2013 Annual FDA Medical Device Quality System Data

FDA Form 483 Observations

and

Warning Letter Citations

Why is FDA making these data available?

In support of the FDA Transparency Initiative and Case for Quality, the Center for Devices and Radiological Health (CDRH) is providing data on inspectional observations and warning letter citations issued in 2013.

We believe that the following information will:

- Help industry improve device quality by sharing common observations from inspections
- Identify possible areas of emerging concern
- Possibly help firms avoid receiving warning letters

Key Inspection Findings CY2013

- There has been a 3 percent decrease in the number of quality system surveillance inspections. This slight decrease is likely attributed to an increase in the proportion of foreign inspections being performed which requires more agency resources.

- The number of overall inspectional observations decreased by 17 percent in 2013.

- There has been little or no change from 2012 to 2013 in regard to the most frequent inspectional observations. Below are the most frequent observations found in 2013:

    - Corrective and preventive action procedures (21 CFR 820.100(a)),
    - Complaint files, specifically establishing and maintaining procedures for receiving, reviewing and evaluating complaints (21 CFR 820.198(a)), and
    - Quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system (21 CFR 820.22).

Key Warning Letter Findings CY2013

- The number of warning letters (WL) decreased slightly for the first time since 2009. Four percent of domestic firms inspected and 16 percent of foreign firms inspected received WLs.
- The 3 most frequent WL citations in 2013 were in the following subsystems:
  - Corrective and preventive action procedures (21 CFR 820.100(a)),
  - Complaint files, specifically establishing and maintaining procedures for receiving, reviewing and evaluating complaints (21 CFR 820.198(a)), and
  - Quality audit procedures (21 CFR 820.22).
- CDRH found a lower rate of device history record violations in WLs from 2012 to 2013. Fifty-five WLs included a 21 CFR 820.184 device history record violation in 2012 and 44 WLs included the violation in 2013.

The Quality System (QS) regulation

- In October 1996 the FDA published the final rule for the Quality System (QS) regulation.
- In June 1997 revisions to 21 CFR part 820 (covering CGMP) took effect.
- The QS regulation includes requirements related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing, and servicing of medical devices intended for human use.
- The QS regulation established a framework for device manufacturers to follow and gave them greater flexibility in achieving quality requirements. This action was necessary to add preproduction design controls and to achieve consistency with quality system requirements worldwide.
- In support of the FDA Transparency Initiative, CDRH is providing data on how inspection observations and warning letter citations issued in 2013 connect to the various subsystem requirements contained in the QS regulation.

Quality System (QS) regulation Subsystems

P&PC	Production and Process Controls
CAPA	Corrective and Preventive Actions
MGMT	Management Controls
DES	Design Controls
DOC	Document Controls

Descriptions of Quality System Subsystems

Corrective and Preventive Actions (CAPA) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action Each manufacturer shall maintain processes to address non-conforming product and establish and maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. The related sections of the CFR include 21 CFR 820.90, 820.100, 820.198)

Production and Process Controls (P&PC) Each manufacturer is required to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. In addition to process controls, this subsection includes purchasing controls, labeling, packaging, handling, storage, and installation. The related sections of the CFR include 820.50, 820.60, 820.65, 820.70, 820.72, 820.75, 820.80, 820.120, 820.130, 820.140, 820.150, 820.160, 820.170, 820.200, and 820.250).

Management Controls (MGMT) Management is responsible for establishing policy and objectives for, and commitment to, quality. The QS regulation requires that each manufacturer establish and maintain an adequate organizational structure to ensure that devices are designed and produced in accordance with the GMP requirements. To meet these regulatory requirements, manufacturers are required to provide adequate resources, including the assignment of trained personnel for management, performance of work, and assessment activities, including internal quality audits. The related sections of the CFR include 21 CFR 820.5., 820.20, 820.22 and 820.25.

Design Controls (DES) Each manufacturer is required by regulation to establish and maintain design control procedures for any class III or class II device, and a selected group of class I devices. The design control procedures ensure that specified design requirements are met. The Design Control regulation is 21 CFR 820.30.

Document Controls (DOC) Each manufacturer is required to establish and maintain procedures to control the documents for *approval and distribution as well as changes.* Manufacturers are also responsible for creating and maintaining the device master record, the device history record and the Quality System Record. The related sections of the CFR include 820.40, 820.180, 820.181, 820.186 and 820.184).

