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HEALTHCARE PURCHASING & MATERIALS MANAGERS

Medical Device Approval and Product Recalls

Presented by
Sean P. Farley, MBA, CMRP
Director, Organizational Procurement
Virginia Mason Medical Center
President, WSHMMA

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Outline

- Introduction and the Business Environment
- Medical Device Recalls and a Little Bit of History
- More Recent Recall Information
- How Recalls are Discovered at the Facility/Clinic Level
- Recall Management Process
- Questions/Discussion

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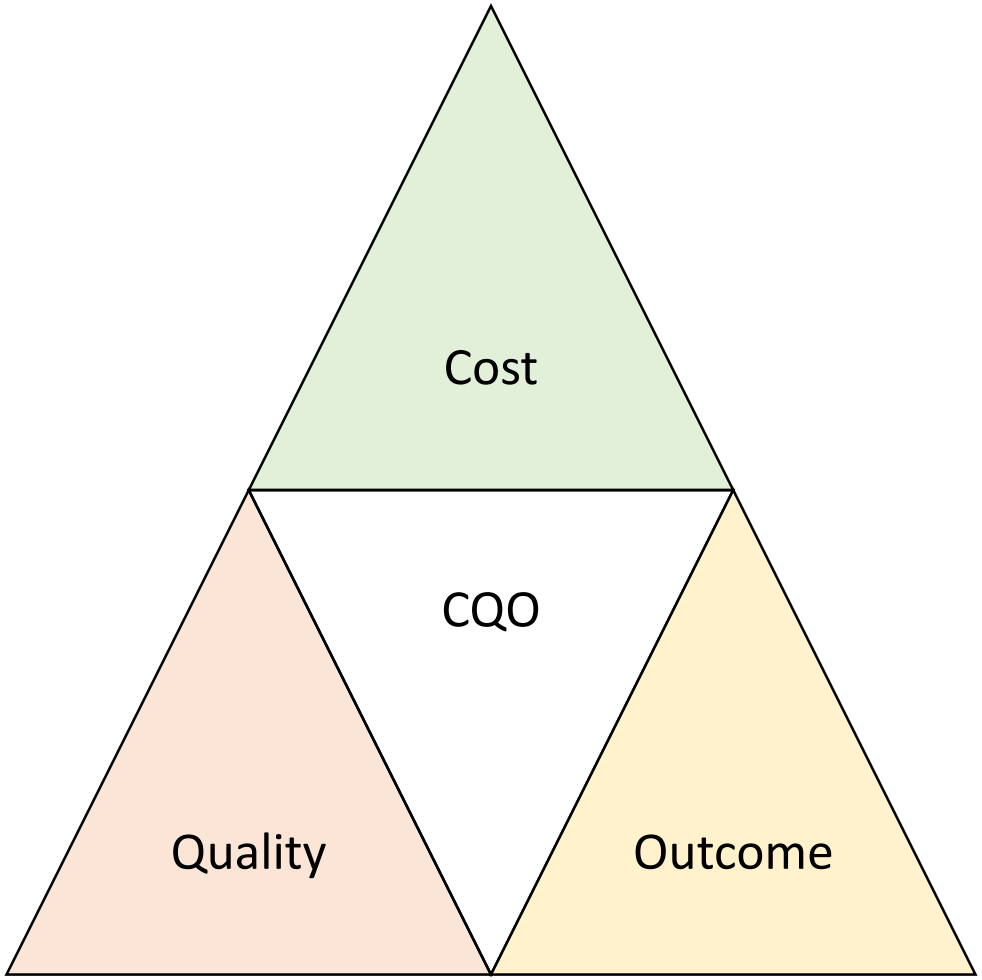
Where do Recalls Fit in the Triple Aim and CQO?



Improve the patient experience of care

Improving the health of populations

Reducing the per capita cost of healthcare

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Medical Device Approval and Bringing New Product to Market

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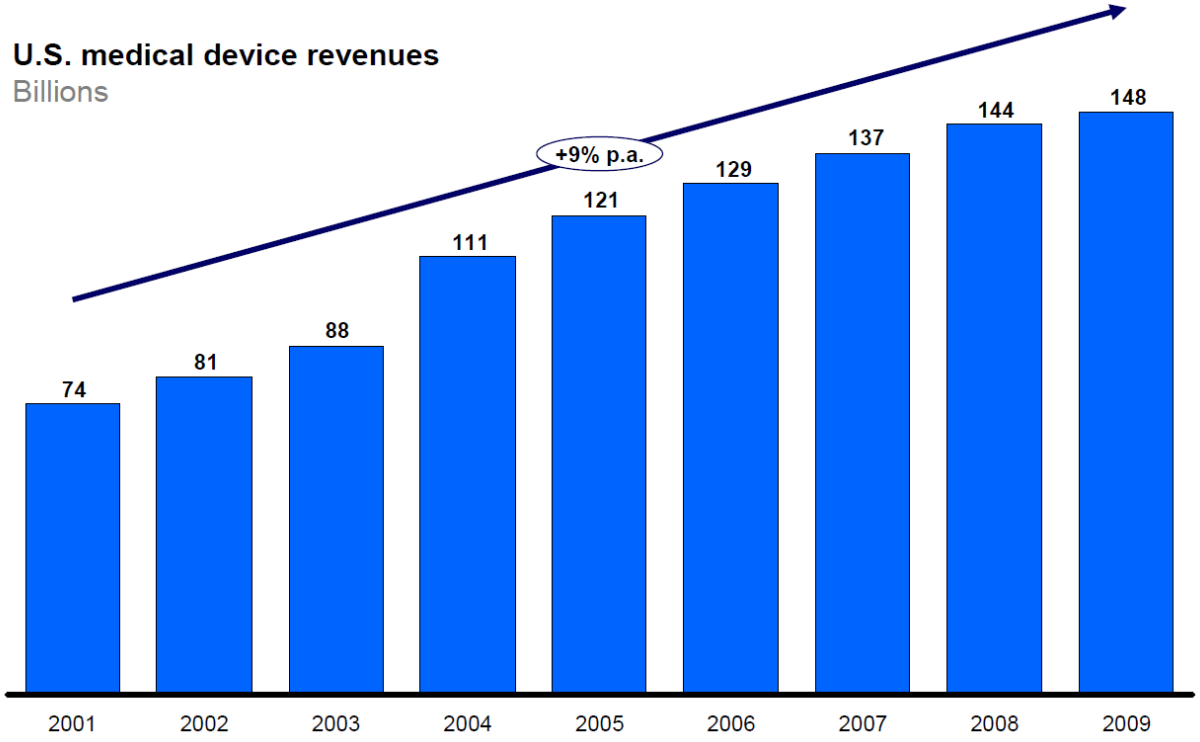
Medical Device Industry Growth

- From 2001 to 2009 the size of the US medical device industry nearly doubled
- Revenues in the medical device industry grew at a compound annual growth rate of 9%
- Devices in this market have grown increasingly complex and sophisticated



Reference: Food and Drug Administration Medical Device Recall Report

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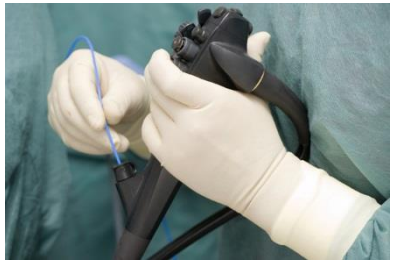
FDA Regulatory Approvals

<u>Pre-Market Notification (510K)</u>
"the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is <u>not subject to premarket approval (PMA)</u>"

<u>Pre-Market Approval</u>
"PMA approval is to be based on a determination by FDA that the PMA contains sufficient valid scientific evidence to provide reasonable assurance that the device is safe and effective"

<u>Humanitarian Device Exemption</u>
Humanitarian Use Device (HUD) is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year



<u>De novo Approval</u>
option provides an alternate method to classify novel devices of low-moderate risk. Devices classified through the de novo process may be marketed and used as predicates for future 510(k)

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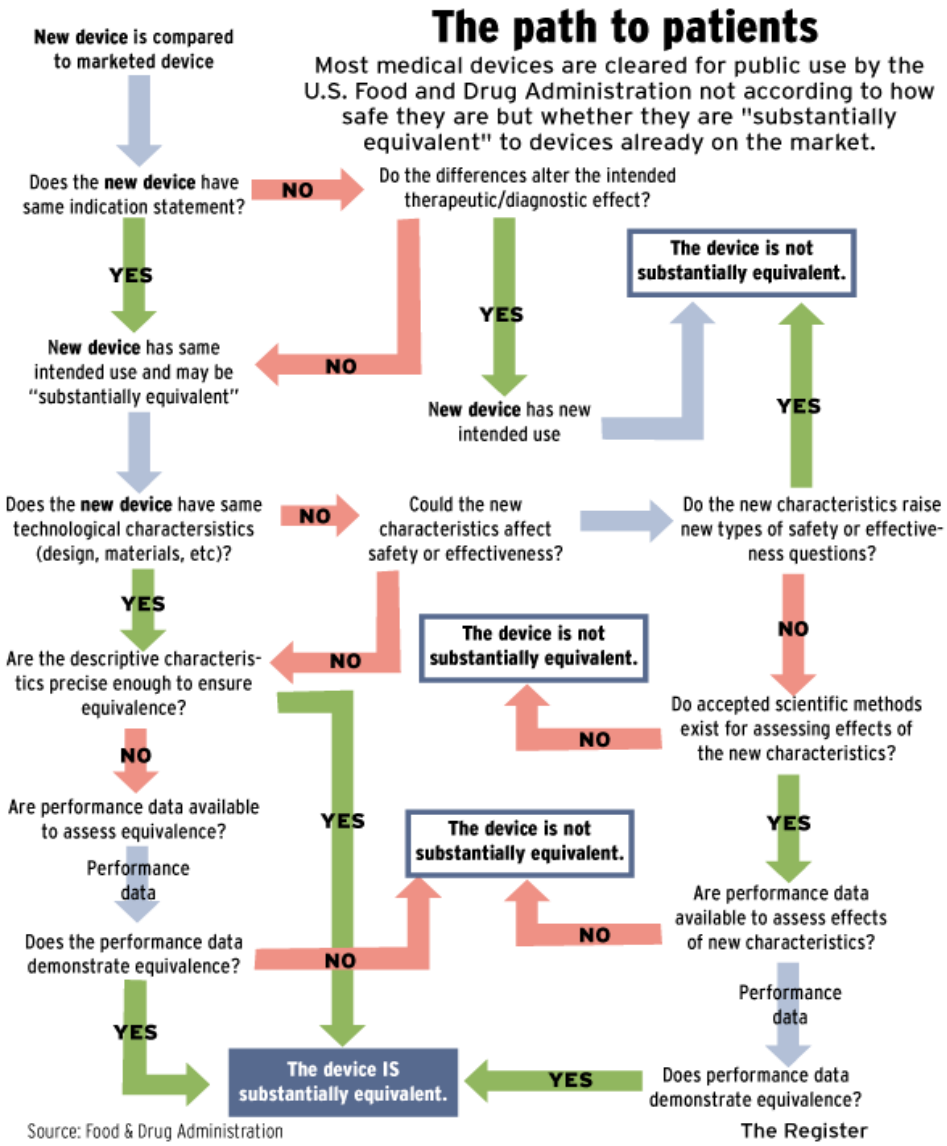
The "Simple" Process



