into the idea.*

**The maintenance of success:** Effectively integrate all new employees into the network in order to avoid dips in competency and commitment due to attrition. Assuming an attitude of “stakeholder” does not come automatically for new staff, and both mentoring and coaching are important strategies in helping each person become an effective part of the team. It is vital that recent hires gain ownership of corporate values with the expectation that they will have ongoing input.

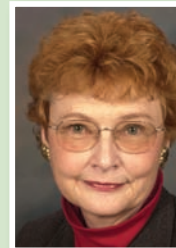
**The shared focus of training:** The ultimate objective of the laboratory is to provide a synergistic collaboration that produces a gestalt — the whole is greater than the sum of its parts. Such teamwork forms a web of excellence that guides the professionalism of the lab and improves the service it provides its clientele. □

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The work of laboratory professionals is described best by an anonymous quote I have admired for many years: “Every job is a self-portrait of the person who does it.” As professionals, we autograph our work with excellence. We are unequivocally top-notch in the contributions we are routinely able to make to patient care. Thanks to one and all!



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## Update on lab regulatory preparedness for inspections

By Kirsten Cowan

**T**he landscape of laboratory regulations is continually changing. For example, major accreditation agencies are making changes in how they do inspections or in the stringency of their requirements. The move to unannounced inspections, in particular, has had long-ranging effects on how labs conduct their quality-management programs and their operations in general. Other labs find that as they build their volume of outreach work in other states, they now undergo inspections from those states' regulatory agencies. Another big change is the adoption of ISO 15189 accreditation: more clinical labs in the U.S. are following the lead of their international counterparts and are exploring what it takes to prepare for ISO 15189 inspections.



Kirsten Cowan

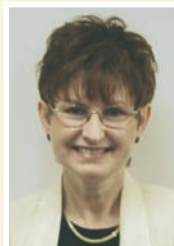
All of these changes point to the need for more thoughtful, adaptive preparations for regulatory inspections. In the words of Lab Director Roberta Provencal, "unannounced CAP and AABB inspections keep us in a state of readiness 365 days a year." We asked Ms. Provencal of Catholic Medical Center (CMC) in Manchester, NH, how labs like hers have changed the way they do things to answer to the need for constant preparedness. For another perspective, especially on making the change to ISO 15189 inspection preparedness, we also talked to Bonnie Van Schoik (director of Laboratory Services) and Doug Hughes (LIS coordinator), both of Blanchard Valley Hospital in Findlay, OH.

**Kirsten Cowan: Tell us some quick facts about your lab.**

**Roberta Provencal:** CMC is a community hospital with 330 licensed beds; our lab-test volume is about 45% inpatient; and 55% outpatient including outreach. We are a full-service laboratory with lines of automation to include preanalytical, hematology, and chemistry. CMC lab services used to be contracted out to LabCorp but came back under the hospital in 2007. We moved into a new clinical lab facility on the main level of the hospital last year, and we just opened pathology services in a new LEAN facility in January 2010, after being contracted off-site for 11 years.



Roberta Provencal



Bonnie Van Schoik

**Bonnie Van Schoik:** The laboratory at Blanchard Valley Hospital is a full-service laboratory performing more than 500,000 billable procedures annually. Our facility supports a Level III trauma emergency department as well as an open-heart surgery service. We were the third laboratory in the nation to become accredited to the College of American Pathologists (CAP) ISO 15189 standard.

**Cowan: What regulatory inspections does your lab undergo?**

**Van Schoik:** [In addition to ISO 15189], we are accredited by AABB, CAP, and our hospital is a Joint Commission-accredited facility.

**Provencal:** [We are inspected by] AABB, CAP, and the state of New Hampshire.

**Cowan: Describe some of the lab's operations that are most directly involved in regulatory compliance.**

**Provencal:** [Some of the areas involved are] document control; our quality-management (QM) program, which includes quarterly QM meetings; an annual quality plan; and quality-plan annual appraisals. We also have 15 quality-improvement indicators in process currently, and we monitor 35+ quality-assurance indicators.

**Doug Hughes:** Our laboratory has made an investment in our document-control and quality-management systems (QMS) as required by our ISO 15189 accreditation.



Doug Hughes

**Cowan: Have there been any changes or updates in the regulatory inspections to which your lab has had to adapt?**

**Hughes:** The largest, latest change in our regulatory inspections has been achievement of CAP ISO 15189 accreditation. We have had to examine *all* of our processes in great detail over the past couple of years for improvement and quality. Without a solid QMS in place, our job of achieving and maintaining this required quality/process improvement would be so much harder. Our staff worked very hard to reach this lofty goal, and our document-control software was a key vehicle to complete our journey.