QS Regulation Citations by Subsystem

P&PC	CAPA	MGMT	DES	DOC
820.50	820.90	820.5	820.30	820.40
820.60	820.100	820.20		820.180
820.65	820.198	820.22		820.181
820.70		820.25		820.184
820.72				820.186
820.75				
820.80				
820.86				
820.120				
820.130				
820.140				
820.150				
820.160				
820.170				
820.200				
820.250				

P&PC Descriptions

P&PC	Description
820.50	Purchasing Controls
820.60	Identification
820.65	Traceability
820.70	Production and process controls
820.72	Inspection, measuring, and test equipment
820.75	Process validation
820.80	Receiving, in-process, and finished device acceptance
820.86	Acceptance status
820.120	Device labeling
820.130	Device packaging
820.140	Handling
820.150	Storage
820.160	Distribution
820.170	Installation
820.200	Servicing
820.250	Statistical techniques

CAPA & MGMT Descriptions

CAPA	Description	MGMT	Description
820.90	Nonconforming product	820.5	Quality system
820.100	Corrective and preventive action	820.20	Management respnsibility
820.198	Complaint files	820.22	Quality audit
		820.25	Personnel

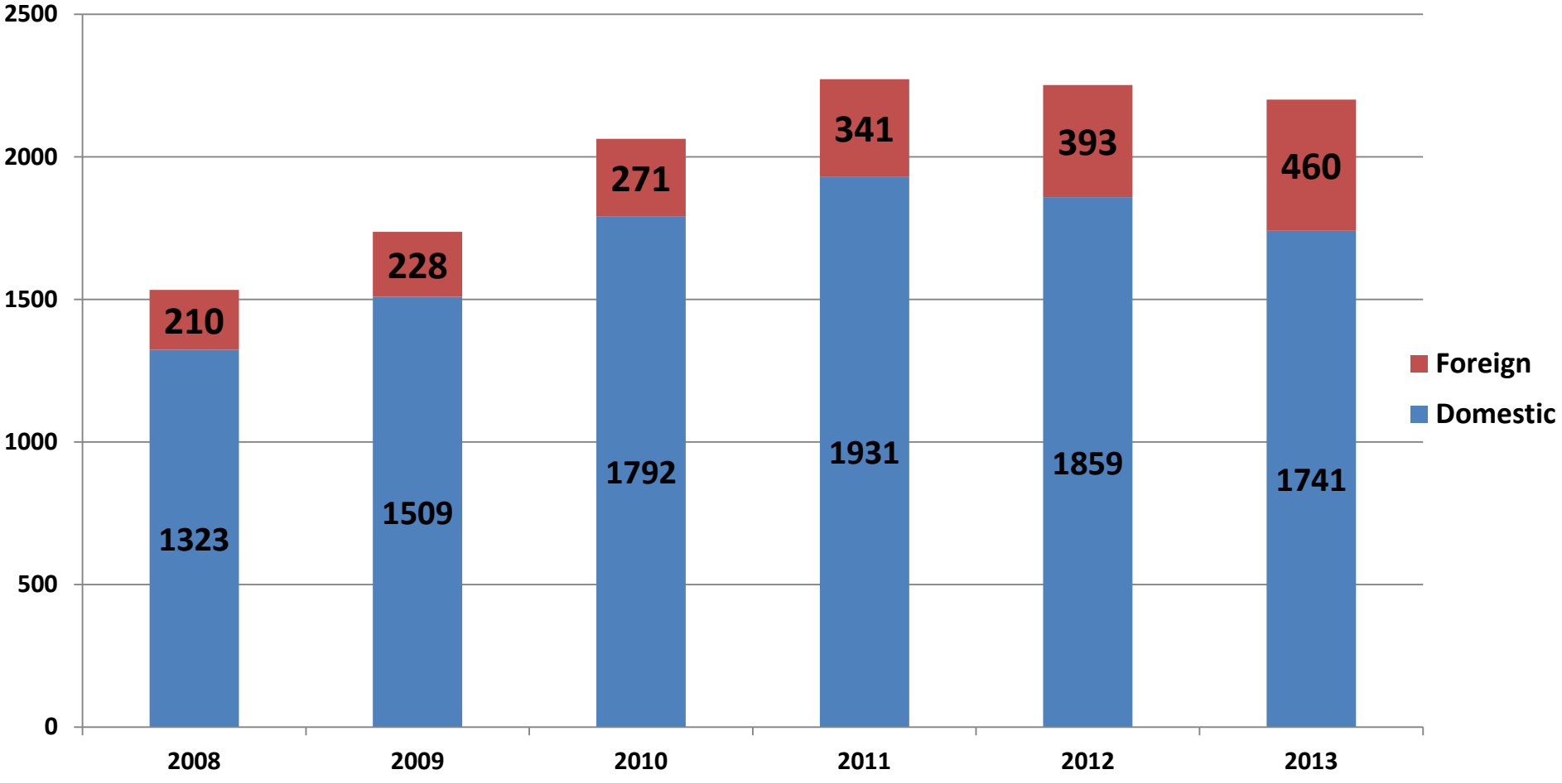
DES & DOC Descriptions

DES	Description	DOC	Description
820.30	Design controls	820.40	Document controls
		820.180	General requirements
		820.181	Device master record
		820.184	Device history record
		820.186	Quality system record