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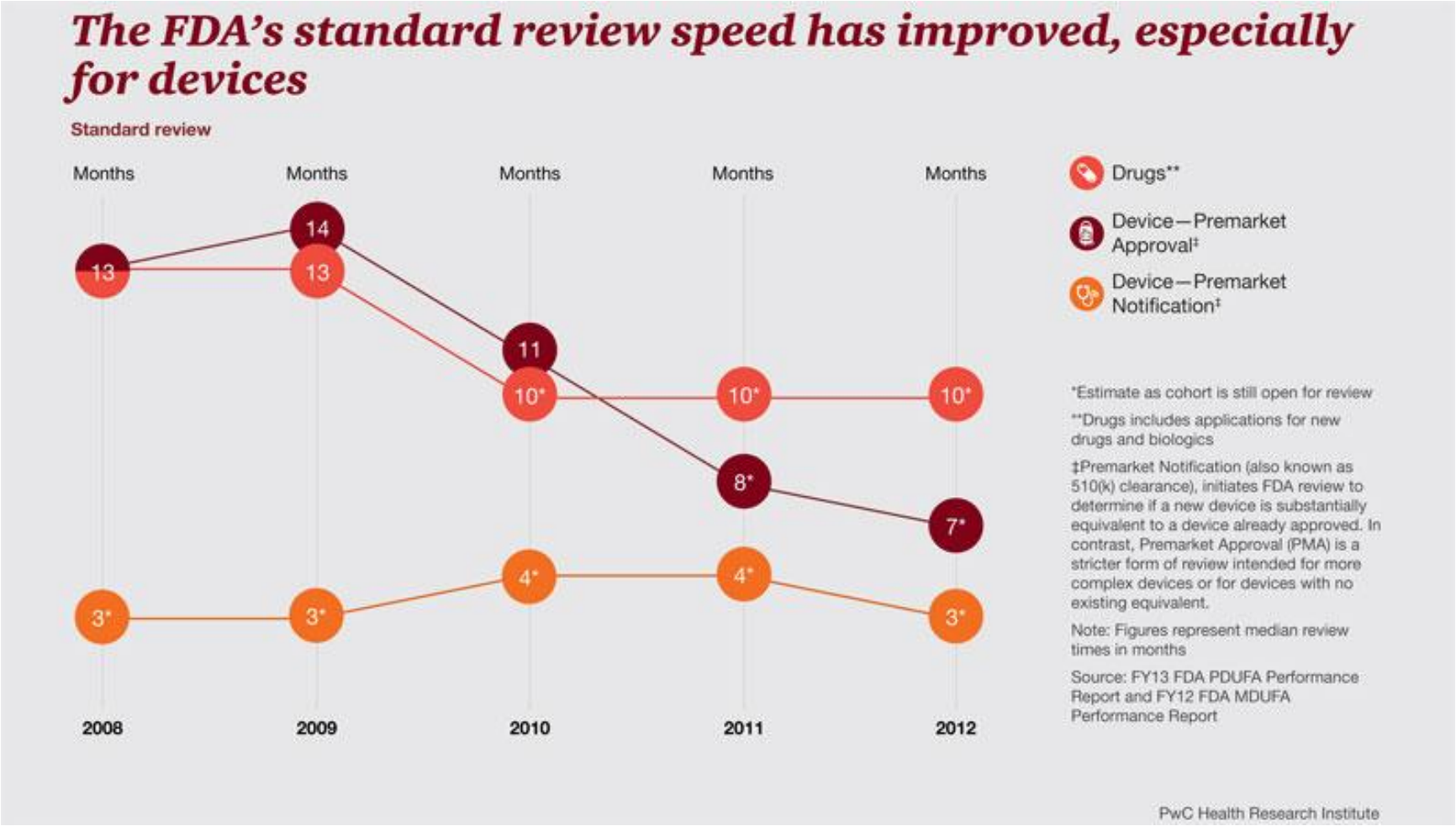
FDA Approval Timeline from 2008-2011

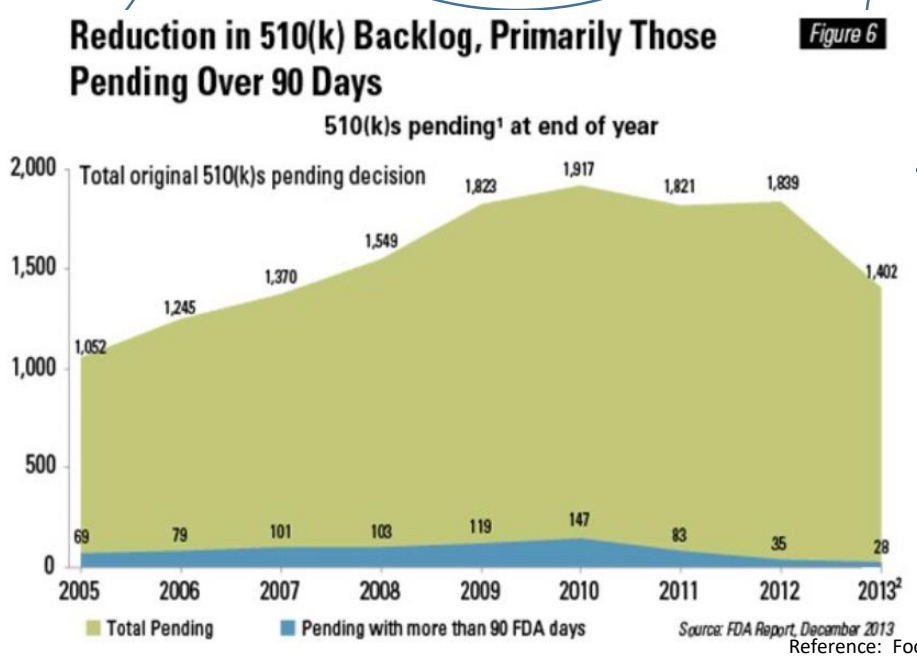


Concerns with the 510K Approval Process

"Substantially equivalent" products released without clinical trials

Promotes development of higher cost items with only small tech improvements

many devices cleared for use in patients had no clinical data accessible in the literature to support their use



Reference: Food and Drug Administration Medical Device Recall Report

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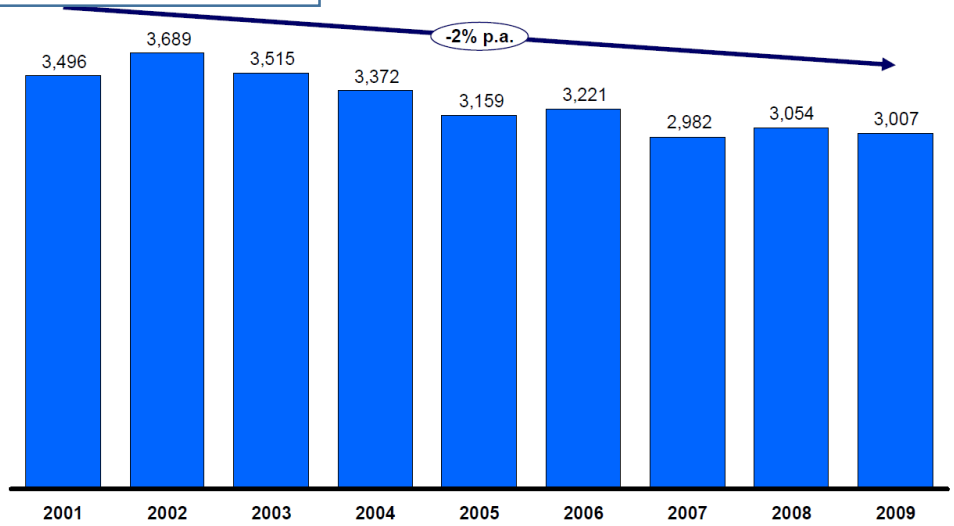
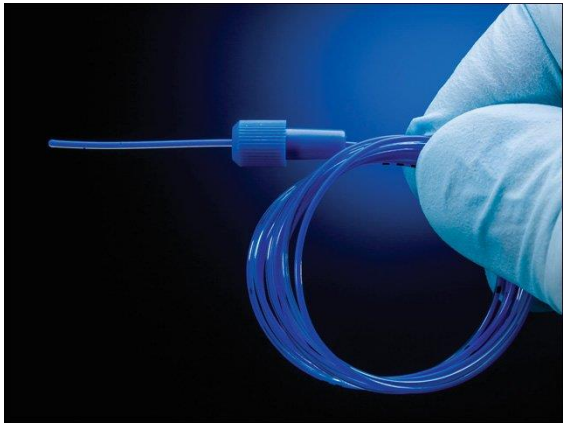
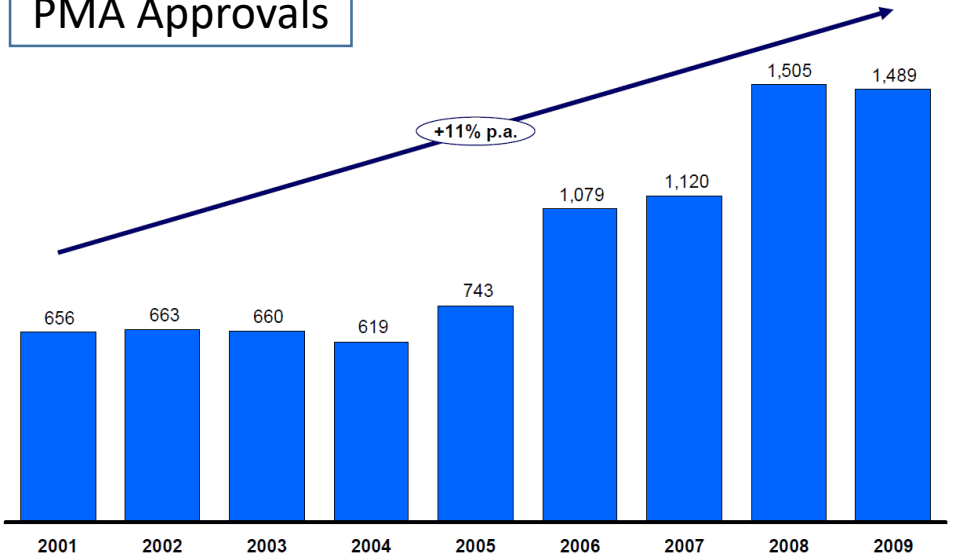
FDA Regulatory Approvals Trends

510K Approvals





PMA Approvals



Reference: Food and Drug Administration Medical Device Recall Report

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Medical Device Recalls and a Little Bit of History

