

Optimizing Regulatory Compliance: Nine Strategies for Success

Regulatory Outlook

Medical device firms need to create an organizational structure around the QSR, and they need to follow the procedures it prescribes.

*Nancy Singer and Richard DeRisio
Compliance-Alliance LLC and Kinetic Concepts Inc.*

Eight years have passed since FDA finalized the quality system regulation (QSR). Most medical device firms are familiar with the requirements. In a high proportion of its warning letters, however, FDA is still citing companies for failure to implement management controls. One of the most important aspects of management controls is the requirement for firms to have an adequate organizational structure. In building this structure, management needs to empower the regulatory affairs/quality assurance (RA/QA) function to establish systems that produce quality products and comply with regulatory requirements.

This article presents the legal requirements for establishing an organizational structure that supports the RA/QA function, management attitudes toward the RA/QA function, and ways the RA/QA function can motivate others to comply with regulatory requirements.

Legal Requirements

The requirements for management controls under 21 CFR 820 Subpart B are succinct.¹ They take up less than two pages in the Code of Federal Regulations. There are three major sections: Management Responsibility, Quality Audits, and Personnel.

Under the Management Responsibility provisions, 21 CFR 820.20(b), medical device firms are required to have an adequate organizational structure in which people who perform and assess quality have the necessary authority, responsibility, independence, and resources. Unfortunately, published warning letter citations and input from RA/QA professionals suggest that numerous firms in the medical device industry are not complying with this provision.

In particular, on the Form FDA 483 list of observations and also in warning letters, FDA has cited companies for their inadequate organizational structure. Listed below are just a few examples.

On January 20, 2004, the Division of Enforcement A in CDRH's Office of Compliance cited a medical device firm for "failure to assign the appropriate responsibility and authority to employees who manage, perform, and assess work affecting quality and provide them with the independence and authority to accomplish their work...."

On June 17, 2004, the Detroit district director cited a company for “failure to establish and maintain an adequate organizational structure to ensure that your medical devices are designed and produced in accordance with the requirements....” On November 25, 2003, the Los Angeles district director cited a firm saying, “You have not provided adequate resources...for management, performance of work, and assessment activities...to meet the requirements.”

Compliance-Alliance Survey

In February 2005, Compliance-Alliance sent out a survey to assess the influence of RA/QA professionals in medical device firms.² During a two-week period, 1024 medical device professionals responded. The breakdown included 108 senior executives (including CEOs); 351 regulatory officials; 373 quality officials; 30 officials in manufacturing/operations; and 162 others including sales, marketing, R&D, clinical, and legal officials.

Some of the results were disturbing. When asked about top management's perception of the RA/QA function, 226 reported that the function was viewed by top management as a necessary evil, and 36 reported that the function was viewed as a deterrent to making the firm's revenue goals.

When responding to questions on typical challenges for getting cooperation for regulatory compliance, 383 respondents reported inadequate commitment from senior executives, and 377 reported that the RA/QA function had inadequate authority. In determining which functions in the organization could ignore RA/QA recommendations with impunity, 333 singled out the sales function, 337 indicated marketing, and 185 said senior management.

When responding to questions about the areas that most urgently needed additional funding, 613 cited increased staffing in the RA/QA area. This indicates that many respondents do not consider their firms to be complying with the requirement to provide the necessary authority, independence, and resources to RA/QA professionals responsible for product quality and regulatory compliance.

What to Do

Of the 1024 people who responded to the survey, 843 provided additional comments. The responses included techniques to change the culture to ensure that the RA/QA function would have the necessary authority, independence, and resources. The suggestions were grouped into the following nine categories:

- Creating an environment that supports compliance.
- Making compliance part of everyone's job.
- Empowering the RA/QA function.
- Having the RA/QA function employ the appropriate skills to obtain cooperation.
- Educating other departments.
- Selling the benefits of quality and compliance.
- Using internal audits effectively.

- Reviewing and reporting quality and compliance data.
- Explaining the consequences of noncompliance.

Each category will be discussed below.

Strategy 1: Creating an Environment that Supports Compliance. The quality policy and quality objectives are the key documents in which management with executive responsibility (top management) states its commitment to quality and to complying with all relevant regulatory requirements. Creating the quality policy and setting quality objectives should be top management's first step in establishing the company's quality system.

The work, however, is not done once these documents are written. Top management must support the principles articulated in the quality policy. Furthermore, all employees need to be aware of the policy, and employees should be assured that the company will always follow the systems that implement the quality policy.

Unfortunately this does not always occur. On April 16, 2004, the district director for the FDA Cincinnati district cited a company saying, "Management with executive responsibility has not ensured that the quality policy is understood at all levels of the organization.... Specifically, two out of three employees questioned did not know your quality policy."

