CY2016 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, FDA Form 483 observations (483), and Warning Letter (WL) citations issued in 2016.

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 CY2016

- **NOTE: Beginning in FY18 we will prepare this presentation by FY and not CY. Therefore the data will include Oct 1 2016 – Sept 30 2017. Data will be run the 2nd week in December.**

- The overall number of QS surveillance inspections increased slightly. Foreign inspections increased and domestic inspections decreased consistent with the continuing increase in foreign inventory (foreign firms actively registered and listed).

- There was an increase in No Action Indicated (NAI) inspection outcomes both domestic and foreign. Further, fewer 483s were issued to firms in CY2016.

- All QS subsystems saw a drop in the number of 483 observations.

- Production and Process Controls (P&PC) and Corrective and Preventive Actions (CAPA) continue to be the most frequently observed and cited QS subsystems.

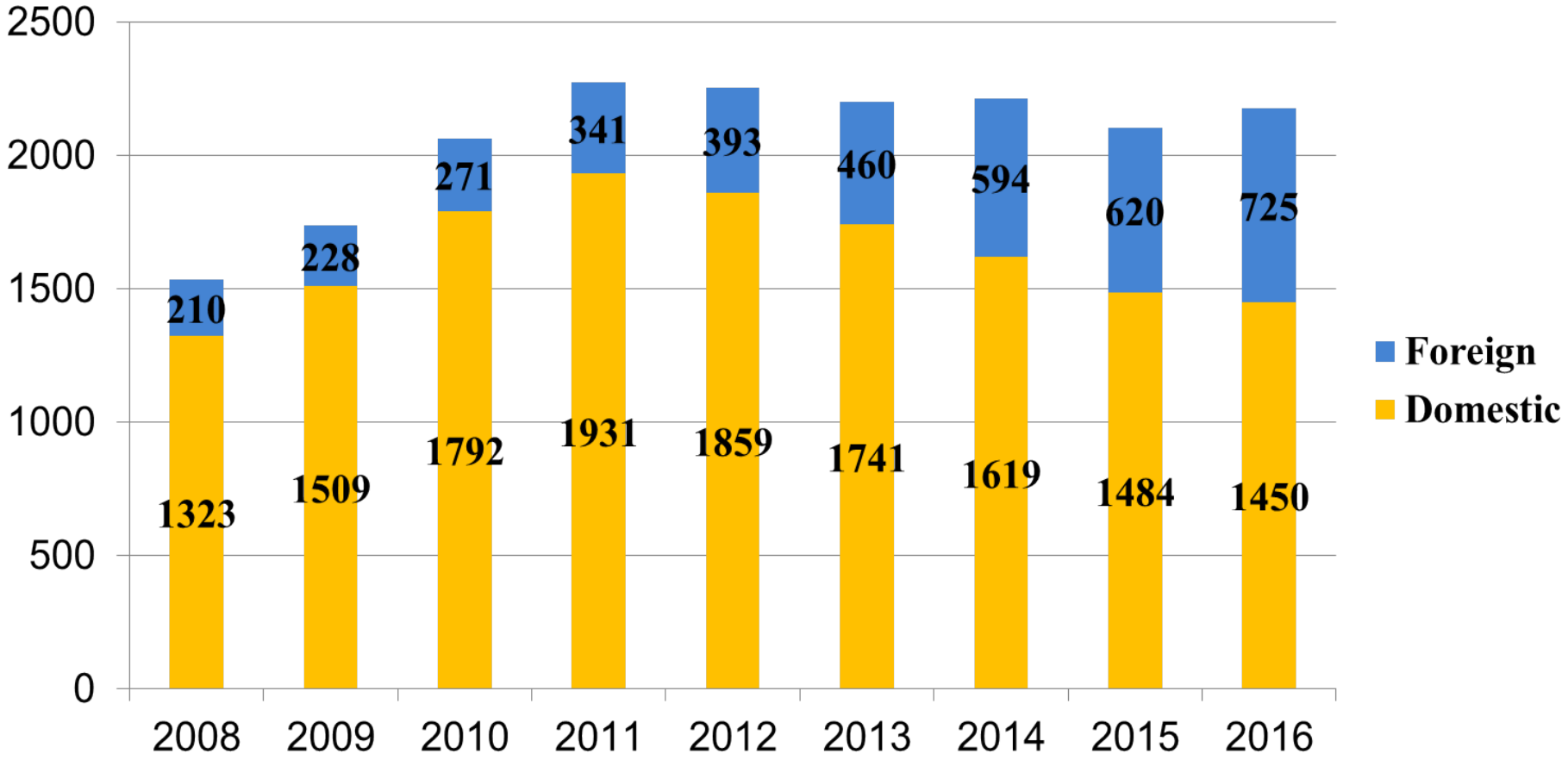
- The number of WLs dropped in CY2016 from 121 WLs in CY2015 to 57 WLs in CY2016.

