

Design Controls: Are They Worth the Effort?

Compliance-Alliance conducted a survey to measure the effects of FDA's design control regulation on the industry. Most respondents believe the controls have helped.

By: Erik Swain

Q&A

In January 1990, FDA published *Device Recalls: A Study of Quality Problems* (55 FR 21108, May 22, 1990). The study reported that 44% of quality problems were attributed to errors or deficiencies that were designed into particular devices. These errors may have been prevented by adequate design control. FDA's Center for Devices and Radiological Health conducted a subsequent study titled *Software Related Recalls for Fiscal Years FY 83-91*. This study stated that more than 90% of all software-related device failures were due to design errors. The most common problem was failing to validate software prior to routine maintenance.



Singer



Jones

Congress gave FDA the authority to add preproduction design controls to the current good manufacturing practices regulation via the Safe Medical Devices Act of 1990. After seeking input from numerous parties, FDA issued the quality system regulation (QSR), whose provisions were effective June 1, 1997. FDA provided a one-year transition period during which the agency expected industry to comply with the design control requirements of 21 CFR 820.30. However, the agency refrained from issuing 483 observations based on failure to comply with the provisions until June 1, 1998.

The design controls regulation has now been in effect for 10 years. Nancy Singer, president of Compliance-Alliance LLC, wanted to assist companies in their understanding the requirements. Her company sponsored four educational seminars on the topic and conducted a survey to measure the effect that the regulation has had on the medical device industry. She then got the feedback of David R. Jones, the quality assurance director in the Regulatory Affairs and Philips Business Excellence division of Philips Consumer Healthcare Solutions. They spoke to *MD&DI* Editor-in-Chief Erik Swain in August.

Q: It has been a number of years since FDA started requiring design controls. How well accepted is the practice within the medical device industry?

Singer: To find out about device firms' acceptance and use of design controls, Compliance-Alliance prepared a 20-question survey that we sent to quality and regulatory officials at medical device firms. There was a lot of interest in the topic, as 155 device professionals completed the survey. The respondents consisted of

roughly equal numbers of manufacturers of implantable devices, in vitro diagnostic devices, monitoring devices, and therapeutic devices.

We asked how firms viewed FDA's requirements for design controls. Almost half viewed it as a valued activity for the business, and most of the other respondents viewed it either as an obligation to the users of their products, or they viewed it as a cost of doing business in a regulated industry.

Jones: One of my responsibilities is to establish as well as oversee the implementation of design controls for personal emergency-response systems and home telemonitoring products. If I were to generalize, I would say design controls provide the robust common engineering language across the organization, which allows the continuum of customer requirements to product execution strategy to be predictable and repeatable. This includes both hardware- and software-based medical devices and services. Design controls are a best practice. They leverage the product generation process to unite marketing, research and development, operations and the supply chain, finance, and general management to meet both compliance and business growth goals. When executed flawlessly, schedules, product performance, defect identification, and removal processes are predictable.

Q: Is industry satisfied with the way the regulation has been implemented?

Singer: More than 80% of the respondents indicated that the regulation takes the correct approach, with the rest of the respondents believing that it is either not prescriptive enough or too prescriptive. The survey asked about firms' experience with the FDA investigator who inspected their design controls process. Here again, 80% believed that the investigator understood the regulation and went into appropriate depth during the inspection. Only 3% believed that the investigator put too much emphasis on design controls, and 17% believed that the investigator improperly interpreted the requirements.

Jones: It is my personal belief that the regulation has helped the medical device industry, especially those companies that take a platform-based approach to product road map execution. Design controls help add-on products leverage the benefits of prior products, from the standpoints of configuration management, common components, and verification and validation. This includes hardware, software, and services.

Q: Does industry understand the value that design controls can add to the development process?

Singer: Eighty-six percent of the survey respondents reported that design controls contributed positively to the development process, and 14% said it had a neutral or detrimental effect.

Jones: Design controls have enabled us to leverage real-time feedback from customers and complaints to help produce the next generation of products for which there is built-in market demand. A major hidden benefit of the design controls regulation is that it helps an organization make the appropriate trade-offs

between scope and available resources up front so that it doesn't promise what it can't deliver. Design controls also benefit the coordination of activities when multiple design sites are engaged on a project. From a personnel training perspective, design controls help new engineers quickly get up to speed because prior examples of the design-through-validation process can be referenced. The project-phase exit meetings, in which projects formally move from one phase to the next, provide a disciplined communications vehicle for all team members.

Q: Which regulatory documents are most useful for understanding design control?

Jones: The guidance documents Design Control Guidance for Medical Device Manufacturers and General Principles of Software Validation have been invaluable for software-based medical device and service companies. Similarly important are the preamble to the QSR and ISO 14971 for risk assessment and management. For worldwide product regulatory approvals for software-based medical devices, additional regulatory documents that have helped include:

- IEC 60601-1-4:1996 + A1:1999, the collateral standard on programmable electrical medical systems.
- IEC 60601-1-6, general requirements for safety and the collateral standard on usability.
- IEC 62304, life-cycle processes for medical device software.