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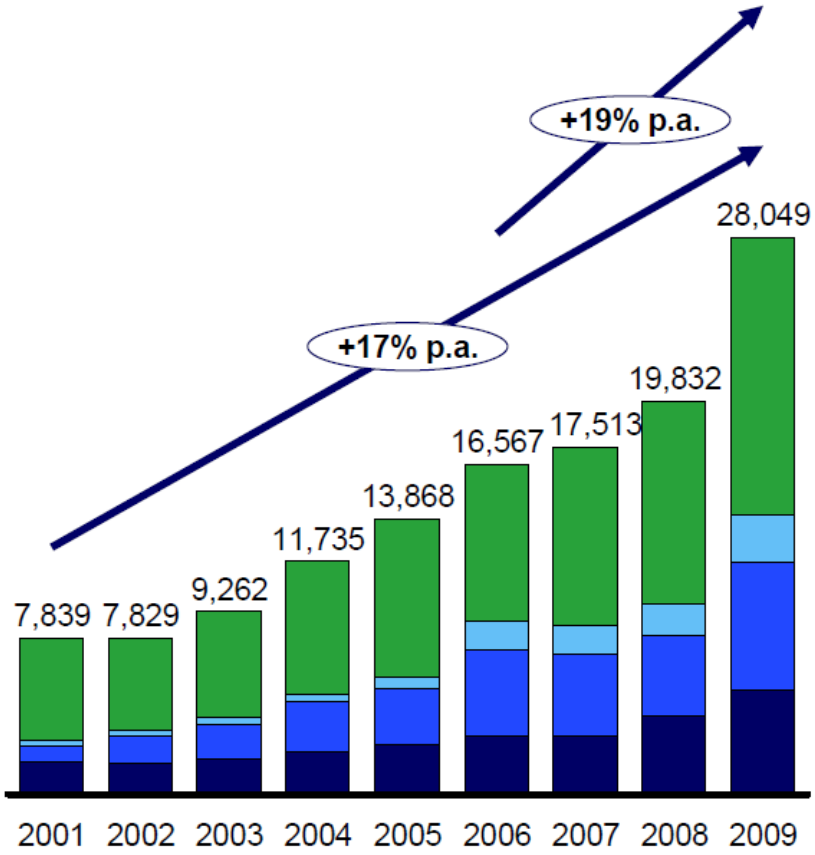
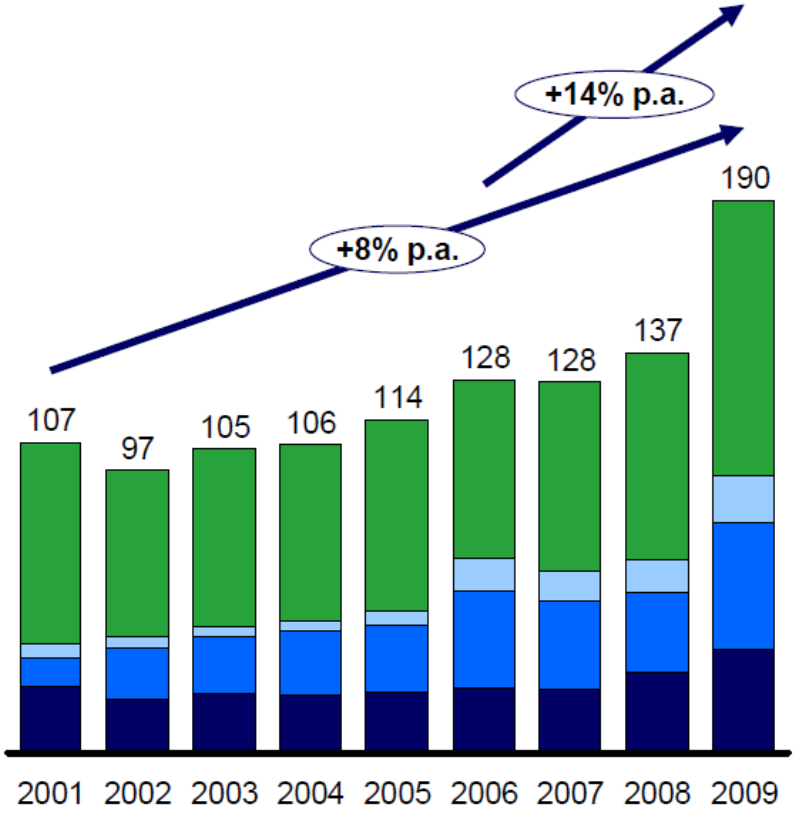
Why do Medical Device Recalls Matter

Patients injured in serious adverse events
Number of patients injured



Patients injured in serious adverse events
Patients injured per $billion in medical device spend



Reference: Food and Drug Administration Medical Device Recall Report

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Classes of Medical Device Recalls

- **Class I recall:** a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

- **Class II recall:** a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

- **Class III recall:** a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

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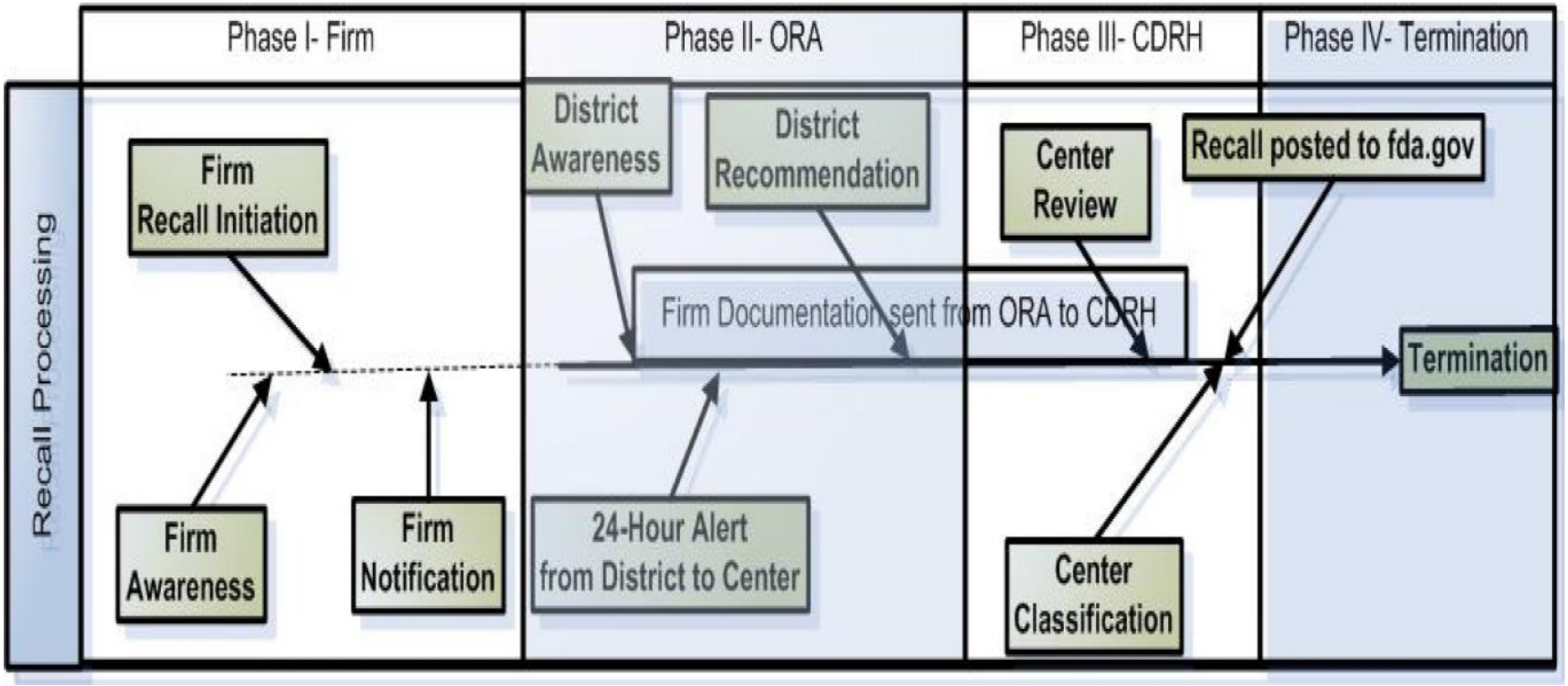
The FDA Recall Process



- The annual average time from firm awareness to recall posting during this time period ranged from 233.7 days to 256.6 days

Reference: Food and Drug Administration Medical Device Recall Report

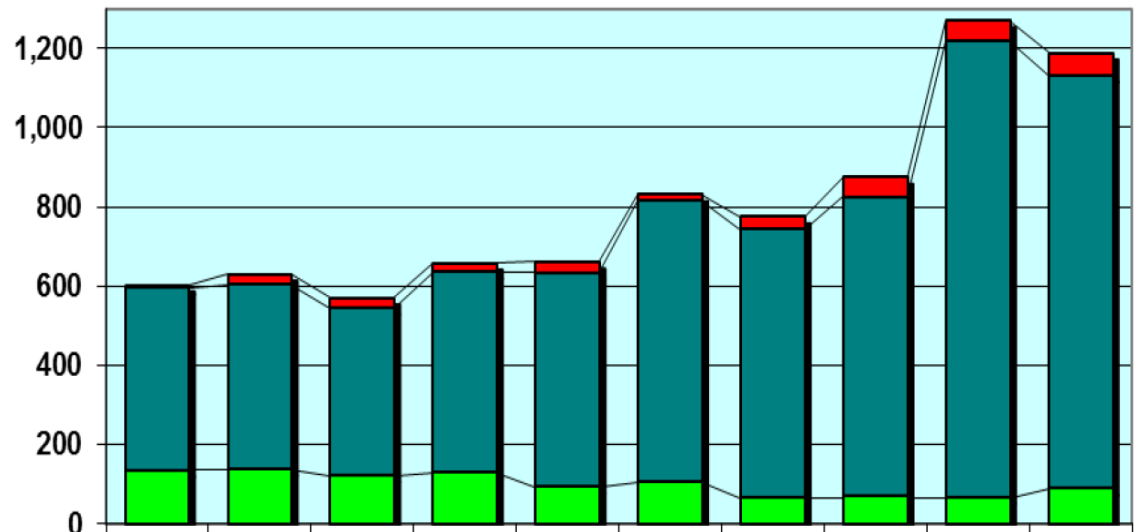
Medical Device Recalls

FDA Study 2003-2012

Class 1 Recalls:
-1% of total recalls in 2003
-5% of total recalls in 2012

Class 2 Recalls:
-More than doubled between 2003 and 2012

Class 3 Recalls:
-Declined by 35% from 2003 To 2012



	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Class I	7	24	26	22	26	14	32	49	50	57
Class II	460	467	422	505	540	710	677	753	1,152	1,043
Class III	137	140	124	132	96	108	67	74	69	90
Totals	*604*	*631*	*572*	*659*	*662*	*832*	*776*	*876*	*1,271*	*1,190*

Reference: Food and Drug Administration Medical Device Recall Report

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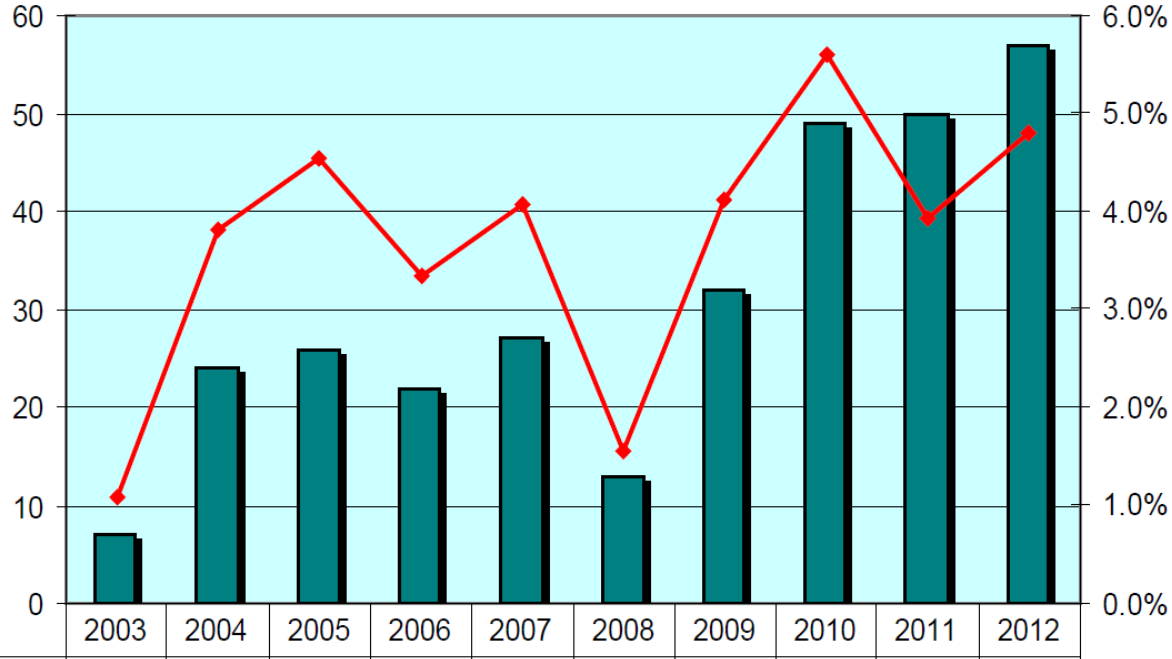
Class 1 Recall Procode Progression

