Tackling Compliance Reviews

Pressed for time, tight on resources, and eager to reach their target market wherever in the world it is, medical device manufacturers are embracing third-party compliance reviews. This exclusive report examines how several companies met their goals with a new program from Underwriters Laboratories.

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A company can save a significant chunk of time by choosing a third-party 510(k) review rather than submitting it directly to the FDA. Gil Bassak, a technical journalist with a BSEE from the City College of New York, is a former test engineer. The articles he has researched and written cover a wide range of topics within the computer, electronics, and manufacturing industries. Among the recent topics he has written about is the emerging use of microelectromechanical systems (MEMS) in medical devices. By Gil Bassak, Technical Editor Here’s an idea: At a time when product life cycles are shrinking, streamline the regulatory compliance process for medical device manufacturers, giving those vendors relatively fast access to the markets they seek, whether local or worldwide. Do it well, letting them focus on product development, and maybe even save them money. Like it? So apparently did Underwriters Laboratories Inc. (UL) when they announced just such a plan last June, dubbing it the Complete Regulatory Compliance Solution.

Okay, the name is a mouthful. But since UL rolled out the program, a comprehensive and flexible portfolio of compliance-related services, the offering has made fans out of firms ranging from such manufacturing giants as Fujifilm Medical Systems USA Inc. and Philips Medical Systems to smaller fish like NeoMedix Corp. and AccuTech LLC. “With the launch of the Complete Regulatory Compliance Solution,” says Harvey Rudolph, UL’s global program manager and one of the project’s prime architects, “manufacturers can quickly gain clearance for their products in markets such as North America, Europe, Japan, and Brazil.”

Indeed, feedback from customers such as Frank Gianelli, a regulatory coordinator for Fujifilm Medical Systems USA, Stamford, CT, suggests that UL has a hit on its hands. “So far, my experience of UL is that it has worked out very well. I’ve found them to be very flexible,” says Gianelli, who recently used UL as a third-party reviewer of terminals that go into the company’s PC-based digital radiography systems.

In particular, Gianelli was impressed with UL's ability to hand off work from an office that was maxed out to one that was available, regardless of where it was. "If we do a purchase order for them to review one of our 510(k)s, and the reviewers in that particular office can't do it right away, they automatically send it to another office. So, we always have a resource available, whether it is in North Carolina, New York, or California." *(For details on 510(k)s, see "Anatomy of a 510(k) Review.")* While trying not to sound like an advertisement for UL and its program, it must be said that what customers&#151at least those interviewed for this article&#151appreciate most is how easy UL is to work with and the high degree of technical expertise it makes available.

In the Beginning

The market for so-called third-party compliance reviews, a business opportunity that other test and standards houses besides UL are pursuing, was sparked by the decision of governmental regulators, such as the FDA, to authorize them. The regulators' impetus, in turn, has been to speed the compliance certification process and, presumably, shed some of their own workload.
To execute its program, UL has garnered authorization from a number of government agencies around the world. To date, it is authorized by the FDA to serve as an "accredited person" for performing 510(k) reviews, by Europe's Common Market to serve as a "notified body" through the CE marking process for the Medical Device Directive and Invitro Diagnostic Directive, by Canada's CMDCAS service through the Health Canada Therapeutic Products Directorate, by Japan's Ministry of Health and Welfare to perform testing and certification, and by Brazil's certification agency to qualify manufacturers for that country's Inmetro mark.

Also, because some certification requirements, notably those of the North American and European regulators, include the need to demonstrate that a vendor follows acceptable quality management practices, UL has sought and won accreditation to certify that a vendor complies with ISO 13485, the medical equipment counterpart to ISO 9000.

Part of the beauty of how UL crafted the program is not just in the fact that it offers compliance certification in any of those regions, but also that it does so in the manufacturer's native language and through a single point of contact. For medical device manufacturers, UL has indeed become a one-stop shop for regulatory compliance.

Manufacturers are engaging UL's complete regulatory compliance solution not just for its convenience but for the time, and sometimes the money, it saves them. Part of the time saved is simply the result of going to a third party rather than directly through the regulating body. In the U.S., for example, a company can save a significant chunk of time by choosing a third-party 510(k) review rather than submitting it directly to the FDA.

Specifically, citing the FDA's own published data, UL's Rudolph says that a 510(k) review for a "fairly simple device takes a total of 105 days if you go directly through the FDA compared to 74 days if you go through a third party and then on to the FDA." For a complex device, the numbers are 156 days going directly to the FDA and 83 days when going through a third party, a 46 percent time savings. These numbers are averages that, Rudolph says, UL usually beats in its third-party role.

An important bottom line benefit of such time savings for companies like Philips Medical Systems, Andover, MA, says Coleen Coleman, senior regulatory affairs specialist, is the ability "to take orders and get our product to the market quicker. It allows us to be more competitive."

The time savings counts more these days, when the pace of change for technology is fast. "We make a lot of PC-based equipment and things change rapidly," says Fujifilm's Gianelli. "When PC makers improve their hardware, you have to react and get things to market quickly." Toward this end, what Gianelli especially likes about third-party reviews is that he can get fast answers to questions. "I personally like the dialog. Probably there are certain kinds of products that we would still submit directly to the FDA, but once that's done, it is very difficult to set up a dialog with them."