On November 22, 2004, the New England district director cited a company saying, "Management with executive responsibility has not ensured that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization. Specifically...the Quality Policy has not been implemented." The Compliance-Alliance survey confirms that firms are not always following the systems that implement their quality policy. For instance, 564 respondents indicated that their companies only follow the systems that implement the quality policy most of the time. Another 109 respondents reported following the systems only when it is convenient. And finally, 16 respondents reported that the company's quality policy was seen as a joke in their organizations.

One of the best ways to convince employees that top management is sincere about its quality policy and committed to complying with regulatory requirements is for management to visit with employees on the line and actually talk about the quality policy and management's commitment to regulatory compliance. The CEO of one leading medical device firm routinely visits the employees working in the manufacturing facilities, talks to them about the quality policy, and thanks them for complying with it.

Other ways that management can design an organizational structure to support regulatory compliance is to develop an annual compliance strategy and implementation plan. The strategy and implementation plan should be reviewed on a quarterly basis, and important achievements—such as not having any Form FDA 483 observations during an inspection—should be announced to all employees.

Strategy 2: Making Compliance Part of Everyone's Job. An effective way to center the organizational structure on quality and complying with regulatory requirements is to explain how the regulatory requirements affect each department within the company. These efforts can be reinforced by including compliance in everyone's job description, goals, and objectives.

One company implemented a personal accountability index that measures performance in tasks such as timely implementation of corrective actions, improvement in product quality, and customer satisfaction. When the employees knew that they were going to be rated on these criteria, they took their compliance obligations seriously.

Some companies provide a bonus for measurable compliance factors. In many cases, this seems to be very effective. Although negative reinforcement is not the method of choice, many firms use a disciplinary system for not meeting compliance obligations. In fact, FDA expects firms to take strong disciplinary action toward employees who falsify records or repeatedly fail to follow standard operating procedures.

Strategy 3: Empowering the RA/QA Function. Under 21 CFR 820.20(b)(3), management is required to appoint a management representative who is charged with ensuring that quality system requirements are established and effectively maintained. This representative should also report on the performance of the quality system to management with executive responsibility.

In a February 1, 2005, warning letter, the New Jersey district director cited a firm for not appointing "a representative with authority and responsibility to assure that the quality system requirements were effectively established and maintained...." The Florida district director similarly cited a firm for failing to appoint a management representative with authority and responsibility in a January 6, 2005, warning letter.

Generally, the senior RA/QA official in a company occupies the position of management representative. To ensure that compliance is a priority, many companies have the senior RA/QA professional report directly to the president or CEO. This allows other management team members to have a direct line of communication to the management representative on important quality and compliance issues.

This structure also ensures that the RA/QA official can easily approach the most senior management official in other functional areas when support is needed for critical improvements. The QSR does not have a requirement for a particular reporting structure; however, the effectiveness of the organization will be evaluated based on the performance of the RA/QA function in ensuring product quality and maintaining a state of regulatory compliance.

Many people oversimplify the importance of the management responsibility provisions of the QSR. It is not simply about senior management's authority to approve additional head count, increase spending, and redirect priorities. More significant is senior management's obligation to make substantive

recommendations (and pose challenges) regarding product quality and compliance. These individuals have reached their position in the organization because of their capability and experience. They understand their role in shaping the culture of the organization.

If the RA/QA function has done an effective job informing senior management on the business benefits of impeccable product quality and compliance, senior managers will see quality and compliance objectives as an opportunity to create a competitive advantage and avert product and compliance liability. At that point, the RA/QA professional will not have to lobby for top management interest and support. In a truly effective organization, the RA/QA professional is a key player in all strategy meetings where critical business decisions are discussed. Many times when a RA/QA professional is not included, decisions are made without regard to the regulatory implications. In these instances, companies find themselves going full speed ahead on an initiative such as an acquisition of a product, technology, or business, or the launch of a costly marketing campaign, without considering the regulatory consequences. Then the company may be forced to change direction later, resulting in wasted effort and increased expense.

Generally, the RA/QA function serves as an adviser to other departments. When this function is not at an equal level with officials in other departments, the RA/QA professional lacks the authority to stop a specific course of action even though there may be potential regulatory consequences. In these instances, the RA/QA professional needs to be able to escalate issues and to have direct access to functional heads of groups such as manufacturing, R&D, field service, and operations. In instances where senior management and other officials in the chain of command could be held accountable, sound business practices dictate that they be informed of all relevant risks before the firm goes forward.

To be effective, the RA/QA function requires adequate resources. In fact, 21 CFR 820.20(b)(2) requires that adequate resources be given to those who are charged with meeting the requirements of the QSR. To determine whether firms are providing adequate resources, top management should periodically ask what is not being done because of lack of trained personnel, time, or other resources. If the RA/QA priorities cannot be changed, then top management is obligated to provide more resources to support regulatory compliance.