The most frequent device procodes for Class I recalls were:

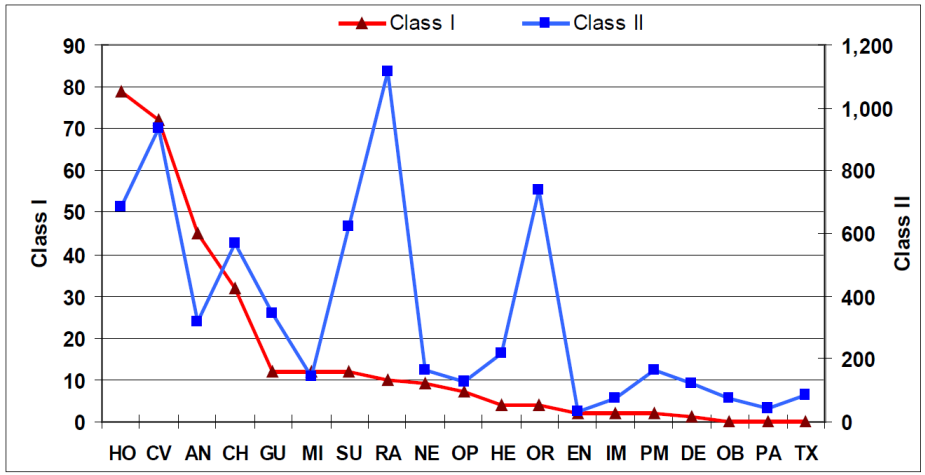
1. Pump, Infusion
2. Automated External Defibrillators
3. Ventilator, Continuous
4. System, Test, Blood Glucose
5. Introducer, Catheter



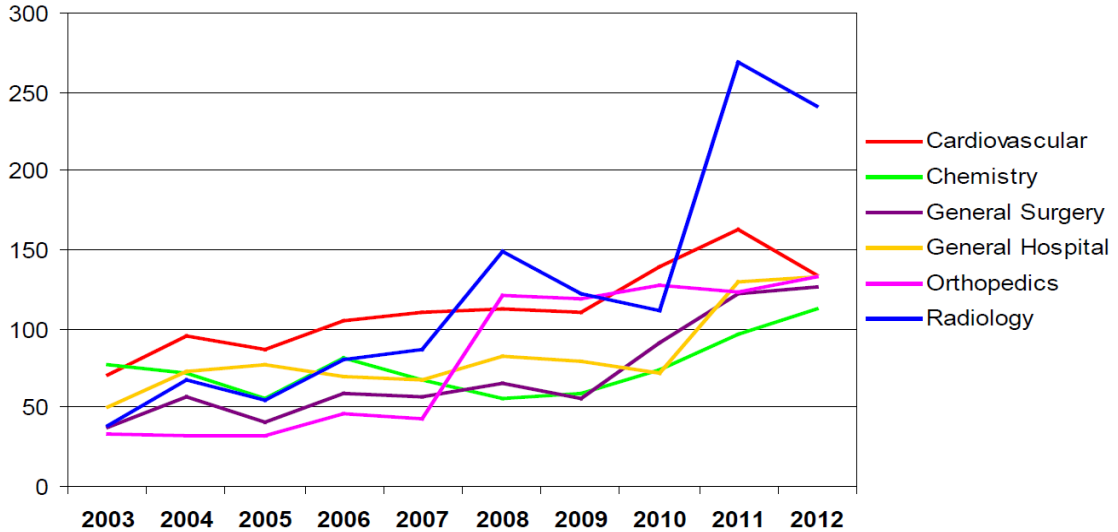
	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Class I recall counts	7	24	26	22	27	13	32	49	50	57
All recalls % Class I	1.1%	3.8%	4.5%	3.3%	4.1%	1.6%	4.1%	5.6%	3.9%	4.8%

Reference: Food and Drug Administration Medical Device Recall Report

Categorized Recalls



AN- Anesthesiology
CH- Chemistry
CV- Cardiovascular
DE- Dental
EN- Ear, Nose and Throat
GU- Gastro and Urology
HE- Hematology
HO- General Hospital
IM- Immunology
MI- Microbiology
NE- Neurology
OB-OB and Gynecology
OP- Ophthalmic
OR- Orthopedics
PA- Pathology
PM- Physical Medicine
RA - Radiology
SU- General Surgery
TX- Toxicology



Reference: Food and Drug Administration Medical Device Recall Report

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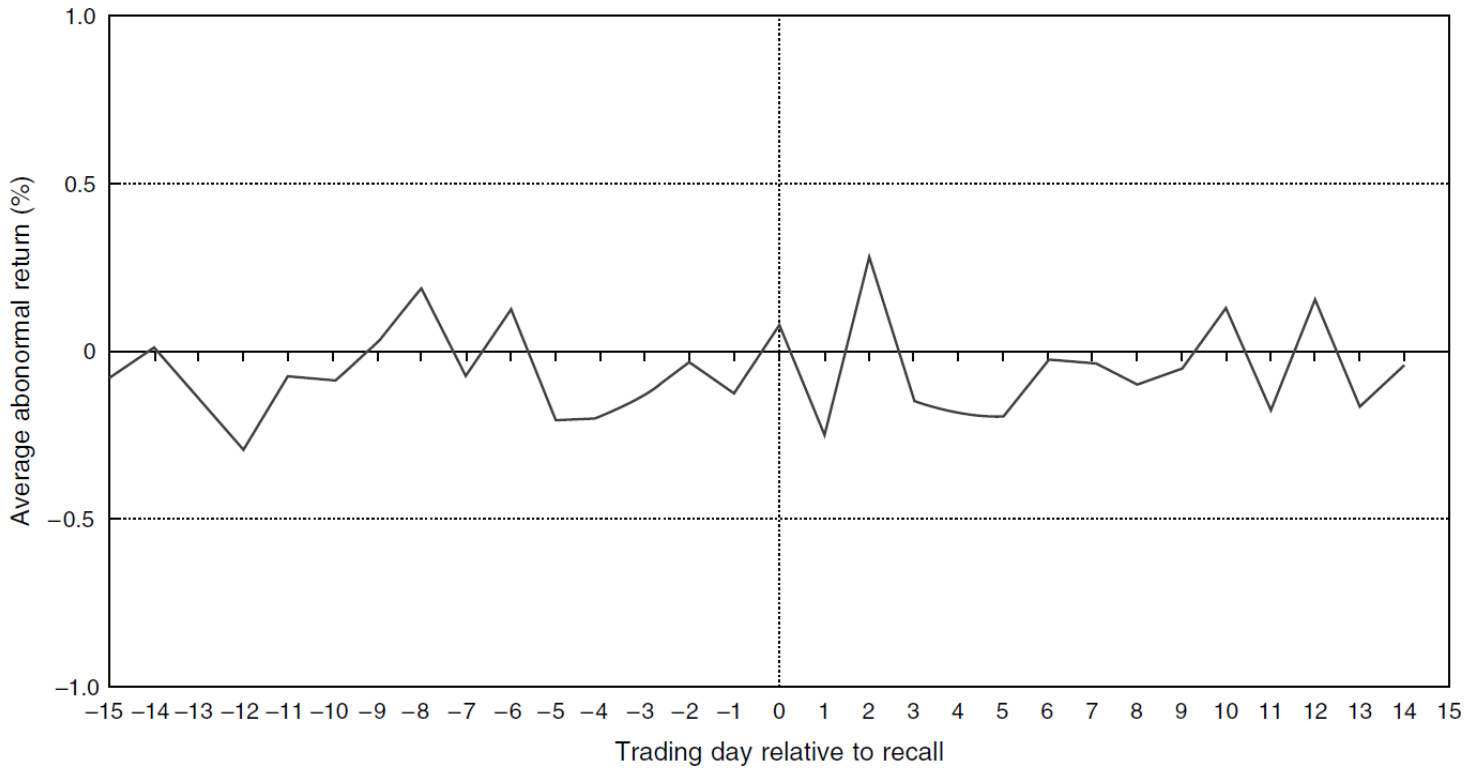
Capital Market Reaction to Device Recalls



"Capital market penalties for medical device recalls are not severe and that market Reaction to recall announcements is varied in heterogeneous firms"

Reference: Food and Drug Administration Medical Device Recall Report

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Root Cause Behind Recalls

Model recalls (case numbers), 2003-2009, N=4,391

>=15%
5-14%
1-5%

	Design	Suppliers	Manufacturing	Postproduction & change ctrl	Other	Unknown	Total by product attribute
Hardware	15%	12%		2%			29%
Software	8%			7%			15%
Labeling	4%		3%	1%			8%
Packaging	1%		3%				5%
Process	3%	2%	18%	1%			24%
Regulation					1%		1%
Other					9%		9%
Unknown						9%	9%
Total by value stream	31%	14%	24%	12%	10%	9%	100%

Reference: Food and Drug Administration Medical Device Recall Report

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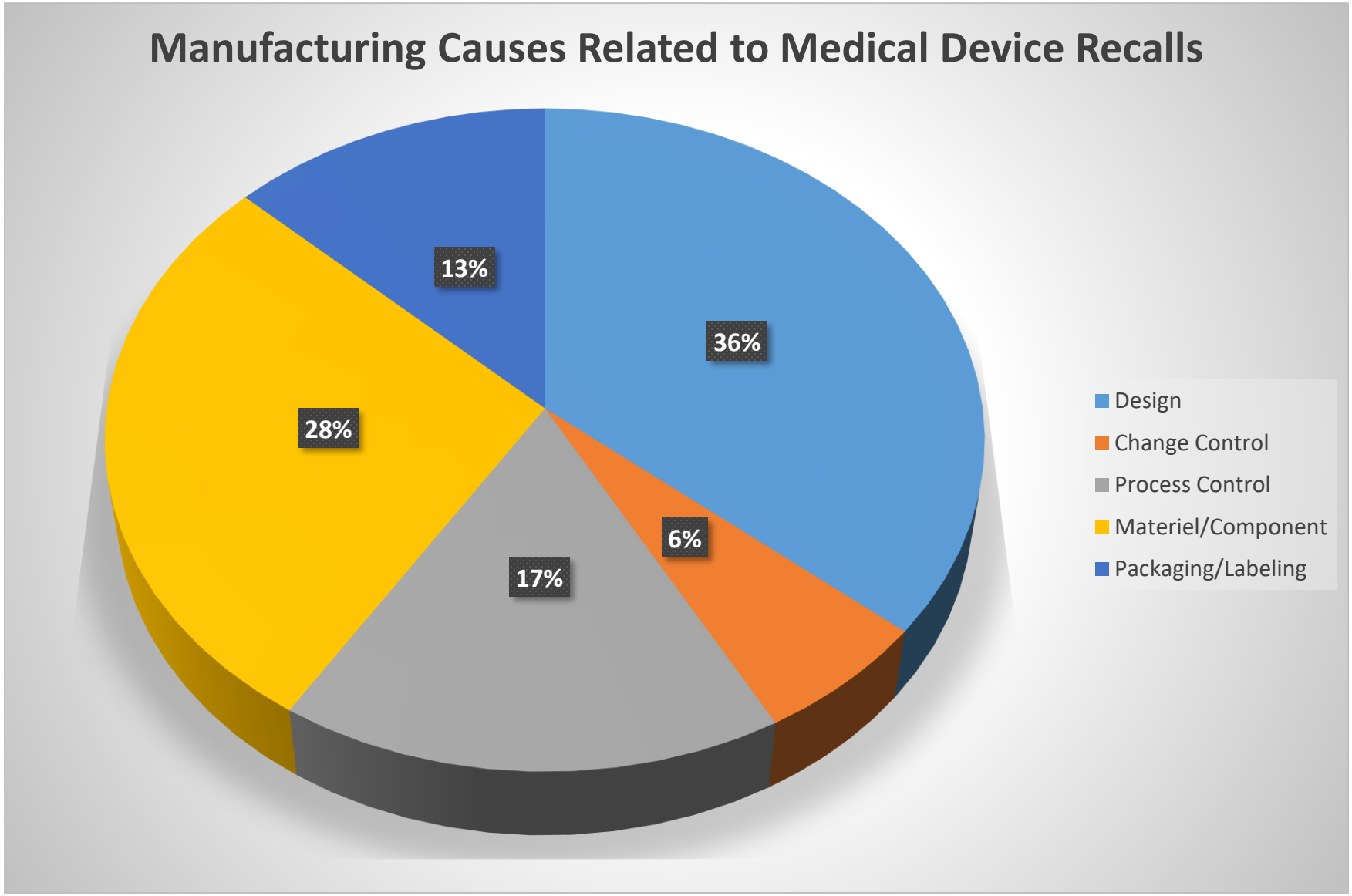