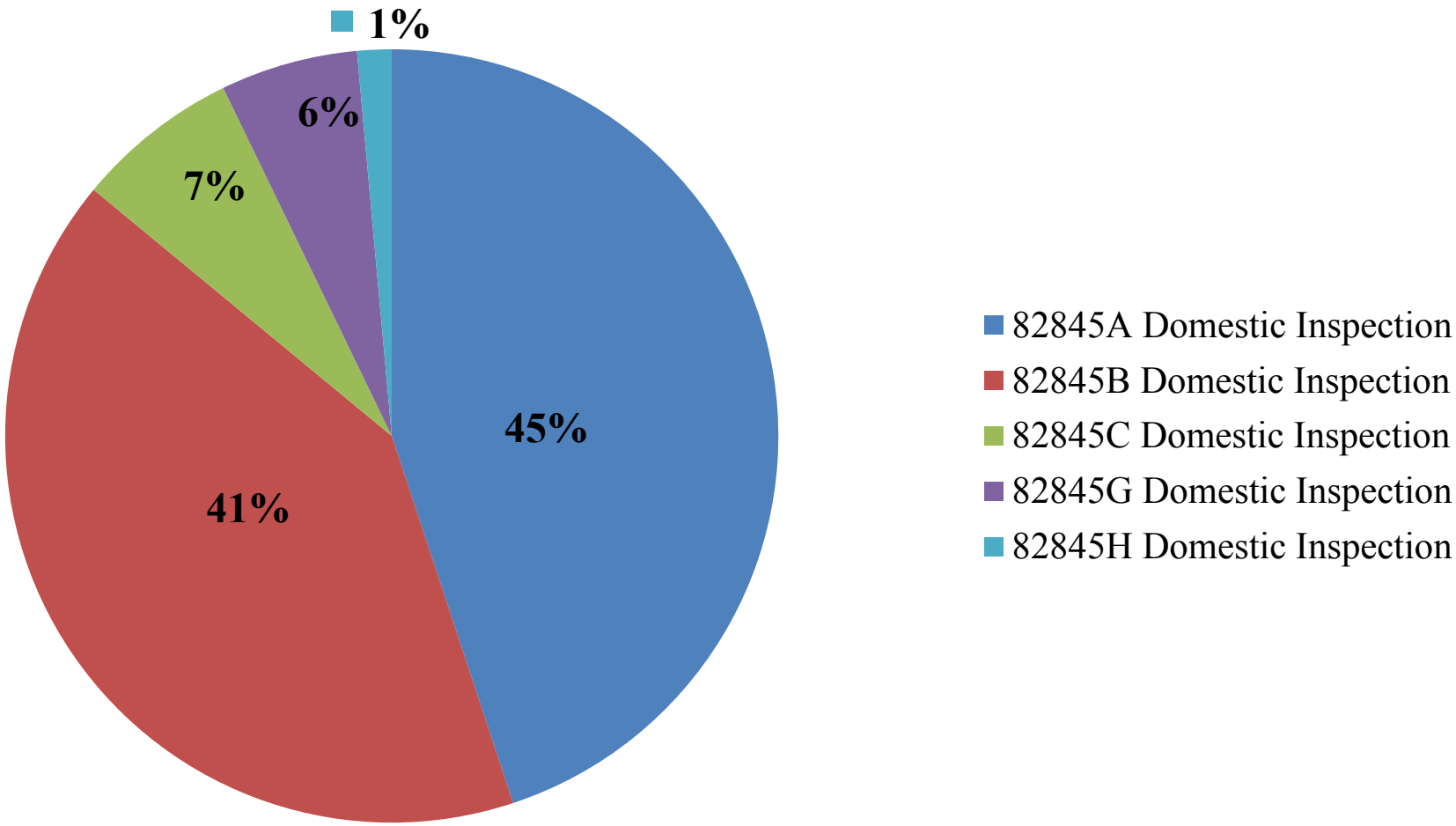
Routine Medical Device Quality System Surveillance PAC Codes

Program Assignment Code (PAC)	PAC Inspection Description
82845A	Medical Device Level I (Abbreviated)
82845B	Medical Device Level II (Baseline)
82845C	Medical Device Level III (Compliance Follow-up)
82845G	Medical Device "For Cause"
82845H	Medical Device High Risk GMP

