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The Evolution of Medical Device Industry Training Requirements

Requirements for training have changed for medical device manufacturers under the US Food and Drug Administration's (FDA) new Quality Management System Regulation. Under the QMSR rule, the former Quality System Regulation's (QSR) 21 CFR Part 820.25 (Personnel) was replaced by ISO 13485's Clause 6.2 (Human Resources).

Training has always been a hot topic in the medical device industry. It's often the de facto root cause in nonconformances and corrective and preventive actions (CAPA). It's also often listed as a corrective action or preventive action in these records as evidence of steps taken to remediate problems and achieve compliance.

Compliance is going to require systemic improvements in defining competency requirements based on job function and the performance, management, and documentation of training. Improvements in training could theoretically lower the temperature of problems related to employee competence. Understanding how ISO 13485 differs from the former QSR – and how it's sometimes the same – will help companies successfully navigate future FDA inspections, maintain compliance, and embrace a Culture of Quality within the organization.

Several features of ISO 13485 go beyond expectations conveyed through 21CFR Part 820. These include the ISO standard's direct delineation of who requires training; the correlation between training

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Engaging With FDA Easy As 1-2-3, Former Device Center Leader Says

When a manufacturer works within the constraints of a highly regulated industry like MedTech, situations will undoubtedly arise when opening a line of communication with the US Food and Drug Administration (FDA) becomes appropriate, or even necessary.

A company's first step after making the decision to reach out to the FDA should be to contact the pre-market, post-market, or compliance team that will serve as the first line of review, said Sean Boyd, QualityHub's corporate VP and a 31-year veteran of the agency. He stressed that resolving issues at the ground level of the FDA's Center for Devices and Radiological Health (CDRH) is often the fastest and most accessible way to gain a resolution because a review team can swiftly field technical, submission, or issue-specific questions.

"Start with a review team because that's where the most knowledgeable people and most intimately involved people are within the device center," Boyd said. "The team will know all the details of the issue that

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Red Flags Your Device Firm Lacks Quality Culture

Top management at MedTech companies must ensure a culture of quality is systemically embedded within their organization, the US Food and Drug Administration's (FDA) new Quality Management System Regulation (QMSR) makes clear.

Below, Rebecca Fuller, QualityHub's VP of Regulatory Compliance, highlights red flags that could make it apparent to regulators that establishing and maintaining a quality culture is not a priority for a MedTech company.

Red Flag: Failing to periodically audit your company's audit program. "Internal auditors repeatedly see the same systems and same processes, and interview the same personnel," Fuller said. "They're intimately familiar with company operations and may have relationships with the people they're auditing. After awhile they're not going to be as effective as they could be at recognizing problems that may have become, over time, the most acceptable way to do things."

Red Flag: Systemic risk management activities don't occur. "The ISO 13485 standard and the preamble to the FDA's QMSR emphasize the need to apply risk management principles within all areas of the Quality Management System," Fuller said. "During inspections and audits, a company will need to show examples of how risk-based thinking is used in decision-making and how risk information is fed back into risk management files. Failure to fully understand how to use risk to drive decisions and accurately and consistently connect risk information to and from the risk management file will be an indication that that company does not fully support a culture seated in quality."

Red Flag: Employees are unhappy and have a perception that they aren't valued. "Manufacturers with a good culture of quality have happier employees and less employee turnover because they feel like their comments and concerns as they relate to quality are being recognized and there is attention being paid," Fuller said. "People who work in Quality Assurance should feel like they have value and they're not just overhead. That feeling of value means you're a happier employee and you're going to stick around longer."

Read the full article at https://shorturl.at/FPUOy.

QualityHub Expert White Paper
"Building a Culture of Quality in Medical Device Organizations: Best Practices for QMSR Compliance"
Online now at https://shorturl.at/07IhY

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the company has provided, conduct their own internal reviews, and perhaps even pull in some additional data or experts to determine if there are more issues to discuss with the firm beyond the single issue that was brought to the agency."

Should a manufacturer and an FDA review team come to an impasse, the company can escalate the issue to CDRH management to gain additional review or meet for a conversation. Boyd recommends meeting first with a team assistant director and moving up the chain of command to a division or office director if necessary.

Tell A Complete Story

When engaging with the FDA, it's vital for a manufacturer to tell its full story by framing highly technical, complex, and voluminous material in the context of a "big picture," explaining the issue at hand, how the company plans to handle it, and the outcome that is sought. The agency will also want to know when milestones will be accomplished and efforts completed.

"It's helpful to have that big picture story in front of the agency, as well as the discrete fixes to the problems that have been identified and the company is addressing," Boyd said.

Telling a complete story is also important if a company is asking the FDA for permission to use an alternative approach to tackling a problem.

