2014 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's Transparency and Case for Quality Initiatives, the Center for Devices and Radiological Health (CDRH) is providing data on inspectional observations and Warning Letter citations issued in 2014.

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 Warning Letters

Key Findings CY2014

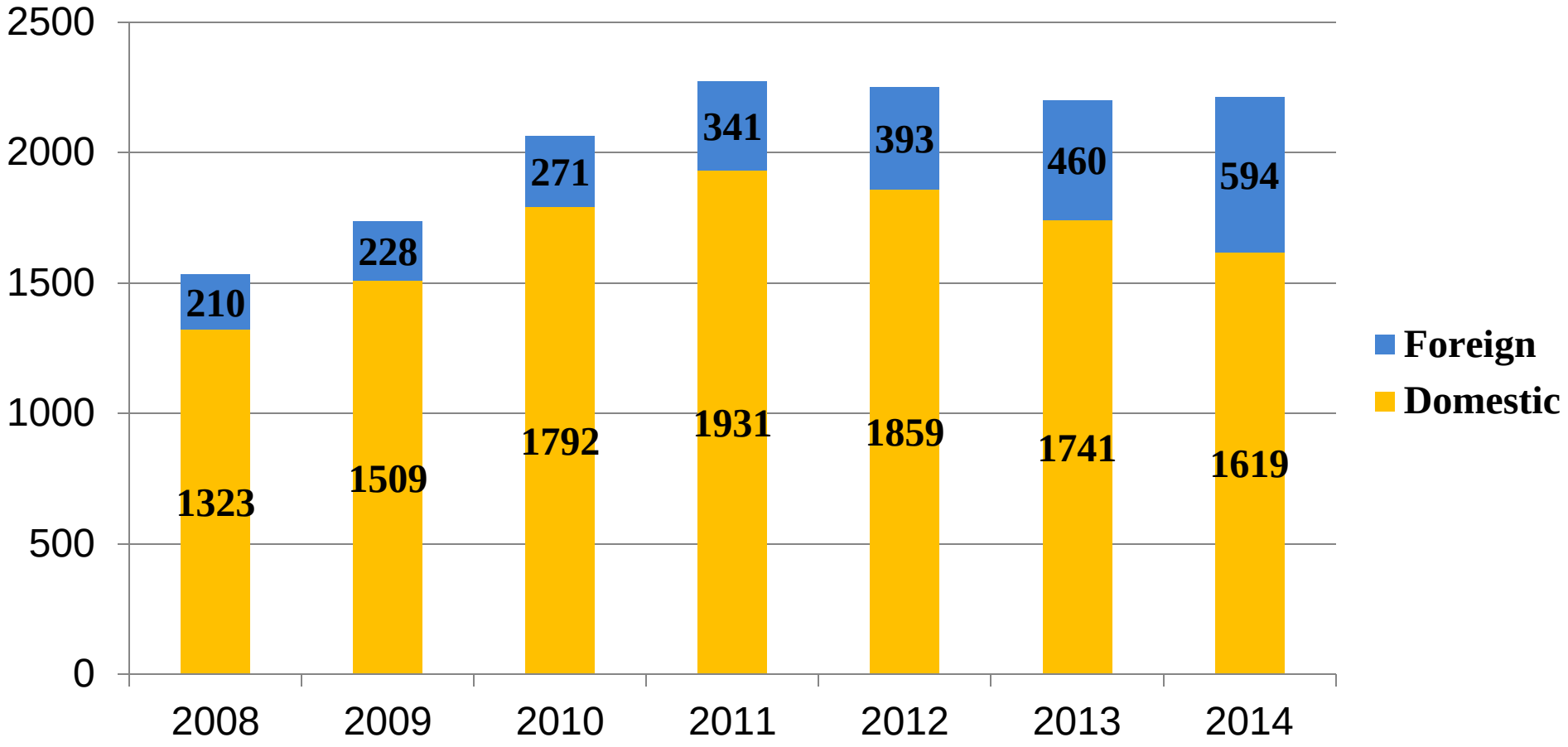
- The overall number of quality system surveillance inspections increased slightly from CY2013 to CY2014.
- The number of foreign quality system surveillance inspections increased from 460 in CY2013 to 594 in CY2014. The agency has been working toward increased foreign inspections as foreign manufacturer 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) decreased slightly from 144 in CY2013 to 121 in CY2014.

