2015 Annual FDA Medical Device Quality System Data

Inspections, FDA Form 483 Observations, and Warning Letter Citations

Why is FDA making these data available?

In support of the FDA's Transparency and Case for Quality Initiatives, the Center for Devices and Radiological Health (CDRH) is providing data on inspections, inspectional observations, and Warning Letter (WL) citations issued in 2015.

We believe that this information will:

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

The Quality System (QS) regulation

- In October 1996 the FDA published the final rule for the QS regulation.
- In 1997 and 1998 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's Transparency and Case for Quality Initiatives, CDRH is providing data on how QS inspections, inspection observations, and Warning Letter citations connect to the various subsystem requirements contained in the QS regulation.

Key Findings CY2015

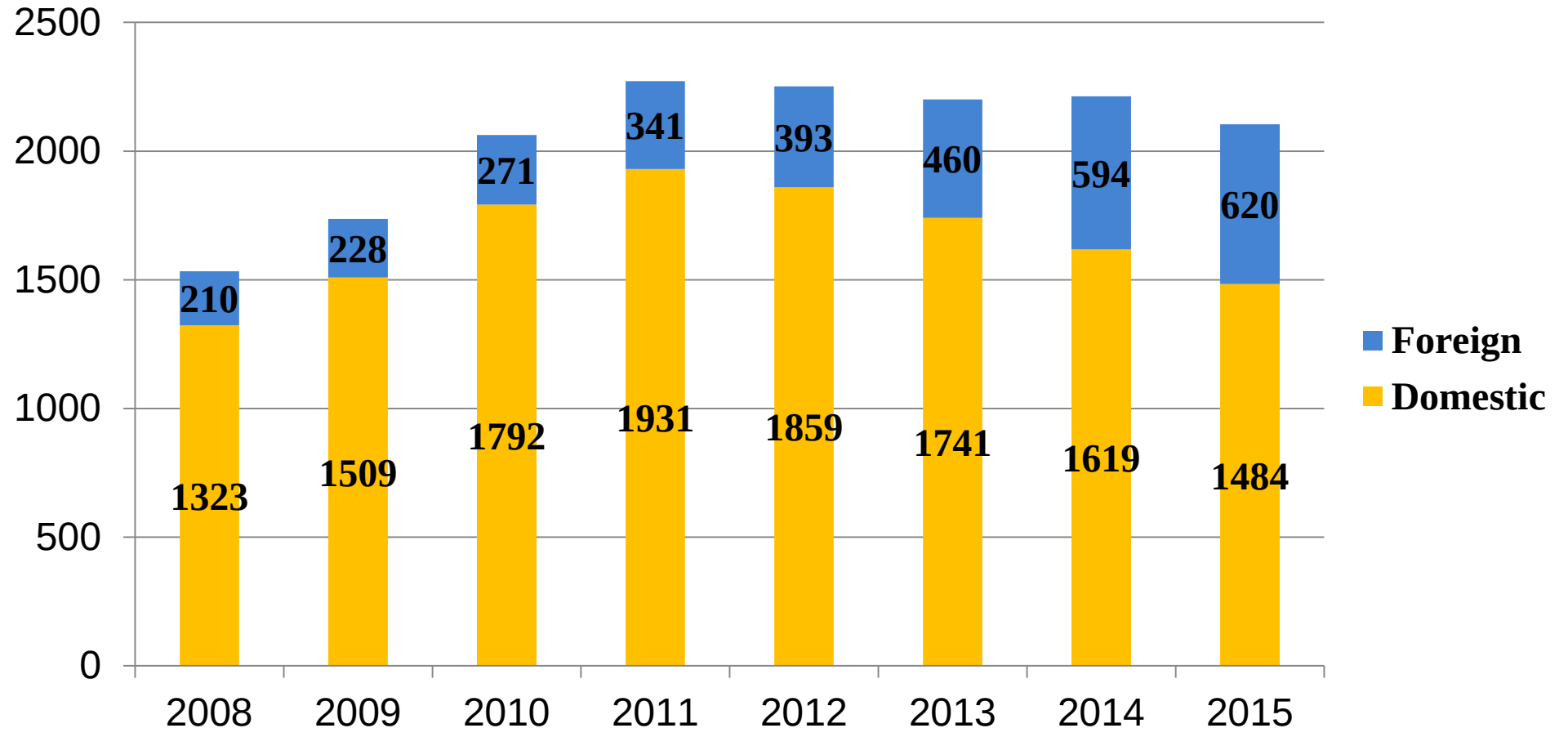
- The overall number of QS surveillance inspections decreased slightly from CY2014 to CY2015.
- The number of foreign QS surveillance inspections continues to increase. Foreign inspections increased from 594 in CY2014 to 620 in CY2015. The agency has been working toward increased foreign inspections as foreign manufacturer inventory has been growing rapidly.
- Production and Process Controls and Corrective and Preventive Actions continue to be the most frequently cited QS subsystems.
- The number of Warning Letters (WL) remained exactly the same from CY2014 to CY2015 at 121 WLs.

