



Corrective and Preventive Action

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Disclaimer

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

Overview

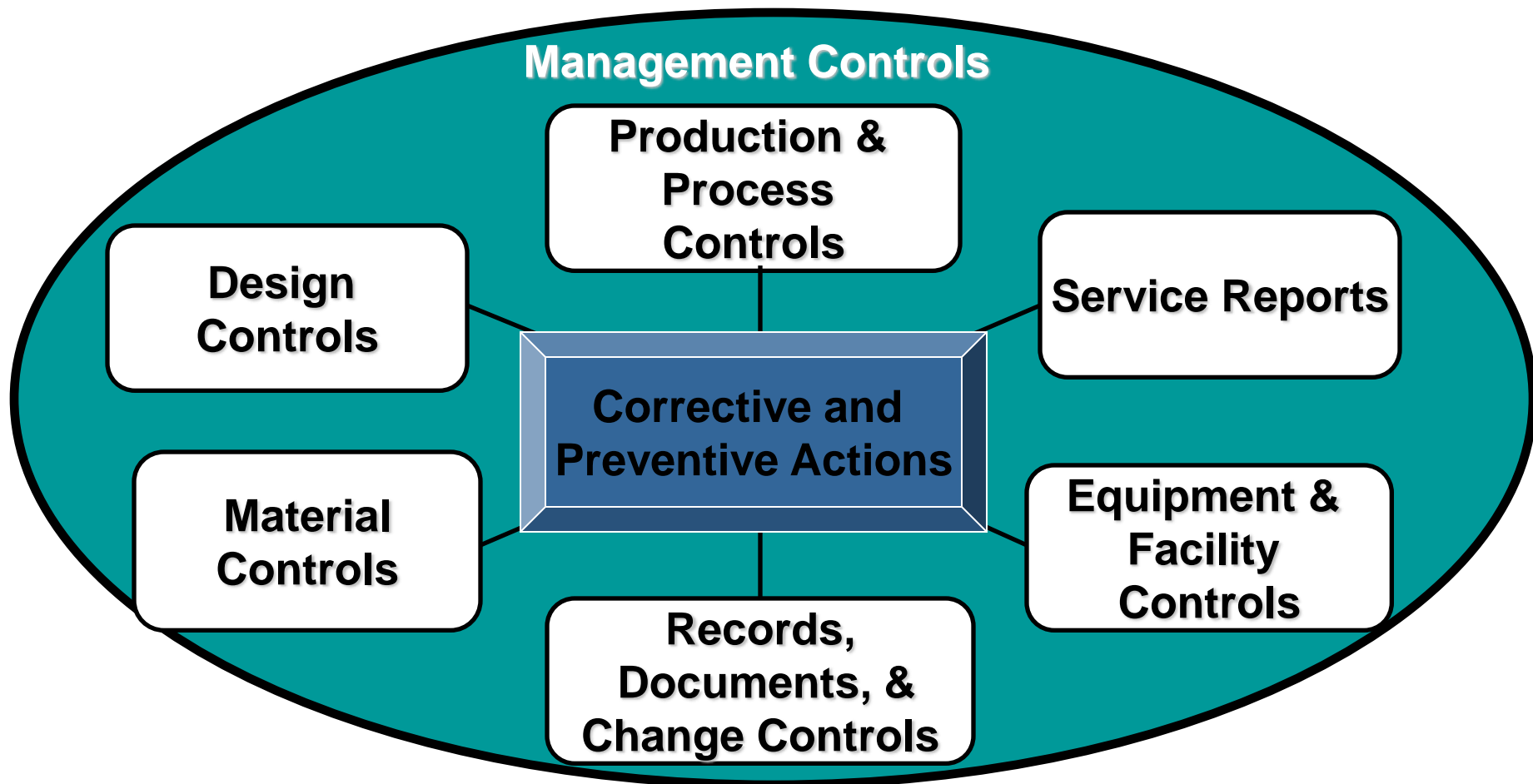
- Background and Requirements
- Why Closed Loop System
- Review CY2012 and CY2013 Quality System (QS) Data
 - Inspection and Warning Letter Data
- Review CY2012 and CY2013 CAPA subsystem Data
 - Inspection and Warning Letter Data
- Recent CAPA Warning Letter Examples

Purpose of the CAPA Subsystem

- Collect and Analyze Information
- Identify and Investigate Existing and Potential Product and Quality Problems
- Take Appropriate, Effective, and Comprehensive Corrective and/or Preventive Actions



CAPA Subsystem in Context

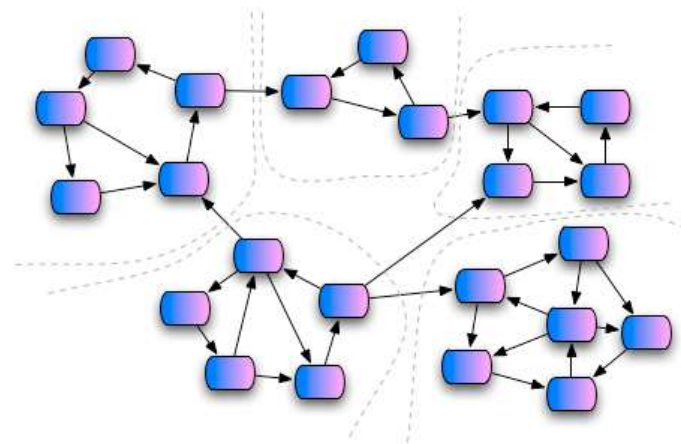


Definition

	Correction	Corrective Action	Preventive Action
Key Term	Existing	Reoccurrence	Occurrence
The Focus Is	Immediate solution	Eliminating the root cause(s)	What could <i>potentially</i> happen

Why is CAPA Important?