Strategy 4: Having the RA/QA Function Employ the Appropriate Skills to Obtain Cooperation. Necessary skills for people serving in the RA/QA function include knowing the regulatory requirements and knowing how to apply them in a way that minimizes the risk to patients and device users.

RA/QA professionals need to respect their position as advisers to the company and provide accurate and timely advice. In effect, almost every function in a company is, at one time or another, a customer of RA/QA. Guessing about whether a course of action is permissible is simply unacceptable. The RA/QA professional who provides incorrect advice loses all credibility and will not be asked to give an opinion in the future. It is okay to say, "I'd like to research this," or "let me run this by some of the others in the group so that I can give you the best answer." In

many cases, those outside the RA/QA function underestimate the level of uncertainty in areas for which FDA guidance is absent, enforcement is variable among FDA regions and individuals, or answers are specific for the type of device and its care setting.

Equally damaging for the credibility of RA/QA professionals is when an FDA investigator fails to cite as a Form FDA 483 observation instances in which a firm has not complied with an onerous regulatory requirement and there was evidence that the firm had no intention of complying. Mandating adherence to a specific requirement is much harder if the regulatory agency has failed to hold a firm accountable.

In such instances, RA/QA professionals might want to bring in a former FDA investigator or an attorney in a food and drug law practice who can explain that a firm can still be held accountable in a subsequent enforcement or product liability action even if an FDA investigator failed to cite the deficiency on the Form FDA 483. The use of outside experts can also be highly effective in impressing upon the top management team that each member is personally responsible for regulatory compliance.

Ideally, RA/QA professionals should be temporarily assigned to operations, R&D, or marketing. By spending time in these other departments, they learn to understand their colleagues' needs and primary business drivers. With these insights, RA/QA professionals can explain the requirements in a manner that demonstrates how conformance to quality and compliance objectives supports business goals. The skills that the RA/QA officials develop from such a program should justify the cost.

Strategy 5: Educating Other Departments. Education is a key component in building an organizational structure in which all employees understand the regulatory requirements. Manufacturers are required by 21 CFR 820.25(b) to establish procedures for identifying training needs and to ensure that all personnel are trained to adequately perform their assigned responsibilities. Unfortunately, many firms do not take the time to properly educate their employees.

In a January 30, 2003, warning letter, the director of the Office of Compliance in CDRH cited a firm for failing to "ensure that all personnel are trained to perform their assigned responsibilities...[specifically] the sales and marketing associate whose duties include complaint handling and implementing CAPA [corrective action/preventative action] has not been trained in the quality system regulation."

In a March 2, 2004, warning letter, the Florida district director cited a company stating, "Personnel responsible for marketing devices and overseeing manufacturing operations have not received quality system regulation training...."

RA/QA staff should work with the human resources department to set minimum requirements for employees whose job functions affect product quality. These training needs can be incorporated into each employee's job description.

A basic element, even for low-wage-scale positions, is to evaluate each applicant's attitude toward quality improvement and compliance. By including compliance requirements in the orientation program during new employees' initial exposure to

the company, management can impress upon the employees the seriousness of the firm's commitment to this area.

To make training interesting as well as informative, firms should hold on-site in-person training sessions and consider bringing in an outside speaker with a different perspective. A training session should begin with statements like, "Our medical device can be used to treat your child, spouse, or parent when they are injured or sick, and we don't want to be responsible for hurting, not curing, or not helping those who are ill." By starting with a strong statement like this one, the training on the requirements becomes more relevant. Incorporating these concepts can inspire employees to pursue the goal of designing safe and effective products that are manufactured free of defects.

Training at out-of-town seminars can be time-consuming and expensive. Useful alternatives include teleconferences, online training, and Webcasts. To ensure that employees comprehend the material, firms should consider instituting tests to measure comprehension and retention. Additionally, recognition for completing curricula can also serve as a motivating factor.

Strategy 6: Selling the Benefits of Quality and Compliance. To sell the benefits of quality and compliance, RA/QA professionals should talk about how device firms occupy a special place in society. They should explain that those who work in our field are empowered by the government to produce devices that help to cure the sick, treat the injured, and diagnose and prevent disease. Along with authority goes the responsibility to comply with the government regulations and to manufacture and distribute safe and effective products.

RA/QA professionals need to be able to work with many departments to explain the rationale for specific regulatory requirements. They should use examples to demonstrate how the quality system will improve business operations. For example, manufacturing can lower costs by standardizing processes and trending failure codes. By correcting issues found in customer complaints and ensuring that corrective and preventive actions are implemented effectively and in a timely manner, sales and marketing will be able to sell more products to a loyal and growing base of satisfied customers.

Other benefits of compliance, suggested by the survey respondents, include, "By understanding what is required up front, we can shorten the time to market," and "We stay in business by supplying quality products that meet our customer's needs and exceed their expectations."

