REGULATORYSCIENCE
UNIVERSITY OF SOUTHERN CALIFORNIA

Risk Management & Medical Device Recalls: A Survey of Medical Device Manufacturers

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Agenda

- What is the Real Problem?
- Are We Using Risk Management Appropriately?
- However, We Currently Know Little About . . .
- What Did the Study Reveal?
- Conclusions
- Summary of Research to Date

What is the Real Problem?

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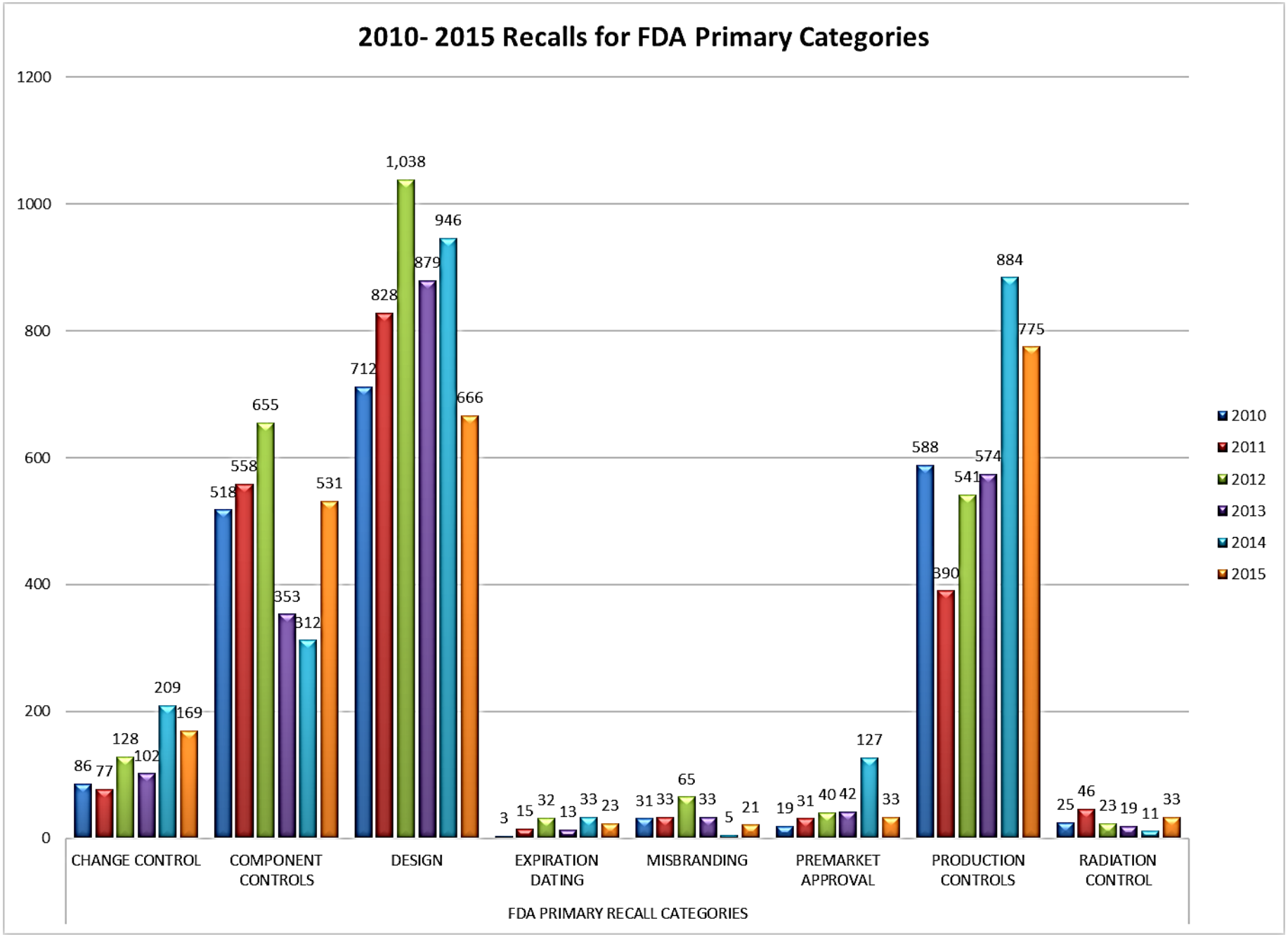
How can this continue to happen?