- Linked to many other requirements
 - 820.198 Complaint Files
 - 820.90 Nonconforming Product
 - 820.80 Acceptance Activities
 - 820.200 Servicing
 - 820.22 Audits
 - 803 Medical Device Reporting
 - 806 Reports of Corrections and Removals
 - ... and many more
- Ensures problems are detected AND resolved



Why is CAPA Important?

“... The **objective** of § 820.100 is to correct and prevent poor practices, not simply bad product ...

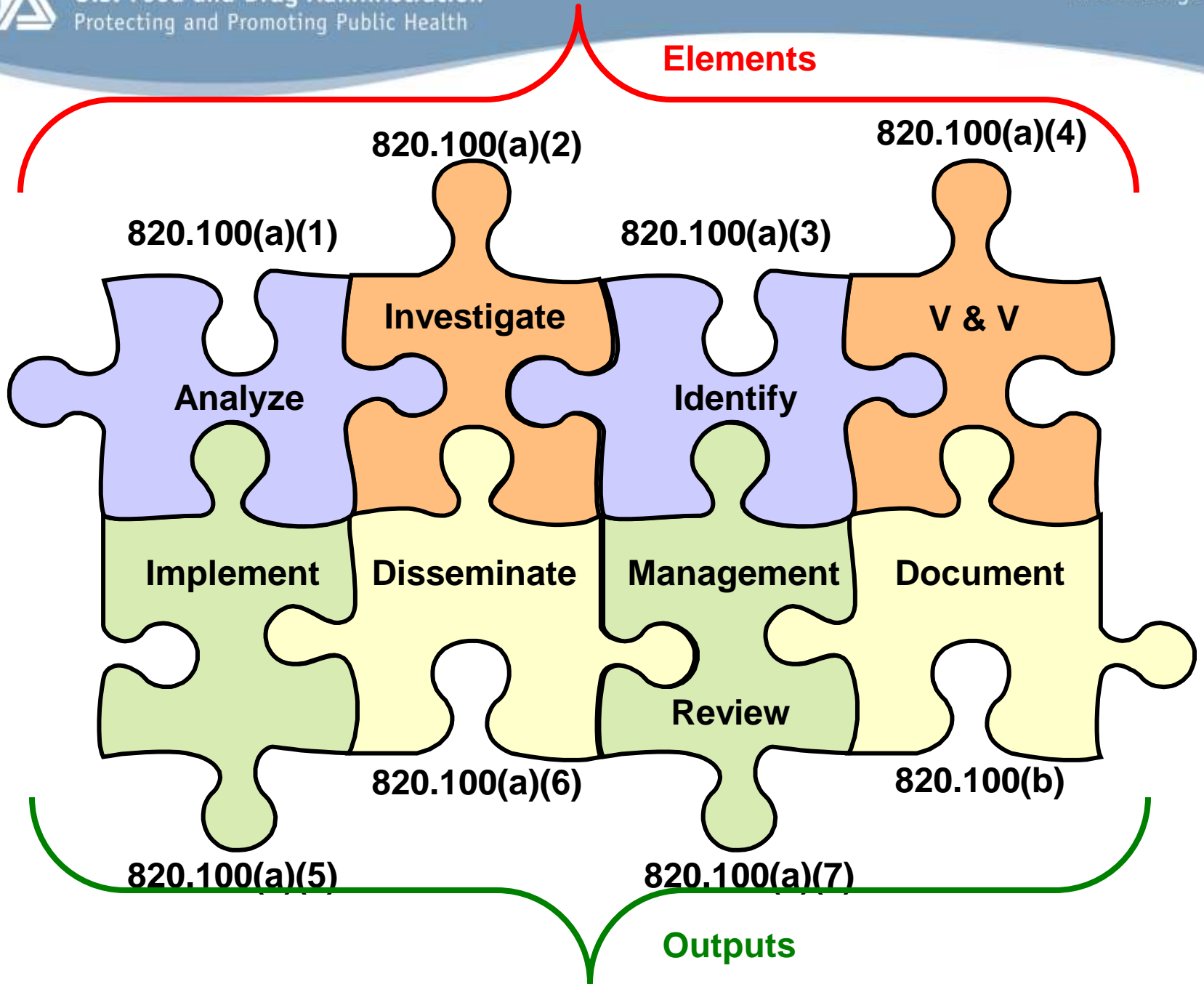
Correction and prevention of **unacceptable quality system practices**

should result in fewer nonconformities related to product.