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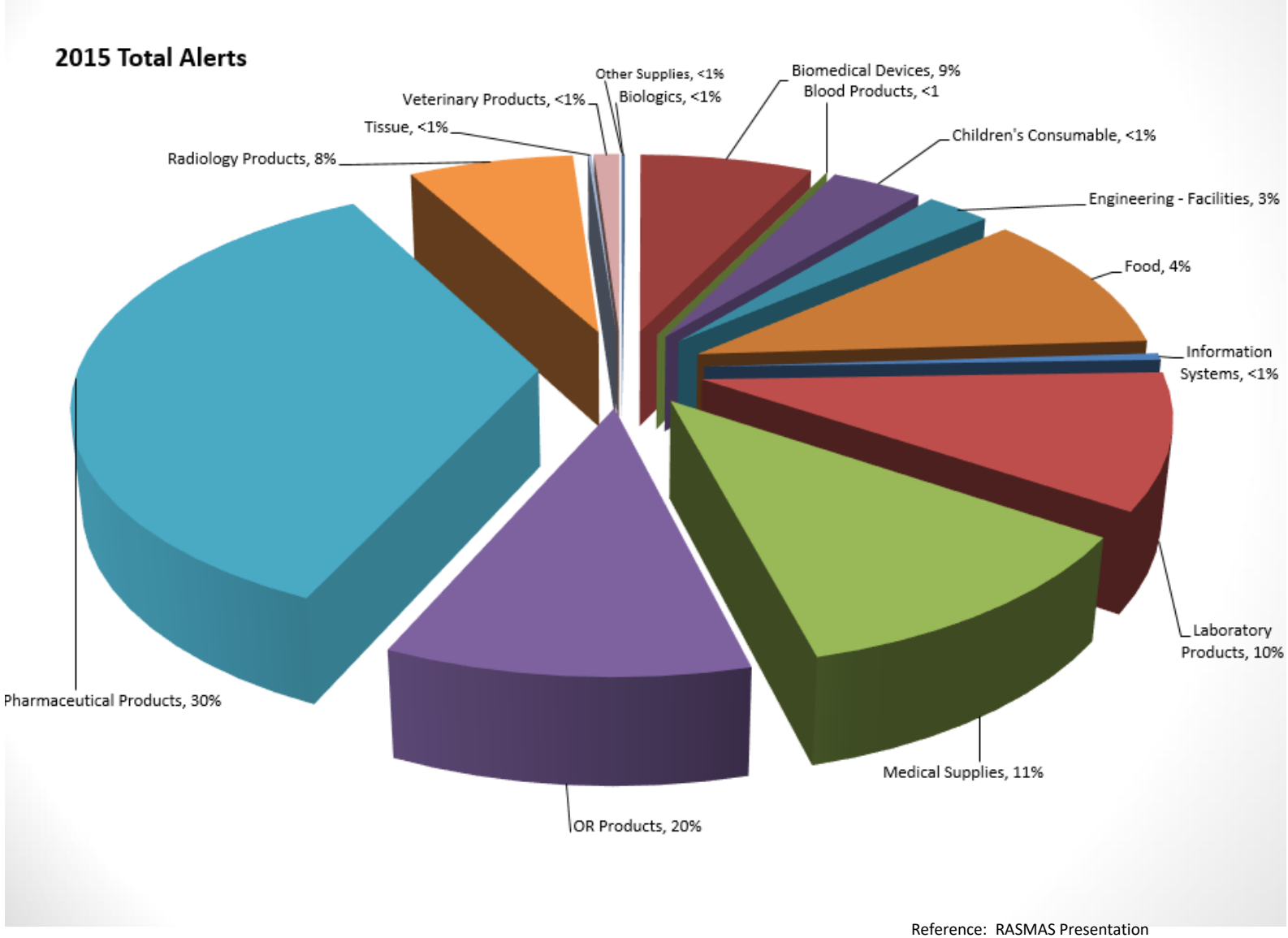
More Recent Recall Information

A Breakdown of 2015 Recall Alerts



Reference: RASMAS Presentation

Resources: OpenFDA

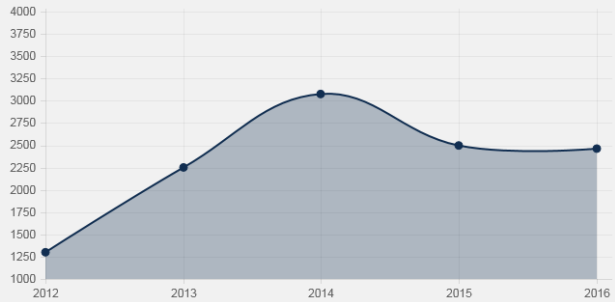
All device product enforcement reports

Recalls mentioning "catheter"

11589 records match these search parameters

report_date

Date that the FDA issued the enforcement report for the product recall.



current query

```
https://api.fda.gov/device/enforcement.json?count=report_date
```

search= parameter

Type in a custom search parameter, and then press Enter to

count= parameter

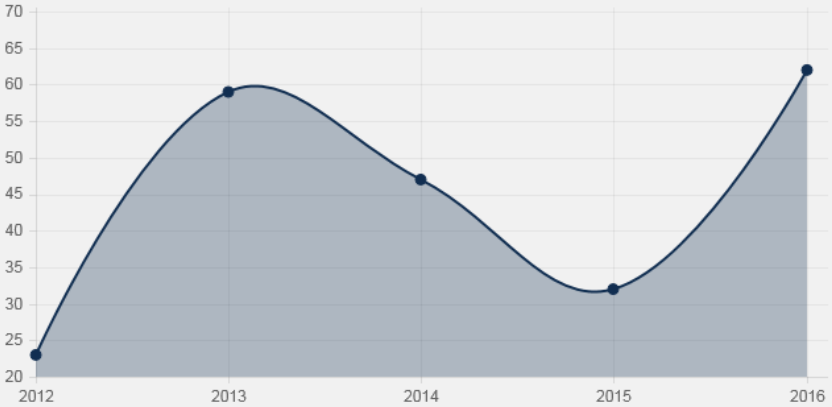
All device product enforcement reports

Recalls mentioning "catheter"

223 records match these search parameters

report_date

Date that the FDA issued the enforcement report for the product recall.



Reference: Food and Drug Administration Medical Device Recall Report

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How Recalls are Discovered at the Facility/Clinic Level

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Pull it from the FDA Website

Medical Device Recalls

FDA Home › Medical Devices › Databases

1 to 10 of 500 Results *

1 2 3 4 5 6 7 8 9 10 >

Results per Page 10

New Search

Export To Excel | Help

Product Description	Recall Class	Recall Date	Recalling Firm
TBS INsight Version V.3.0.1 Product Usage: TBS INsight Is A Medical Device Software That Is Inst...	2	Nov-05-2016	Medimaps Group
Zimmer® Air Dermatome II Handpiece Loaner, Item Number 01-8851-001-00. Device Is Packaged Inside Of ...	2	Nov-05-2016	Zimmer Surgical Inc
X-Force Nephrostomy Balloon Dilation Catheter Kit With Inflation Device, PTFE Sheath, 8 Mm X 15 Cm, ...	2	Nov-04-2016	C.R. Bard, Inc.
Symbiq One Channel Infuser; An Rx Medical Device Infusion Pump Used To Administer I.V. Fluids. List...	2	Nov-04-2016	Hospira Inc.
Symbiq Two Channel Infuser; An Rx Medical Device Infusion Pump Used To Administer I.V. Fluids. List...	2	Nov-04-2016	Hospira Inc.
TANDEM (TM) COCR SHELL UHMWPE LINER BIPOLAR, REF NUMBERS: 71322040, 71322041, 71322042, 7132204...	2	Nov-03-2016	Smith & Nephew, Inc.
TANDEM (TM) INTL COCR SHELL UHMWPE LINER BIPOLAR, REF NUMBERS: 71324038, 71324039, 71324040, 71...	2	Nov-03-2016	Smith & Nephew, Inc.
Heater Cooler Unit Usage: The Heater-Cooler Unit (HCU 30) Supplies Temperature-Controlled Water ...	2	Nov-03-2016	Maquet Cardiovascular Us Sales, Llc
Infusion Set, Comfort, 23" Hosp 10; Comfort 13mm, 23", STD 5/5; Comfort 13mm, 23" Hosp 10; Infusion ...	2	Nov-03-2016	Unomedical As
Silhouette Paradigm 13mm, 18"; Silhouette 43"; Silhouette 23"; Silhouette Paradigm 43"; Silhouette P...	2	Nov-03-2016	Unomedical As

Reference: Food and Drug Administration Medical Device Recall Report

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Company Websites

COOK MEDICAL

PRODUCTS SUPPORT ABOUT DIVISIONS

Newsroom

MAY 2ND, 2016

Cook Medical issues global voluntary recall of catheters with Beacon Tip technology

Cook Medical has initiated a global, voluntary recall of all catheters with Beacon® Tip technology. This recall includes all lots of catheters with the Beacon Tip technology. The catheters were recalled on April 15, 2016 due to complaints of tip splitting and/or fracture. The U.S. Food and Drug Administration (FDA) has not yet classified the recall. A complete list of products affected by this recall can be found below.

Catheters with Beacon Tip technology have been found to exhibit polymer degradation of the catheter tip, resulting in tip fracture and/or separation. Most of the fractures and/or separations were discovered prior to patient contact. The FDA and other regulatory agencies around the world have been notified of this action.

In 2015, Cook recalled specific lot numbers of Beacon Tip catheters and then expanded that recall to all 4 French lots. Due to an increase in complaints about tip splitting and/or fracture, in April 2016 Cook has now recalled all lots and sizes to assure patient safety around the world.

"We've been investigating a variety of factors including environmental influences and it's been difficult for us to reproduce the exact failures that our customers have experienced," said Pete Yonkman, president of Cook Medical and Cook Group. "If we cannot tell our customers how to keep our products safe, then we aren't comfortable leaving them on the market. It's a risk we're not willing to take. Patient safety comes first – period."