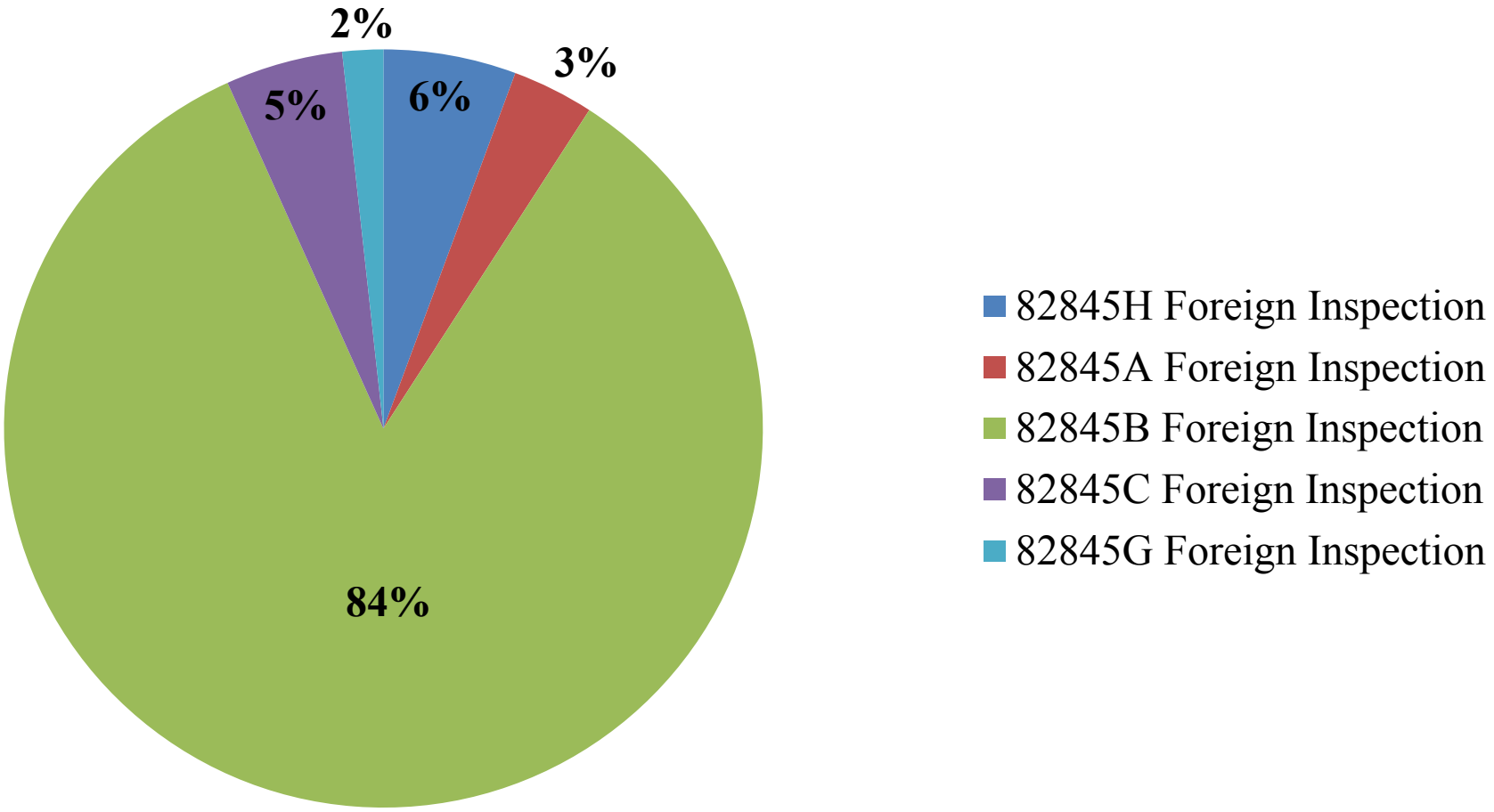
Routine Medical Device Quality System Surveillance Inspections CY2008 – CY2013



