What's Behind Medtech's Recall Epidemic?

Medical device recalls hit an all-time high in 2014, and nearly a third of manufacturers experience multiple recalls for similar reasons.

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Since the release of the 1970 Cooper Committee Report documenting thousands of deaths and serious injuries related to the use of medical devices, FDA has taken a focused approach in its microscopic tracking of medical device adverse events and recalls. The agency's efforts culminated in the October 2014 issuance of the guidance *Distinguishing Medical Device Recalls from Medical Device Enhancements*. As advancements in technology have provided FDA with greater resources to compile and communicate data to industry and consumers alike, reports of events like those first demonstrated in the Cooper Report have become more frequent and progressively alarming.

At the end of 2006, FDA communicated a staggering set of data to the medical device community. A calendar year's worth of agency data was conclusive in attributing 116,000 injuries, 96,000 malfunctions, and 4500 deaths to the use—or, in this case, misuse—of medical devices.[1] Further analysis released in 2012 in the *Medical Device Recall Report FY 2003 to FY 2012* reported a 97% increase in recalls from fiscal year (FY) 2003 (604 total) to FY 2012 (1190 total).

Recent analysis conducted for this article used CDRH's recall repository to collect data and evaluate trends in both voluntary and involuntary recalls established between January 2010 and December 2015. The product of this evaluation demonstrates an average of approximately 2600 recalls annually, according to ongoing analysis of medical device recalls provided by Blue Lynx Consulting (Figure 1). The data also specifies a progressive yearly occurrence rate, with trending indicating an upward swing in the following root causes as identified by the agency: device design, software controls, and production controls.

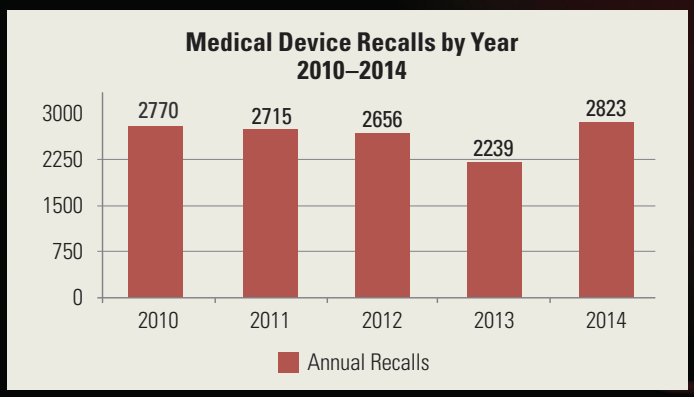

Figure 1. There were an average of approximately 2600 medical device recalls each year from 2010 through 2014.

This article explores the specific recalls, hazardous situations, trends, and possible mitigations related to each of the three root causes FDA directly correlated to a five-year upward trend in medical device recalls (Figure 2).

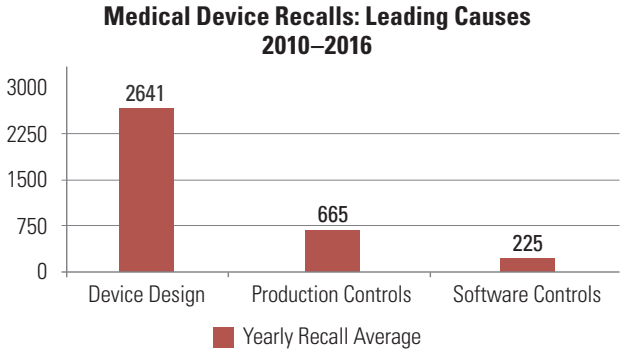

Figure 2. Device design, production controls, and software controls are the leading causes of medical device recalls.

Device Design

Since 2010, issues with device design have accounted for nearly 35% of all recall root causes determined upon firm or FDA investigation. Included in this analysis are root causes determined to be directly correlated to subcategories of device design, such as component design, labeling design, packaging design, process design, and software design. While the five-year analysis of design-related recalls does not necessarily demonstrate a consistent upward trend, the mean number of recalls per year documented in this investigation hovers well above 900, indicating continued recall problems across multiple medical device companies and platforms.

In addition to being the most prevalent cause of medical device recalls, recalls related to device design are also the most likely to cause serious health problems or death to the end user. Recalls correlated to device design encapsulate close to 46% of the five-year total of Class I recalls, with a 303% increase between FY 2013 and FY 2014, according to analysis by Blue Lynx Consulting. (Note: 2015 data provided by FDA is incomplete, therefore growth between 2013 and 2014 was the latest information available at time of press.)