FDA Medical Device Inspection Data

- Source of data - FDA's Field Accomplishment and Compliance Tracking System (FACTS)
- Timeframe January 1, 2015 – December 31, 2015
- 2,104 FDA medical device inspections (domestic/foreign)

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

Medical Device QS Surveillance Inspections CY2008 – CY2015

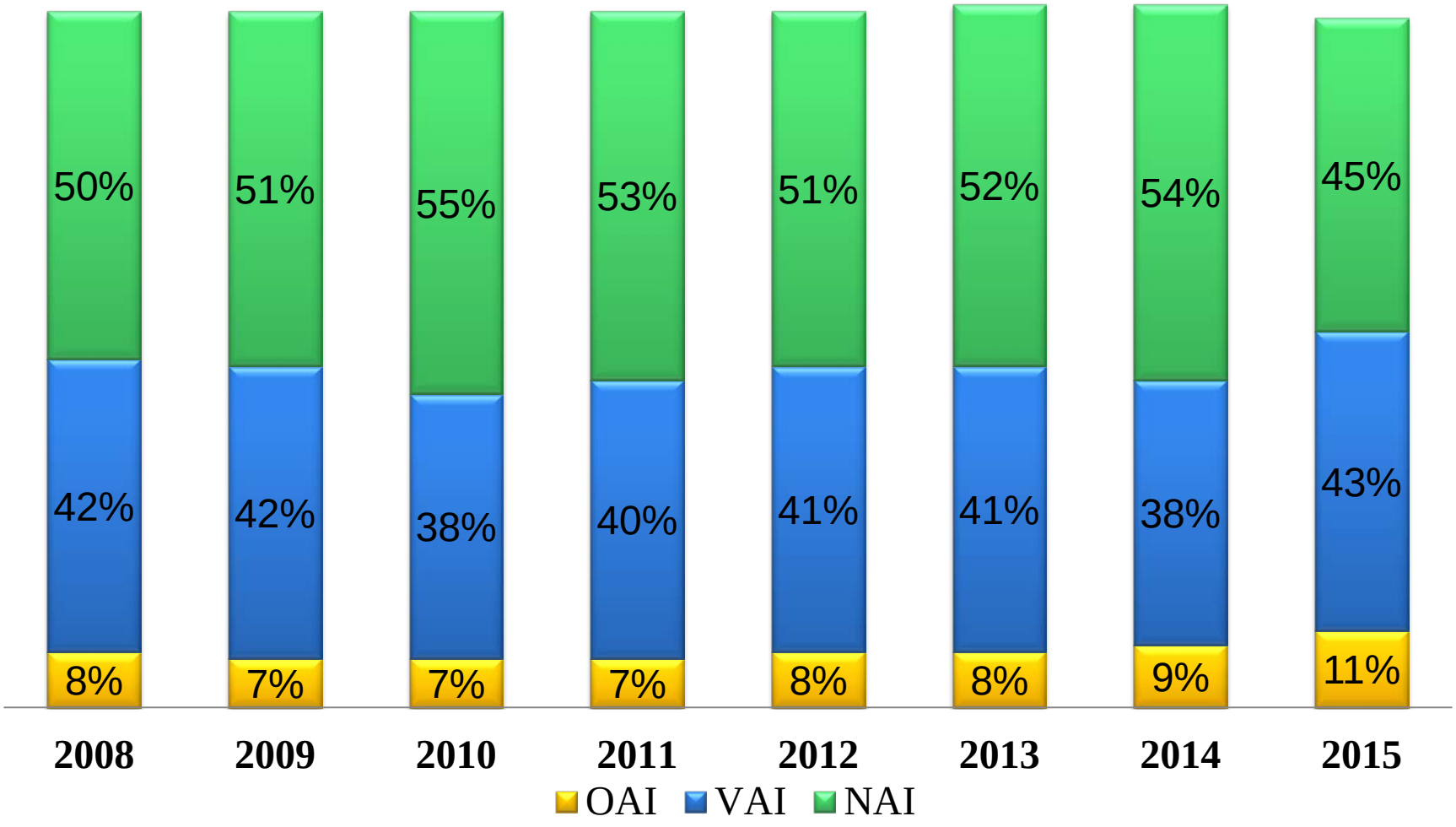


Top 10 Foreign Inspection Locations

Country Name	CY2014 # of Inspections
China	190
Germany	72
Japan	37
Taiwan	29
Switzerland	25
Canada	24
Ireland	23
Korea, Republic of South	23
United Kingdom	23
France	16

Country Name	CY2015 # of Inspections
China	126
Germany	90
Japan	44
Canada	42
United Kingdom	35
Taiwan	35
France	30
Italy	26
Korea, Republic of South	22
Ireland	19

CY2008-2015
QS Medical Device Inspection Outcomes



CY2015 QS Medical Device Inspections

Total Domestic Inspections	Total Foreign Inspections
1484	620

Domestic Inspection Outcomes		Foreign Inspection Outcomes	
NAI	49%	NAI	39%
VAI	41%	VAI	46%
OAI	10%	OAI	15%

CY2015 Top Foreign OAI QS Medical Device Inspections

Country	OAI Inspections
China	19
United Kingdom	10
Germany	10
Japan	7
Italy	6
Canada	6
Taiwan	4
South Korea	4
France	4
India	3
Denmark	3

FDA Form 483 (483) Observations Data

- Source of data - FDA's Turbo Establishment Inspection Reporting (EIR) Database
- Timeframe January 1, 2015 – December 31, 2015
- 924 FDA Form 483s were issued in CY2015.
- 3,525 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

Descriptions of QS Subsystems

Corrective and Preventive Action (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 section 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 Observations 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