> "It's a risk we're not willing to take. Patient safety comes first – period."
>
> Pete Yonkman
> President of Cook Medical and Cook Group

Reference: Cook Medical Website

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Recall Letters (Email or Snail Mail)

COOK® MEDICAL

COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 USA
OFFICE 812.339.2235 PHONE 800.468.1379 EXT 102232
FAX 812.335.5710
WWW.COOKMEDICAL.COM

April 15, 2016

URGENT: MEDICAL DEVICE RECALL

ATTENTION:
Risk Management / Recall Administration

Our records indicate that you may have received some of the affected products listed below.

Details on affected devices:

Product Brand Name	Catalog Identifier*	Lot Number
Beacon® Tip Torcon NB® Advantage Catheter	HNBR5.0 HNBR6.0	All lots
Beacon® Tip Royal Flush® Plus High-Flow Catheter	HNR5.0	All lots
Beacon® Tip Centimeter Sizing Catheter, Beacon® Tip White Vessel Sizing Catheter,	NR5.0	All lots

Reference: Cook Medical Website

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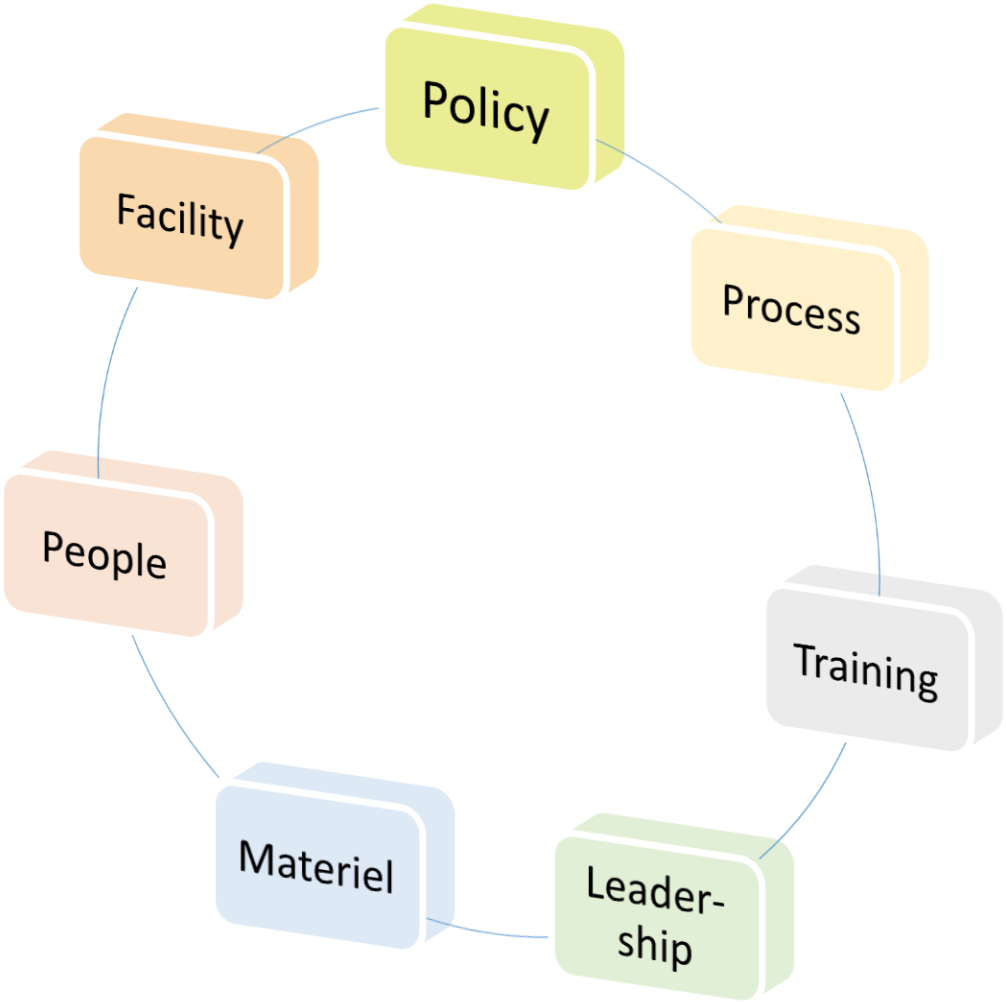
Recall Management Process

Managing Product Recalls



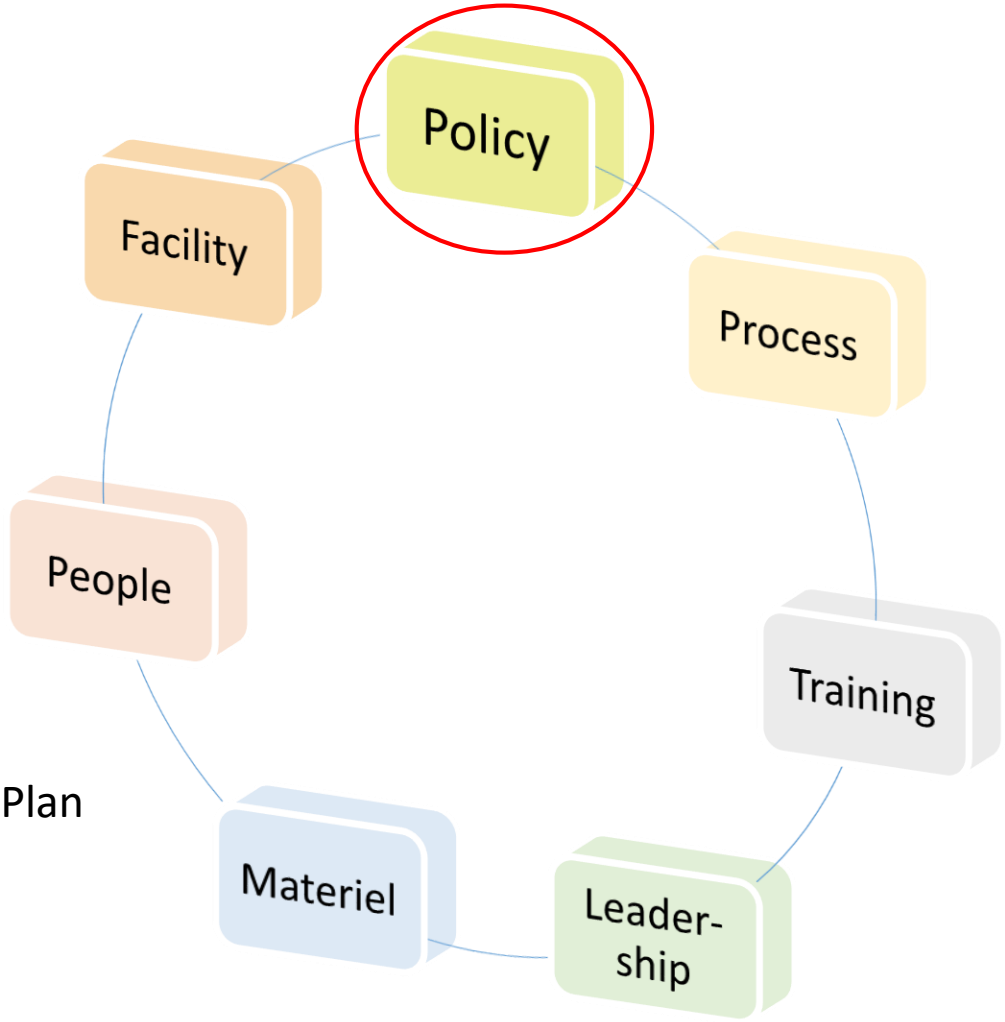
"The burden of proof that all reasonable efforts have been made to remove the product rest on the recalling firm"

Managing Product Recalls: Policy

Supply Chain
Patient Safety
Clinical Teams
Contracting

Standard Work

Communication Plan



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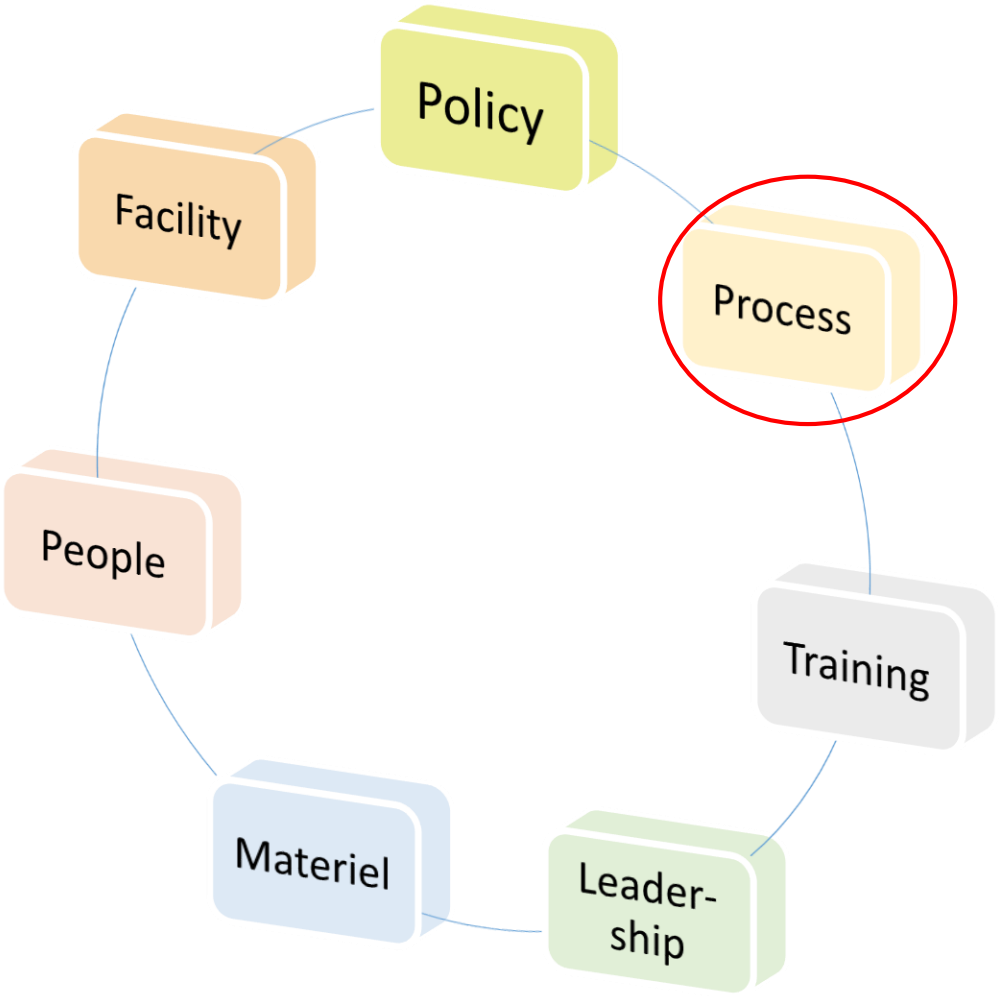
Managing Product Recalls: Process

- Receive Notification
- Process Notification
- Identify Recalled Product
- Identify Impacted Patient Populations
- Patient Notification Processes
- Research Alternative Products
- Sequester Product
- Coordinate Return Goods
- Notify Supplier
- Close the Recall Action



