IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY | an informa business
Unlimited Validation Knowledge Awaits...
Published on *IVT Network* (http://www.ivtnetwork.com)

Recall Epidemic 2010-2015: Medical Devices

Jul 27, 2016 7:00 am EDT

Peer Reviewed: Medical Device

1. Introduction

Beginning with the 1970 Cooper Commission Report (Cooper Commission, 1970) documenting thousands of death and serious injuries related to the use of Medical Devices, the Food and Drug Administration (FDA) has taken a focused approach in their microscopic tracking of medical device adverse events and recalls, culminating in the October 2014 issuance of the guidance *Distinguishing Medical Device Recalls from Medical Device Enhancements.* As advancements in technology have provided the agency 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 conclusion of 2006, the FDA communicated a staggering set of data to the Medical Device community. A calendar year of agency data was conclusive in attributing 116,000 injuries, 96,000 malfunctions, and 4,500 deaths to the use, or in this case misuse, of medical devices. (Johnson, 2012). Further analysis released in 2012 in the *Medical Device Recall Report FY, 2003 to FY 2012* reported a 97% increase in recalls from the fiscal year (FY) 2003 **(604 total)** to the FY 2012 **(1,190 total)** (CDRH, 2012).

A recent analysis, conducted as part of this research, used the FDA's Center for Device Evaluation and Radiological Health's (CDRH) 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 2,600 recalls annually **(See Table 1: Recalls by Year 2010-2014 for Raw Data)** (Blue Lynx Consulting, 2015). The data also specify 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.

Initiated here with device design and concluding with production controls, this writing will explore the specific recalls, hazardous situations, trends, and possible mitigations related to each of the three root causes that FDA directly correlated to a five year upward trend in medical device recalls.

2. Device Design

Since 2010, issues with device design have accounted for nearly thirty five percent 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 nine hundred, indicating continued recall issues across

multiple medical device companies and platforms.

In addition to being the most prevalent cause of medical device recalls, device design related recalls are also the most likely to cause serious health problems or death to the end user. As defined by the Agency, Class I recalls are ones in which "dangerous or defective products predictably could cause serious health problems or death." Recalls correlated to device design encapsulate close to **46%** (Blue Lynx Consulting, 2015) of the five year total of these dangerous Class I types, with a **303%** (Blue Lynx Consulting, 2015) growth between **FY 2013 and FY 2014 (See Table 2: Device Design Related Class I Recalls 2010-2014 for Raw Data)** *(note: 2015 data provided by the FDA is incomplete, therefore the growth between 2013 and 2014 is the latest information available.)*

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 which experience recalls for the same reasons annually, it is clear device companies still struggle to identify proper mitigations for the reoccurrence of these hazards. Information collected from the Agency's database shows **44%** (Blue Lynx Consulting, 2015) of device companies who instituted a recall for device designs in 2010, were once again opening recalls in 2014 for similar reasons.

2.1 Why Do Issues Reoccur?

To understand why companies struggle with device design, it is imperative to recognize the various elements of device design and where companies continually fall short. In correlation with the upward trending of device design recalls, medical device manufacturers have failed consistently to mitigate hazards associated with component design, labeling design, packaging design, process design, and software design. Each of these sub components of device design has seen a drastic upward trend in related recalls over the last five years, with only component **(-51%)** and **(+70%)** staying under a 100% growth rate average over the same five year span.

As demonstrated by **Table 3: Recall Growth by % 2010-2014**below, over the last five years companies have struggled immensely in their attempts to mitigate recalls derived from elements of device design, specifically these manufacturers struggled most profoundly in the areas of labeling design **(+361%)**, packaging design **(+761%)**, and process design **(+872%). See Table 4: Device Design Related Annual Recalls by Subcategory 2010-2014 for Raw Data**

Although each of these sub components can be tied back to device design, their unique complications should be seen as impediments for the mitigations of the remaining failures and hazardous situations. While each of these areas of device design come 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. As noted in Francisco Polidoro Jr.'s 2016 Harvard Business Review article "Why Do Organizations Forget What They Learn" *"The occurrenceofaseriouserrorsuchasashuttleexplosion,alarge-scaleoilspill,orasafety-relatedproductrecall triggersthelearning cycle. It stimulatesanorganizationtoemphasizesafety asaprimaryconcern,asitseekstoidentifytherootcausesandtomakethe corresponding correctionsinitsprocesses,structureandculture.Theproblemisthatthesesafety-related behaviorsfadeovertimeand othermotivatingforcescometothefore,graduallylaunchingthe seedsofthenexterror."* Using this ideal in the context of a company or industry facing multiple complex challenges concurrently, it is logical to attribute the fluctuation of these recall issues to companies who are unable to mitigate every known issue at once. This is to say when a company or industry focuses heavily on an upward trend of one issue, they are simply "launching the seeds" for the next upward trend in another area.