Despite the proliferation of more complex guidance documents such as the agency's 2002 *General Principles of Software Validation*, the upswing of death and serious injuries related to design issues continues. As evidenced by the upward trend of recalls and the multiplicity among those companies that experience recalls for the same reasons annually, it is clear that device companies still struggle to identify proper mitigations for the reoccurrence of these hazards. Information collected from the agency's database by Blue Lynx Consulting shows that 30% of device companies that instituted a recall for device designs in 2010 were once again opening recalls in 2014 for similar reasons.

Why Do Design-Related Issues Reoccur?

As demonstrated by Figure 3, companies have struggled immensely over the past five years in their attempts to mitigate recalls derived from elements of device design. Specifically, manufacturers struggled most profoundly in the areas of labeling design, packaging design, and process design.

Although each of these subcomponents can be tied back to device design, their unique complications should be viewed as impediments for the mitigation of the remaining failures and hazardous situations. While each of these areas of device design comes with associated regulations, guidance, and standards, the current reactive state of medical device companies does not allow for continuous growth over a wide variety of situations where the issues are both unique and complex.

It is logical to attribute the fluctuation of these recall issues to companies that are unable to mitigate every known issue at once. When a company focuses on curbing growth of one type of recall, they are simply "launching the seeds" for the next upward trend in another area.

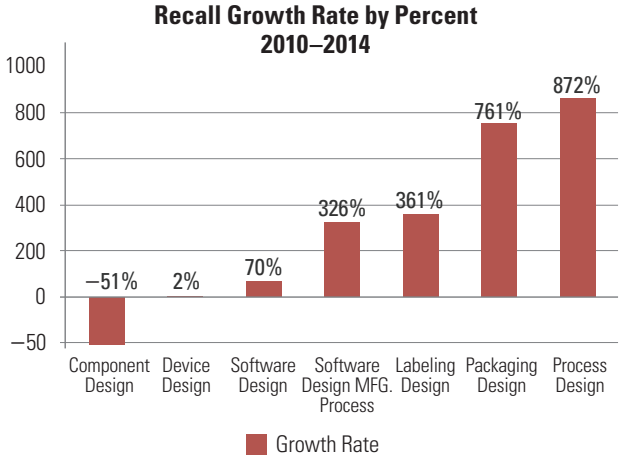

Figure 3. Process design, packaging design, and labeling design have proved challenging for medical device manufacturers.

Software Controls

Much like the Cooper Committee legislation of 1970, both FDA's Safe Medical Devices Act of 1990 and the 1996 Quality System Requirements were prompted into legislation by a set of tragic events related to the use of medical devices. Between 1985 and 1987, cancer patients undergoing radiation treatment via the Therac 25 Accelerator device were given massive overdoses of radiation due to a concurrent programming error in the device's software.[2] The incident, thought of as the worst series of radiation accidents in the 35-year history of the technology, resulted in six adverse events, including multiple instances of severe burns, irreversible limb paralysis, and, catastrophically, the death of two patients.

While the Therac 25 tragedy brought to light the dangers of software-controlled medical devices and prompted health authorities to establish more stringent regulatory controls regarding the design, validation, and manufacture of software, the continuing advancement of technology coupled with a reactive industry model has led to a vicious cycle of exciting progress followed by an equal and even more frustrating regression.

Between January 2010 and December 2015, there were an average of approximately 225 software-related recalls annually, accounting for nearly 8% of the total recalls during that time, according to Blue Lynx Consulting. There was also a progressive yearly occurrence rate, with trending indicating an upward swing in the following root causes as identified by the agency: software change control, software manufacturing process design, and software design.

Software-related recalls are also rising steadily, accounting for a 111% cumulative increase since 2010. Unlike other root causes of device issues, software-related recalls are unique in the sense that each of the three subcategories has also shown a steep and steady growth. As demonstrated in Figure 4, software design, software change control, and software process design have each shown an implausible upward trend over the past five years.

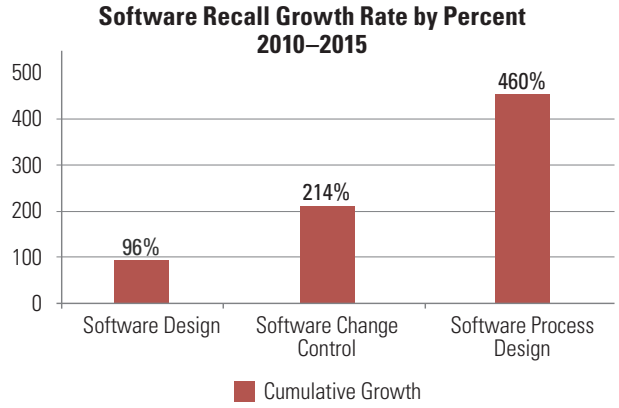

Figure 4. Recalls related to software design, software change control, and software process design have been on the rise.