- Approximately 2,200 recalls occur annually (2010-2015)
- Costs due to non-routine quality events (2013 data):
  - $400m Consent Decree
  - $2m Recall
  - $1m Warning Letter(s)
  - $0.1m 483(s)

What is the Real Problem?

- The following data is analysis of approximately **16,300** recalls which grows daily
- The data is from January 1, 2010 to Present day
- The database was developed as part of a doctoral dissertation in regulatory sciences
- The database is composed of 8 primary categories & 21 sub-categories

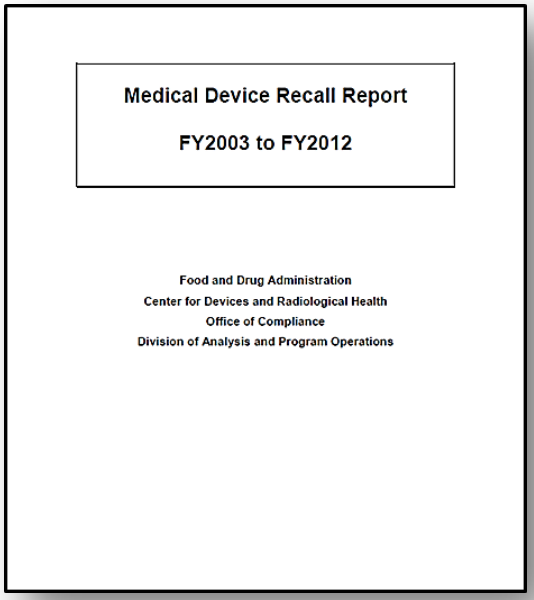
How can this information not be readily available to industry?


2010- 2015 Recalls for FDA Primary Categories
1200
1000
800
600
400
200
0
86 77 128 102 209 169
518 558 655 353 312 531
712 828 1,038 879 946 666
3 15 32 13 33 23
31 33 65 33 5 21
19 31 40 42 127 33
588 390 541 574 884 775
25 46 23 19 11 33
CHANGE CONTROL
COMPONENT CONTROLS
DESIGN
EXPIRATION DATING
MISBRANDING
PREMARKET APPROVAL
PRODUCTION CONTROLS
RADIATION CONTROL
FDA PRIMARY RECALL CATEGORIES
2010
2011
2012
2013
2014
2015

What is the Real Problem?

What are the critical factors contributing to recalls?

- Awareness?
- Quality challenges?
- Overall Risk Management system?
- Culture?


Medical Device Recall Report

FY2003 to FY2012

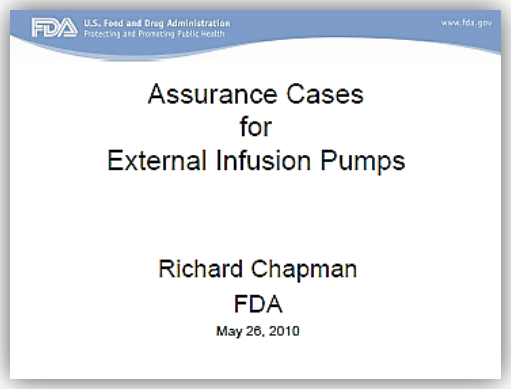
Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Division of Analysis and Program Operations

- The annual number of medical device recalls increased by 97 percent from FY 2003 to FY 2012. We attribute this increase to: enhanced awareness by device firms, including those that were cited for reporting violations; and specific CDRH efforts to improve medical device safety.

What is the Real Problem?

Rick Chapman, former Chief of General Hospital Devices Branch at FDA-CDRH, has been quoted as saying the following:

“Recognize that QMS do not usually expose a bad decision, or a bad design but, when overly burdensome, can often hide these mistakes!”



Are We Using Risk Management Appropriately?