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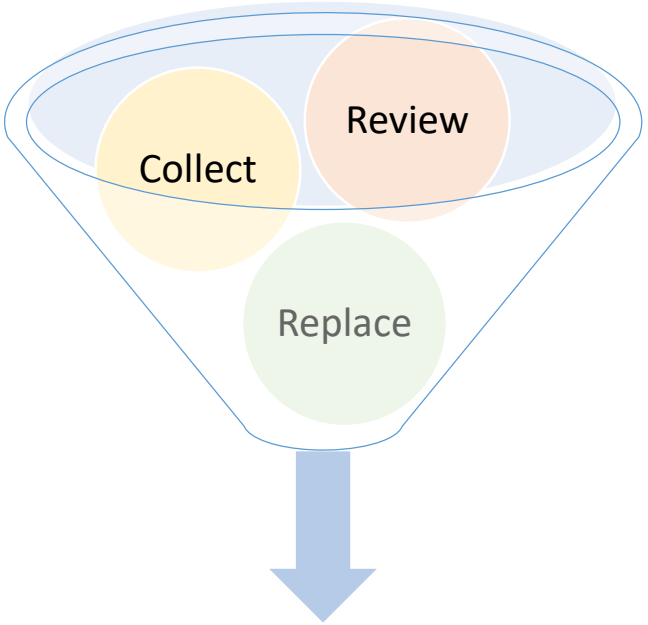
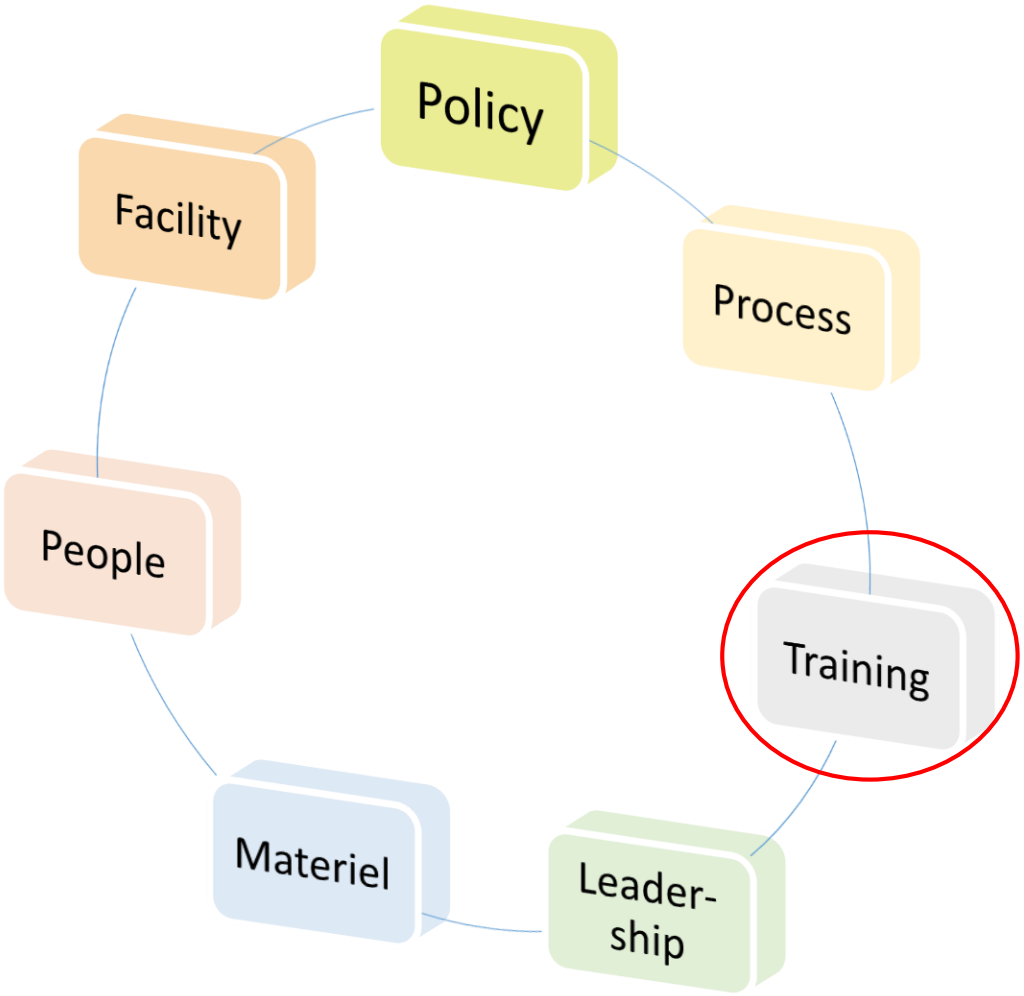
Managing Product Recalls: Training



Recall Product Risk Removed



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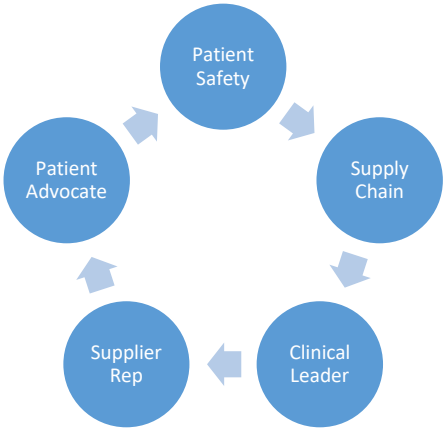
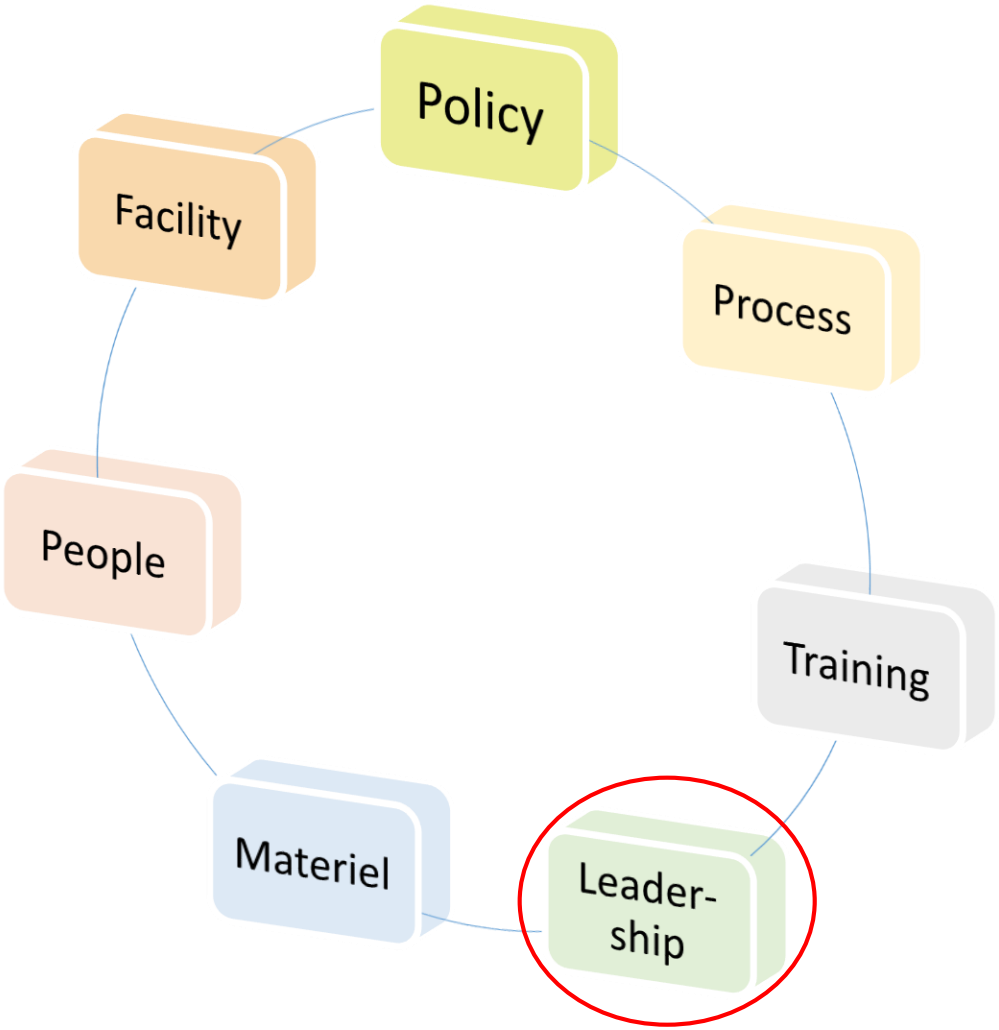
Managing Product Recalls: Leadership

Executive Oversight

Committee Responsibility



Subject Matter Experts



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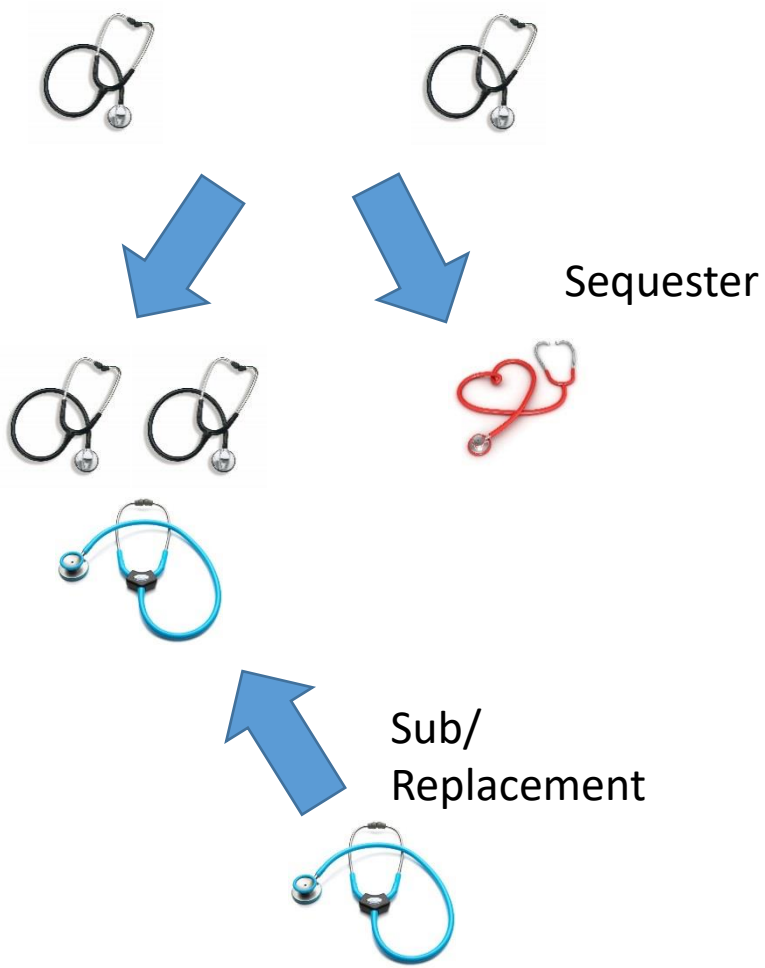
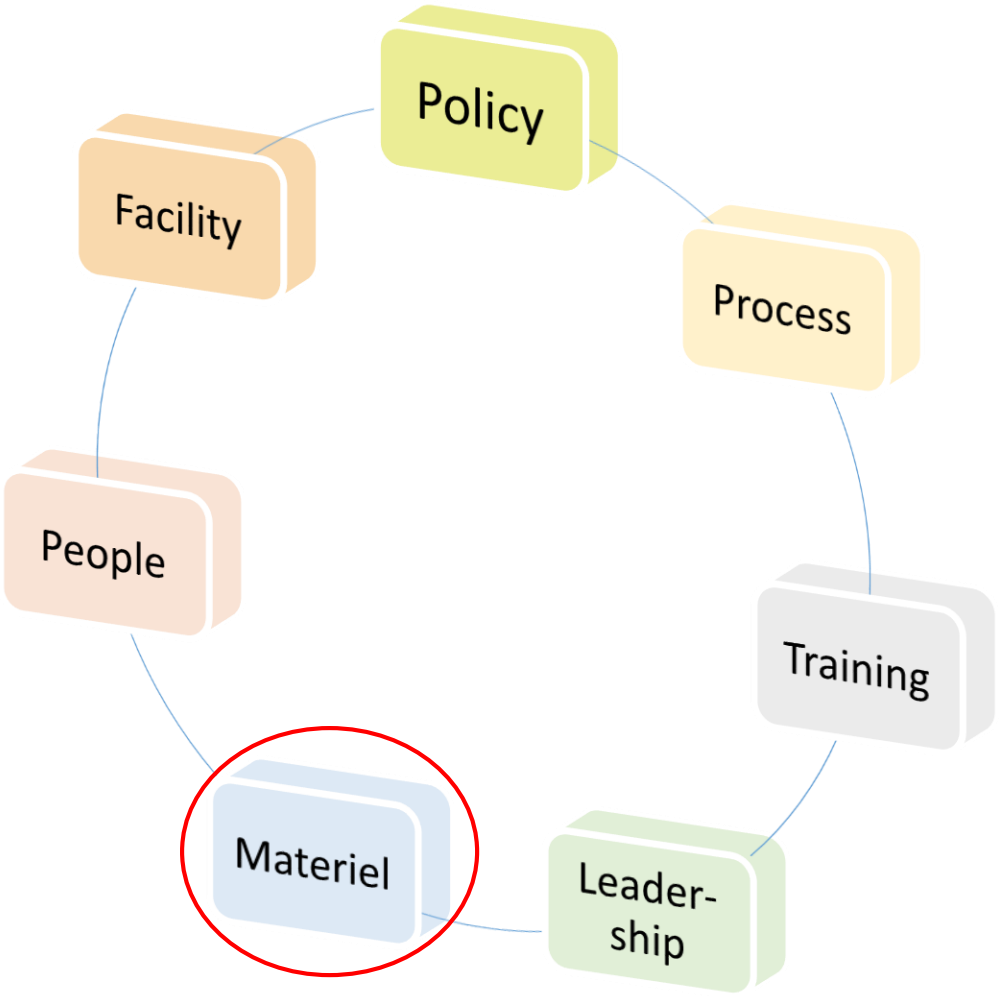
Managing Product Recalls: Materiel