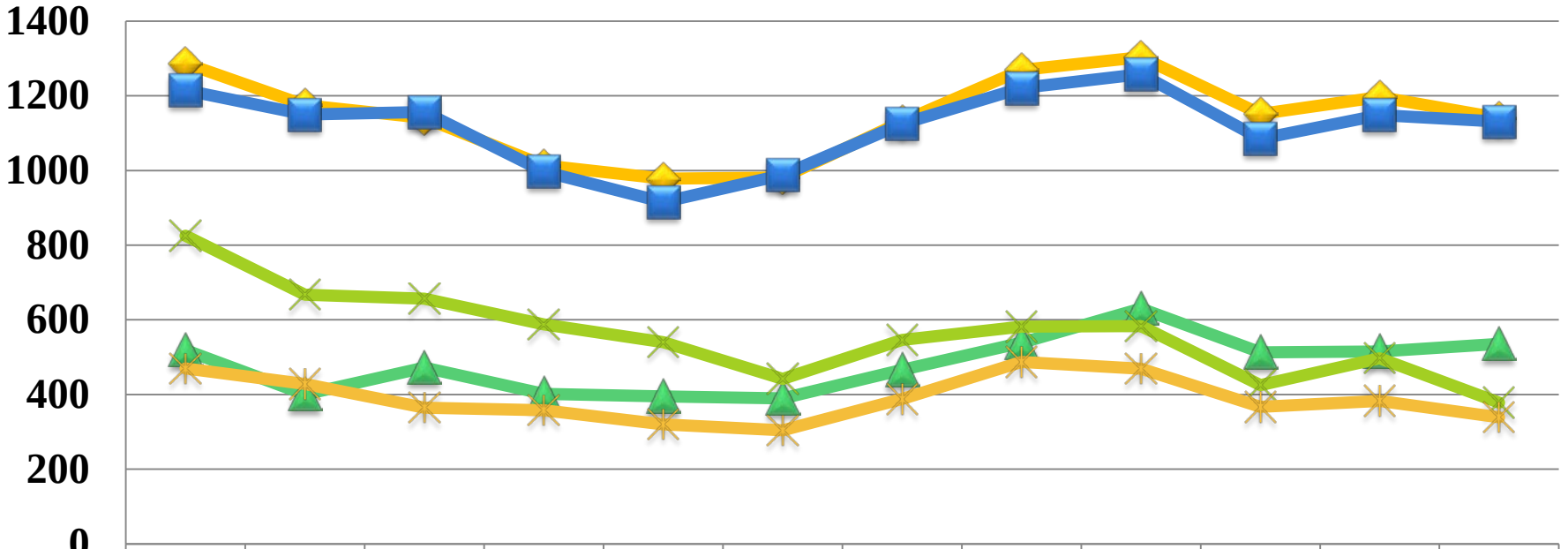
CAPA & MGMT Descriptions

CAPA	Description	MGMT	Description
820.90	Nonconforming product	820.5	Quality system
820.100	Corrective and preventive action	820.20	Management responsibility
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 records requirements
		820.181	Device Master Record
		820.184	Device History Record
		820.186	Quality System Record

Inspectional Observations CY2004-CY2015 by QS Subsystem



	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
P&PC	1287	1175	1141	1014	978	981	1131	1269	1303	1151	1197	1141
CAPA	1215	1150	1157	997	915	988	1125	1221	1258	1085	1148	1131
DES	519	400	472	402	395	390	466	539	630	513	515	536
MGMT	825	667	657	588	540	442	546	582	583	425	497	378
DOC	470	428	365	358	320	304	388	487	469	367	383	339

CY2015 483 Observations

QS Subsystem	# of Observations	Percentage
P&PC	1141	32%
CAPA	1131	32%
DES	536	15%
MGMT	378	11%
DOC	339	10%
	Total: 3,525	**100%**

CY2015 Top CAPA Observations

Ref No	QS Subsystem	Number of Observations	Percentage
21 CFR 820.100(a)	CAPA	381	34%
21 CFR 820.198(a)	CAPA	330	29%
21 CFR 820.90(a)	CAPA	157	14%
21 CFR 820.100(b)	CAPA	90	8%
21 CFR 820.198(c)	CAPA	58	5%
21 CFR 820.90(b)(2)	CAPA	36	3%
21 CFR 820.90(b)(1)	CAPA	29	3%
21 CFR 820.198(e)	CAPA	20	2%