**Provencal:** Document-control software has been integrated into our quality-management program since 2009, and aids in efficient and effective documentation of procedural updates and ease of access to procedures 24/7.

**Cowan: What were the most difficult challenges for your lab in terms of regulatory compliance?**

**Provencal:** When we were still using a manual system for QM/document control, ease of access to updated procedures was a challenge, and so was managing the flow of updates to procedures and annual procedural reviews. The time for all involved parties to review a procedure was lengthy and cumbersome.

**Hughes:** Where do I start? It is difficult to imagine trying to meet our new quality standards using our old manual practices. Before implementation of our QM software, we struggled mightily with document control. Our staff could not be sure documents were always being reviewed properly — we used paper sign-off sheets — lost large amounts of time with the review process we used for the new or edited paper documents, and often duplicated procedures because we did not know one already existed. Automating the document life cycle has solved these problems for us.

Using a manual system to try to track and trend problems for quality improvement was difficult at best. Most of the time,

the data collected was only a small representation of what was actually occurring, so any conclusions drawn from it would be flawed. By automating the entry of these problems, we made it easier for users to document when/what has occurred and easier for our management staff to compile the data into a useful tool for quality improvement.

Last, our manual system of preparing for audits, such as CAP, AABB, ISO, and others, was very paper oriented. It is quite a contrast to see an inspection team sit down with several tables loaded with manuals and binders containing policies, procedures, and evidence from our old system compared to now, with our software, where inspector(s) can sit at a PC and see everything they need. No more books!

**Cowan: How has the change to using software for document control improved your readiness for regulatory compliance?**

**Provencal:** Now only up-to-date policies and procedures are available online and accessible 24/7 which always meets regulatory requirements and reduces risk. The keyword searches have been valuable for quick retrieval of information. The approval process for updates and new procedures has been streamlined and is much more efficient. Also, security in the document-control system only allows for authorized users to view documents and edit documents.

**Hughes:** The manual paper system we used to use was difficult to maintain. Often, documents would slip through without being regularly reviewed. Paper had to be shuffled from one desk to another. Hard copies of procedures had to be maintained in books when obsolete or retired. In short, the paper system was inconsistent and costly — in time and money. With electronic regulatory-compliance software, each stage in the document-control process has been automated and can be tracked. Also, documents can be easily archived and old versions can be stored. All of this can be tracked and viewed to show historical information for any instance.

**Cowan: Apart from better preparation for regulatory inspections, have the changes that you have made to your QM and document-control processes had any side effects?**

**Provencal:** Shortly after our document-control software was installed and implemented, I received a call at 4:55 on a Friday afternoon; everyone had just left for the weekend. Nursing was looking for a policy pertaining to whether or not a patient could have an item which had been surgically removed. With the thousands of procedures in the lab, this would have been a cumbersome search. By using keywords to search procedures within the document-control system, the related policies and procedures were able to be referenced within minutes.

**Van Schoik:** Before the implementation of our QM software, a very experienced tech informed me that it took her 20 minutes to find one procedure in a manual with which she was not familiar. Now, with the electronic QMS system, in just a few seconds a search is complete.

**A never-ending process**

Lab directors, quality managers, and others who are familiar with clinical laboratory regulatory compliance see several trends that bear out the experiences shared here. First, a growing number of labs are turning to automated systems to

enable 24/7 preparedness for inspections. Second, labs are undergoing more inspections (sometimes by choice, as with Blanchard Valley Hospital seeking ISO 15189 accreditation), and often those inspections are increasingly focused on document control as a part of QM compliance. Last, and most important, better regulatory preparedness means that the lab is operating more efficiently — so assessing and improving the lab's QM system is not only better for regulatory inspections but turns out to be better for the laboratory overall.

Over the years, hundreds of laboratorians across the country have pointed to a growing awareness of quality management in general. Whereas at one time the quality manager or regulatory compliance specialist was the perceived owner of quality-management and document-control processes in the lab, this awareness is now more likely to be shared, especially with section supervisors and other management personnel. Whether due to the need for better inspection readiness or to a shift toward 24/7 QM awareness, the end result has been that the day-to-day thinking of laboratorians now includes thinking about quality management as an ongoing process — not just something that must be done when an inspection team is due. □

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