"You have to do a good job presenting that approach," Boyd said. "What's the standard approach that the agency requires? Why doesn't that work? In this case, what are you going to do differently? How does that mitigate any potential concerns or risks that the agency might have?"

Read the full article at https://shorturl.at/dP8eA.

QHub Viewpoint

After QSIT: Why the MedTech Industry Still Needs an FDA Inspection Roadmap

The Food and Drug Administration (FDA) has sunset the longstanding Quality System Regulation (QSR) and its companion inspectional guide, the Quality System Inspection Technique (QSIT). In their place stands the new Quality Management System Regulation (QMSR) and revised Compliance Program Manual (CPM) 7382.850 for the inspection of MedTech manufacturers.

This was an important step forward to align US medical device requirements with international quality systems standard ISO 13485:2016 and streamline expectations of device makers worldwide.

Regulatory modernization isn't a problem, but the lack of inspectional clarity may be.

QSIT functioned as the de facto roadmap for device inspections for 27 years. Implemented in 1999 by an FDA team led by QualityHub Founder and President Tim Wells, QSIT did something profoundly important for both facility investigators and industry: it made the inspection process transparent. It laid out how inspections would flow, what subsystems would be emphasized, and how compliance would be evaluated in sequence. It reduced ambiguity.

The updated CPM for device inspections, however, doesn't provide that same transparency

industry has grown accustomed to. The CPM now outlines six core elements investigators will evaluate, including Change Control; Design and Development; Management Oversight; Measurement, Analysis, and Improvement; Production and Service Provision; and Outsourcing and Purchasing.

These elements aren't controversial or unknown. They are foundational pillars of any Quality Management System. What is missing is the inspectional structure. What is needed is predictability and transparency of the FDA's approach for evaluating compliance.

The FDA's regulatory modernization and harmonization by way of the QMSR is strategically sound. But harmonization doesn't eliminate the need for inspectional transparency.

Regulation without inspection clarity is incomplete.

The sunset of QSIT leaves a gap and the agency's CPM, as currently structured, doesn't fully fill it. Regulation without inspection clarity is incomplete. If the FDA doesn't intend to publish another QSIT, it should nevertheless provide an inspection technique framework under another name.

The FDA didn't develop QSIT immediately when the QSR was finalized, but the agency did start work on the inspectional approach when the need for it became evident. That need for a comprehensive approach still exists for many. MedTech manufacturers have been so accustomed to having QSIT as a resource and guide that its absence has already been felt by many.

And this time, industry shouldn't wait in silence and hope for a new QSIT to emerge. Stakeholders should contact the agency today and let them know a new inspectional approach is needed to replace QSIT, which worked wonderfully for 27 years.

Read the full article at https://shorturl.at/rKOXJ.

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and quality objectives; the types of records that may be audited; the requirement for establishing and maintaining competence; and the need to demonstrate effectiveness.

Regarding demonstrating training effectiveness, FDA investigators and those auditing to the former Part 820 could only review training effectiveness in instances where training was used as a corrective or preventive action in a CAPA or nonconformance. But under ISO 13485, all training requires effectiveness. Training effectiveness isn't easy to establish, and this will require some improvements in how training is performed and managed.

For example, many organizations use a "Read and Understand" process. With the need for training effectiveness, simply asking an employee to read a procedure isn't adequate. Some types of training will lend themselves to confirmation of a person's understanding through a simple post-training written test. In cases where an operator's skill or ability to perform a specific task impacts product quality, an operator certification program can be established.

Certification implies that ability is demonstrated by a combination of evaluating the operator's outputs to confirm proper performance of the task, along with other tests to confirm understanding of the task and defects that may occur if the task isn't performed correctly. Monitoring nonconformance trends in operations may provide measurable evidence of operators' skill levels, which can then be linked to the overall effectiveness of training programs.

Another point to consider is the linkage between training and the achievement of the organization's quality objectives. The ISO requirement is that the organization shall ensure its personnel are aware of the organization's quality objectives. With the former QSR, personnel weren't specifically required to know about an organization's quality objectives. That's because Part 820 was silent on "quality objectives" altogether. Those of us in the quality industry are appreciative of the need for clearly stated and well understood quality objectives as listed in ISO 13485.

Quality objectives are an important element of Management Responsibility (ISO 13485, Clause 5.4.1). The objectives help top management ensure product and regulatory requirements are established. It makes good sense for employees to be aware of the organization's quality objectives and how these are relevant to their job function.

ISO's reference to "Quality Objectives" should be interpreted broadly as both the company's overall quality objectives and the quality objectives related to ensuring products meet specifications. Ensuring employees understand these objectives broadly and how they're directly relevant to their job function contributes to demonstrate a strong Culture of Quality.

Read the full article at https://shorturl.at/4jtEm.