21 CFR 820.198(b)	CAPA	15	1%
21 CFR 820.198(d)	CAPA	12	1%
21 CFR 820.100(a)(3)	CAPA	2	0%
21 CFR 820.100(a)(5)	CAPA	1	0%
		Total: 1131	**100%**

CY2015 DES Observations

Ref No	QS Subsystem	Number of Observations	Percentage:
21 CFR 820.30(g)	DES	171	32%
21 CFR 820.30(i)	DES	87	16%
21 CFR 820.30(f)	DES	76	14%
21 CFR 820.30(e)	DES	50	9%
21 CFR 820.30(a)	DES	36	7%
21 CFR 820.30(j)	DES	30	6%
21 CFR 820.30(c)	DES	21	4%
21 CFR 820.30(h)	DES	21	4%
21 CFR 820.30(c)	DES	16	3%
21 CFR 820.30(d)	DES	16	3%
21 CFR 820.30(b)	DES	12	2%
		Total: 536	**100%**

CY2015 DOC Observations

Ref No	QS Subsystem	Number of Observations	Percentage
21 CFR 820.184	DOC	150	44%
21 CFR 820.181	DOC	71	21%
21 CFR 820.40	DOC	65	19%
21 CFR 820.40(a)	DOC	23	7%
21 CFR 820.40(b)	DOC	12	4%
21 CFR 820.186	DOC	9	3%
21 CFR 820.180	DOC	6	2%
21 CFR 820.184(e)	DOC	2	1%
21 CFR 820.181(a)	DOC	1	0%
		Total: 339	**100%**

CY2015 MGMT Observations

Ref No	QS Subsystem	Number of Observations	Percentage
21 CFR 820.22	MGMT	145	38%
21 CFR 820.25(b)	MGMT	85	22%
21 CFR 820.20(c)	MGMT	75	20%
21 CFR 820.20(b)	MGMT	25	7%
21 CFR 820.20(e)	MGMT	20	5%
21 CFR 820.25(a)	MGMT	11	3%
21 CFR 820.20(a)	MGMT	10	3%
21 CFR 820.20(d)	MGMT	4	1%
21 CFR 820.20(b)(3)	MGMT	2	1%
21 CFR 820.20	MGMT	1	0%
		Total: 378	**100%**