FDA Medical Device Inspection Data

- Source of data - FDA's Field Accomplishment and Compliance Tracking System (FACTS)
- Timeframe January 1, 2016 – December 31, 2016
- 2,175 FDA medical device inspections (domestic/foreign)

- **NOTE: Beginning in FY18 we will prepare this presentation by FY and not CY. Therefore the data will include Oct 1 2016 – Sept 30 2017. Data will be run the 2nd week in December.**

Medical Device QS Surveillance Inspections CY2008 – CY2016



Top 10 Foreign Inspection Locations

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

Country Name	CY2016 # of Inspections
China	179
Germany	71
Japan	60
United Kingdom	50
Taiwan	35
France	29
Switzerland	29
Italy	27
Canada	26
Ireland	25

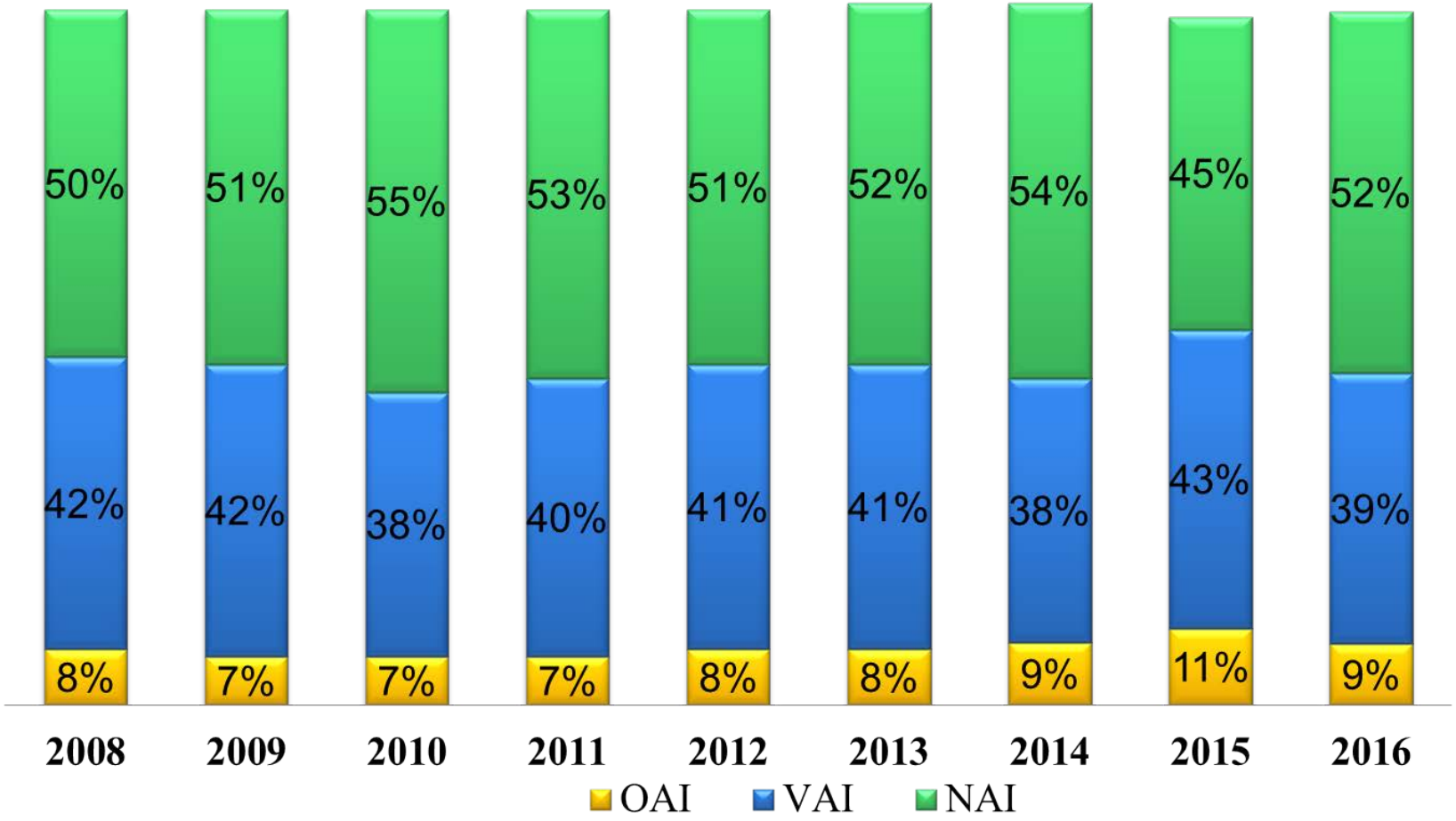
FDA Medical Device Inspection Data
Inspection Outcomes

