Shifting the Compliance PARADIGM

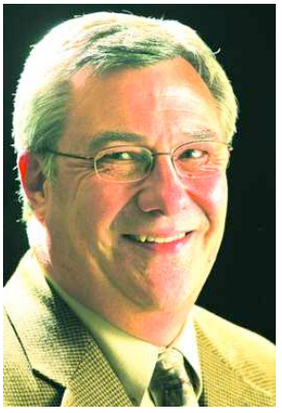
Developing an innovative methodology for regulatory compliance can provide companies with a strategic advantage

IN THE DESIGN AND DEVELOPMENT OF NEW PRODUCTS AND ROBUST MANUFACTURING PROCESSES BY AVOIDING SUBOPTIMAL RESULTS THAT TYPICALLY DO NOT MEET REQUIREMENTS SET FORTH IN THE FDA GUIDELINES.

MICHAEL KUEHNE IS PRESIDENT OF ACSYS INC., HILLSBOROUGH, N.J., WHICH SPECIALIZES IN DEVELOPING QUALITY AND COMPLIANCE SOLUTIONS THAT COMBINE R&D AND MANUFACTURING CAPABILITIES TO DELIVER SUSTAINED IMPROVEMENT IN R&D, QUALITY, OPERATIONS, CLINICAL, AND REGULATORY AFFAIRS DEPARTMENTS. THIS ENHANCED CAPABILITY SUPPORTS ORGANIZATIONAL CAPABILITIES TO DEVELOP AND LAUNCH NEW PRODUCTS AND PROCESSES.

Many organizations perceive regulatory compliance as an unavoidable obligation in a federally regulated industry. Generally, compliance is a critical element on the list of "must-do items" to be completed before launching a new product. But rarely is compliance recognized as a strategic advantage — an enabler to designing and developing new products and robust manufacturing processes.

"This 'must-do' attitude toward compliance yields suboptimal product designs and manufacturing processes, with documentation that at best minimally meets requirements set forth in FDA guidelines," says Michael Kuehne, president of ACSYS Inc. "The result is secondary product designs because of problems encountered in the field; manufacturing processes with higher costs for rework and scrap; inconsistent product quality; and FDA audits resulting in 483s, warning letters, or some type of field action."



Although compliance is recognized as a critical factor to take into consideration before launching a new product, compliance is not often recognized as a strategic component of the design and development of new products and manufacturing processes.

THE EXISTING PARADIGM

The prevailing sense, according to Mr. Kuehne, is that meeting compliance requirements is a time-consuming, documentation-intensive effort that ultimately delays new product development and manufacturing process startup. The belief that compliance requirements are in conflict with product development and market introduction is prevalent in R&D and operations. Product development initiatives often are managed by R&D departments whose focus is not on compliance or process development. Because organizations routinely reward new products that launch faster, this usually is accomplished with costly, inefficient processes that have greater compliance risk.

"These processes often require secondary engineering to improve yields and increase overall product quality," he says. "Quality and compliance requirements, including detailed process testing and characterization, usually occur late in a project schedule. As such, insufficient time and resources are available to adequately address compliance requirements and world-class process engineering."

While there is an element of time required to create compliance documentation, it is the quality of time and organizational commitment that have the largest potential impact for improvement. With a strong understanding of FDA guidelines and a sensible approach to balancing business needs with compliance requirements, sensible solutions meeting both objectives can be developed.

"In a world-class environment, validation

and compliance enable organizations to launch well-designed products and robust manufacturing processes that require less overall development time and operate with greater efficiency and higher quality," Mr. Kuehne says. "What currently is viewed as restrictive documentation must be analyzed in the context of what is required by the FDA to demonstrate sound design practice, as well as repeatability and reliability in production processes. Applying this filter usually uncovers opportunities for companies to be compliant in a more efficient manner and develop improved production processes. The organization must actively participate in these efforts to ensure that what is developed will fit in the quality system and satisfy elements of the quality plan."

COMPETITIVE COMPLIANCE: THE NEW PARADIGM

Shifting the compliance paradigm is the first step toward dramatic improvement in product commercialization success as well as satisfying regulatory compliance requirements.

"Validation and compliance should be enablers of outstanding results for both products and processes, as opposed to required elements gating product launch," Mr. Kuehne says. "Organizational focus can become proactive, supporting proper design and development early in the product commercialization cycle versus being reactive to production process problems, product design issues, and regulatory compliance shortfalls."

Moving this emphasis up front fosters design improvements, as process capabilities are established and strong manufacturing systems are developed. As a result, engineering design, prototyping, process testing, and measurement become capabilities that give organizations competitive advantages leading to efficient, cost-effective, and high-quality manufacturing processes. Regulatory compliance and validation become conduits for success rather than a drag on development and implementation.

"We call this enhanced capability 'competitive compliance,'" he says. "It is the ability to use compliance processes to enable dramatic improvements in product and process design to deliver results that surpass the competition."

THE NEED FOR CHANGE

In a competitive environment that rewards product innovation, value to customers, and speed to market, Mr. Kuehne says there is a need to integrate the current approach to product/process development, regulatory compliance, and manufacturing processes. Operations executives typically look for ways to get improved processes into manufacturing; R&D leaders look for ways to optimize product design; and quality managers focus on following established guidelines and meeting requirements set forth in a quality plan.