FDA Inspection Data

- Source of data - FDA's Field Accomplishment and Compliance Tracking System (FACTS)
- Timeframe January 1, 2008 – December 31, 2014
- 14,271 FDA medical device inspections (domestic/foreign)

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

Routine Medical Device Quality System Surveillance Inspections CY2008 – CY2014



CY2014 Top 10 Foreign Inspection Locations

Country Name	Number 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

CY2008-2014 Inspection Outcomes

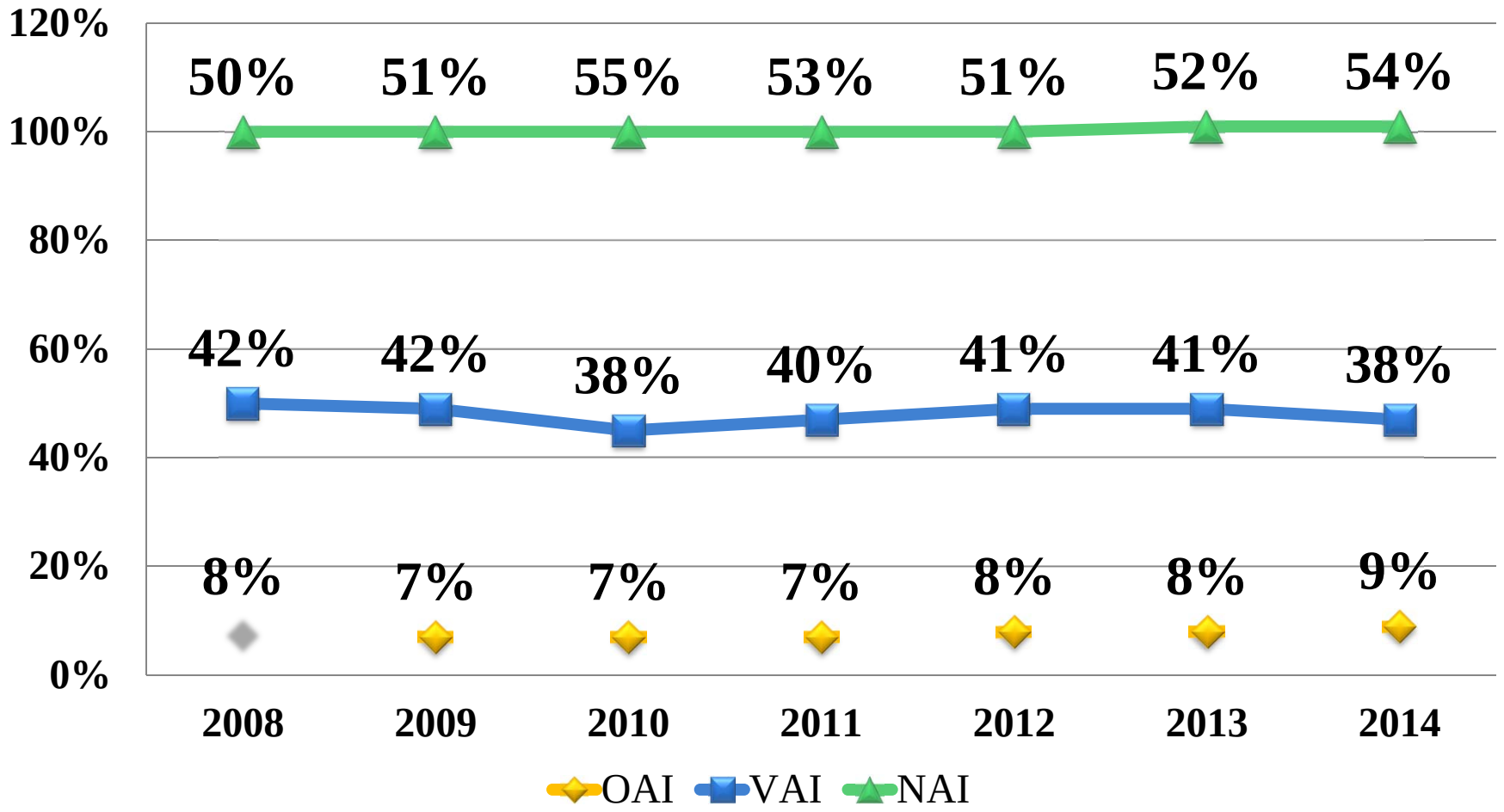
Domestic Inspections

Decision	Percentage
No Action Indicated	52%
Voluntary Action Indicated	40%
Official Action Indicated	8%
Total	100%

