CS ANALYTICAL

CONTAINING QUALITY

"THE EXECUTIVE THREE"

Three questions for the company executive that establishes their vision and leadership style.

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As a quality expert that has had a 30+ year career working in the regulated, contract laboratory setting, how would you define and describe a quality system that is under your management?

I define three key attributes of a successful quality system as the critical "C's" – a quality system that is comprehensive, consistent, and communicable. A cGMP quality system that meets all the elements of 21 CFR Part 210 and Part 211 must be comprehensive in that it reaches across the entire organization. The best practice for a contract laboratory dedicated to regulated industries is to be fully cGMP – not partly cGMP or cGMP at certain times. This leads to exceptions and habits formed that do not comply to cGMP expectations, easily contributing to deviations and quality incidents. A quality program in which there are no exceptions from norms inherently covers and applies to the entire operation; it becomes engrained.

Consistency is the second critical attribute. This is true internally and externally. The structure, expectations, and processes the system delivers to key stakeholders – the client, the laboratory staff, executive management – must be repeatable, reproducible, and robust across the board. This furthers adherence to established good documentation practices and SOPs.

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The third key attribute is communicability. The quality system, and its contents, must be easily accessed and disseminated across employees and platforms. This is best accomplished via integration of electronic systems with routine training sessions that use lectures, document review, hands-on training for specific test methods and most importantly, the use of quizzes and assessment tools to ensure understanding and comprehension.

Over the course of your career, you have seen the evolution of both quality systems and the expectations around them, not the least of which has been the shift from paper-based systems to electronic systems. What are some ways you've experienced this shift?

The move from paper to electronic systems has certainly accelerated over the past 7-10 years and from my perspective, it is a much needed and welcome improvement. Some of this comes from increasing regulatory demands: it is much harder to deviate from good documentation practices (ALCOA) in an electronic system that tracks every action than it is a paper-based system. However, from the end-user perspective, the key to an effective quality system really starts with oversight – something certainly enabled by electronic systems. Oversight across an organization, rather than relying on physically viewing documents, in turn enables efficiency, namely in audit and review processes.

As an example, to revise and implement a paper-based SOP required the following actions to happen in sequence: the author must revise and include a detailed entry in the changelog, which lived at the bottom of each document, sometimes matching the length of the SOP as years went by. Once drafting and review was complete, it had to be printed on special paper, stamped as a controlled copy, and circulated, physically, for signatures, including a training form for all analysts to sign. Once all signatures were obtained, it could return to quality to receive an effective stamp and be filed in a binder for reference. With an EQMS (Electronic Quality Management System) in use, all revisions are tracked automatically, with the user, date and time and saved as part of the comprehensive audit trail. Review and approvals are timely and completed with a few clicks and with electronic signature. Training can occur in the same fashion, with each analyst independently reviewing the controlled copy and completing a training assessment. Gone are the days of standing for hours at the copy machine printing on colored coded paper, using an ink pad to stamp dates, and waiting for SOPs to circulate for signature.

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Another critical component of a comprehensive electronic quality system is the use of an ELN (Electronic Laboratory Notebook). As with the EQMS, the tracking mechanisms in current ELN products are a game changer in terms of efficiency and, more importantly, data integrity. With the majority of the data capture and storage occurring through 21 CFR Part 11 compliant software and secured networking, the human error factor in documentation practices is almost entirely removed. All data is easily accessible and demonstrably valid, as tracked by an audit trail, yielding a faster, cleaner quality review process. Sifting through pages of handwritten data, verifying calculations, and cross-checking instrument logbooks is no longer required.

For me personally, the most import factor in tying these systems together as part of an effective and secure quality system is a LIMS (Laboratory Information Management System). It has been my experience that "off the shelf" LIMS programs are mostly ineffective. They are difficult to set-up and tailor to the specialized operations of a contract laboratory, leading to a loss of efficiency – one of the intended benefits of electronic systems. At CS Analytical, with full support of the executive management team, I have directed the development of a custom LIMS solution that meets all 21 CFR Part 11 requirements, utilizes electronic signature, and communicates across a secure platform with our EQMS and ELN. The systems, in tandem, exceed my expectations when it comes to being comprehensive, consistent, and communicable across all levels of employees and management.

Testing services provided in the contract laboratory setting are highly dependent on meeting a certain level of client satisfaction and expectation. How does the electronic quality system assist, improve, or impede on this need?

The comprehensive electronic quality system in place at CS Analytical is revolutionary from the client perspective. Let's start with the audit and inspection process. Client onsite audits that required travel expenses and weeks of time to issue reports are no longer needed. In today's pandemic environment, I can host a virtual audit using a video conference to provide a lab tour and securely demonstrate all critical lab functions and quality documents, transferring where applicable, to the auditor in just a few minutes. With audit trails built into the systems, tracking, viewing, and exporting documents is easily achieved. This is a huge cost and time savings for the client. The sample submission process, again done completely electronically, has been streamlined and enables the client to process and ship a sample to the laboratory using pre-filled forms specific to their sample and the testing requested. Again, the human error factor is being removed. When the work is completed, the client can receive a final report, in a much- improved timeline, and the supporting raw data, which in the past had to be copied and date stamped, can be easily included. The efficiencies that the CS Analytical 21 CFR Part 11 compliant Quality System brings to our laboratory operation enables us to deliver a better, faster, and more cost-effective program to our clients in a secure and cGMP compliant manner that is a model for best practices.

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