- FDA provides initial classification of the inspection based on the observations noted during the inspection.

- An inspection classification reflects the compliance status of the establishment at the time of the inspection, based on the observations documented, prior to final classification by the District or Center.

- The conclusions of the inspection are reported as:
  - Official Action Indicated (OAI)
  - Voluntary Action Indicated (VAI)
  - No Action Indicated (NAI)

CY2008-2016
QS Medical Device Inspection Outcomes



CY2016 QS Medical Device Inspections

Total Domestic Inspections	Total Foreign Inspections
1450	725

Domestic Inspection Outcomes		%	Foreign Inspection Outcomes		%
NAI	779	54%	NAI	351	48%
VAI	567	39%	VAI	288	40%
OAI	104	7%	OAI	86	12%

CY2016 Top Foreign OAI QS Medical Device Inspections

Country Name	CY2015 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

Country Name	CY2016 OAI Inspections
China	19
Germany	10
United Kingdom	7
Japan	6
Canada	4
South Korea	4
Taiwan	4
France	3
Ireland	3
Italy	3
Malaysia	3

FDA Form 483 (483) Observations Data

- Source of data - FDA's Turbo Establishment Inspection Reporting Database
- Timeframe January 1, 2016 – December 31, 2016
- 854 FDA Form 483s were issued in CY2016.
- 3,027 FDA Form 483 observations cited for 21 CFR 820 (Quality System regulation*) deficiencies.

- **NOTE: Beginning in FY18 we will prepare this presentation by FY and not CY. Therefore the data will include Oct 1 2016 – Sept 30 2017. Data will be run the 2nd week in December.**