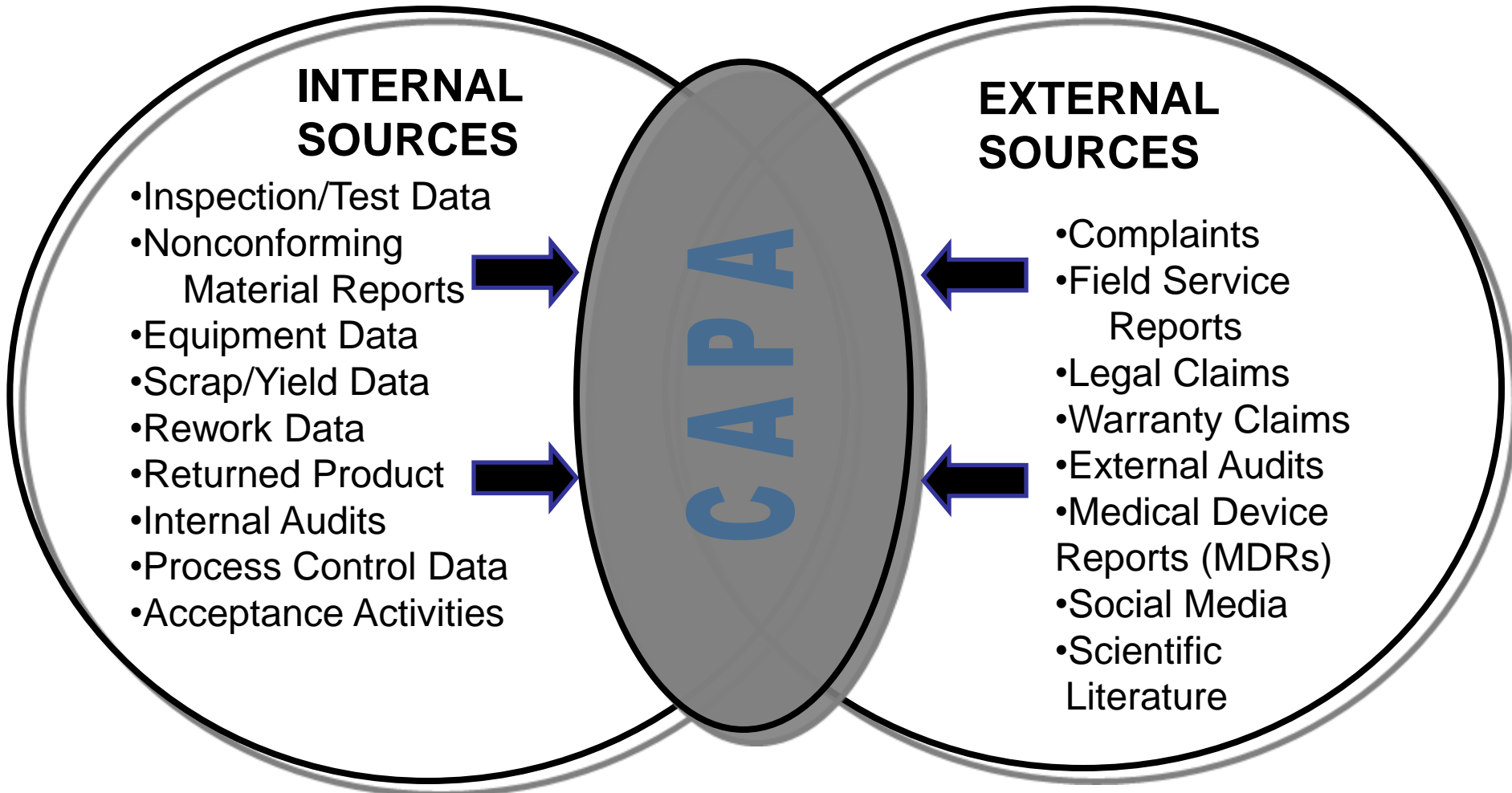
... For example, it [CAPA] should identify and correct improper personnel training, the failure to follow procedures, and inadequate procedures, among other things”