CY2013 Medical Device Domestic Inspections



CY2013 Medical Device Foreign Inspections



CY2013 Top 10 Foreign Inspections

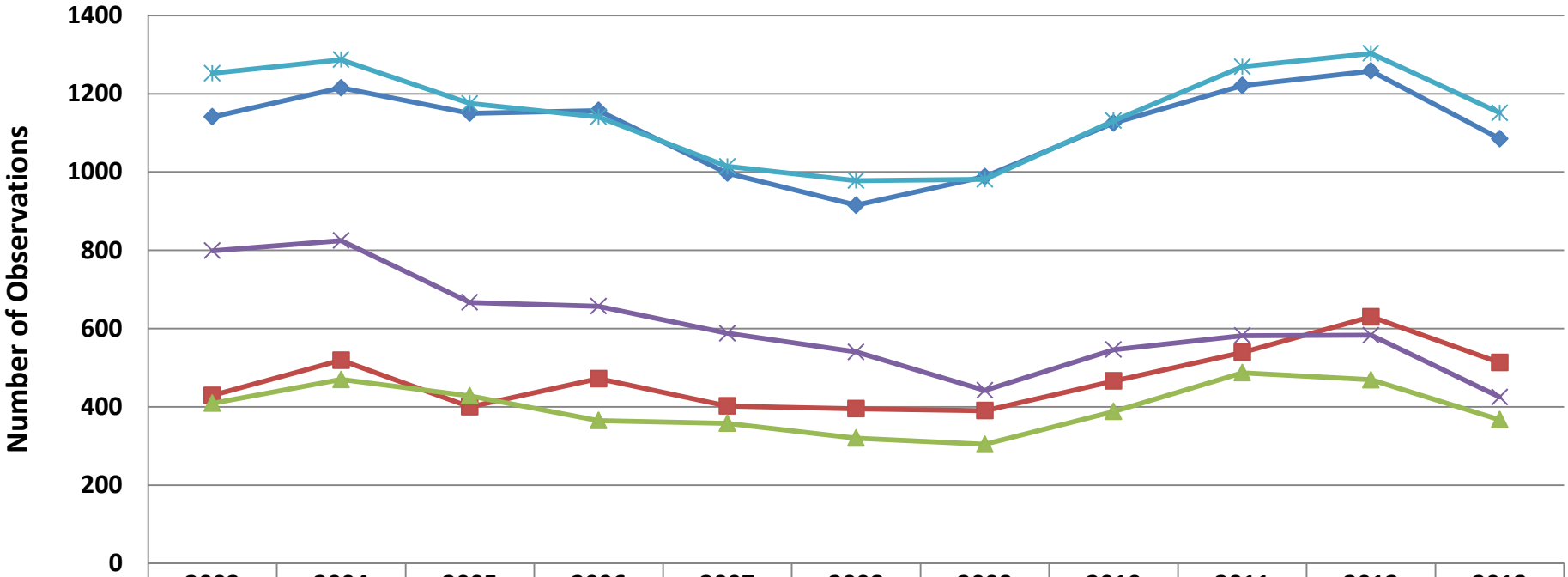
Country Name	Number of Inspections
Germany	86
China	82
Canada	35
France	33
Japan	24
Korea, Republic Of (South)	24
Italy	20
Switzerland	20
Sweden	17
Ireland	16

2013 FDA Form 483 (483) Observations Data

- Source of data - FDA's Turbo Establishment Inspection Reporting (EIR) Database
- Timeframe January 1, 2013 – December 31, 2013
- **3,534** FDA Form 483 observations cited for 21 CFR 820 (Quality System regulation*) deficiencies

*http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1

Inspectional Observations 2003-2012 by Quality System Subsystem



	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
CAPA	1141	1215	1150	1157	997	915	988	1125	1221	1258	1085
DES	429	519	400	472	402	395	390	466	539	630	513
DOC	409	470	428	365	358	320	304	388	487	469	367
MGMT	799	825	667	657	588	540	442	546	582	583	425
P&PC	1252	1287	1175	1141	1014	978	981	1131	1269	1303	1151

2013 483 Observations Data

QS Subsystem	# of Observations	Percentage
P&PC	1,151	33%
CAPA	1,085	31%
MGMT	425	12%
DES	506	14%
DOC	367	10%
	Total: 3,534	

CY2013 CAPA Observations (cont. on next page)

Observation (QS Regulation)	# of Observations	Percentage
21 CFR 820.100(a)	355	33%
21 CFR 820.198(a)	280	26%
21 CFR 820.100(b)	133	12%
21 CFR 820.90(a)	120	11%
21 CFR 820.198(c)	71	7%
21 CFR 820.198(e)	34	3%

CY2013 CAPA Observations (cont. on next page)

Observation (QS Regulation)	# of Observations	Percentage
21 CFR 820.198(b)	28	3%
21 CFR 820.90(b)(2)	23	2%
21 CFR 820.90(b)(1)	22	2%
21 CFR 820.198(d)	12	1%
21 CFR 820.100(a)(4)	2	<1%
21 CFR 820.100(a)(1)	1	<1%
21 CFR 820.198(a)(3)	1	<1%
21 CFR 820.198(e)(4)	1	<1%
21 CFR 820.198(f)	1	<1%
21 CFR 820.198(g)	1	<1%
	Total: 1,085	**100%**

CY2013 DES Observations

Observation (QS Regulation)	# of Observations	Percentage
21 CFR 820.30(g)	149	29%
21 CFR 820.30(i)	89	18%
21 CFR 820.30(f)	65	13%
21 CFR 820.30(a)	54	11%
21 CFR 820.30(j)	36	7%
21 CFR 820.30(e)	30	6%
21 CFR 820.30(c)	20	4%
21 CFR 820.30(h)	20	4%
21 CFR 820.30(b)	17	3%
21 CFR 820.30(d)	14	3%
21 CFR 820.30©	12	2%
	Total: 503	**100%**