Market Solutions: Third Party

ECRI Institute Report Viewer

Zoom : 75% Zoom | Select Format : Acrobat PDF Export | Print Close

ECRI Alerts Tracker

Coordinator General Search Results Detail

Accession Number : A25251 Priority : High Publication Date : 10/22/2015

Headline/Source/Title : ?CareFusion—SmartSite Extension Sets May Disconnect and Leak

User Name : [OR/Surgery] Kristina Cybularz

Status Date	Status	Action Taken
10/23/2015	Viewed	None
10/23/2015	Applicable - Closed	Isolated Affected Product
	Action Note : affected quant:2 lot#1234	

User Name : [Materials Management] Irina Tracker

Status Date	Status	Action Taken
10/23/2015	Applicable - Closed	Isolated Affected Product
	Action Note : [Proxy entry recorded by Kristina Cybularz	

User Name : [OR/Surgery] Kay Kiss

Status Date	Status	Ac
10/23/2015	Applicable - Closed	Is
	Action Note : [Proxy entry recorded by Kristina Cybularz	

User Name : [Materials Management] Steven Rohs

Status Date	Status	Ac
10/23/2015	Applicable - Closed	Is
	Action Note : [Proxy entry recorded by Kristina Cybularz	

Alert Current Status Details

Status: Applicable - Open
Action Taken: Called Supplier
Action Notes: Called supplier at 800-123-4567...

Alert Tracking

Status: Applicable - Closed
Action Taken: Isolated Affected Product
Action Notes: Isolated 7 boxes of affected tubing from cath lab and returned to mfr. using RA#12345-6-78

SAVE | CLEAR | ADD COMMENT | STATUS HISTORY

Reference: ECRI Alerts Tracker

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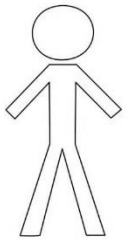
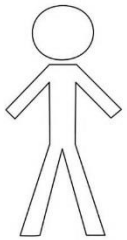
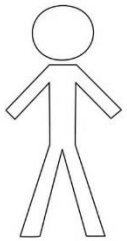
Managing Product Recalls: People



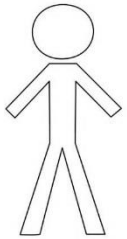
Quality Assurance



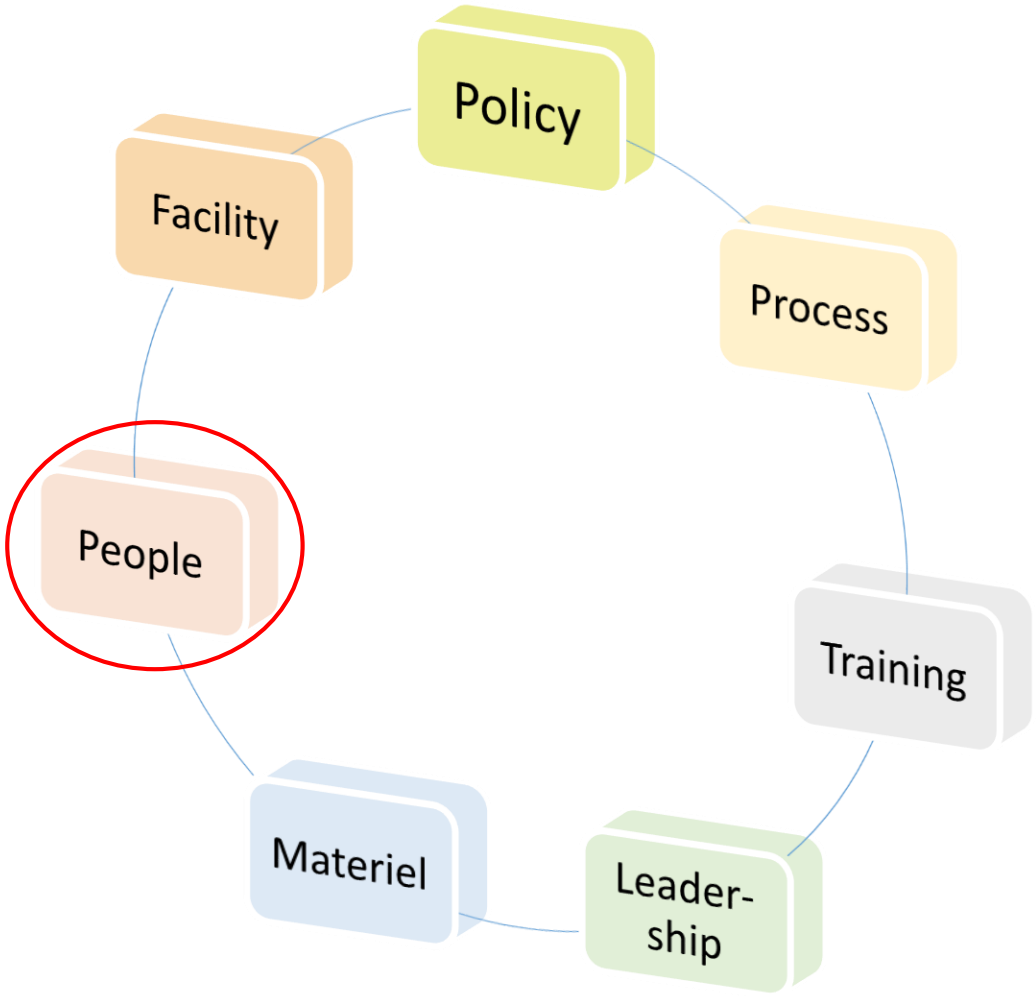
Supplier Quality Engineer



Customer Relations Manager



100's of other options



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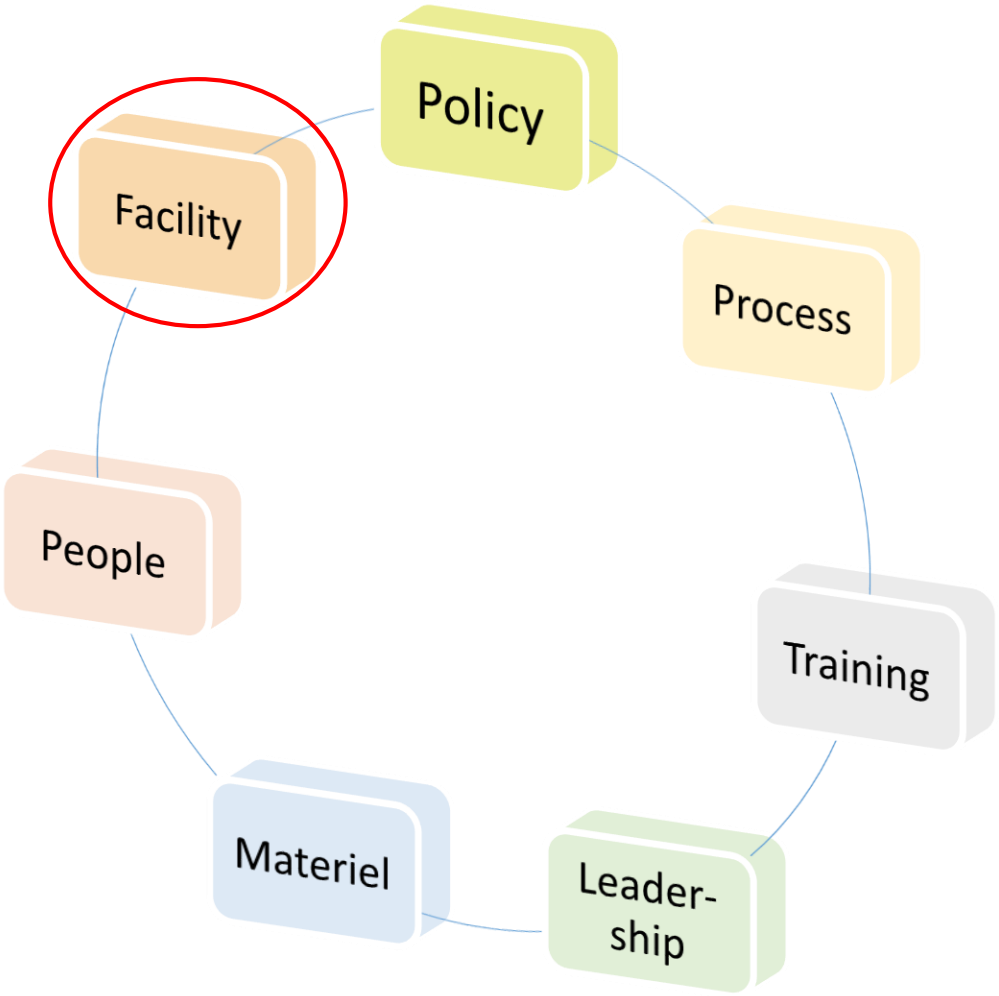
Managing Product Recalls: Facility

Recalled product must have a segregated location, that restricts the ability to put product back into the supply flow



Where Should We Go Now

- Customers pay for expedited shipments, special handling, and similar circumstances… why shouldn't expenses associated with recalls be passed on to suppliers?
- Clinical decision authorities need to provide a change dynamic that makes repeated recall situations punitive
- Contracts should be drafted that place recalls as a failure to comply and not an exempted occurrence

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Questions/Discussion