The CAPA Process



Data Sources



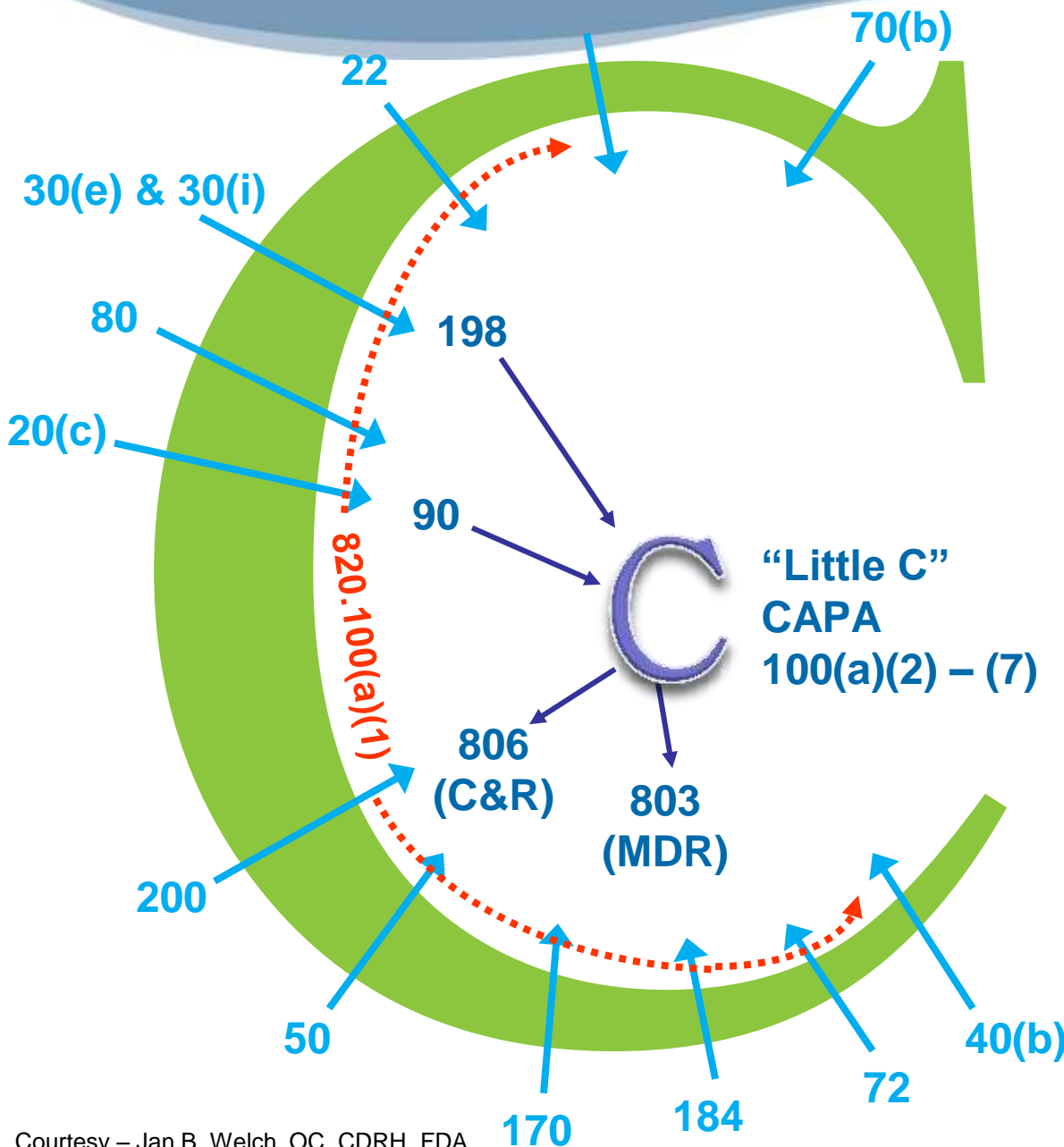
INTERNAL SOURCES

- Inspection/Test Data
- Nonconforming Material Reports
- Equipment Data
- Scrap/Yield Data
- Rework Data
- Returned Product
- Internal Audits
- Process Control Data
- Acceptance Activities

EXTERNAL SOURCES

- Complaints
- Field Service Reports
- Legal Claims
- Warranty Claims
- External Audits
- Medical Device Reports (MDRs)
- Social Media
- Scientific Literature

CAP A



“BIG C” CAPA SYSTEM

Quality Data Sources Within the QMS

820.200	Service
820.198	Complaints
820.170	Installation
820.100	CAPA
820.90	Nonconforming Prod.
820.80	Acceptance Activities
820.75(c)	Process Changes (PV)
820.72	Calibration
820.70(b)	Production & Proc Chg
820.50	Purchasing
820.40(b)	Document Changes
820.30(e)	Design Review
820.30(i)	Design Changes
820.22	Quality Audit
820.20(c)	Management Review
803	MDRs
806	Corrections & Removals

CAPA and Management

“FDA agrees that the **degree of corrective and preventive action taken** to eliminate or minimize actual or potential nonconformities **must be appropriate to the magnitude of the problem and commensurate with the risks encountered**...FDA does expect the manufacturer to develop procedures for assessing the risk, the actions that need to be taken for different levels of risk, and how to correct or prevent the problem from recurring, depending on that risk assessment”

61 Fed. Reg. at 52633-52634, Comment 159

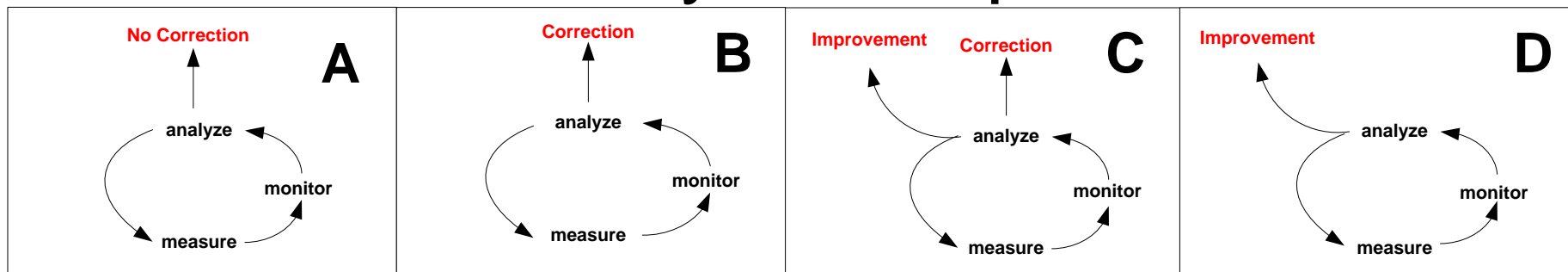
Closed Loop System

“The involvement of management with executive responsibility, **the concept of a total quality system which is a closed feedback loop system, and the practice of using that closed loop system in taking appropriate corrective and preventive action is paramount** in

ensuring that safe and effective medical devices are available to the public”



CAPA System Options



Scenario	Option
A	No correction required, continue measurement and monitoring
B	Correction required, continue measurement and monitoring
C	Correction required, escalation to further investigation under the improvement phase
D	No correction required, escalation for further investigation under the improvement phase

Symptoms of a Less than Effective CAPA System

- Recurring issues
- Inability to “manage” sources of quality data to understand early trends and issues
- More reaction than prevention
- Resources are spent on “handling” failure rather than learning from it and preventing “more of the same”
- Field issues

When Does FDA Review CAPA?