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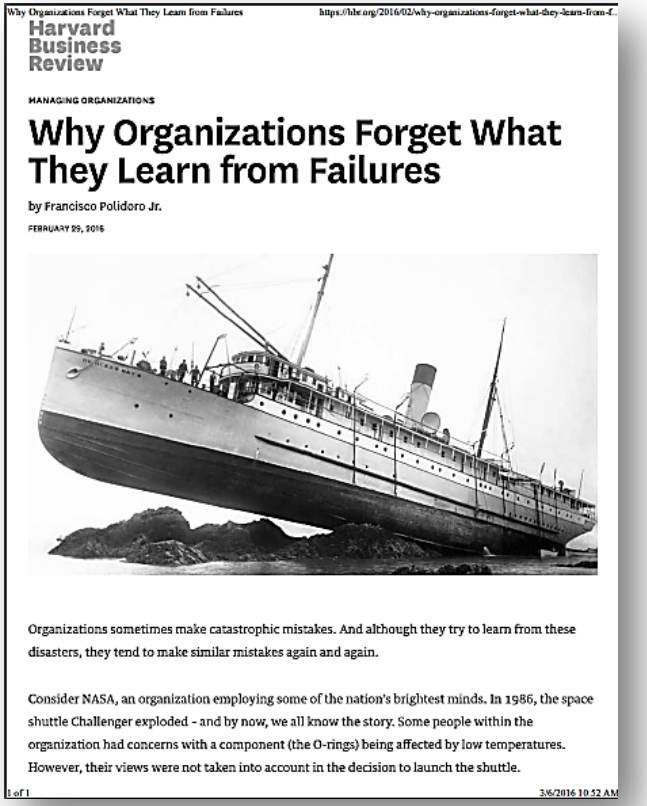
Kim Trautman, former Associate Director for International Affairs at FDA-CDRH, has been quoted as saying the following:

"Are FMEA or FMECA… good tools? Yes. They are very good tools that can be utilized. Are they in and of themselves a risk management system? Absolutely not. I can't tell you how many manufacturers I have seen that have tried to present their risk management system by simply presenting a FMEA—that is not a risk management system. Do not make the mistake of presenting FMEAs as your whole risk management system."

Are We Using Risk Management Appropriately?

- When tragedy does occur organizations change the behavior as a result of a knee-jerk reaction to prevent this from happening again
- The initial attention to risk management in the wake of a disaster can fade gradually over time
- Consistent behaviors were found in the pharmaceutical, aerospace, & petroleum industries



Why Organizations Forget What They Learn from Failures https://hbr.org/2016/02/why-organizations-forget-what-they-learn-from-f...

Harvard Business Review

MANAGING ORGANIZATIONS

Why Organizations Forget What They Learn from Failures

by Francisco Polidoro Jr.

FEBRUARY 29, 2016

Organizations sometimes make catastrophic mistakes. And although they try to learn from these disasters, they tend to make similar mistakes again and again.

Consider NASA, an organization employing some of the nation's brightest minds. In 1986, the space shuttle Challenger exploded - and by now, we all know the story. Some people within the organization had concerns with a component (the O-rings) being affected by low temperatures. However, their views were not taken into account in the decision to launch the shuttle.

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This seems to be counterintuitive to the overall goal of risk management

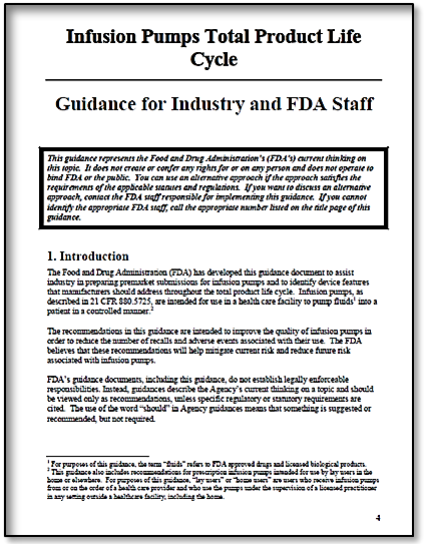
Are We Using Risk Management Appropriately?

Risk Management is more than a standard it needs to be embedded in the organizational culture….