Even after the industry has had ample time to digest guidance documents such as FDA's 2002 *General Principles of Software Validation*, the upswing in death and serious injuries related to design issues continues. As evidenced by the upward trend of recalls and the multiplicity of companies that experience recalls for the same reasons annually, it is clear device companies still struggle to identify proper mitigations for the reoccurrence of these hazards.

Why Do Issues Related to Software Controls Reoccur?

While software-controlled devices predate the 1976 Food, Drug, and Cosmetic Act that officially expanded FDA's scope of jurisdiction to cover medical devices, the ever-escalating complexity of software technology continues to be a challenge for health authorities. As evidenced by the release of both the 2002 *General Principles of Software Validation* and 2005 *Content of Pre-Market Submission for Software Controlled Medical Devices* guidance documents, FDA has initiated "ongoing efforts to state their recommendations more clearly and ensure they remain current as technology advances." In addition, 11% of FDA's planned draft guidance documents for 2016 are specific to the topic of software.

Despite FDA's best efforts to stay ahead of technological complications posed by an influx of intricate software-controlled devices, analytics of recall trends related to software continue to demonstrate a disconnect between the availability of guidance and risk information to manufacturers, and the ability of those manufacturers to actually mitigate issues.

It is apparent that FDA is investing considerable time and effort in trying to reduce device problems and recalls; it is also clear that regulations for manufacturers incorporating risk management have been in place for several years. What is not clear is how device manufacturers are implementing these requirements. Therefore, we must again ask whether the information provided in this article indicates a problem that is more behavioral than technological.

Production Controls

When you take into consideration that elements of the manufacture and servicing of medical devices make up nearly a quarter of the controls set in place by FDA's 21 *CFR* 820 Quality System Requirements, it comes as no surprise that recalls related to these same controls make up 24% of all recalls since 2010, according to Blue Lynx Consulting.

While the controls set forth by FDA in the 1978 Food, Drug, and Cosmetic Act (amended in 1990 to include design controls) were aimed at providing consumers with safer and more effective products, recalls related to production controls have accounted for an average of 665 recalls per year since 2010, with an annual growth rate of 11% percent over the same five-year span, according to Blue Lynx Consulting.

In comparison with the astronomical growth rates of the other two leading causes of medical device recalls, those related to production controls are growing at a much slower rate, according to Blue Lynx Consulting's analysis. But while some members of industry may view this as a positive, production controls continue to be the second leading cause of medical device recalls on a yearly basis. Furthermore, the year-to-year fluctuations of both production control recalls and their subcategories demonstrates the inability of industry to adequately control these recalls and set into place the proper mitigations to prevent their growth. Specifically, the giant swings in areas of production controls like errors in labeling and packaging (Figure 5) exhibit industry's inability to control adverse events in areas of business that should be easy wins.

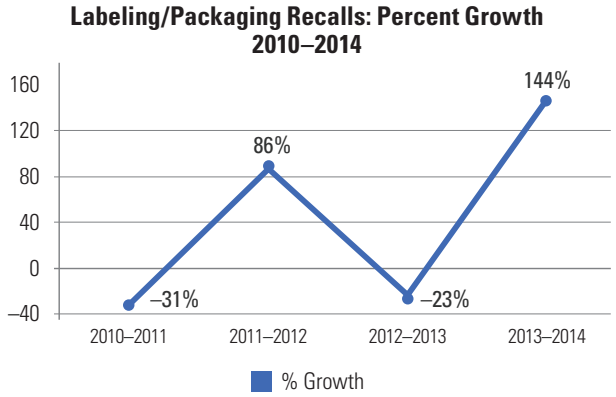

Figure 5. There have been huge swings in areas of production controls such as errors in labeling and packaging.

Why Do Issues Related to Production Controls Reoccur?

While the fluctuations in yearly growth percentages related to production control recalls may be vast, three failure modes consistently account from more than 65% of all manufacturers' recalls of the same category. Specifically, recalls related to process controls, packaging, and packaging controls made up an average of 68% of all production control recalls from 2010 to 2015, with bookend highs coming in 2010 (77%) and 2015 (76%).

As a result, any hope the medical device industry has of stemming future issues related to production controls must begin with a tactical plan aimed at reducing the hazards associated with these specific failure modes and working outward throughout the year without losing focus on other known issues that are potentially harmful to both the business and end user.