- Establishment Inspections
 - Quality System Inspection Technique (QSIT) – CAPA Subsystem
 - Compliance Program (7382.845) – Inspection of Medical Device Manufacturers
- Premarket Approval Applications (PMAs)
 - Original PMAs
 - PMA supplements e.g. Site changes, 30-Day Notices
- Recalls
- CAPA is NOT Reviewed in 510(k)s

FDA CY2012 and CY2013 Quality System Data

483 Observations and Warning Letters



CY2012 and CY2013 Data

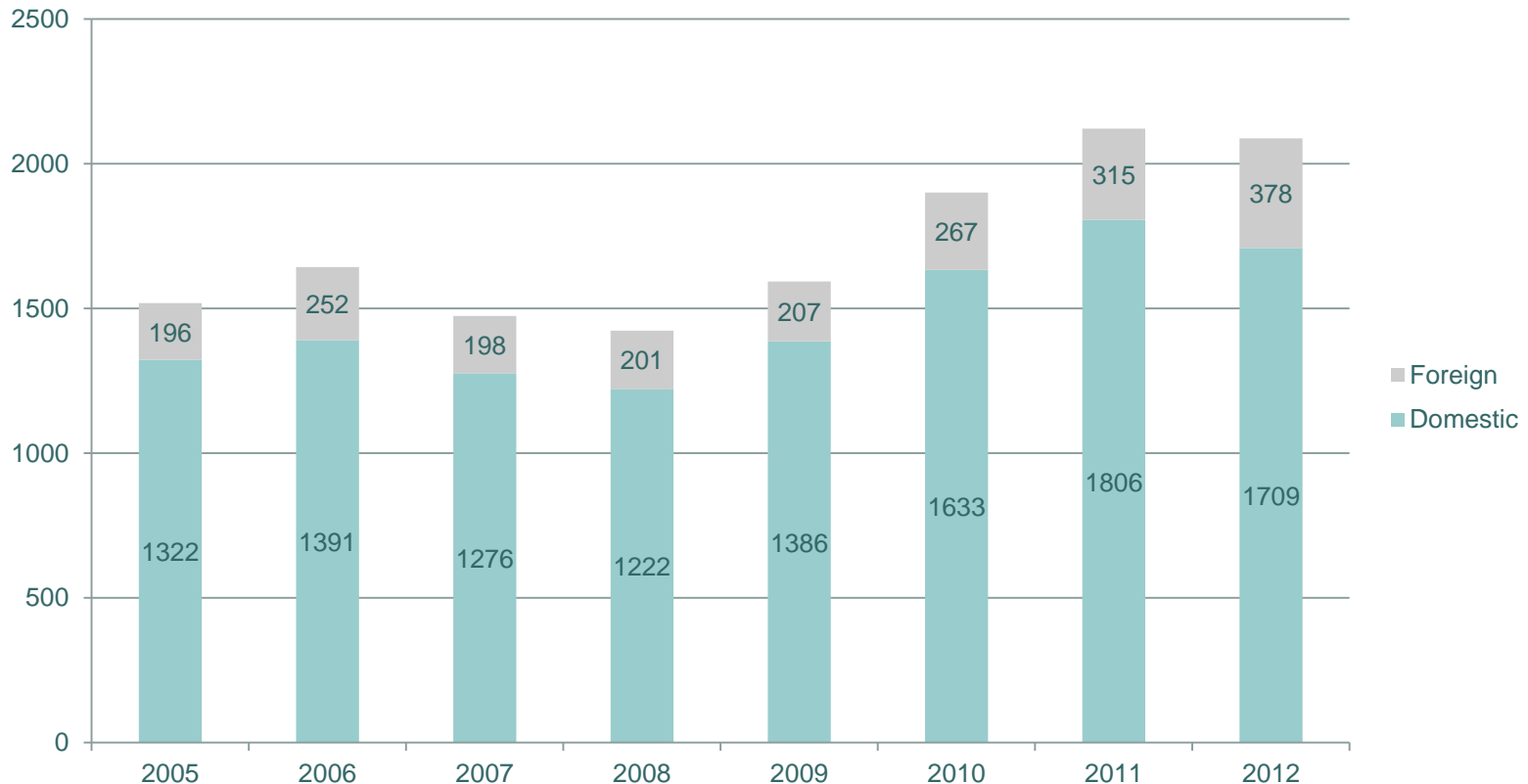
- Source of data :
FDA's Turbo EIR database
- Time frame :
January 2012 – December 2012
January 2013 – December 2013

QS Regulation Cites by Subsystem

Production and Process Controls (P&PC)		Corrective and Preventive Action (CAPA)	Management (MGMT)	Design Controls (DES)	Document Controls (DOC)
820.50	820.120	820.90	820.5	820.30	820.40
820.60	820.130	820.100	820.20		820.180
820.70	820.140	820.198	820.22		820.181
820.72	820.150		820.25		820.184
820.75	820.160				820.186
820.80	820.170				
820.86	820.200				
	820.250				