"It is the combination of all of these goals, and the balance between them, that ultimately drives improvements in products and processes, leading to higher-quality, cost-effective manufacturing," he says. Organizations don't have to look far to find compelling reasons to upgrade compliance capabilities and embrace change. As technology has become more sophisticated, so too has the FDA. Through the implementation of new inspection techniques, the FDA has become much more effective at

finding organizational deficiencies in meeting compliance guidelines. This has resulted in larger fines, greater management accountability, and more warning letters that require corrective action and that divert resources from developing and launching new products and processes.

"Resolving corrective actions can delay FDA approvals, stop production, or force costly redevelopment and relocation "Doors are opened for competitors to gain exposure for their products, launch new competitive products, and ultimately shift the marketplace to their advantage. There are many examples of these circumstances in recent years, as organizations struggle to balance business needs with compliance requirements."

Products and processes also have dramatically increased in complexity with the integration of innovative technologies. This increased sophistication requires a more disciplined approach to development, validation, and production systems. Efficiently managing the rigors of design and process development with effective validation presents opportunities to increase product commercialization success.

"When performed according to world-class principles, disciplined validation improves designs; drives reliable, efficient processes; and results in high-quality, cost-effective manufacturing systems," Mr. Kuehne says. "In the context of total time, the product commercialization cycle is reduced, since product redesign and systemic manufacturing process troubleshooting are not required. Product quality becomes measurable and repeatable within tight limits, manufacturing costs are not burdened by high levels of waste or rework, and statistical sampling replaces 100% inspection."

While there are compelling reasons to improve validation and compliance capabilities, Mr. Kuehne says there are barriers to change.

"Organizations without FDA actions pending may be lulled into a false sense of security believing things are in compliance," he says. "Organizational priorities are centered on rapid product launch in an attempt to stay ahead of, or catch, competitors. Validation and compliance are viewed as support processes and not given the same importance as product commercialization. Unfortunately, this complacency prevails until organizations are confronted with products that are not approved, documentation that is determined to be inaccurate or missing, designs that are scrutinized based on customer complaints, and poor-performing production processes."

The result is that product shipments may be halted or, worse, recalled if prevailing compliance issues are deemed critical.

"This can have a devastating effect on business, as customers who previously provided support through product purchases develop negative views of the product and the organization," he says. "Loyalties quickly shift to competitive products, and the damage may take years to repair even after compliance issues are resolved."

For organizations that decide to upgrade compliance capabilities, obstacles to change may still exist. Compliance requires a discipline and commitment that may be perceived as inflexible. Quality audits that uncover compliance gaps ultimately lead to accountability on the part of a team and its leader. This heightened accountability is not always welcome and may be perceived as imposing and contrary to rapid product commercialization. These organizations often are confronted with high levels of frustration over product commercialization results and high anxiety over potential FDA reviews.

"Having a formal system in place does not guarantee it will be followed when the pressures of rapidly developing and delivering new products arises," Mr. Kuehne says. "The disciplines of validation must be formally integrated into a new product commercialization process. In this way, validation becomes a vehicle for rigorous development, as testing and measurement of new processes are implemented into manufacturing. Process capabilities and performance standards must be established and measured to determine their repeatability and reliability. Parameters with critical impact on product quality must be identified, along with the ranges for these parameters. Testing must be performed to determine the relationship these parameters and ranges have on each other, and, by using statistical testing methods, operating ranges are established and documented. If a particular process or equipment fails the tests of repeatability and reliability, as determined by process capability measurements, a design upgrade is implemented to get the desired level of process performance. The validation process becomes the driver for robust manufacturing systems. The concepts of rapid product development, competitive manufacturing costs, and regulatory compliance are no longer mutually exclusive."

For more information, visit acsys.org.✦

A Validation Case Study

MICHAEL KUEHNE, PRESIDENT OF ACSYS INC., CITES HOW ONE MEDICAL-DEVICE MANUFACTURER'S ADOPTION OF CORRECT VALIDATION PROCESS ENHANCED ITS MANUFACTURING.

The device manufacturer was plagued with varying process yields ranging from 45% to 65%. Varying causes were associated with these poor results, yet they could not be resolved successfully to improve manufacturing efficiency; 100% inspection was required.

The organization perceived that validation did not support timely product development, and the market was so competitive that any delay would be devastating.

The company's belief was that its processes were too complex to be validated, which created significant internal debate followed by a concession to try validation as a means of gaining insight into its process.

The first step was learning to identify and measure critical process parameters. Progress was noted during the validation process, and variability in production output was substantially reduced with improved product quality. Consequently, the company became convinced of the benefits validation provided.

Calibration methods for measurement equipment were modified to be relevant for the equipment's application and performed at the proper times in the validation process.

Equipment setup procedures were formalized and documented with an emphasis on parameters that critically impacted repeatability and reliability.

Maintenance programs were revised and intervals changed so that critical machine parts would not wear beyond established tolerances due to continuous equipment operation.

Supervisor, mechanic, and operator training were implemented to ensure complete understanding and integration of all changes.

Within two months, the resulting validated process delivered consistent production yields between 86% and 91%. Statistical sampling of products replaced 100% manual inspection, allowing resources to be deployed in other areas of operations.

The total benefit of validated processes far exceeded the expectations in all areas, and the resulting decrease in the cost of goods sold enabled greater profitability and competitiveness in the company's market.

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