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

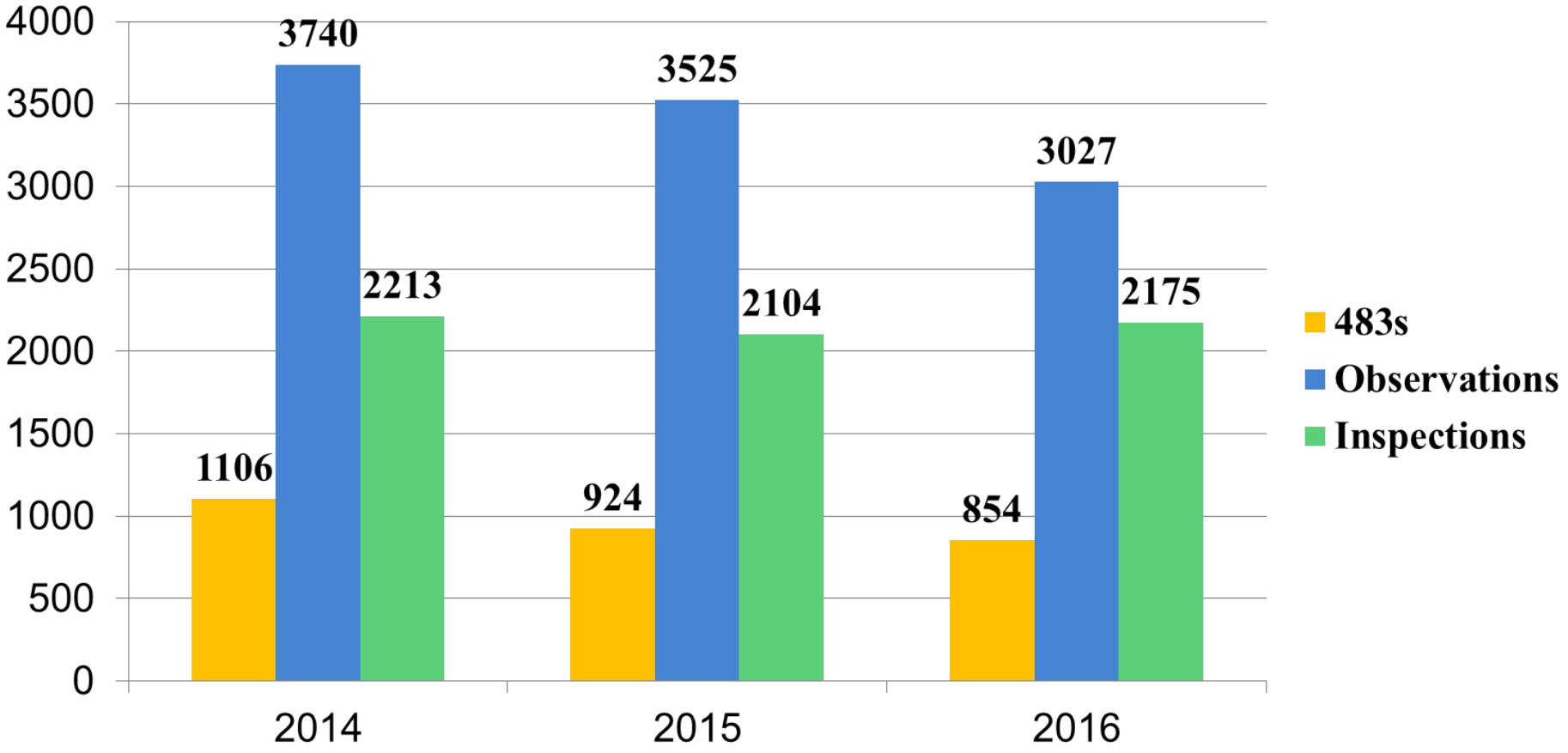
CAPA & MGMT Descriptions

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

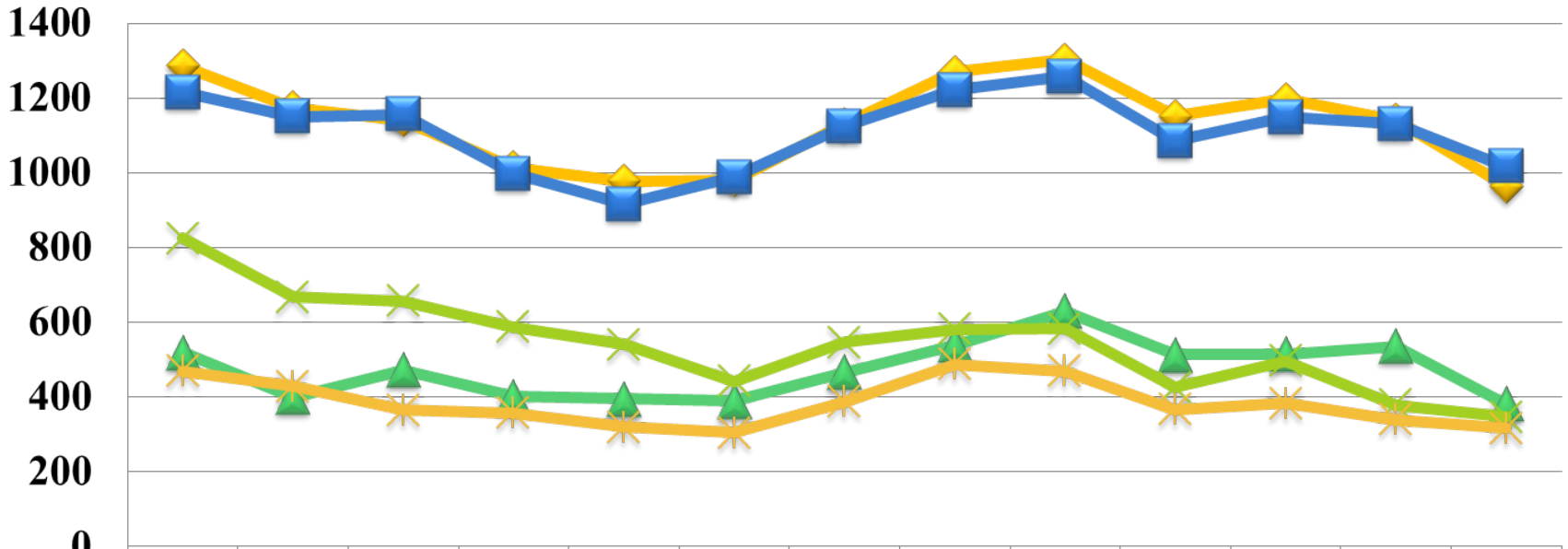
DES & DOC Descriptions