Foreign Inspections

Decision	Percentage
No Action Indicated	42%
Voluntary Action Indicated	43%
Official Action Indicated	15%
Total	100%

CY2008-2014 Inspection Outcomes



FDA Form 483 (483) Observations Data

- Source of data - FDA's Turbo Establishment Inspection Reporting (EIR) Database
- Timeframe January 1, 2008 – December 31, 2014

- In 2014
  - **1,106** FDA Form 483s were issued covering 2213 QSIT inspections.
  - **3,740** 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

The Quality System (QS) regulation

- In October 1996 the FDA published the final rule for the Quality System (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 inspection observations and Warning Letter citations issued in 2014 connect to the various subsystem requirements contained in the QS regulation.

Descriptions of Quality System 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

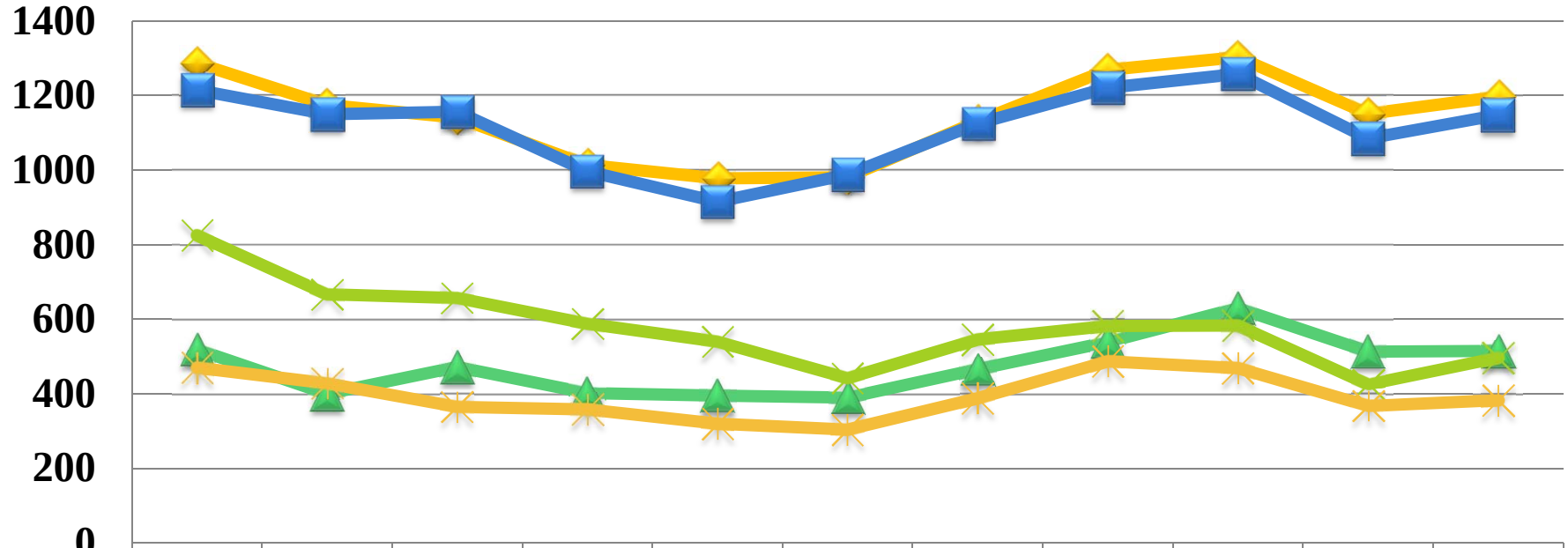
CAPA & MGMT Descriptions

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-CY2014 by Quality System Subsystem



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

Issuance of FDA Form 483 CY2014 Quality System Surveillance Inspections

Domestic/ Foreign	483 Issued	Number of Inspections	Percentage
Domestic	No	850	53%
Domestic	Yes	769	47%
Foreign	No	257	43%
Foreign	Yes	337	57%

CY2014 483 Observations Data

QS Subsystem	# of Observations	Percentage
P&PC	1,197	32%
CAPA	1,148	31%
DES	515	14%
MGMT	497	13%
DOC	383	10%
	Total: 3,740	