Conclusion

Throughout this article, the statistical evidence has demonstrated that issues that result in medical device recalls do not only reoccur; the existence of the reoccurrence points to a more severe and altogether disconcerting problem. When more granular analysis is applied to the reoccurrence of these adverse events, evidence unveils industry's inability to demonstrate year-to-year control over its products.

Sadly, the history of the medical device industry parallels Newton's Third Law of Physics. For every Cooper Committee, there is a Therac 25 tragedy; for every 21 *CFR* 820, there is a Super Bug outbreak. The question remains: Does it have to be this way?

It has been more than 75 years since U.S. lawmakers explicitly recognized the safety challenges posed by medical devices and included them as a distinct category of products regulated by the Food, Drug, and Cosmetic Act of 1938. Since the establishment of this early legislation, the risks related to medical devices and their ever-expanding technologies have come to fruition despite FDA's efforts to provide industry with a set of proactive tools for mitigation. Despite the availability of information and legislation born from FDA-sanctioned committees like 1970's Cooper Committee and an influx of device regulations promulgated by the agency in the 1990s, medical device recalls reached an all-time high in 2014 (2823 recalls).

While it is apparent that FDA is investing considerable time and effort to reduce device issues and recalls, the upward trend related to recalls appears to point to a disconnect between the efforts of the health authority and manufacturers' ultimate understanding of mitigation strategies. To fully understand this disconnect, consider the following: Between January 1, 2010, and December 31, 2015, FDA released 183 draft and final guidance documents related to the life cycle management of medical devices. In that same time period, Class I recalls grew at an annual rate of 29%, topping out in 2014 with 543 total recalls.

Given the plethora of information health authorities provide medical device manufacturers, it seems unfathomable that those same manufacturers would have multiple recalls in a five-year span. However, as our research demonstrates, 30% of manufacturers experiencing field actions in 2010 were once again opening recalls for similar product issues within the next five years. With first-quarter 2016 recall numbers peaking above the industry horizon, early averages show a recall epidemic that has the ability to grow another 2% over final returns from 2015. These returns, coupled with the five-year upward trend of adverse events, beg the question: Why do these problems keep reoccurring?

In response to this confounding query, global health authorities have spent the past five years placing a greater emphasis on the use of risk management in the medical device total product life cycle. With the institution of safety assurance cases from FDA for infusion pumps and the more recent revision to ISO 13485, health authorities and standards associations alike have provided industry a foundation aimed at integrating risk management throughout the product's life cycle, including playing a larger role in quality management system processes. Still, the efforts surrounding a more mature and holistic version of risk management have done little to stem the tide of this recall epidemic.

As such, research conducted regarding industry's view of risk management points to a problem more rooted in culture. A 2011 survey of risk management professionals reported that many individuals involved with risk management had a relatively shallow understanding of the tools and techniques available to aid in their risk management initiatives.[3] It also found that risk management was viewed as a necessary evil; one group of participants (16 out of 46) suggested that organizations do not know how to tie risk management into the elements of a quality system. This information, when coupled with health authorities' proliferation of guidance to aid manufacturers in their fight against adverse events, uncovers a more viable truth: The reactive behavior of manufacturers is a massive contributor to their unmitigated failures.

In a February 29, 2016, article for the *Harvard Business Review*, Francisco Poliodoro tackled a similar question in response to business failures at U.S. space agency NASA and global oil and gas company BP. While each organization had experienced catastrophic events leading to the deaths of employees and the loss of millions of dollars, they were unable to introduce the proper controls to prevent reoccurrences. BP, for example, experienced two large oil disasters within five years of each other, leading to the death of 26 workers. The second of the two events, 2010's explosion of the Deepwater Horizon oil rig, caused an oil spill of epic proportions, leading to severe long-term environmental effects in the Gulf of Mexico. The company also suffered huge losses, including multiple public protests by consumers and an $8 billion loss of funds in a court settlement.

Analogous to what is happening in the medical device industry regarding reoccurring recalls, both NASA and BP were provided with the foresight to produce a proactive culture to ensure safer and more effective business practices. However, as Poliodoro pointed out, "safety-related behaviors fade over time and other motivating forces come to the fore, gradually launching the seeds of the next error."

If you consider the current issues facing medical device manufacturers in parallel with Poliodoro's theory regarding the reoccurrence of adverse events being tied to behavioral issues—or, in this case, a company's inability to disengage from the reactive cycle and learn from both the knowledge afforded it by health authorities and its own past failures—it is clear that the main impediments to the reduction of adverse events are the companies themselves.

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