

The Secret Ingredient

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Kung Fu Panda's father runs a noodle shop where the patrons rave over the special soup with the secret ingredient. The father wants to share the secret recipe with his son, but Panda Po is much too busy trying to become the Dragon Warrior. . . and failing miserably. Just when it looks like the bad guy is going to take over the peaceful valley, Po finds his father in the mass exodus. His father shares the secret ingredient of the famous special soup: there is no secret ingredient. The answer lies within.

I was the quality coordinator for a medium-sized community hospital laboratory where I had worked for many years. It was frustrating for me to constantly hear from my laboratory colleagues, "I'm much too busy just trying to get my job done than to do all that quality stuff Luci wants me to do." As a quality consultant for many years, I've learned that the faces change but the problems stay the same. Now I constantly hear in my workshops and consultations, "We're much too busy trying to get our jobs done than to do all that quality stuff Luci/CLIA/CAP/AABB want us to do." Yet, I'm often contacted by laboratories that have had some quality issues with their CLIA/CAP/AABB inspectors and want the special recipe with the secret ingredient to "get ready" for their next inspection.

Listen up! There is no secret ingredient. The answer lies within. Your laboratory is likely to have many or most of the elements needed for managing the quality of services to clinicians and patients; it's just a matter of organizing these elements in a meaningful way. Just as the practice of Kung Fu is the blending of one's strength, flexibility, and balance into an efficient and effective whole person, laboratory quality management is a matter of building strength, flexibility, and balance into your laboratory's policies, processes, and procedures. Kung Fu requires intention and practice; quality management requires intention and practice. Neither simply happens on its own.

How does a laboratory acquire strength, flexibility, and balance of its policies, processes, and procedures? First, it's a fundamental requirement to understand the difference between policy, process, and procedure—both as concepts and as types of documents. Policy is stated intent, process is a sequence of activities, and procedure is stepwise instructions. However, for three decades we have written "SOPs," which blend the three concepts into one topic or analyte-oriented document type that subsequently gets very long and unwieldy. These SOPs are unsuccessful in communicating how work sequences occur in your laboratory and are a source of many inspection deficiencies. Therefore, it makes sense to separate the concepts into their respective documents.

Policy is a documented statement of intent only—there is no description of how it's implemented. Process is best documented as a flowchart depicting the sequence of activities; for example, a flowchart of the activities from the receipt of an order to collect a blood sample through the return of the collected sample to the laboratory. Procedure is the documented stepwise instructions for one person to accomplish a single activity in the process. The process above includes an activity for the steps

of collecting the blood sample either by venipuncture or by capillary puncture. Note: labeling the blood sample is the next activity in the sequence and would have a separate procedure.

Now, back to the question of acquiring strength, flexibility, and balance. The answer lies within the model for quality management that shows the 12 Quality System Essentials (QSEs) supporting the laboratory's path of workflow. The strength of this quality model is that the QSEs form a solid foundation for laboratory work because they embody activities specified by all the regulatory and accreditation requirements for laboratories. This foundation is made up of your laboratory's policies, processes, and procedures for the specified QSE activities.

The flexibility inherent in this quality model is that the laboratory's path of workflow is universal to any size, scope, or specialty of laboratory anywhere in the world. The path of workflow—described as the sequence of activities from the order for a laboratory test to the application of the results for patient care—is as relevant for a small HIV-testing laboratory in Africa as it is to the largest commercial laboratory in the United States. The documents that describe the policies, processes, and procedures for your laboratory's path of workflow can easily be made flexible to your laboratory's operations. It's just a matter of jettisoning the old SOP dogma.

The balance provided by the quality model is significant. Most laboratories are unbalanced because they focus on acquiring the latest greatest technology as a means to solve problems, rather than understanding, documenting, and improving key laboratory processes. Laboratories are unbalanced because they focus on getting ready for accreditation assessments rather than having inherently efficient and effective laboratory processes that deliver laboratory results to customers in a timely manner and provide inherent readiness for unannounced inspections. This unbalance causes needless stress and tension—just look around at your colleagues.

Some people think Lean is the secret ingredient. Sorry—it's not. You can have a Lean automated testing line and a badly performing anatomic pathology service, or vice versa. Lean is a single process improvement tool, albeit a very effective one. But it doesn't lie within and it's not the magic answer.

I go to yoga regularly to increase my personal strength, flexibility, and balance but many days I fail miserably. I know—the answer lies within. Oooooooooommmmm. . . .

This Month's Quality Quote:

"Where quality is built in, not added on."

—American Motors

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