CY2014 Top 10 CAPA Observations

Observation (QS Regulation)	# of Observations	Percentage
21 CFR 820.100(a)	376	33%
21 CFR 820.198(a)	325	28%
21 CFR 820.90(a)	136	12%
21 CFR 820.100(b)	99	9%
21 CFR 820.198(c)	67	6%
21 CFR 820.90(b)(1)	38	3%
21 CFR 820.90(b)(2)	37	3%
21 CFR 820.198(e)	32	3%
21 CFR 820.198(b)	20	2%
21 CFR 820.198(d)	12	1%

CY2014 DES Observations

Observation (QS Regulation)	# of Observations	Percentage
21 CFR 820.30(g)	137	27%
21 CFR 820.30(i)	99	19%
21 CFR 820.30(f)	64	12%
21 CFR 820.30(a)	51	10%
21 CFR 820.30(e)	39	8%
21 CFR 820.30(j)	39	8%
21 CFR 820.30(c)	38	7%
21 CFR 820.30(h)	23	4%
21 CFR 820.30(d)	16	3%
21 CFR 820.30(b)	9	2%
	Total: 515	**100%**

CY2014 DOC Observations

Observation (QS Regulation)	# of Observations	Percentage
21 CFR 820.184	134	35%
21 CFR 820.40	107	28%
21 CFR 820.181	74	19%
21 CFR 820.40(a)	37	10%
21 CFR 820.40(b)	14	4%
21 CFR 820.186	5	1%
21 CFR 820.180	4	1%
21 CFR 820.180(b)	3	<1%
21 CFR 820.181(a)	2	<1%
21 CFR 820.184(d)	2	<1%
21 CFR 820.184(e)	1	<1%
	Total: 383	**100%**

CY2014 MGMT Observations

Observation (QS Regulation)	# of Observations	Percentage:
21 CFR 820.22	186	37%
21 CFR 820.25(b)	109	22%
21 CFR 820.20(c)	106	21%
21 CFR 820.20(b)	32	6%
21 CFR 820.20(e)	21	4%
21 CFR 820.20(d)	16	3%
21 CFR 820.20(a)	15	3%
21 CFR 820.25(a)	11	2%
21 CFR 820.20	1	<1%
	Total: 497	**100%**

CY2014 Top 10 P&PC Observations

Observation (QS Regulation)	# of Observations	Percentage
21 CFR 820.75(a)	175	15%
21 CFR 820.50	143	12%
21 CFR 820.70(a)	95	8%
21 CFR 820.72(a)	74	6%
21 CFR 820.80(b)	56	5%
21 CFR 820.80(d)	55	5%
21 CFR 820.70(c)	53	5%
21 CFR 820.80(a)	45	4%
21 CFR 820.250(b)	33	3%
21 CFR 820.70(i)	32	3%