CY2013 DOC Observations

Observation (QS Regulation)	# of Observations	Percentage
21 CFR 820.184	147	40%
21 CFR 820.40	86	24%
21 CFR 820.181	71	19%
21 CFR 820.40(a)	32	9%
21 CFR 820.40(b)	15	4%
21 CFR 820.180	4	1%
21 CFR 820.181(a)	4	1%
21 CFR 820.180(b)	2	<1%
21 CFR 820.184(e)	2	<1%
21 CFR 820.186	2	<1%
21 CFR 820.181(b)	1	<1%
21 CFR 820.184(d)	1	<1%
	Total: 367	**100%**

CY2013 MGMT Observations

Observation (QS Regulation)	# of Observations	Percentage:
21 CFR 820.22	165	39%
21 CFR 820.20(c)	94	22%
21 CFR 820.25(b)	80	19%
21 CFR 820.20(b)	28	7%
21 CFR 820.20(e)	23	5%
21 CFR 820.25(a)	15	4%
21 CFR 820.20(a)	14	3%
21 CFR 820.20(d)	6	1%
	Total: 425	**100%**

CY2013 P&PC Observations (cont. on next page)

Observation (QS Regulation)	Count	Percentage:
21 CFR 820.75(a)	159	14%
21 CFR 820.50	107	9%
21 CFR 820.70(a)	81	7%
21 CFR 820.80(d)	68	6%
21 CFR 820.72(a)	63	5%
21 CFR 820.80(b)	59	5%
21 CFR 820.80(a)	44	4%
21 CFR 820.70(c)	41	4%
21 CFR 820.80(e)	36	3%
21 CFR 820.70(i)	32	3%
21 CFR 820.50(a)(1)	31	3%
21 CFR 820.80(c)	31	3%
21 CFR 820.50(a)(2)	28	2%
21 CFR 820.250(b)	26	2%

CY2013 P&PC Observations (cont. on next page)

Observation (QS Regulation)	# of Observations	Percentage:
21 CFR 820.50(a)	25	2%
21 CFR 820.50(a)(3)	25	2%
21 CFR 820.70(b)	24	2%
21 CFR 820.120	23	2%
21 CFR 820.50(b)	20	2%
21 CFR 820.75(b)	15	2%
21 CFR 820.200(a)	14	1%
21 CFR 820.70(e)	14	1%
21 CFR 820.120(b)	11	1%
21 CFR 820.70(g)	11	1%
21 CFR 820.120(d)	10	1%
21 CFR 820.250(a)	10	1%

CY2013 P&PC Observations (cont. on next page)

Observation (QS Regulation)	# of Observations	Percentage:
21 CFR 820.86	8	1%
21 CFR 820.160(a)	7	1%
21 CFR 820.60	7	1%
21 CFR 820.70(g)(2)	7	1%
21 CFR 820.75(b)(2)	7	1%
21 CFR 820.140	6	1%
21 CFR 820.70(d)	6	1%
21 CFR 820.130	5	0%
21 CFR 820.170(a)	5	0%
21 CFR 820.200(b)	5	0%
21 CFR 820.200(d)	4	0%
21 CFR 820.170(b)	2	0%
21 CFR 820.65	2	0%

CY2013 P&PC Observations (cont. on next page)

Observation (QS Regulation)	# of Observations	Percentage:
21 CFR 820.70(f)	2	0%
21 CFR 820.70(h)	2	0%
21 CFR 820.200(c)	1	0%
21 CFR 820.200(d)(6)	1	0%
21 CFR 820.70(a)(2)	1	0%
	Total: 1,151	**100%**