Routine Quality System Surveillance Inspections



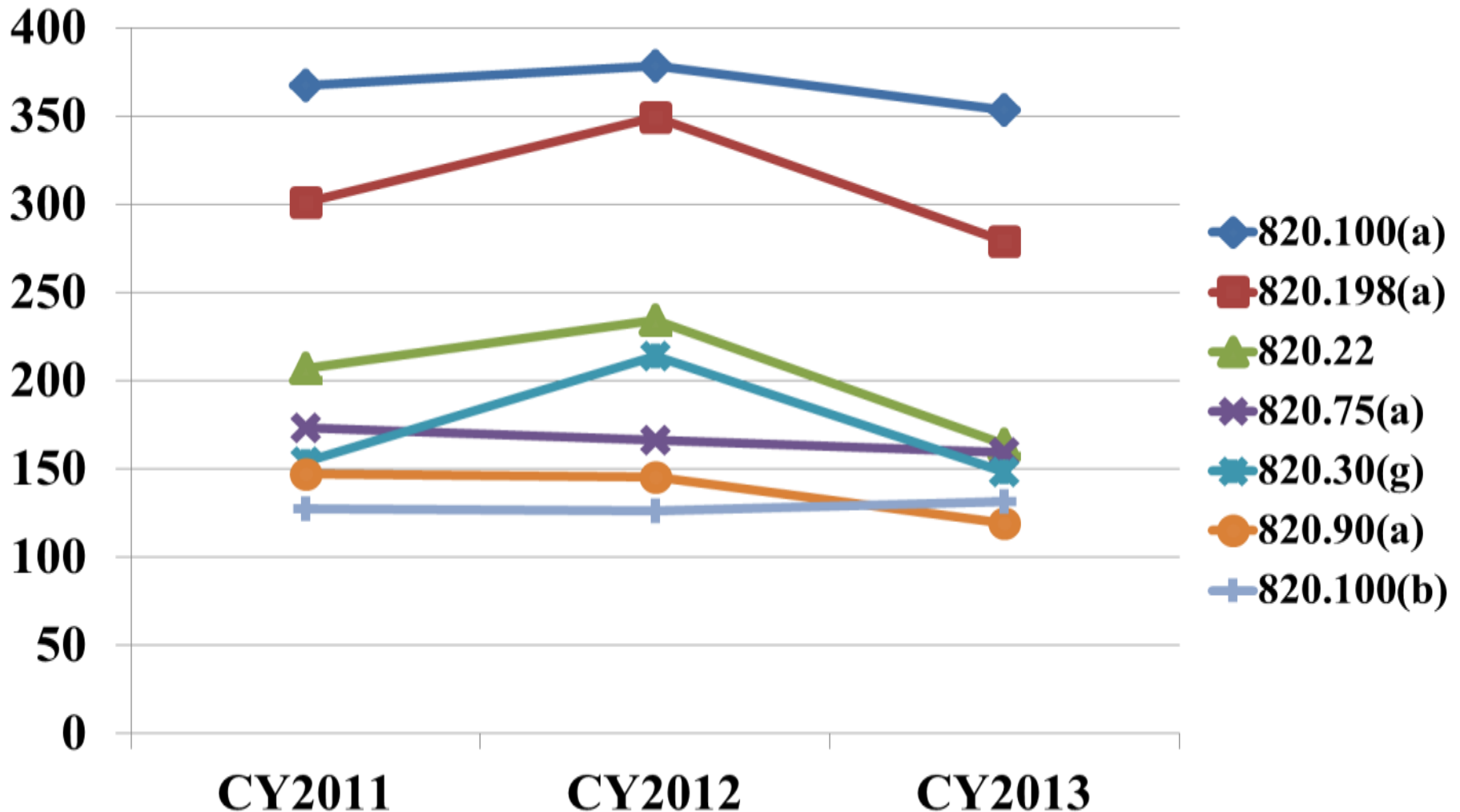


Most Frequent QS 483 Observations

2011	No. of Observations	2012	No. of Observations	2013	No. of Observations
820.100(a)	367	820.100(a)	378	820.100(a)	355
820.198(a)	301	820.198(a)	349	820.198(a)	280
820.22	207	820.22	234	820.22	165
820.75(a)	173	820.30(g)	214	820.75(a)	159
820.30(g)	154	820.184	190	820.30(g)	149
820.90(a)	147	820.75(a)	166	820.184	147
820.100(b)	127	820.90(a)	145	820.100(b)	133
820.25(b)	117	820.100(b)	126	820.90(a)	120
820.20(c)	112	820.25(b)	119	820.50	107
820.50	105	820.20(c)	109	820.30(i)	89
820.40	101	820.40	101	820.198(c)	71



Most Frequent QS 483 Observations



483 Observations

QS Subsystem	483 Observations	
	2012	2013
CAPA	1258 (30%)	1085 (31%)
P&PC	1303 (30%)	1151 (33%)
DES	630 (15%)	506 (14%)
DOC	469 (11%)	367 (10%)
MGMT	583 (14%)	425 (12%)
TOTAL	4243	3534