Others agree. "The FDA is a bureaucracy and it can be difficult to deal with," says Madison Rogers, the quality assurance manager for AccuTech LLC, Vista, CA. "Sometimes you think things may have gone into a black hole." The company manufactures and sells over-the-counter cholesterol tests in the United States and Europe, as well as theophylline and C-reactive protein tests to clinics and doctors. Third-party reviews, he acknowledges, is the FDA's way of addressing the problem.

In addition, when a third-party review is well planned, savings in time and resources can accrue by streamlining quality management certification, says UL's Rudolph. For example, he notes that Canadian and European regulations for quality systems are similar, but not the same. By recognizing those similarities and differences for a client seeking certification for both, UL can perform one audit where others might do several. "Not only is the amount that we charge for time less, which manufacturers love," says Rudolph, "but we don't tie up key personnel with multiple audits, and that's a real savings."

A Certification Buffet

UL's Complete Regulatory Compliance Solution, to fulfill the claim of its name, builds on the company's ability to offer a smorgasbord of testing services, like those for electrical safety and electromagnetic compatibility. That was important to NeoMedix Corp., San Juan Capistrano, CA, which designs, develops, and manufactures electrosurgical devices for treating ophthalmic diseases, and which hired UL to perform third-party reviews for three different technologies as well as conduct electrical and safety testing on its units.
"We were looking for a company that would be able to do a third-party analysis of our 510(k)s, and UL is a very well recognized brand from a safety testing point of view," says Soheila Mirhashemi, NeoMedix's president and CEO. "We thought UL

would be a very good choice because they have the ability to take a technology through the complete regulatory process as well as assist with testing. Also their international recognition for safety certification was very significant to us."

Her choice seems to have been right. "We have had three 510(k) submissions approved and all safety and electrical tests cleared," says Mirhashemi. Does she have any complaints? Apparently, the cost was a little steep. "It would be beneficial if they would be more competitive in their pricing, which was relatively high compared to other companies.

The next goal, says Mirhashemi, is to take her products to the global market. For that, she says, "we have to get CE marking for the company's devices and ISO 9000 certification." Is she going back to UL for this? "Yes, we are very satisfied with the work they have done for us and look forward to many years of a growing business collaboration."

Weaving its vast resources and technical expertise and offering them in a way that simplifies its customer's life seems to be the final ingredient that has spelled success for UL's Complete Regulatory Compliance Solution. "When I first started here," says Annie Wright, a product safety compliance engineer for Philips Medical Systems, which builds nuclear medicine imaging machines, "we were working with some of UL's competitors and, if I had a problem, I had to make my case with an account manager, who more than likely did not have the technical expertise to discuss the project. The account manager then becomes an obstacle to deal with rather than someone who could provide the assistance I needed."

Now, Wright, herself a former staff engineer at UL, deals directly with the UL engineers whom she once worked with. "What I especially like about UL is its technical knowledge base and the fact that they have technical expertise in the field all around the world." Her fear, however, is that UL may be going the way of its competitors by having account managers handle its clients' technical concerns. "I realize the value in having administrative people, but I don't think they should be your main connection. It is definitely beneficial for manufacturers to work directly with engineers and project handlers with whom they have built a relationship. It creates a situation where the manufacturers can feel confident that who they are working with is not only familiar with their product line but are also aware of their specific circumstances and able to accommodate them."

ONLINE

For additional information on the technologies discussed in this article, see *Medical Design Technology* online at www.mdtmag.com and the following websites:

&#149 www.ul.com
&#149 www.fujimed.com
&#149 www.medical.philips.com
&#149 www.accutech-llc.com
&#149 www.neomedix.net

Sidebar 1 Anatomy of a 510(k) Review
Section 510(k) of the Food, Drug, and Cosmetic Act requires manufacturers to notify the FDA at least 90 days in advance of their intent to market a medical device. Called a premarket notification, PMN, or 510(k) review, this notification aims to show the FDA that the intended device is substantially equivalent to a legally marketed device&#151and specifically to a technology that has gone through the 510(k) process or that has been on the market since before 1976&#151in terms of its design, material, chemical composition, energy source, manufacturing process, and intended use. If it isn't substantially similar, then the vendor may need to conduct clinical trials to prove the device's safety and effectiveness.

A 510(k) review can be performed by the FDA or by an entity that it authorizes as an "accredited person," which performs a third-party compliance review. In either case, the review assesses what is called a submittal. According to Anil Patel, manager of UL's U.S. medical strategic business unit, "the submittal basically consists of information about the product, including its efficacy," so the specifics of the submittal depend on the device.

In addition, notes Annie Wright, a product safety compliance manager for Philips Medical Systems, the 510(k) review is intended to show that a product complies with federal regulations and that its manufacturer follows good quality management practices. For that reason, UL also offers ISO 13485 certification. Moreover, says Wright, although the 510(k) does not itself involve testing, "it provides references to testing that might be done by a third party, like UL." Indeed, notes UL's Patel, "not only can we review the submission for a client, if there are tests to be performed that need to be included in the submission, as a testing organization, we can do these too."

Sidebar 2 Statistics on UL Services
An independent, not-for-profit product safety organization headquartered in Northbrook, IL, Underwriters Laboratories Inc. has been testing products for 110 years. A leading provider of testing and certification services&#151the largest in the United States&#151its operations are worldwide, with locations in 71 countries spanning North and Latin America, Europe, and the Asia Pacific region. In all, UL's family of companies, affiliates, and service providers includes 60 laboratories and testing and certification facilities, which review more than 18,850 types of products annually. In one year, UL listing marks appear on more than 19 billion products.