FDA Warning Letter (WL) Citations

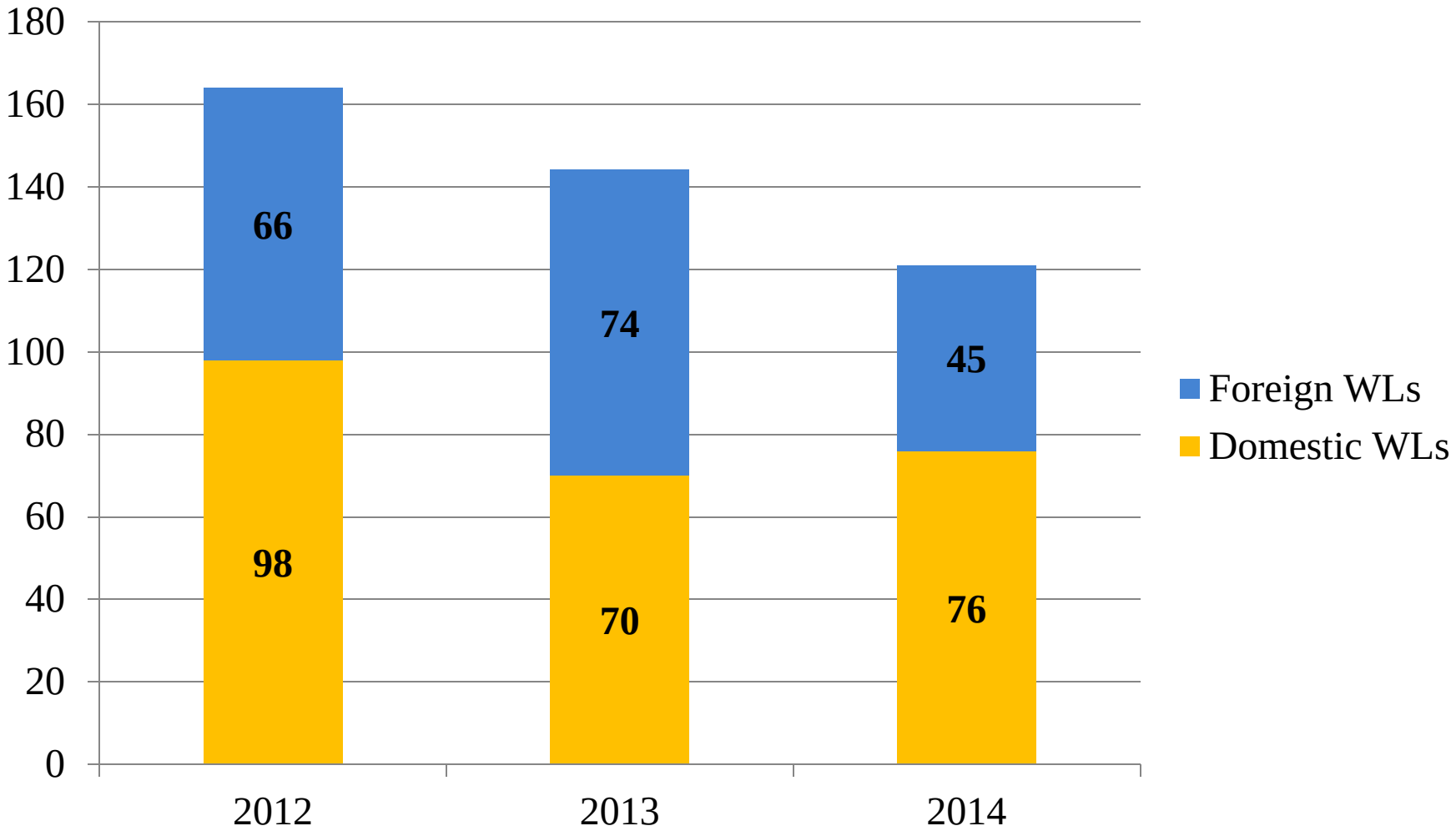
- Source of data - FDA's Warning Letters and FDA's Compliance Management System (CMS)
- Timeframe January 1, 2004 – December 31, 2014
- **121** Warning Letters with 21 CFR 820 (Quality System regulation*) deficiencies

