Perspectives On Validation Audit

For your area of the industry, what is your best suggestion for aiding a medical device manufacturing company with a validation audit?

John Arnold
Director of Quality, Fort Wayne Metals Research Products Corp.

Fort Wayne Metals has provided medical device raw materials and components since 1970. Today's medical device patient and regulatory climate demands raw material and component manufacturers to partner with medical device suppliers to produce and validate products that consistently perform as designed when used.

The following are a few key requirements that we believe are critical for the success of a validation audit.

Partnership: Every supplier in the medical device supply chain is a partner in the production of a device. Each partner must realize this partnership and their contribution to the partnership.

Communication: Open, timely, and candid communication is required for a thorough validation audit. The use of conference calls and face-to-face meetings is crucial for success.

Expertise: Product and process experts with intimate knowledge of the product's processing, performance, failure modes, key characteristics, expectations, and limitations must be involved in the audit. These items should be thoroughly tested.

Conditional Scenarios: "What If" scenarios should be discussed and explored during the audit to ensure product efficacy.

Although not an exhaustive list, every partner in the supply chain can utilize these key requirements to ensure a thorough validation audit.

Gabriel O. Adusei, MSc, PhD
Independent MedTech Consultant, Founder, International Association of Medical Technology Consultants

Validation audits are conducted to verify through objective evidence (i.e., interviews, procedures, records, work instructions, etc.) that Quality Management System or process has been developed, documented, and effectively implemented. Validation is required to ensure that a process, system, material, method, product, piece of equipment, or personnel practice will meet its intended purpose and function or allow functioning in a reliable, consistent manner.

Apply any one of the different types of validation approaches: prospective, retrospective, concurrent. It is advisable to identify all operational performance characteristics that should be defined and translated into specifications, including acceptable ranges, which should be expressed in measurable terms. The validity of such specifications is verified through testing and challenge during development and initial production. The organization is required to define the frequency of when Annual Process Review is conducted and, if there is any indication that “drift” is occurring, revalidation must be done. Any deviation from the written procedures shall be recorded and justified. For equipment, usually the process consists of Design Qualification, Installation Qualification, Operational Qualification, and Performance Qualification.

Check to ensure that process that could add variability to performance in achieving any predetermined results is validated.

Joy Gray
Validation Specialist, Pilgrim Software

My best suggestion is to start with a meaningful validation program, particularly for oft-dreaded computer systems validation.

The “bury ‘em in paperwork” approach is a waste of company resources in building meaningless documentation. The “everyone else does it” rationale doesn’t consider your organization’s resources or requirements.

- Review the regulations, guidances, and warning letters issued by regulatory bodies. Determine what is applicable to your organization, and what is actually required. Take 820.70(i): “validate computer software for its intended use according to an established protocol.” Intended use, not unused functions. An established protocol, not necessarily IQ/OQ/PQ.
- Leverage established industry expertise to assist in meeting applicable regulations. GAMP and GAMP Good Practice Guides apply common sense and basic good business practices to quality activities. They are thorough, but remind you to analyze risk and focus on your requirements.
- Leverage well-documented risk analysis. Identify and focus on critical areas and system functions and leverage it to scale-down a validation effort from the start.
- Failure *is* an option. 820.25(b)(2). An auditor questions the results of a “flawless” validation.

A meaningful validation program, thoughtfully designed and effectively documented, promotes compliance and operational efficiency…and, eases the nerves during a validation audit.

Meredith May
Validation, Certification and Technical Specialist, Empirical Testing Corp.

In medical device manufacturing, there are several types of validation, including design, process, equipment, and inspection methods. Whether validating a steam sterilization process or an implant design, the most important tool in an audit is to understand validation principles. Initially, an effective validation includes understanding the basics of your organization’s equipment, process, and products. The second aspect is to identify and challenge the limits of a process/product and is something to be taken very seriously.

Never underestimate the importance of a solid investigation program, including validation, in an audit. A strong system for handling failures is designed to trickle down the following path: product/process failure, corrective action, preventive action, validation, and monitoring. The validation should include evaluating

“normal” conditions as well as “extreme” conditions, regardless of whether validating a process or a design. Another important aspect of design validation of product changes is to test the exact conditions for the failure whenever possible.

At the risk of sounding simplistic, my advice is that the more comprehensive your understanding of validation principles and your dedication to inculcating those principles into your organization’s routine operations, the better the audit outcome, and in the end, the better your product and your company.

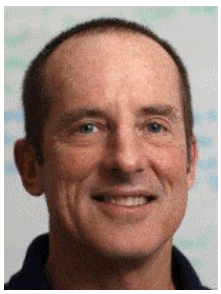
Tim Mohn
Industry Principal, Sparta Systems

While there are many tools, techniques, and schools of thought about the best way to manage or execute validation audits, I find that most of those strategies focus on the actual audit itself and don't necessarily help organizations realize the full business benefits of their investment in the overarching audit program.

Companies would be wise to focus more attention on the “back office” aspects of auditing—in particular, tracking and trending across audits. Let's face it, auditors are highly trained professionals whose unique expertise is used to identify problem areas, and their efforts are traditionally reported in some variation of a Microsoft Word file. Sure, you might store those results in an electronic system and use that tool to manage auditee responses, but this still may not be getting at the systemic issues that led to the problem in the first place.

This is a challenge I expect to continue to grow as more and more validation audits are performed by third parties. To address it, forward-thinking organizations are taking their electronic systems one step farther and capturing the relevant data that allows them to look across the holistic audit program and identify trends, such as root causes, organization, or systemic line of business challenges. Having this data allows audits to move away from “what is seen” and resolve truly systemic issues that are at the heart of the matter.

Jeff Lind
President, Compliance West



When a regulatory engineer takes a look at your project, he will put it into a niche and think about applying the correct Standard. With so many different particular requirements of IEC 60601, and new usages being developed so rapidly, it is extremely important that the correct Standard is selected.

We suggest discussing the entire project with the regulatory department so they can make sure they completely understand all the uses of the new product. If there is a thought of adding a feature later, it’s most appropriate to make the regulatory engineer aware of it as early as possible in case the new feature will require further testing.

Slightly different product uses can change the test program pretty remarkably so it’s best to take the time up front to make sure your regulatory engineer understands the product completely.

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