While the information and technologies available to the medical device industry have grown exponentially since the days of the Cooper Commission, analytics of recall trends related to device design demonstrate a disconnect in the parallel between availability and use. Does the information provided as part of this writing point to a problem that is more behavioral than technological? One has to wonder if the Cooper Commission was conducted at present day, would it drive additional reform in the area of device design based on the reoccurring number of recalls and complaints. As we move into the next part of this series, we will focus heavily on the recall trends related to software controls, and further explore the questions surrounding how medical device companies can counteract the current negative trends.

3. Statistical Evidence- Graphs

Table 1. Recalls by Year 2010-2014

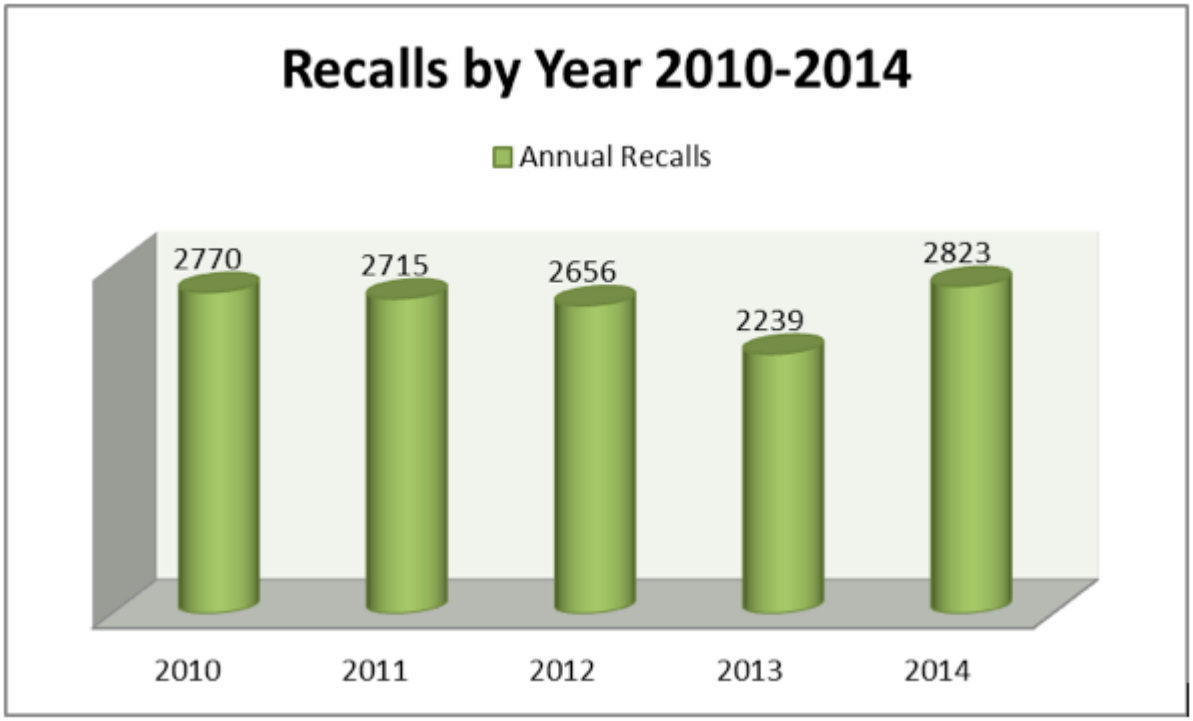


Table 2. Device Design Related Class I Recalls 2010-2014

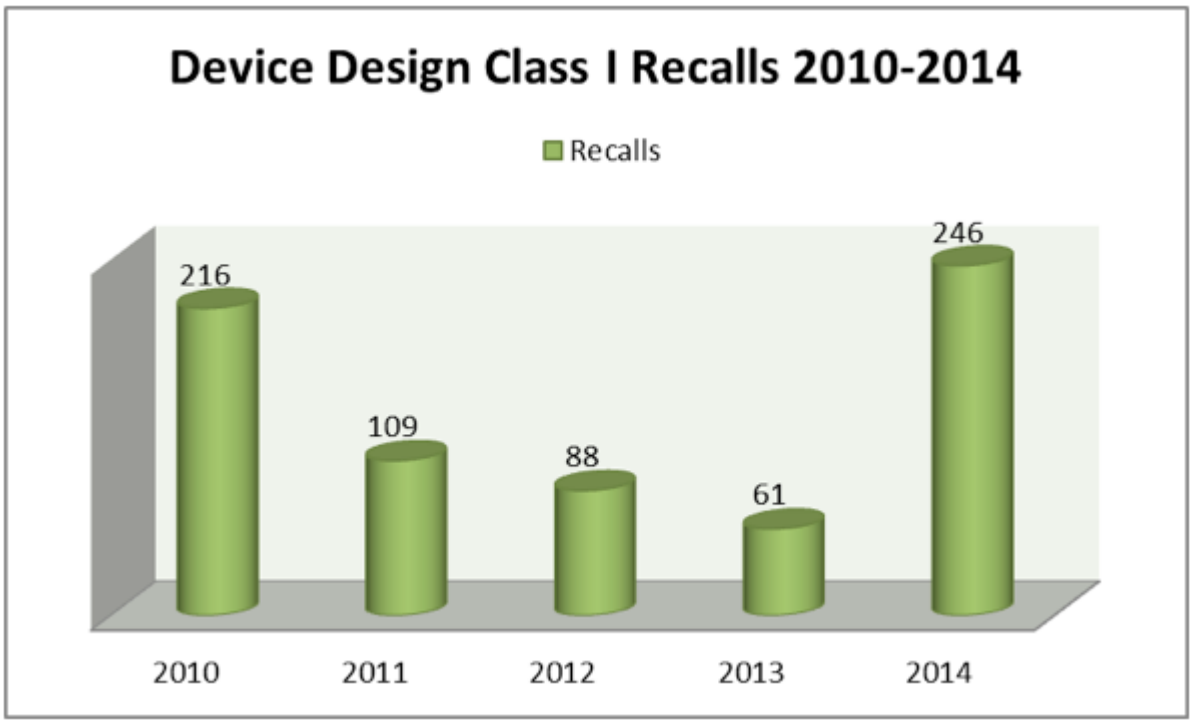


Table 3. Recall Growth Rate % 2010-2014

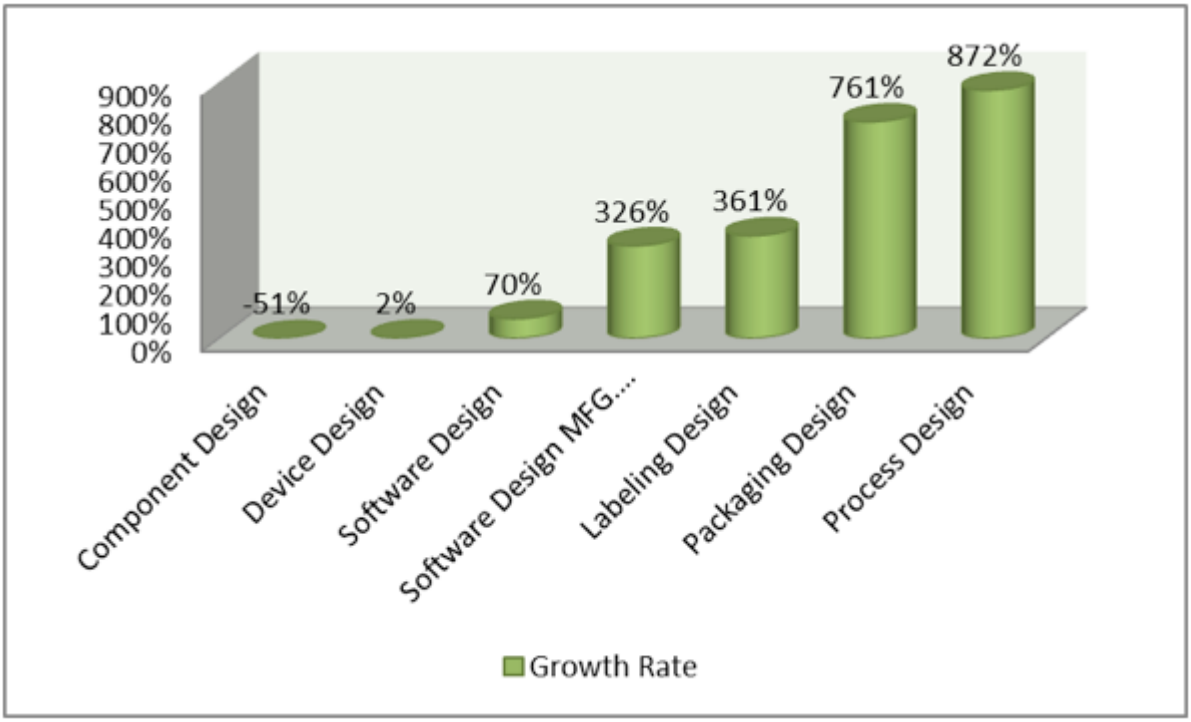
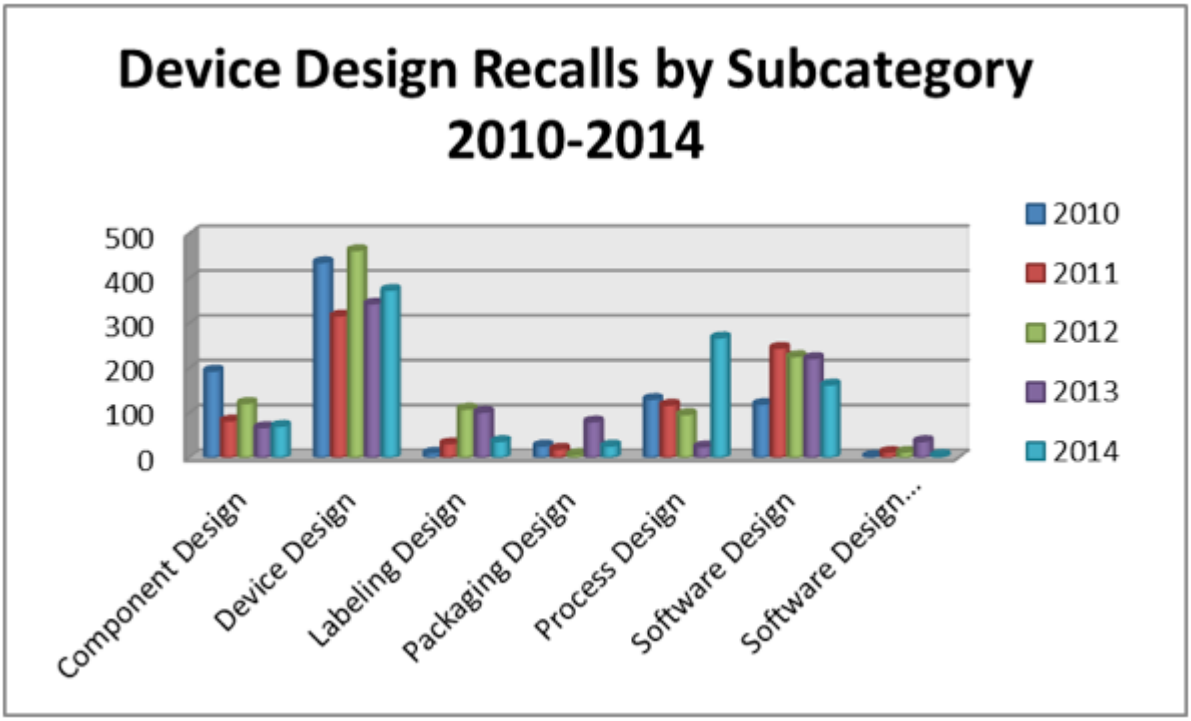


Table 4. Device Design Related Annual Recalls by Subcategory 2010-2014



References

1. Cooper Commission, Medical Devices, A Legislative Plan, September 1970/
2. Johnson, J. A. (2012). *FDA Regulation of Medical Devices*. Retrieved from https://www.fas.org/sgp/crs/misc/R42130.pdf
3. Polidoro Jr, Francisco (2016). *Why Organizations Forget What They Learn from Failures* Retrieved from https://hbr.org/2016/02/why-organizations-forget-what-they-learn-from-failures
4. U.S. Food and Drug Administration. *General Principles of Software Validation* Office of Device Evaluation and Center for Device and Radiological Health, January 11th, 2002

5. U.S. Food and Drug Administration. *Distinguishing Medical Device Recalls from Medical Device Enhancements* Office of Device Evaluation and Center for Device and Radiological Health, October 15th, 2014
6. U.S. Food and Drug Administration. *Medical Device Recall Report FY, 2003 to FY 2012* Center for Device and Radiological Health, Office of Compliance, Division of Analysis and Program Operations, 2012

Note: All supporting statistical information garnered from the FDA Recall Database in support of this article was compiled and provided by Blue Lynx Consulting.