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

Warning Letters with QS Citations

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

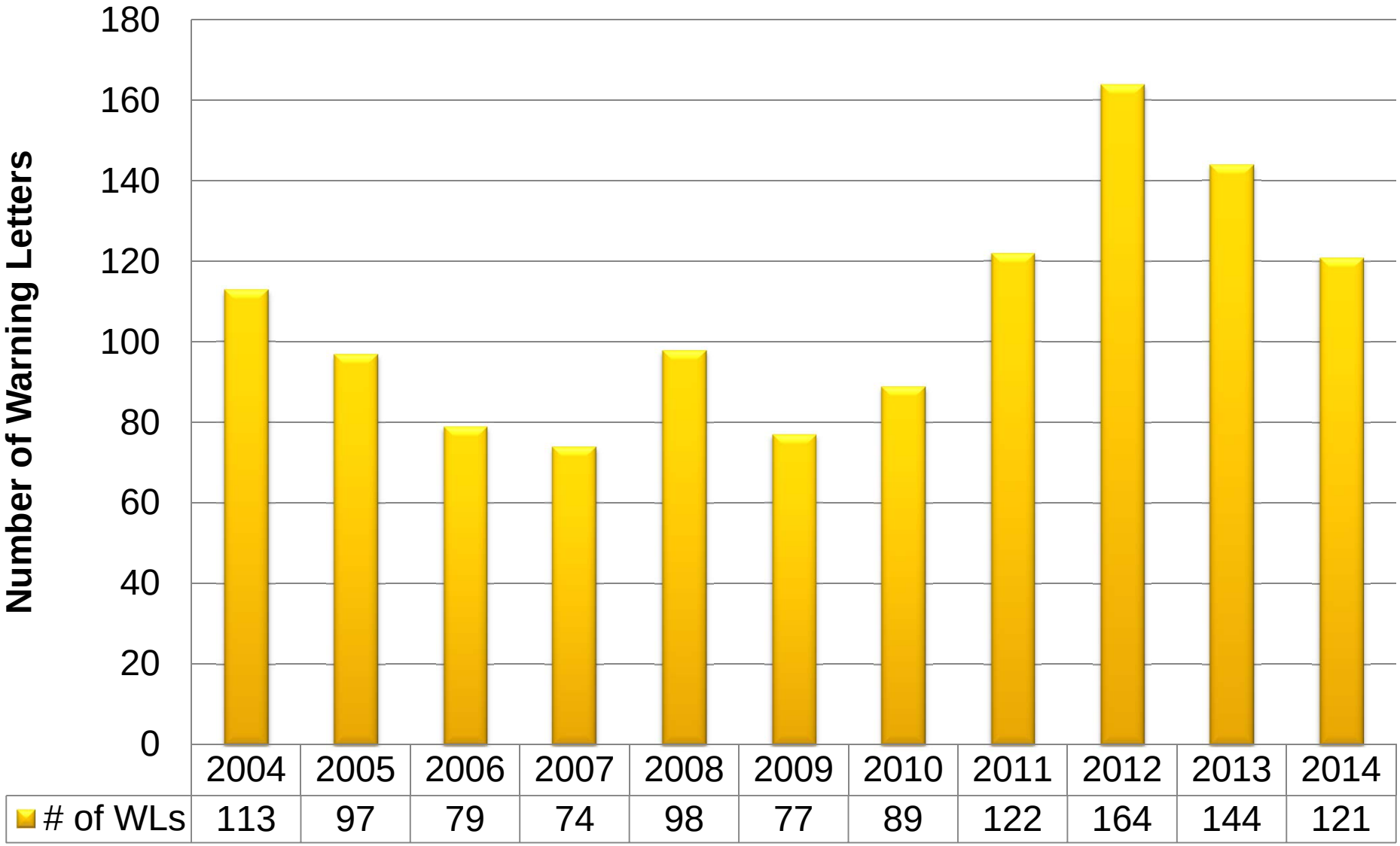
Warning Letters with QS Citations



CY2014 Warning Letters with QS Citations (Foreign/Domestic)

Country	# WL's
Domestic	76 (63%)
Foreign	45 (37%)
	Sum: 121

CY2004 – CY2014
Warning Letters with QS Citations



	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
# of WLs	113	97	79	74	98	77	89	122	164	144	121

CY2014 Warning Letters

QS Subsystem	# of Citations	Percentage
CAPA	262	34%
P&PC	254	33%
DES	121	16%
MGMT	74	10%
DOC	63	8%
	Total: 774	

CY2014 Warning Letters

QS Subsystem	# of WLs w/Cite	Percentage (121 Total WLs)
CAPA	109	90%
P&PC	103	85%
DES	68	56%
MGMT	47	39%
DOC	45	37%

Most Frequent CY2014 QS Warning Letter Cites

WL Citation	QS Subsystem	# of WL Cites
21 CFR 820.100(a)	CAPA	77
21 CFR 820.198(a)	CAPA	55
21 CFR 820.75(a)	P&PC	35
21 CFR 820.30(g)	DES	31
21 CFR 820.90(a)	CAPA	27
21 CFR 820.22	MGMT	26
21 CFR 820.50	P&PC	26
21 CFR 820.30(i)	DES	24
21 CFR 820.184	DOC	23
21 CFR 820.70(a)	P&PC	22

CY2013 CAPA Subsystem
Warning Letter Cites

WL Citations	# of Cites
21 CFR 820.100	118
21 CFR 820.198	100
21 CFR 820.90	44
	Total: 262

CY2014 Design Control Subsystem Warning Letter Cites

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

CY2014 P&PC Subsystem Warning Letter Cites

WL Citations	# of WL Cites
21 CFR 820.70	56
21 CFR 820.50	54
21 CFR 820.75	48
21 CFR 820.80	48
21 CFR 820.72	17
21 CFR 820.250	12
21 CFR 820.120	4
21 CFR 820.200	4
21 CFR 820.60	4
21 CFR 820.150	2
21 CFR 820.130	2
21 CFR 820.86	1
21 CFR 820.140	1
21 CFR 820.160	1
	Total: 254

CY2014 Management Control Subsystem Warning Letter Cites

WL Citations	# of WL Cites
21 CFR 820.20	28
21 CFR 820.22	27
21 CFR 820.25	14
21 CFR 820.5	5
	Total: 74

CY2013 Document Control Subsystem Warning Letter Cites

WL Citations	# of WL Cites
21 CFR 820.184	28
21 CFR 820.40	21
21 CFR 820.181	14
	Total: 63

Contact Information

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