- ISO 13485: 2016 Increased Areas of Emphasis
  - Risk Management
  - Regulatory Requirements
  - Outsourced Processes
  - Supplier Control
  - Design Control
  - Validation
  - Training

Are We Using Risk Management Appropriately?

"The recommendations in this guidance are intended to improve the quality of infusion pumps in order to reduce the number of recalls and adverse events associated with their use. The FDA believes that these recommendations will help mitigate current risk and reduce future risk associated with infusion pumps."



Infusion Pumps Total Product Life Cycle

Guidance for Industry and FDA Staff

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

The Food and Drug Administration (FDA) has developed this guidance document to assist industry in preparing premarket submissions for infusion pumps and to identify device features that manufacturers should address throughout the total product life cycle. Infusion pumps, as described in 21 CFR 880.5725, are intended for use in a health care facility to pump fluids[1] into a patient in a controlled manner.[2]

The recommendations in this guidance are intended to improve the quality of infusion pumps in order to reduce the number of recalls and adverse events associated with their use. The FDA believes that these recommendations will help mitigate current risk and reduce future risk associated with infusion pumps.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidances means that something is suggested or recommended, but not required.

[1] For purposes of this guidance, the term "fluids" refers to FDA approved drugs and licensed biological products.
[2] This guidance also includes recommendations for prescription infusion pumps intended for use by lay users in the home or elsewhere. For purposes of this guidance, "lay users" or "home users" are users who receive infusion pumps from or on the order of a health care provider and who use the pumps under the supervision of a licensed practitioner in any setting outside a healthcare facility, including the home.

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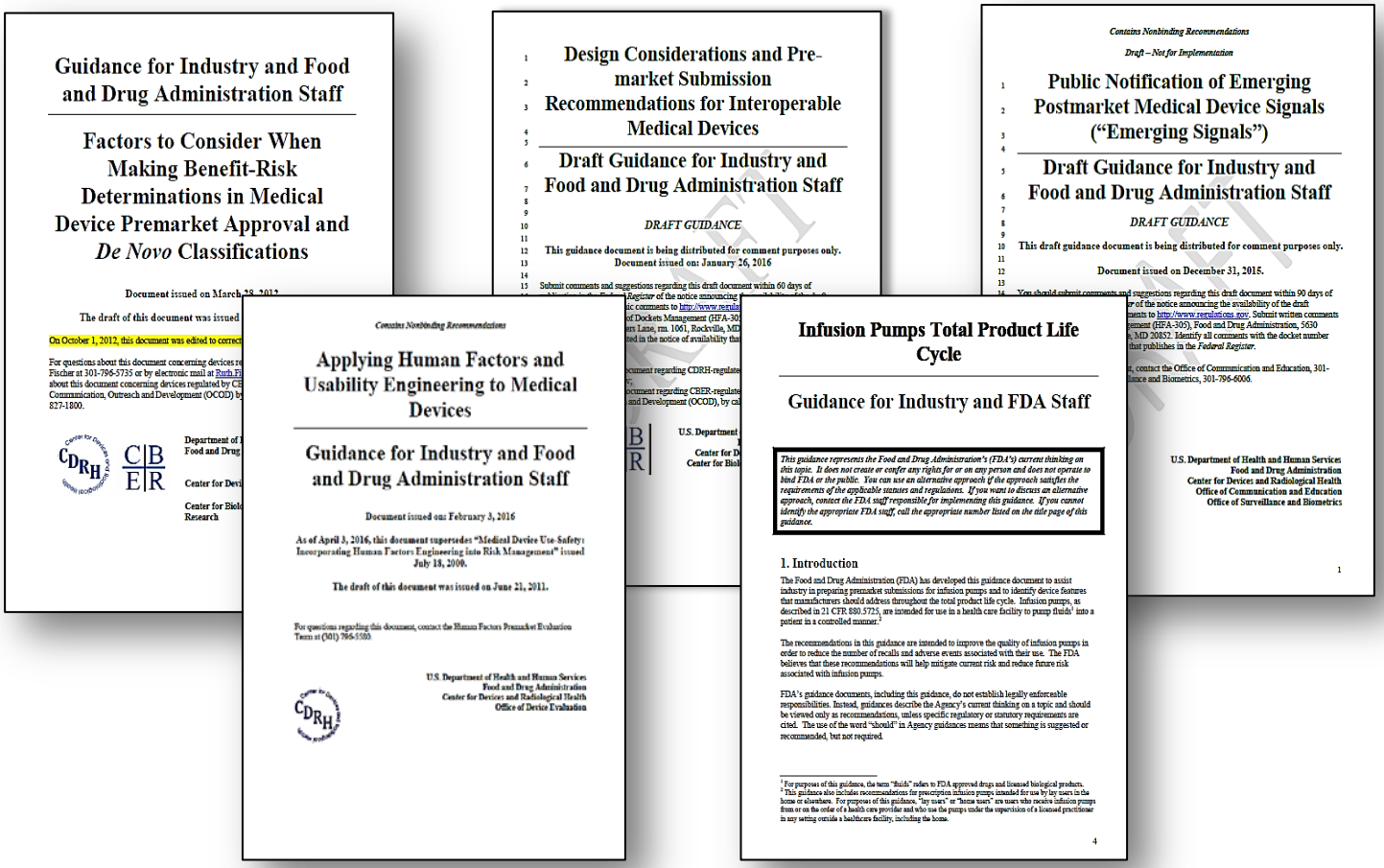
Are We Using Risk Management Appropriately?



