Life & Health

# MEDICAL DEVICE Communiqué

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## The FDA Makes a Case for Quality

The US Food and Drug Administration (FDA) has taken its "Case for Quality" on the road, showing Medical Device companies how it plans to move forward in assuring quality and patient safety. The underlying theme of the new initiative is straightforward: compliance is no guarantee of quality. For Medical Device companies, for which the primary drivers traditionally have been regulatory compliance and operations, the FDA's quality initiative presents the need for change on multiple levels.

Steve Silverman has been one of the FDA's lead representatives in explaining the Case for Quality. As Director of the (Center for Devices and Radiological Health) CDRH's Office of Compliance, Silverman provides an ironic illustration of how entrenched the compliance culture has been in the Medical Device industry, even at the regulatory level. Notwithstanding the compliance focus that pervades the industry, Silverman's comments on the FDA's Case for Quality should give notice to Medical Device companies that the traditional compliance-centered approach is a poor substitute for a quality culture.

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# The FDA Makes a Case for Quality *(continued)*

## Making the Case

The FDA makes a straightforward case for the benefits of, and the need for, a quality culture. The benefits include gains – enhanced process stability that drives improved productivity and performance – and the reduction of compliance risks and costs. The best plants enjoy enhanced productivity and performance while being subject to fewer complaints and investigations.

Escalating quality risks drive the need for a quality approach capable of mitigating those risks. In its late-2011 report "Understanding Barriers to Medical Device Quality" the FDA shows just how risky the landscape is for Medical Device companies – and how uneven those risks are distributed. For example:

- Devices are increasingly complex and sophisticated, requiring more precise components, quality control, supply chain management and manufacturing oversight.
- Adverse events (AEs) are reported more frequently, outpacing overall industry growth by a wide margin. Between 2005 and 2009, the rate of reporting increased to 22% per year, with "serious adverse event" reports growing at a rate of 8% a year. In general, critical, life-sustaining devices are responsible for a growing share of adverse event reports; by 2009, Class III devices were associated with 40% of AEs.
- Recalls are increasing but the increase is not evenly distributed by root cause or product type. About 25% of recalls overall are due to manufacturing problems, but a breakdown of that overall number exposes particular risks for certain types of devices. 48% of the root cause for recalls of orthopedic devices is traced to manufacturing, with another 11% related to suppliers. General surgery devices showed 38% of recalls linked to manufacturing while 19% of recalls were traced to suppliers. Even within general therapeutic areas, significant variability was shown in the root cause of recalls. Recalls of catheter guide wires were due to a manufacturing problem while manufacturing accounted for only 8% of recalls for implantable cardioverter defibrillators.
- The increasing cost of quality failure is reflected in costs including lost sales, a reduced share of business segment revenue, and a notable drop in share price following major quality events. Product recalls, repeated FDA inspections and enforcement costs all add to the financial impact of quality failures.

## The FDA's Focus on Quality

In FY 2011, the FDA inspected 34% of registered, domestic Medical Device firms; during the same period, it inspected only 5% of foreign firms. The number of inspections conducted by the FDA cannot keep pace with the industry's expansion. The recognition that it can inspect only a portion of Medical Device facilities has forced the FDA to "... think about other ways to support quality," according to Silverman. That "other way" is the Case for Quality, which incorporates three initiatives: Focus on Quality, Enhanced Transparency and Stakeholder Engagement.

The Focus on Quality promotes quality practices, not just compliance. It contains several objectives for the Agency as well as the Medical Device industry. While the Focus on Quality applies, at least initially, to the FDA, Medical Device companies should expect the plan's elements to flow from the Agency to the entire industry.

In answer to "What is the Focus on Quality," Director Silverman listed the following:

- More focus on good company quality practices that lead to quality outcomes beyond compliance
- Regulatory emphasis on preventive quality practices
- Encouraging companies to view compliance as one part of achieving overall quality rather than the ultimate goal
- Identify and address the underlying causes of quality issues

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## The FDA Makes a Case for Quality *(continued)*

The FDA is already moving forward with the Focus on Quality. Initial activities by the Agency's quality team can be broken down into three areas:

1. **Communicate The FDA's Focus on Quality –** The FDA intends to communicate its focus on good quality practices, not just compliance, to begin an ongoing conversation with industry and other stakeholders as a way of driving implementation of the initiative, and to update FDA's outreach in order to change the too-common perspective in the industry that FDA investigators use a checklist approach to inspections.
2. **Put more emphasis on effectiveness and building-in quality –** The FDA's objectives are to update its compliance approach so that the Agency's efforts are focused on the effectiveness of corrective actions. The FDA also intends to shift its compliance focus away from quantity of QA resources to quality in product development.
3. **Promote root-cause approach –** The FDA will promote a focus at the Agency on root-cause analysis in compliance situations. Equally important, the Agency will unify its approach by developing internal root-cause training as well as a common language and approach.

The second element in the FDA's Focus on Quality centers on transparency. The FDA's transparency initiative is designed to answer the basic question, "How can FDA act to ensure that stakeholders incorporate differentiating quality data into their decisions?" The answer is provided in two parts. Under the general heading of "enhanced transparency", the FDA aims to improve access to information through one integrated data source. The FDA will also provide consistent, predictable analyses of compliance data to support device quality improvements.

The final element of the Focus on Quality is stakeholder engagement. The FDA has embarked on a stakeholder engagement initiative to enhance communication among stakeholders. Multiple engagement touch points between the FDA, industry and other stakeholders have been and will be developed to more effectively communicate the FDA's expectations and solicit input from each group on necessary changes. In addition, the Agency will conduct a change-management program to change potential mindsets and cultures in order to promote optimal quality practices. Finally, to support the initiative and monitor its impact, the FDA will develop a project management structure.