CY2015 Top P&PC Observations

Ref No	QS Subsystem	Number of Observations	Percentage
21 CFR 820.75(a)	P&PC	180	16%
21 CFR 820.50	P&PC	141	12%
21 CFR 820.72(a)	P&PC	76	7%
21 CFR 820.70(a)	P&PC	68	6%
21 CFR 820.80(d)	P&PC	66	6%
21 CFR 820.80(b)	P&PC	58	5%
21 CFR 820.70(c)	P&PC	49	4%
21 CFR 820.70(i)	P&PC	36	3%
21 CFR 820.80(e)	P&PC	36	3%
21 CFR 820.80(a)	P&PC	35	3%
21 CFR 820.250(b)	P&PC	30	3%
21 CFR 820.50(a)	P&PC	28	2%

FDA Warning Letter (WL) Citations

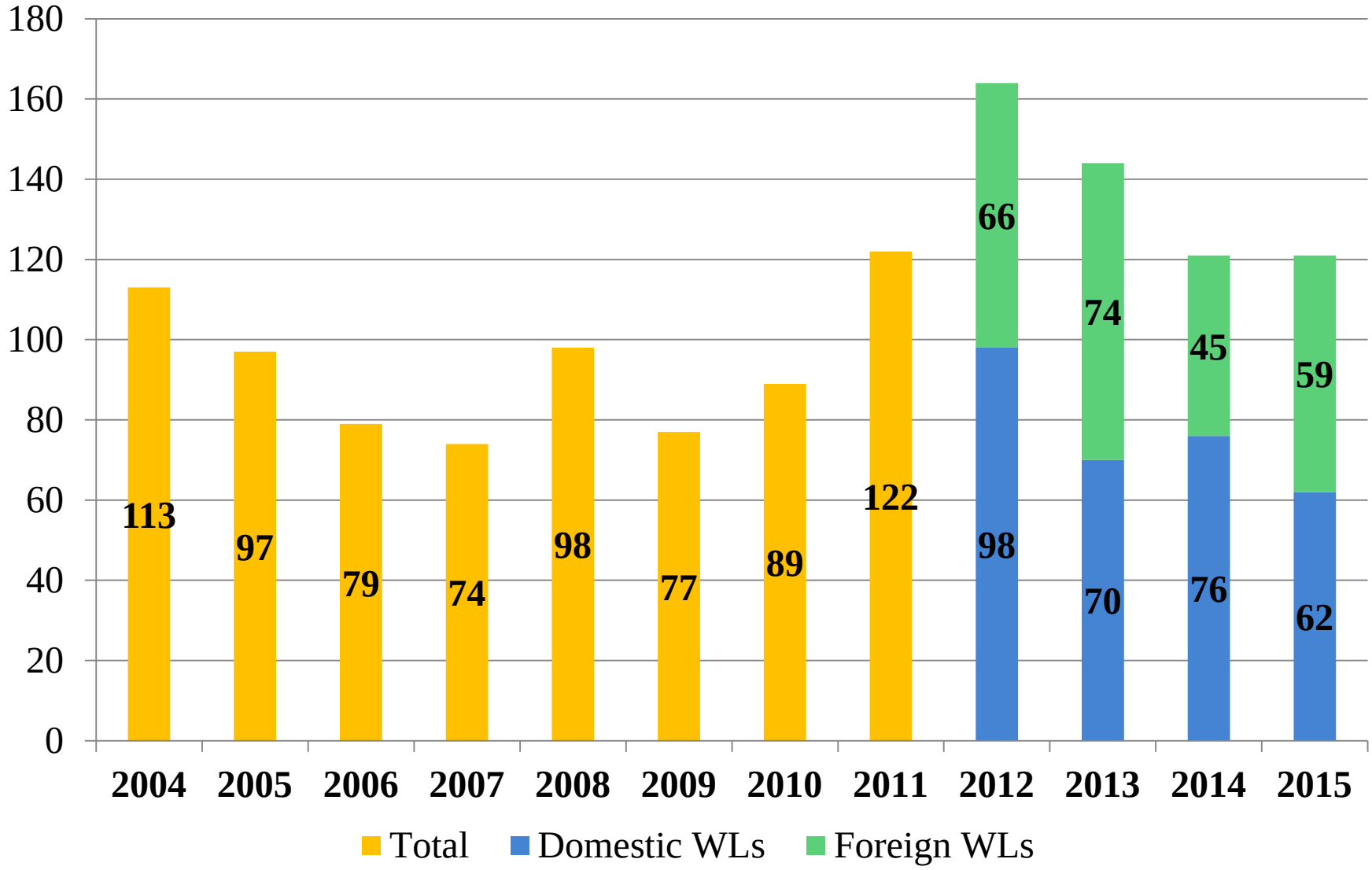
- Source of data - FDA's Warning Letters and FDA's Compliance Management System (CMS)
- Timeframe January 1, 2015 – December 31, 2015
- CY2015 - 121 Warning Letters with 21 CFR 820 (Quality System regulation*) deficiencies