How effective are we as risk practitioners of industry if we are seeing more guidance released on how to evaluate risk?

However, we currently know little about…

However, we currently know little about…

…How manufacturers are utilizing risk tools throughout product development

…How industry views Risk Management throughout the organizations culture

…How industry responds to activities such as recalls and what this does to the risk management culture

Are manufacturers viewing Risk Management activities as a task rather than utilizing the benefits?

What Did the Study Reveal?

What Did the Study Reveal?

- Risk Management adds value
- Risk Management can reduce product recalls and unanticipated product complaints
- Risk Management activities are embedded in goals and objectives
- Current Risk Management systems are effective at organizations
- Organizations are knowledgeable about 21 CFR 820 and ISO 13485

These results are perfect… industry understands the overall value of risk management … right?

What Did the Study Reveal?

- The Quality function is responsible for risk management and other functions provide a support role
- Risk Management updates occur throughout the lifecycle
- Policies and procedures exist for various risk activities
- Organization provide Risk Management training

These results are perfect… industry understands the overall value of risk management … potentially?

What Did the Study Reveal?

A Multifaceted Problem:

Culture, Competency, Memory, Processes, and Resources

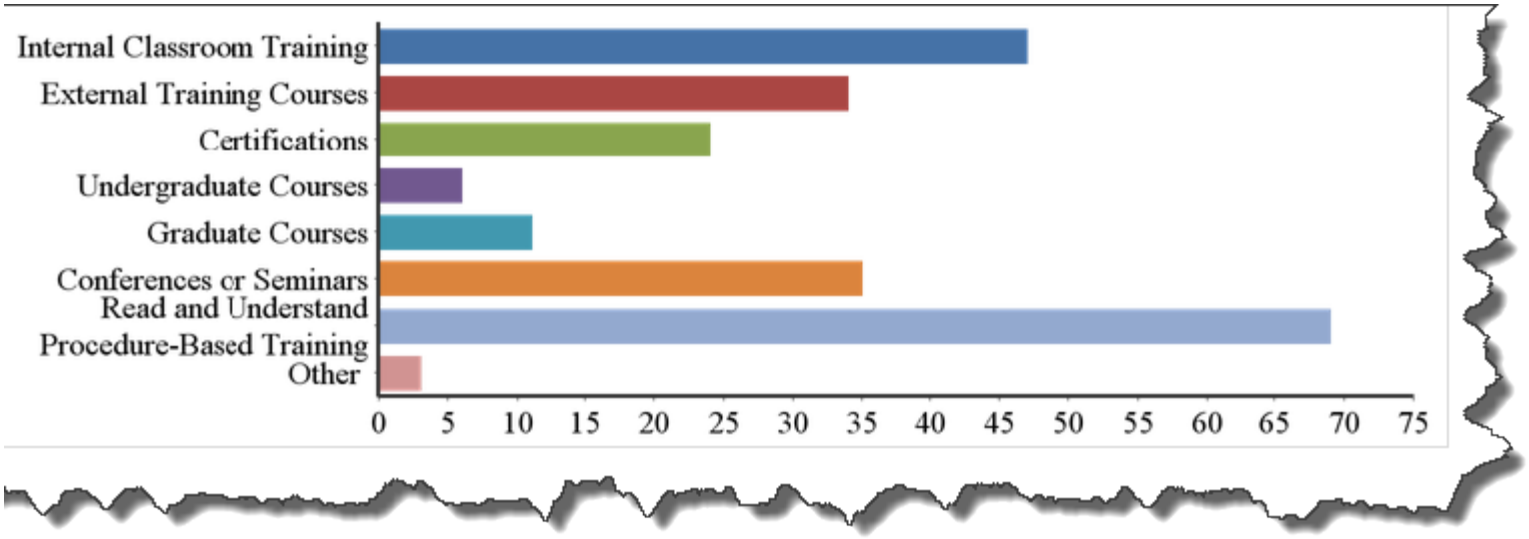
Culture

- Short project timelines impact the ability to identify and mitigate hazardous situations
- Risk Management is burdensome and perceived to be tolerated
- Risk Management activities reduce unanticipated product complaints and recalls

Question	Strongly Agree	Somewhat Agree	Neither Agree nor Disagree	Somewhat Disagree	Strongly Disagree	Cannot Comment	Response
My organization's projecttime lines impact its ability to identify or mitigate hazardous situations	31%	30%	10%	17%	11%	2%	84

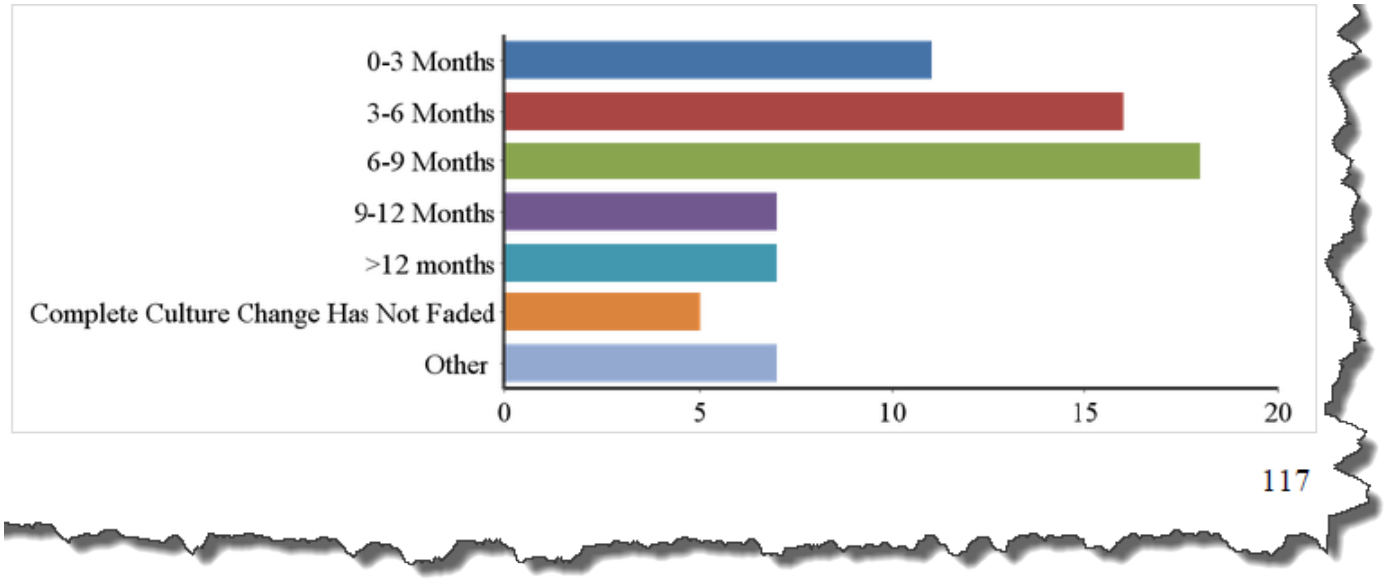
Competency

- Organizations are relying on limited basic tools (1º FMEA, 2º 5-Why, or 3º Preliminary Hazard Analysis)
- Organizations are not knowledgeable in standards for risk tools
- Training is primarily based on read and understand procedures