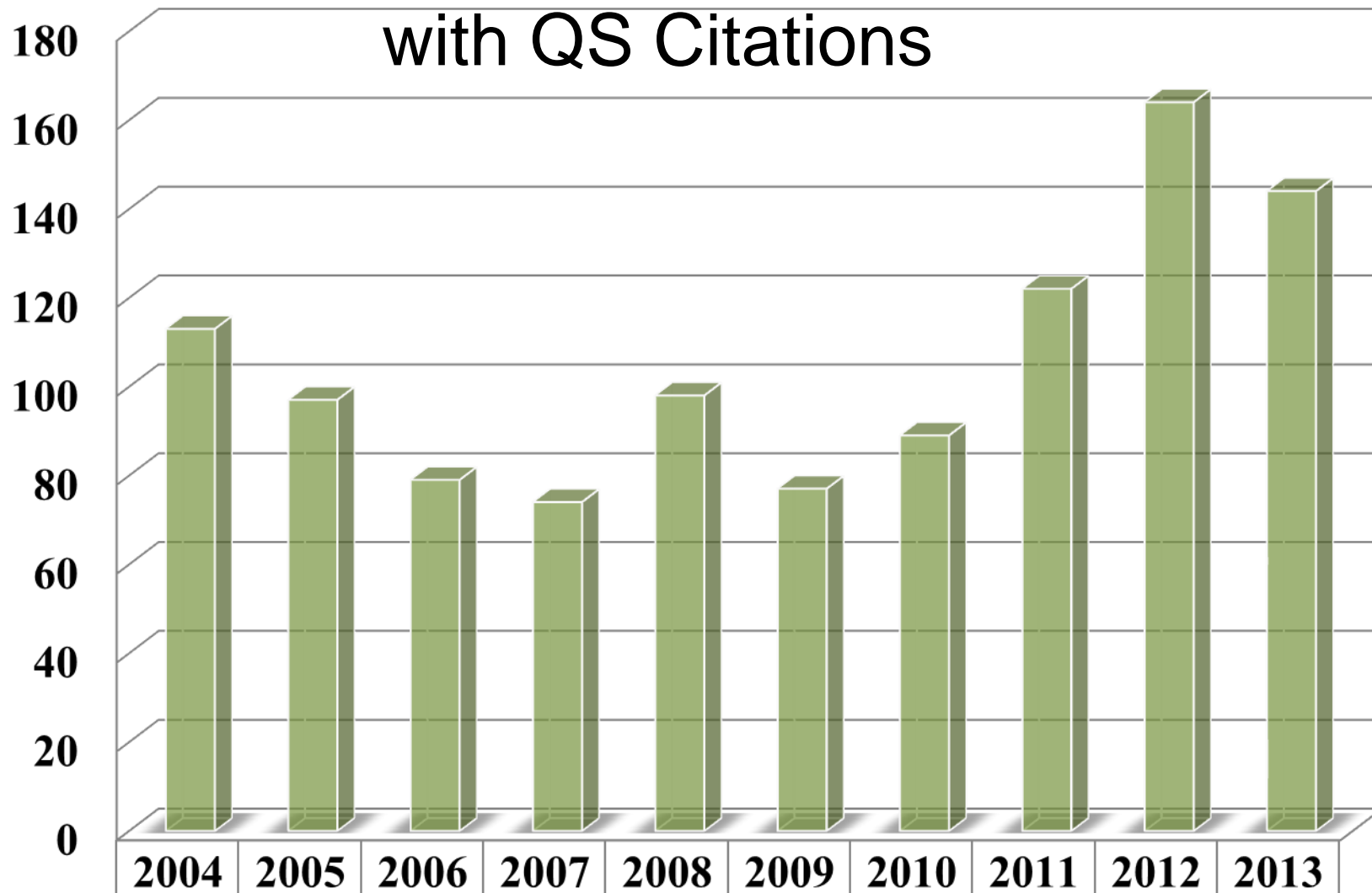
CAPA Subsystem 483 Observations

Citations	Number of 483 Observations	
	2012	2013
Complaint Files (820.198)	534 (42%)	429 (40%)
CAPA (820.100)	505 (40%)	491 (45%)
Nonconforming Product (820.90)	219 (18%)	165 (15%)
TOTAL	1258	1085

A large, light gray warning sign consisting of a triangle with a thick border and a large exclamation mark in the center. The sign is centered on the page.

Warning Letters

CY2004-2013 Warning Letters (WLs) with QS Citations



■ # of WLs

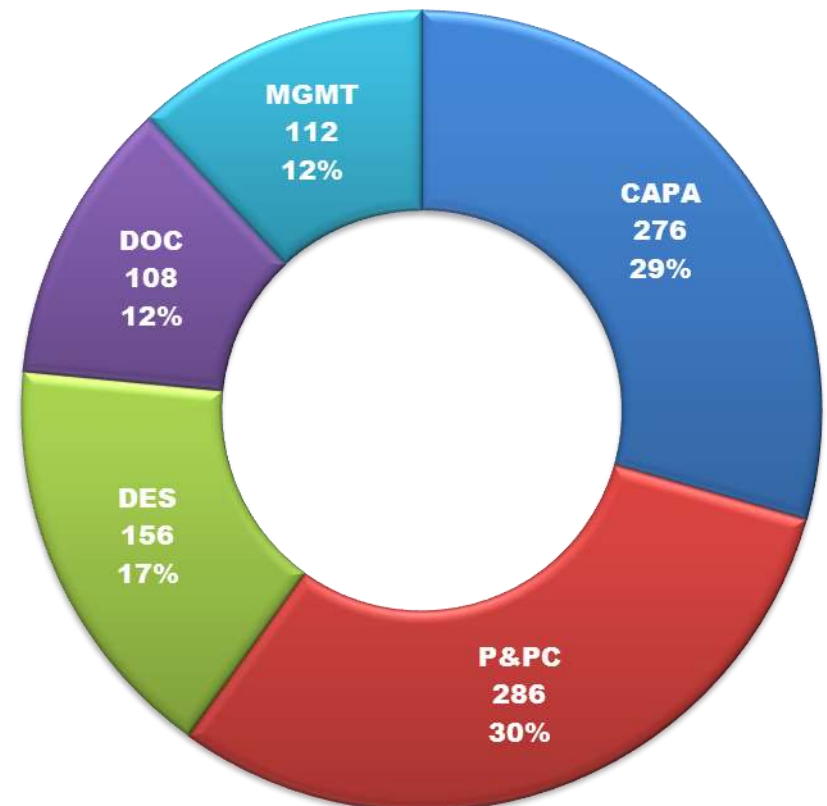
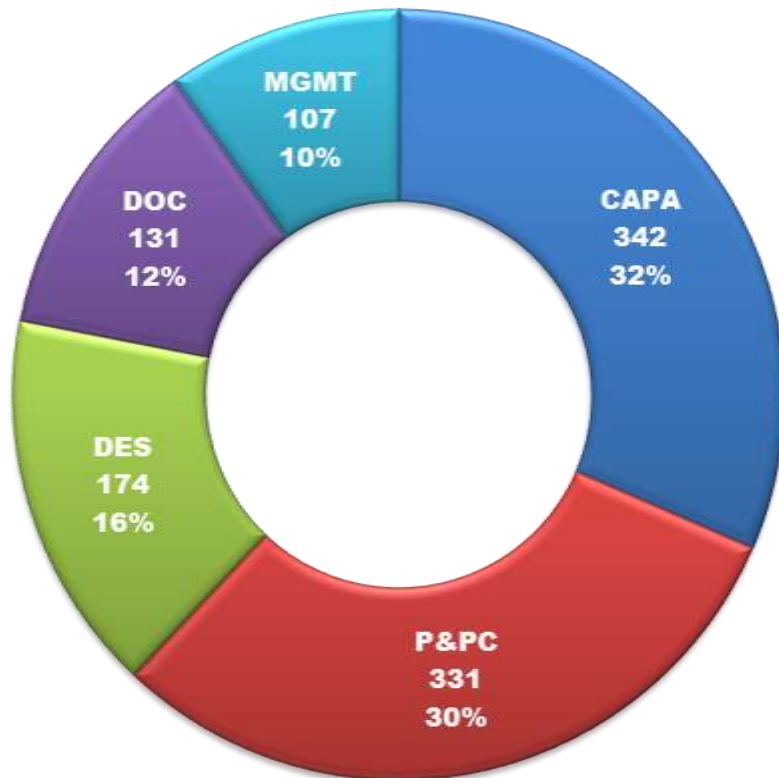
Numbers of WLs with QS Subsystem Citations