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

WLs with QS Citations

Year	# WL's
2015	**121**
2014	121
2013	144
2012	164
2011	122
2010	89
2009	77
2008	98
2007	74
2006	79
2005	97
2004	113

Foreign and Domestic WLs with QS Citations



WLs Citations

QS Subsystem	CY2015 # of Citations	CY2014 # of Citations
CAPA	220	262
P&PC	227	254
DES	102	121
MGMT	71	74
DOC	70	63
	Total: 690	**Total: 774**

WL Citations

QS Subsystem	CY 2015 # of WLs w/Cite	CY 2014 # of WLs w/Cite
CAPA	111	109
P&PC	98	103
DES	68	68
MGMT	48	47
DOC	49	45

Most Frequent QS WL Cites

WL Citation	QS Subsystem	CY2015 # of WL Cites	CY2014 # of WL Cites
21 CFR 820.100(a)	CAPA	65	77
21 CFR 820.198(a)	CAPA	53	55
21 CFR 820.75(a)	P&PC	39	35
21 CFR 820.22	DES	37	26
21 CFR 820.50	CAPA	33	26
21 CFR 820.90(a)	MGMT	29	27
21 CFR 820.184	P&PC	29	23
21 CFR 820.30(g)	DES	27	31
21 CFR 820.30(i)	DOC	21	24
21 CFR 820.181	P&PC	17	14
21 CFR 820.70(a)	P&PC	11	22

CAPA QS Subsystem
WL Cites

WL Citations	CY2015 # of Cites	CY2014 # of Cites
21 CFR 820.100	171	118
21 CFR 820.198	76	100
21 CFR 820.90	48	44
	Total: 295	**Total: 262**

Design Control QS Subsystem
WL Cites

WL Citations	CY2015 # of WL Cites	CY2014 # of WL Cites
21 CFR 820.30(g)	27	32
21 CFR 820.30(i)	21	24
21 CFR 820.30(f)	15	15
21 CFR 820.30(a)	11	14
21 CFR 820.30(e)	10	9
21 CFR 820.30(c)	5	6
21 CFR 820.30(j)	3	9
21 CFR 820.30(h)	3	4
21 CFR 820.30	2	3
21 CFR 820.30(a)(1)	2	1
21 CFR 820.30(b)	1	2
21 CFR 820.30(d)	1	2
	Total: 101	**Total: 121**

P&PC QS Subsystem WL Cites

WL Citations	CY2015 # of WL Cites	CY2014 # of WL Cites
21 CFR 820.50	54	54
21 CFR 820.70	45	56
21 CFR 820.75	45	48
21 CFR 820.80	41	48
21 CFR 820.72	21	17
21 CFR 820.250	6	12
21 CFR 820.120	6	4
21 CFR 820.150	3	2
21 CFR 820.86	3	1
21 CFR 820.140	1	1
21 CFR 820.160	1	1
21 CFR 820.200	0	4
21 CFR 820.60	0	4
21 CFR 820.130	0	2
	Total: 226	**Total: 254**

Management Control QS Subsystem
WL Cites

WL Citations	CY2015 # of WL Cites	CY2014 # of WL Cites
21 CFR 820.22	38	27
21 CFR 820.20	17	28
21 CFR 820.25	15	14
21 CFR 820.5	0	5
	Total: 70	**Total: 74**

Document Control QS Subsystem
WL Cites

WL Citations	CY2015 # of WL Cites	CY2014 # of WL Cites
21 CFR 820.184	29	28
21 CFR 820.181	20	14
21 CFR 820.40	18	21
21 CFR 820.180	3	0
	Total: 70	**Total: 63**

Contact Information

Center for Devices and Radiological Health
Office of Compliance
Division of Analysis and Program Operations
Registration & Risk Branch
Julie “Brandi” Stuart
Program Analyst
Julie.Stuart@fda.hhs.gov