Memory

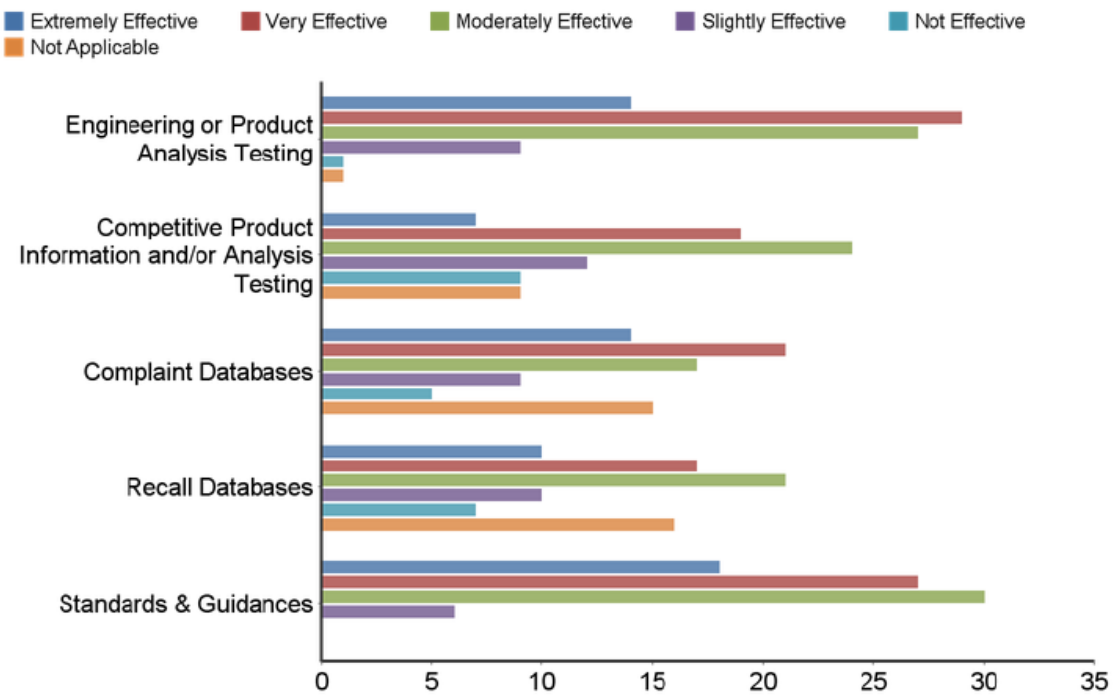
- As memory fades, it might be expected that risk assessment activities lose intensity
- Risks could have been mitigated prior to release
- The use of additional risk management tools may have helped to identify new risks