Singer: The survey generally confirms David's opinion in that:

- 80% use the design controls guidance document.
- 51% use the software validation guidance document.
- 47% use the preamble to the QSR.
- 40% use Medical Device Quality Systems Manual: A Small Entity Guide.
- 38% use human factors guidances such as Do It By Design.

What surprised me most is that more people were not relying on the preamble to the QSR, which explains the intent of many of the requirements.

Q: What is the optimal amount a device company should be spending on design controls and related activities?

Jones: Planning for 10–15% of your annual development budget to be focused on design controls and related activities is not unreasonable for a software platform-based medical device company. This is especially true if the firm plans to release new products within the next five years, although the controls will also provide sustained engineering for software-based medical devices already deployed. This investment is also a barrier to entry to new entrants to your market space and leverages investments in information technology design-history file systems. Design controls and the supporting data enable expeditious 510(k) and PMA filings. Once the initial investments have been made in the design controls process and systems, then subsequent product platform extensions can be made without the extensive additional regression testing that is required for each new product.

Q: What are the best methods by which to train personnel about design controls?

Singer: Quality and regulatory personnel should read 21 CFR 820.30, the preamble to the regulation, and FDA's guidance documents. They should institute a formal training program of lectures and online training in which comprehension of the requirements is measured. As part of the training curriculum, information about FDA priorities exemplified by FDA 483 observations and warning letters should be periodically disseminated. It is important to note that 21 CFR 820.25 requires that manufacturers establish procedures for identifying training needs and ensure that all personnel are trained to perform their assigned responsibilities. Document the existence of the training program and the fact that individuals are trained. To benchmark practices with other firms, key executives responsible for design controls should attend in-person seminars and listen to audioconferences.

Jones: At Philips, online electronic training covering design controls must be completed by every employee prior to being assigned to a design project. Team members are then assigned mentors and peers as they execute their design team responsibilities for their first medical device system or service project.

Q: Under what circumstances is it appropriate to contract out design activities?

Jones: The primary reason to outsource design activities is if they are not aligned with [the company's] core competencies, skills, and experience. System engineering and system integration need to become core competencies to integrate, test, verify, and validate all internally designed products that will be integrated with the outsourced design activities. Design controls can also play the key role in managing the system's architecture, which will define all of the design components, including hardware, software, interfaces, and systems.

Singer: Some firms with limited product lines don't want to make the investment in hiring the highly skilled people necessary to perform R&D. These firms can get a high level of expertise from subcontractors and use their services only when they are needed. It is also appropriate when the requirements are precisely specified and well understood.

Q: If design activities are contracted out, how can a device company ensure that proper design controls are being followed?

Singer: Under the purchasing controls regulation, 21 CFR 820.50, firms are required to select suppliers and consultants on the basis of their ability to meet specifications. Firms need to exercise oversight and maintain records of the suppliers adhering to the specifications. Firms should conduct annual or semiannual audits of organizations that they employ to do design control. If a firm does not have the expertise to perform the audits, it should contract this function out.

Jones: Certification to ISO 13485:2003 is considered the key requirement for subcontracted design activities to assure that design output can be used and integrated, without modification, for medical devices and services. Supplier quality controls are key for components being subcontracted.

Q: Which are the best metrics to evaluate the design process?

Singer: The survey sheds light on what firms are doing.

- 43% are using defect cause categories to define corrective actions.
- 34% are determining the time to market.
- 31% are comparing defects rates across different development projects.
- 24% are measuring the cost of poor quality.
- 29% don't use metrics to evaluate the design process.

Jones: In my experience, I have found that there is a direct correlation between a design team's defect injection rate, the in-house defect discovery rate and the actual defect rate seen by our customers. Your goal should be that your defect discovery rate ensures that you mitigate the opportunity for critical defects to be released to your customers. Thus, your routine quality monitoring needs to measure hardware and software event-rate metrics. It is a well-understood practice that shift-left defect identification and resolution is the most cost-effective way of addressing defects. In this case, defects are measured at each phase of the design control process and the average time to find and fix defects is found to be significantly shorter the earlier in the process they are addressed.

Q: Given the results of the survey, does industry need more education about design controls? If so, what aspects need the most attention?

Jones: The best way to share best practices for design controls is for industry representatives to share examples of case studies and current best practices at industry conferences and in professional journals. Design controls need to be robust enough to address the ongoing technical challenges in hardware, software, and systems in addition to business challenges. We continue to see medical device and diagnostics companies merge and partner together on different projects, each supporting a different design environment, all of which will need to work together seamlessly and harmoniously.

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