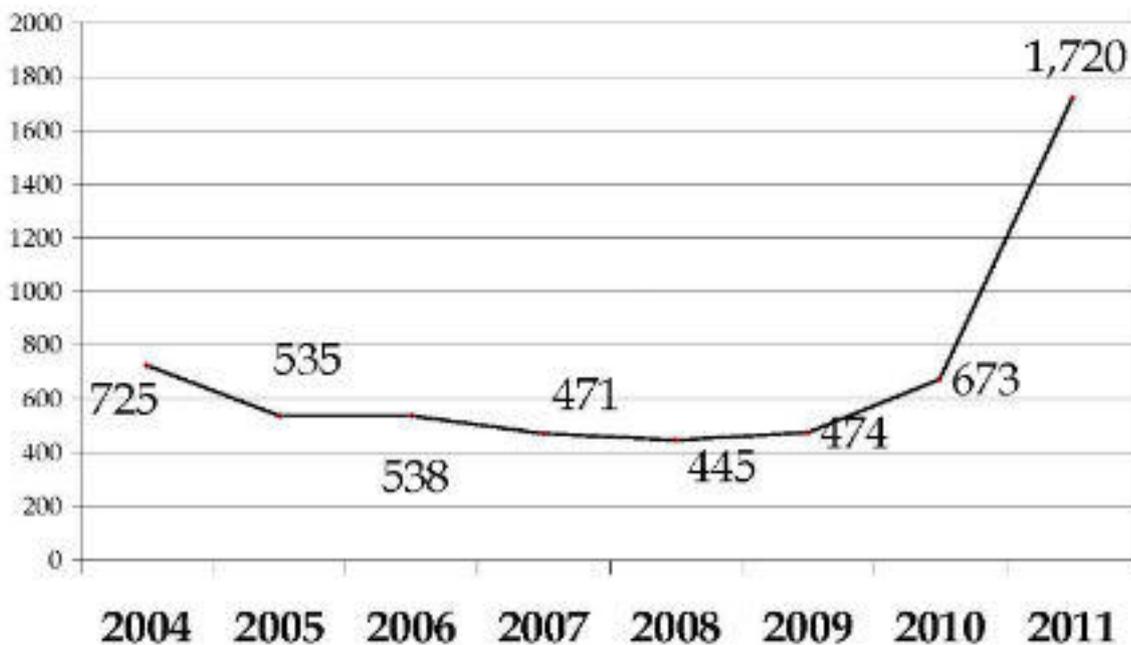


## **Renew Focus on Quality in Medical Device Manufacturing**

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### FDA Warning Letters Fiscal Years 2004 - 2011



The Global Harmonization Task Force (GHTF) was founded in 1992 to respond to the growing need for international harmonization in the regulation of medical devices. For 20 years, the group included regulators and industry leaders from around the world. But when the GHTF disbanded in late 2012, the leading voice for quality management in the worldwide medical device industry fell silent.

One thing has become clear since then: Regulators are doing their jobs quite well, if the volume of inspections and warning letters they're producing is any indication.

Meanwhile, the professional organizations representing the medical device industry have provided little guidance to their members on how to build cultures of quality in their organizations and avoid regulatory compliance issues. The disbanding of the GHTF created a deep chasm between the medical device industry and its regulators. So far, no professional association has stepped up to fill the gap

appropriately. That has to change.

Leadership and guidance is desperately needed in the medical device industry, which is changing quickly due to globalization, increased competition, cost constraints, demands for efficiency, development of international regulation, supply chain complexity, and product/process complexity. In this fast-changing environment, the people and companies that learn to adapt will prosper. But just knowing the regulations, following the standard operating procedures (SOPs) and focusing on compliance will not be enough. Successful companies need to develop high-calibre quality and technical professionals throughout their organizations—not just in traditional quality assurance roles. To succeed, we must all understand how to interpret international regulations, understand processes and product technologies, make sound decisions about quality, facilitate change, and drive business benefit. But who will help industry refocus its efforts on quality?

### **Quality vs. Compliance**

While regulators are understandably focused on compliance, industry needs to focus on quality. The terms are often used interchangeably, but there's a big difference between quality and compliance. Think of quality as the processes, procedures, and culture that permeate an organization—enabling it to consistently develop and produce high-quality medical device products that will meet or exceed regulatory requirements. Quality is everyone's job, from production floor workers to senior executives. Compliance, on the other hand, is a function that demonstrates and documents the quality of an organization's processes and products. You can have quality without compliance, but you can't have compliance without quality.

Another way of looking at it: Compliance deals with the symptoms of a problem. Quality deals with the problem itself. Regulators naturally are concerned with compliance while medical device manufacturers—ideally with the support and guidance of professional organizations like the Chartered Quality Institute (CQI), Regulatory Affairs Professionals Society (RAPS), and The Organization for Professionals in Regulatory Affairs (TOPRA)—must focus on quality as well as compliance.

### **New Regulations Require Identification of a Qualified Person**

Adding to the urgency to refocus on quality, the European Commission recently worked with regulatory agencies to update its directives and publish new proposed regulations. One of the changes would require a Qualified Person (QP) to be responsible for regulatory compliance in medical device and active implantable medical device manufacturers' organizations. This would include ensuring:

- Conformity of the devices is appropriately assessed
- Technical documentation and the declaration of conformity are up to date
- Reporting obligations in accordance with Articles 61 to 66 are fulfilled

Starting this September, the NSF International Health Sciences division will offer the only University-accredited work-based diploma in quality assurance and regulatory affairs (QA/RA) for the medical device industry. This post-graduate certificate can

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also lead to an MSc in medical device quality and regulatory science at Sheffield Hallam University. The diploma provides medical device professionals with the knowledge, tools, and techniques needed to manage the many aspects of worldwide QA/RA. A medical device diploma like this is a mechanism for developing Qualified Persons in the medical device industry, demonstrating QP compliance, and meeting regulatory requirements. But this training program—as useful as it will be—will not solve the industry’s quality issues. Only an active collaboration between professional organizations like the Chartered Quality Institute (CQI), industry, and regulators will address the quality management issues at hand.

### The Solution

Professional organizations need to step up and take a more active role in cultivating quality in the medical device industry. While the GHTF is gone, that shouldn’t stop the appropriate professional organizations from reestablishing quality work groups, starting a new dialogue with regulators, and developing new guidance for manufacturers. If nothing else, one or more professional organization should take the following steps:

- Develop an industry-wide awareness program about the importance of quality management and developing a corporate culture of quality in manufacturing organizations.
- Reestablish industry collaborated work groups to address regulatory, quality, and clinical issues.
- Develop a robust training, education, and competency framework for future quality professionals in the medical device industry.

Now more than ever, someone or some organization needs to take a leadership role and help the medical device industry re-focus on quality. The only question that remains: Who will it be?

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