FDA Warning Letter (WL) Citations

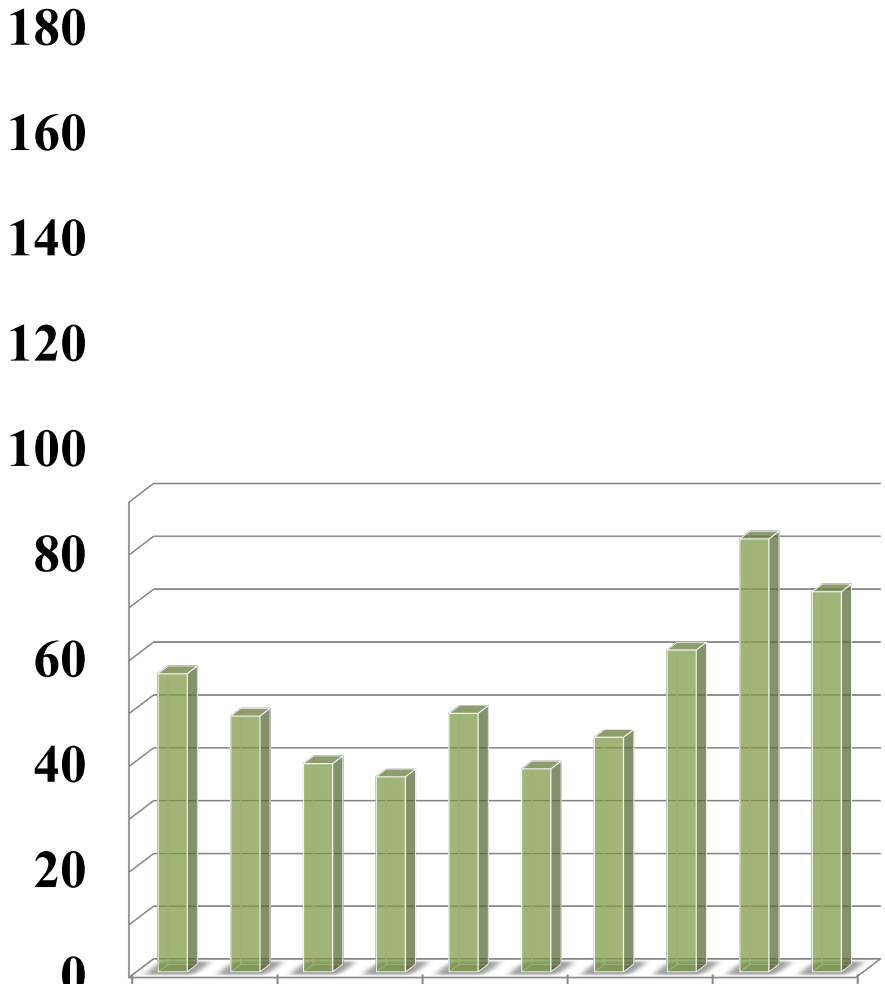
- Source of data - FDA's warning letters
- Timeframe January 1, 2013 – December 31, 2013
- **144 w**arning letters with 21 CFR 820 (Quality System regulation*) deficiencies

*http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1

Warning Letters with QS Citations

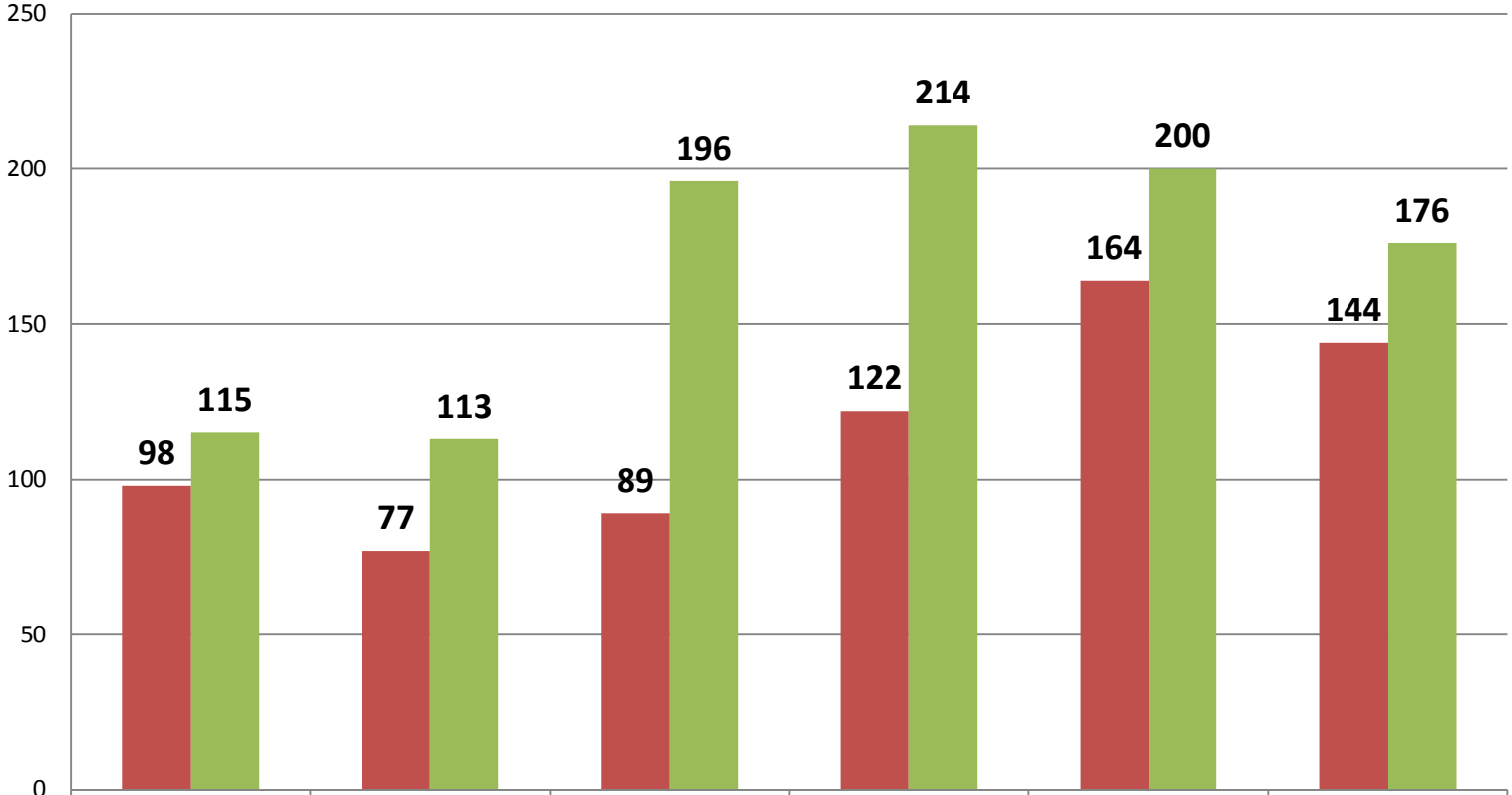
Year	# WL's
2013	144
2012	164
2011	122
2010	89
2009	77
2008	98
2007	74
2006	79
2005	97
2004	113