Industry representatives have already had a role in the development of the FDA's quality initiative, initially by giving input about the obstacles to assuring consistent quality for medical devices. More input can be expected as the FDA integrates the program's goals into its own organization and perspective – and then lets its new approach and tools flow out to the industry as a whole.

## Facilitating Entry to Global Markets

Completing the research and development of a medical device should be a cause for celebration. Instead, many companies face a lengthy, frustrating approval process – not just once but for multiple markets that impose their own unique approval requirements.

UL's Global Market Access (GMA) program provides one test plan that allows companies to certify their products for entry into new markets. No company has earned greater credibility for the integrity of its own mark. Now, that credibility serves Medical Device companies in the following ways:

- UL is accredited to provide Marks recognized around the world. With just one product submission, companies receive multiple market-specific marks of safety indicating product compliance with local and global regulations as well as industry standards

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## Facilitating Entry to Global Markets *(continued)*

- UL can facilitate submissions for global regulatory approvals in jurisdictions including:

  **United States:** As an FDA-Accredited Person, UL can submit 501(K) for review

  **Japan:** UL assesses certain medical devices for Japan regulatory approvals and integrates the Japan Quality requirements into your company's ISO 13485 audit

  **Europe:** UL serves as a Notified Body for the Medical Device Directive (MDD) and In Vitro Diagnostic Directive (IVDD) audits and technical file assessments

  **China:** UL is experienced in regulatory submissions to China's State Food and Drug Administration (SFDA)

- Companies can meet global quality system requirements through UL's integrated ISO 13485 and ISO 14971 Registration services.
- The UL-EU Mark is a new, pan-European Mark for global certification registration, providing access to Europe, Canada and the US with a single mark. The UL-EU Mark is the first transcontinental mark available in UL's portfolio of market-leading certification marks and is the first and only European mark that can be combined with certification for the North American market.

### Credibility and Impartiality

Although many companies offer services related to medical device approval and registration, no firm has greater credibility than UL. UL places the utmost importance on the integrity and impartiality of its management system certification activities and the trust it conveys to clients, their customers and the public at large. The principles inspiring this confidence include impartiality, competence, responsibility and confidentiality. The same principles that infuse UL transfer to the products they test and certify.

## Globalization Risks and Rewards

Axendia conducted a survey of 125 Medical Technology industry executives to gauge the effects of globalization and outsourcing on the industry. The executives represented 89 different companies.

Some of the most interesting findings from the study include what keeps executives "... up at night."

1. The quality of products, raw materials or services provided (60%)
2. The ability to maintain consistent quality standards across internal and external sites (59%)
3. Protecting the company's intellectual property

The research shows that executives are keenly aware of their risk exposure in specific areas, especially the complexity and cost of compliance in a global regulatory environment. 65% of the surveyed executives see the global regulatory environment as the top business threat over the next 3 years.

The findings of the Axendia study echo what we hear from our clients and industry experts. The number and complexity of global regulatory requirements are escalating rapidly. At the same time, companies are outsourcing more functions and relying on suppliers to maintain quality and consistence of their products. Training is a significant issue, not only in quality topics but also in strict regulatory requirements and even non-quality related issues such as anti-corruption laws and rules.

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## Globalization Risks and Rewards *(continued)*

A common refrain from our clients is the need for trust – between manufacturer and supplier as well as between regulatory agency and industry members. The stream of product recalls has chipped away at the trust of consumers and regulators, forcing companies to intensify their attention to quality even when there are no evident problems. Proactive audits, consistent oversight of internal operations and supplier operations, reinforcement of corporate commitment to quality, and adequate resources for the quality unit are all essential elements in protecting a company's brand, its bottom line and its customers.

### *What keeps you up at night?*

**65%** **Biggest Business Threat:** Global Regulatory environment (cost and ability to comply)

**60%** Quality of product, raw material or service provided

**59%** Maintaining quality standards across internal/external sites

**49%** Protecting intellectual property

### Senior Executives' Perspective

**69%** Global regulatory environment is biggest threat over the next 3 years

**67%** Developing a medical device platform to meet multiple customers' needs and cost constraints is a high priority for developing markets

**72%** Globalizing to improve the rate of product innovation

***Innovation continues to be the industry's lifeblood.***

*Industry executives expect to see strong product R&D growth to support new product introductions in both developed and emerging markets.*

### *What level of visibility would you like with key suppliers?*

**90%** Real-time and on-demand data for Critical Suppliers, Contract Manufacturers and other Tier 1 suppliers

### Visibility

**68%** Perceived risk based on access to current information for critical suppliers is moderate to high

**50%** of large organizations still rely on paper and homegrown systems to achieve global visibility

*"Poor visibility" isn't always due to a lack of technology systems. In fact, it is due to having too many ineffective systems.*

Source: Axendia. Based on Axendia Med-Tech survey respondents.

## About UL

UL (www.ULEduNeering.com) is part of UL LLC, a global independent safety science company offering expertise across five key strategic businesses: Product Safety, Environment, Life and Health, Knowledge Services and Verification Services.

UL develops technology-enabled knowledge solutions for helping to assure regulatory compliance and helping to improve business performance. For more than 30 years, the company has served corporate and government clients in the Life Science, Health Care, Energy and Industrial sectors using our award-winning learning management platforms, unique regulatory and business content and professional services.