Having a notified body audit a firm heightens the importance of complying with the requirements. It is valuable to educate all employees that passing the audit is a prerequisite for selling products overseas. Failure to pass the audit results in not selling the firm's devices in certain countries. Lost sales can affect performance bonuses, which in many cases are tied to meeting the company's sales projections and earnings forecast.

Strategy 7: Using Internal Audits Effectively. Firms are required under 21 CFR 820.22 to establish systems to periodically audit all elements of their quality system by individuals who do not have direct responsibility for the matters being audited. Many firms are violating this requirement.

In an April 26, 2004, warning letter the Dallas district director cited a firm saying, "Only two out of the 10 quality system areas were audited in 2003."

In a June 15, 2004, warning letter the Chicago district director cited a firm saying, "Quality audits are not being conducted by individuals who do not have direct responsibility for the matter being audited...."

Respondents to the Compliance-Alliance survey offered numerous innovative ways to employ audits. In order to provide ownership of the internal audit program, some firms appoint a representative from each department to serve as a member of the audit team. When team members are assigned to audit areas for which they are not responsible, they will learn how different departments operate and observe their best practices. They can bring that knowledge back to their departments, which enables the departments to provide better support for complying with the regulatory requirements. Additionally, these individuals will be better prepared to represent their functions and departments during FDA inspections and notified body audits.

To ensure that audit results are taken seriously, disseminating the audit results to all department heads can create peer pressure to get cooperation to institute process improvements. Key audit program findings and trends should be reviewed during periodic management reviews.

To obtain another perspective, firms should consider inviting an outside auditor who was formerly an FDA investigator or who has experience auditing other companies. This person's findings can add credibility and provide an impetus to quickly institute corrective actions.

In most companies, there are typically a few individuals who view their jobs from their own narrow perspective and refuse to do what is required to comply with regulatory requirements. Inviting or requiring these individuals to represent their areas and answer questions posed by the auditor could increase their appreciation of the importance of adhering to regulatory procedures and the intent behind the regulations.

For instance, allowing employees from departments such as manufacturing, R&D, marketing, or service to listen to and observe an auditor's investigation of a product or process issue can instill a keen appreciation of the importance of defensible decisions affecting product quality. This exposure can be valuable whether the subject involves manufacturing and test procedures, product design and development, failure investigations, or service practices.

Many companies have used software to track progress on corrective actions and to ensure that action items are really implemented. In the survey, 80 respondents reported using software, and 526 respondents believed that software could be of assistance in achieving compliance.

Strategy 8: Reviewing and Reporting Quality and Compliance Data. In addition to periodic management reviews in which key quality and compliance indicators are considered, RA/QA management needs to develop a system for periodically publishing this information. Such reports must be sufficiently comprehensive to cover all the various functional groups in the company, but concise and compelling enough to ensure that the information is reviewed.

Figure 1 is a flowchart representing a system for analyzing quality data in a medical device company. There are several subsystems, each of which would have its own review team to assess trends, address individual issues, and prepare reports for the next level of management.

For example, a material review board might meet daily to review nonconforming material reports. Global sourcing teams might review supplier corrective actions and incoming receiving data weekly. Product-line-specific quality improvement teams could meet weekly to review new and open complaints to assess the need for corrective actions.

The teams would provide summaries to a quality improvement board that meets monthly. This board should include managers and directors from many company divisions: R&D, production, manufacturing engineering, purchasing and planning, field service, information systems, training, marketing, quality assurance, quality engineering, and regulatory affairs.

The board is charged with assessing ongoing or emerging quality and compliance issues and, given their senior management level, assess and reassign resources and priorities to projects. Also, the board reviews a standard quality metrics package and makes recommendations regarding information that should be included in the next management review with executive-level management. When the board is managed effectively, members see their role as positively affecting business success and competitiveness.

Strategy 9: Explaining the Consequences of Noncompliance. Knowledge is power. Employees who work for medical device firms work in a government-regulated industry and need to understand the consequences of not complying with the requirements. Companies and responsible individuals can be criminally or civilly prosecuted. FDA can shut down a company's operations, enjoin the company from manufacturing products, or send publicly available warning letters to companies alleging deviations from the QSR.

Techniques to explain the consequences of noncompliance include bringing in outside experts, disseminating reports of actions taken against other companies, and sending inspection and external audit results to all affected employees.

Conclusion

The QSR provides a framework for firms to shape their quality systems according to their needs and to create processes that produce safe and effective products.

Medical device firms need to create organizational structures around the QSR, and they need to follow the procedures that it prescribes. The RA/QA function should establish the system and should be the glue that holds it together.

References

1. 21 CFR 820, Subpart B.
2. "Getting Buy-In for Regulatory Compliance" (Arlington, VA: Compliance-Alliance LLC, February 2005).

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