QS Subsystem	No of WL with Cite	
	2012 (164 WLs)	2013 (144 WLs)
CAPA	143 (87%)	127 (88%)
P&PC	134 (82%)	127 (88%)
DES	91 (55%)	91 (63%)
DOC	78 (48%)	77 (53%)
MGMT	70 (43%)	71 (49%)

Numbers of QS Citations in WLS

2012

2013



CAPA Subsystem Warning Letter Cites

Citations	Number of WL Cites	
	2012	2013
Complaint Files (820.198)	154 (45%)	112 (41%)
CAPA (820.100)	130 (38%)	117 (42%)
Nonconforming Product (820.90)	54 (16%)	47 (17%)
Acceptance Status (820.86)	4 (1%)	0
TOTAL	342	276

CAPA

Warning Letter Examples



Warning Letter Example

CAPA Procedures

- Your firm failed to establish, maintain, and implement a corrective and preventive action procedure, as required by **820.100(a)**. For example,
 - Your **firm has no CAPA procedures as defined in the QS regulation** including: failure investigation, procedures to analyze quality data...procedures to verify/validate corrections, procedures that ensure that information related to quality problems is disseminated and for submitting relevant information on identified quality problems to management for review.

Warning Letter Example

CAPA Procedures

- Failure to establish and maintain adequate procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a).
 - For example, the firm's procedure XYZ, does not include requirements for analyzing sources of quality data (other than complaints) to identify existing and potential causes of nonconforming product, or other quality problems. Nor does the procedure require documentation of the verification/validation of corrective and preventive actions to ensure that such action is effective and does not adversely affect the finished devices.

Warning Letter Example

Verification/Validation of a CAPA

- Failure to establish and maintain adequate procedures for verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a)(4).
 - For example, **no protocol**, including acceptance criteria, was established **for the validation of Change Request XYZ**. Additionally, there was **no documentation showing that this change was validated**. The change was implemented to fix cracked cooling pumps in the device.

Warning Letter Example

Verification/Validation of a CAPA

- Failure to establish and maintain adequate procedures to verify or validate corrective action to ensure that such action is effective and does not adversely affect the finished device, as required by **21 CFR 820.100(a)(4)**.
 - For example, based upon the investigation of the cause of irradiation batches receiving doses below the specified minimum dose requirement (due to incorrect packaging and product density), the **firm implemented new packaging procedures and retrained employees. Irradiation batches receiving doses below the specified minimum dose requirement have recurred** after implementation of the cited corrective action. The firm's management stated that the **recurring nonconformities may be attributed to employees not following directions.**

Warning Letter Example

Verification/Validation of a CAPA

- Failure to establish and maintain adequate procedures for verifying or validating corrective and preventive action to ensure that such action is effective, as required by 21 CFR 820.100(a)(4).
 - For example, CAPA XYZ involved the sticking of silicone tubing used in monitors when the devices remained out of use for 3-6 months. In reaction, **you implemented a design change** (the addition of a talcum coating to the tubing). Your **procedure did not ensure that the corrective action was verified or validated as effective** in preventing the sticking of silicone tubing in distributed products.

References

- 21 CFR Part 820
 - <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=820>
- Preamble to the QS Regulation Final Rule
 - <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/MedicalDeviceQualitySystemsManual/UCM122806.pdf>
- Compliance Program (7382.845) – *Inspection of Medical Device Manufacturers*
 - <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072753.htm>
- Quality System Inspection Technique (QSIT)
 - <http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074883.htm>
- Global Harmonization Task Force (GHTF) Guidance Document on Corrective and Preventive Action
 - http://www.ghtf.org/documents/sg3/sg3_n18.pdf

Providing Industry Assistance

CDRH Resources

- CDRH Learn
 - Modules include various premarket and post-market information
 - Available 24/7
 - Certificate generated per topic upon passing post-tests
 - <http://www.fda.gov/Training/CDRHLearn/default.htm/>

- Device Advice
 - Self-service website
 - Searchable by topic
 - <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>

- Division of Industry and Consumer Education (DICE)
 - Technical Assistance for the Medical Device Industry
 - 301-796-7100
 - DICE@fda.hhs.gov



Discussion



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