CY2004 – CY2013
Warning Letters with QS Citations



	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
# of WLs	113	97	79	74	98	77	89	122	164	144

Official Action Indicated Inspections and Warning Letters with QS Citations



	2008	2009	2010	2011	2012	2013
QS WLs	98	77	89	122	164	144
OAI Inspections	115	113	196	214	200	176

CY2013 Warning Letters

QS Subsystem	# of Citations	Percentage
P&PC	286	30%
CAPA	276	29%
DES	156	17%
MGMT	112	12%
DOC	108	12%
	Total: 938	

CY2013 Warning Letters

QS Subsystem	# of WLs w/Cite	Percentage (144 Total WLs)
CAPA	127	88%
P&PC	127	88%
DES	91	63%
DOC	77	53%
MGMT	71	49%

Most Frequent CY2013 QS Warning Letter Cites

WL Citation	QS Subsystem	# of WL Cites
21 CFR 820.100(a)	CAPA	80
21 CFR 820.198(a)	CAPA	64
21 CFR 820.22	MGMT	52
21 CFR 820.184	DOC	44
21 CFR 820.75(a)	P&PC	43
21 CFR 820.90(a)	CAPA	33
21 CFR 820.30(g)	DES	30
21 CFR 820.30(i)	DES	28
21 CFR 820.50	P&PC	26
21 CFR 820.20(c)	MGMT	25

CY2013 CAPA Subsystem Warning Letter Cites

WL Citations	# of WL Cites
21 CFR 820.100	117
21 CFR 820.198	112
21 CFR 820.90	47
	Total: 276

CY2013 Design Control Subsystem Warning Letter Cites

WL Citations	# of WL Cites
21 CFR 820.30(g)	30
21 CFR 820.30(i)	28
21 CFR 820.30(a)	22
21 CFR 820.30(f)	20
21 CFR 820.30(j)	13
21 CFR 820.30(e)	12
21 CFR 820.30(c)	6
21 CFR 820.30(d)	6
21 CFR 820.30(b)	5
21 CFR 820.30(a)(1)	3
21 CFR 820.30	2
	Total: 156

CY2013 P&PC Subsystem Warning Letter Cites

WL Citations	# of WL Cites
21 CFR 820.80	59
21 CFR 820.70	57
21 CFR 820.75	55
21 CFR 820.50	50
21 CFR 820.72	21
21 CFR 820.250	17
21 CFR 820.120	11
21 CFR 820.200	5
21 CFR 820.86	3
21 CFR 820.150	2
21 CFR 820.160	2
21 CFR 820.60	2
21 CFR 820.130	1
21 CFR 820.140	1
	Total: 286

CY2013 Management Control Subsystem Warning Letter Cites

WL Citations	# of WL Cites
21 CFR 820.22	52
21 CFR 820.20	40
21 CFR 820.25	20
	Total: 112

CY2013 Document Control Subsystem Warning Letter Cites

WL Citations	# of WL Cites
21 CFR 820.184	46
21 CFR 820.40	36
21 CFR 820.181	22
21 CFR 820.180	4
	Total: 108

Contact Information

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