

Quality Qorner

The Quality Road to Compliance... With Any Requirements!

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I recently came across an article written for manufacturing companies about reducing their costs for regulatory compliance.¹ The article suggested 5 strategies that could help biopharmaceutical and medical device companies save at least 1.1% of their total revenues—that's a lot of money, folks! These 5 strategies are equally applicable to medical laboratories, so I thought I'd share them with you. If your laboratory is not already doing the activities described below, there may be some financial benefit in doing so—not to mention improvements in quality and perhaps patient safety.

- **Simplicity.** "Create a simple compliance program under which quality, regulatory, safety, financial controls, electronic security, internal laboratory policies, records management, and so forth are managed. This is often the hardest step, but the one upon which all the others rest."

Fortunately, the medical laboratory community already has a single program that can manage all of the above-mentioned programs. It's the Clinical and Laboratory Standards Institute (CLSI) model for a laboratory quality-management system that is described in detail in guidelines HS1-A2, *A Quality System Model for Health Care*,² and GP26-A3, *Application of a Quality Management System for Laboratory Services*.³ Those familiar with this model will recognize that the programs described above relate directly to several Quality System Essentials (QSEs). Laboratory QSEs were compiled from regulatory and accreditation requirements for medical laboratories; therefore, following the guidance described in the quality system model provides laboratories with a road map to compliance.

- **Rapid prototyping.** "Determine and embed the minimum controls (eg, quality, regulatory, etc.) as early as possible in any process, procedure, or system design."

Some clever laboratory professionals have used the tables in the HS1-A2 guideline as a checklist of all the items to consider when implementing a new laboratory process. When a new or changed process is designed from the beginning to meet requirements and is validated as performing as intended, it is less likely that an important requirement will be missed and need to be added later—as a costly work-around.

- **Agile risk.** "Keep policies and procedures from becoming so rigid that they cannot adapt well to often rapidly changing business climates and priorities."

In the laboratory quality system model, policies are written in very broad language that allows for ready editing when requirements change; process flowcharts provide a high-level view of the sequence of laboratory activities. Once this sequence is documented and understood, it is much easier to see where changes due to shift in requirements can be made, as well as the impact of those changes on other processes and procedures.

- **Grow knowledge.** "Develop a strategy to share metrics, trends, decision logic, results, and current activities across silos, be they departmental or physical sites."

The QSE-based quality system model calls for a period laboratory quality report that is reviewed by management and shared with staff in other appropriate areas such as the hospital's quality function and other system laboratories. The quality report contains information about laboratory performance on measurement indicators, internal audits, external assessments, trends and patterns in identified nonconformances, and customer feedback that reveals readily-identifiable opportunities for improvement.

- **Proof.** "Keep good documents and retain good records to demonstrate compliance and intent to improve."

Quality System Essential *Documents and Records* contains requirements for the laboratory to document its policies, processes, and procedures and maintain records for the required retention periods. Laboratory documents provide management's instructions to staff on how the laboratory's processes happen and how to perform procedure tasks. Your laboratory's records provide objective evidence of compliance with requirements. The quality, condition, and accessibility of your laboratory's documents and records speak volumes about your commitment to quality to inspectors and staff alike.

Does your laboratory have any idea what it costs to comply with all the various regulatory and accreditation requirements that we are subject to? Probably not. I can assure you, though, that if you use the QSE-based quality-management system model to build the activities needed to meet requirements into the daily laboratory processes and procedures practiced by all laboratory staff, compliance will always cost you less than fixing the deficiencies identified during unannounced inspections and after sentinel events.

1. Wilson C. Cerulean outlines strategies to cut FDA compliance costs. *Qual Digest*. 2008;28:11.
2. CLSI. *A quality system model for health care*. CLSI document HS1-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2004.
3. CLSI. *Application of a quality system model for laboratory services*. CLSI document GP26-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2004.

This Month's Quality Quote:

"Good things only happen when planned; bad things happen on their own."

—Philip Crosby

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