Processes

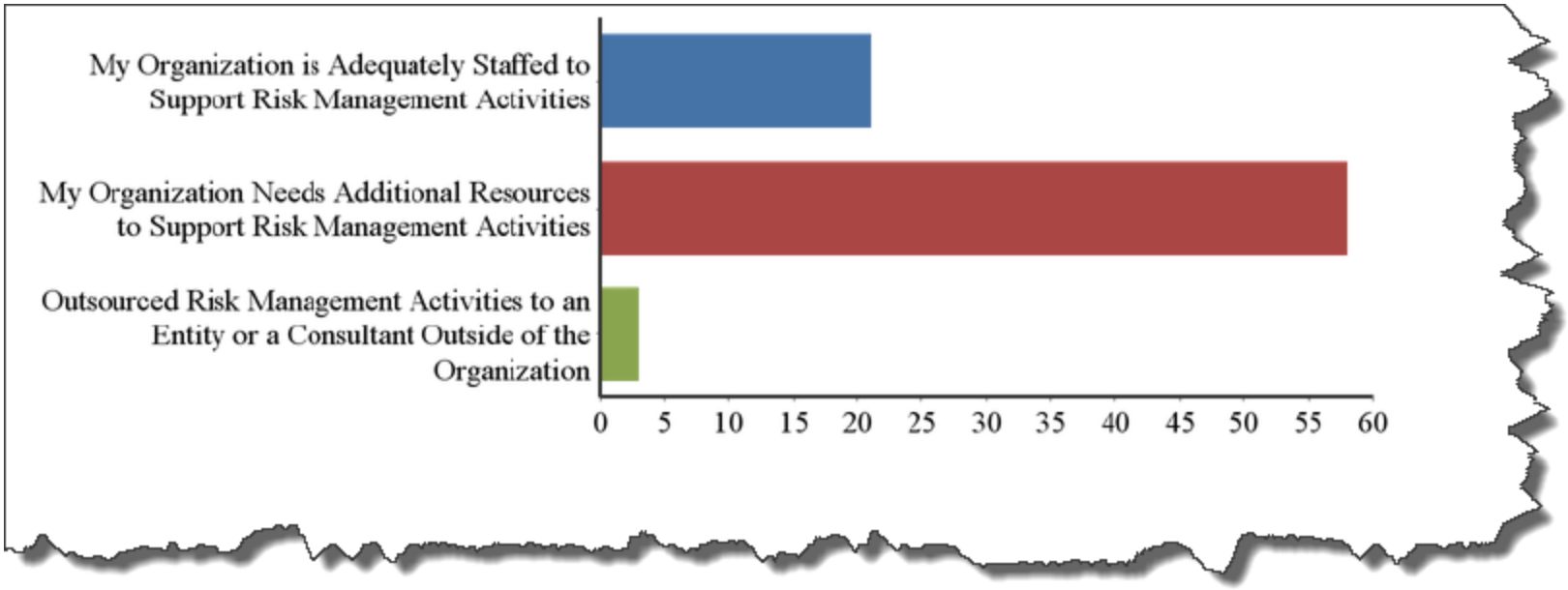
- Organizations are not utilizing FDA complaint and recall databases to identify new hazards or hazardous situations pre or post launch

- Risk Management begins in the development phase when respondents feel it should start in feasibility



Resources

- Most time and resources were spent on risk management at early stages of product development
- Respondents believed that their organization needed to devote additional resources to support risk management activities



Conclusions

- Organizations may meet the spirit of the requirements for a “quality Culture” that embraces Risk Management based on the responses

- These results further support the idea that while organizations are familiar with the needs for risk management as part of a quality system, understanding deeper knowledge regarding the tools and techniques is a significant weakness

- These results suggest that many organizations do not have adequate resources for the optimal support of risk management activities, and are focused on the early stages of product management

- The results suggest that the risk management teams could profit from better education concerning the different types of tools available to inform risk management and a wider appreciation of enterprise risk management approaches

References

Caceres, V. (2014). Clearing the Shelves: Insights on How to Handle Medical Device Recalls. *Biomedical Instrumentation & Technology, 48*(6), 414-422. doi:10.2345/0899-8205-48.6.414

Johnson, J. A. (2012). *FDA Regulation of Medical Devices*. (R42130). Congressional Research Service Retrieved from https://www.fas.org/sgp/crs/misc/R42130.pdf.

ISO. (2009). IEC/ISO 31010:2009 Risk Management - Risk Assessment Techniques (pp. 188). Geneva, Switzerland: International Organization for Standardization.

Polidoro Jr., F. (2016). Why Organizations Forget What They Learn from Failures. *Harvard Business Review*(February 29).

FDA. (2012). *Medical Device Recall Report FY2003 to FY2012*. Rockville, MD: FDA Retrieved from http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/UCM388442.pdf.

FDA. (2014a). *Infusion Pumps Total Product Lifecycle* Rockville, MD Retrieved from http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm209337.pdf.

Trautman, K. A. (2012, March 28–29). *Two Days of ISO 14971.* Paper presented at the FDA NEWS, Boston, MA.

Questions