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 483s Issued/Inspectional Observations/Inspections CY2014-CY2016

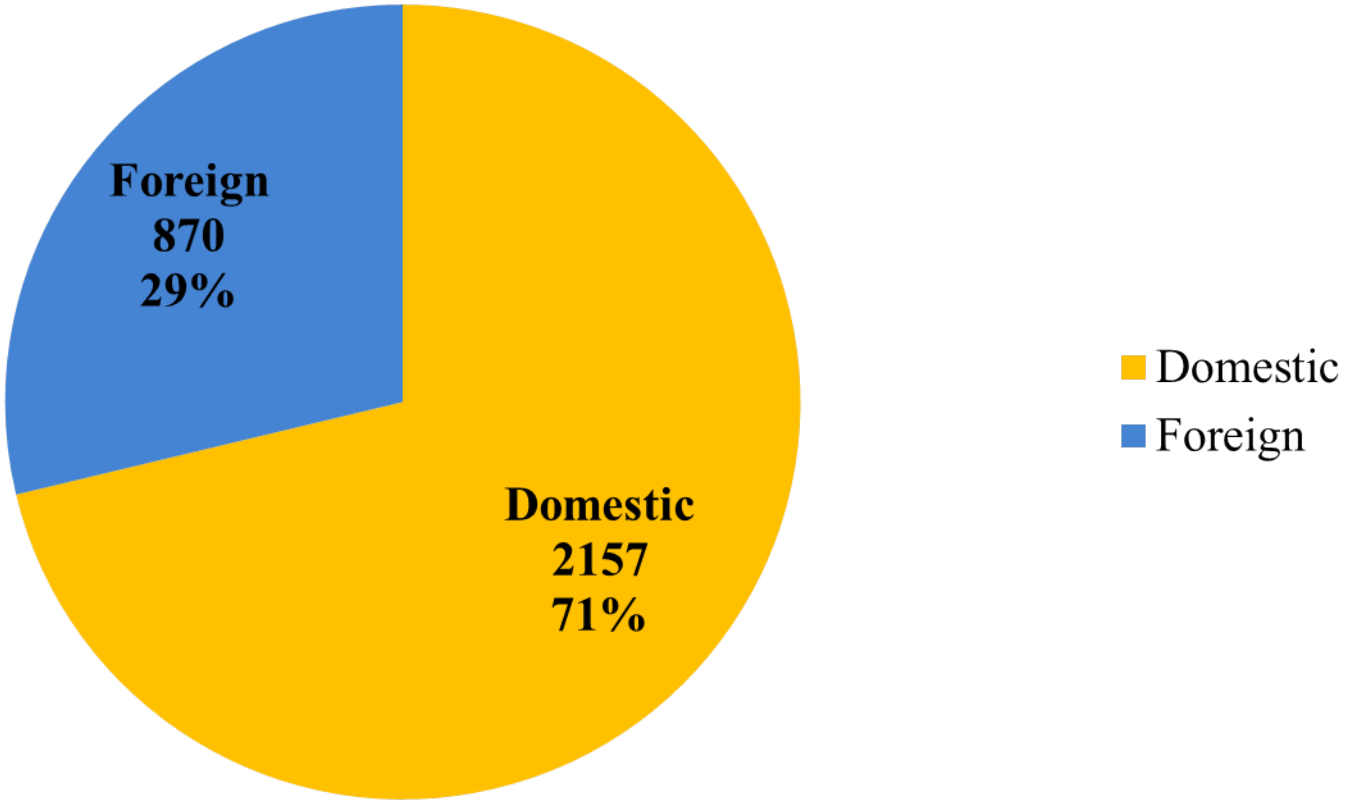


Inspectional FDA Form 483 Observations CY2004-CY2016 by QS Subsystem

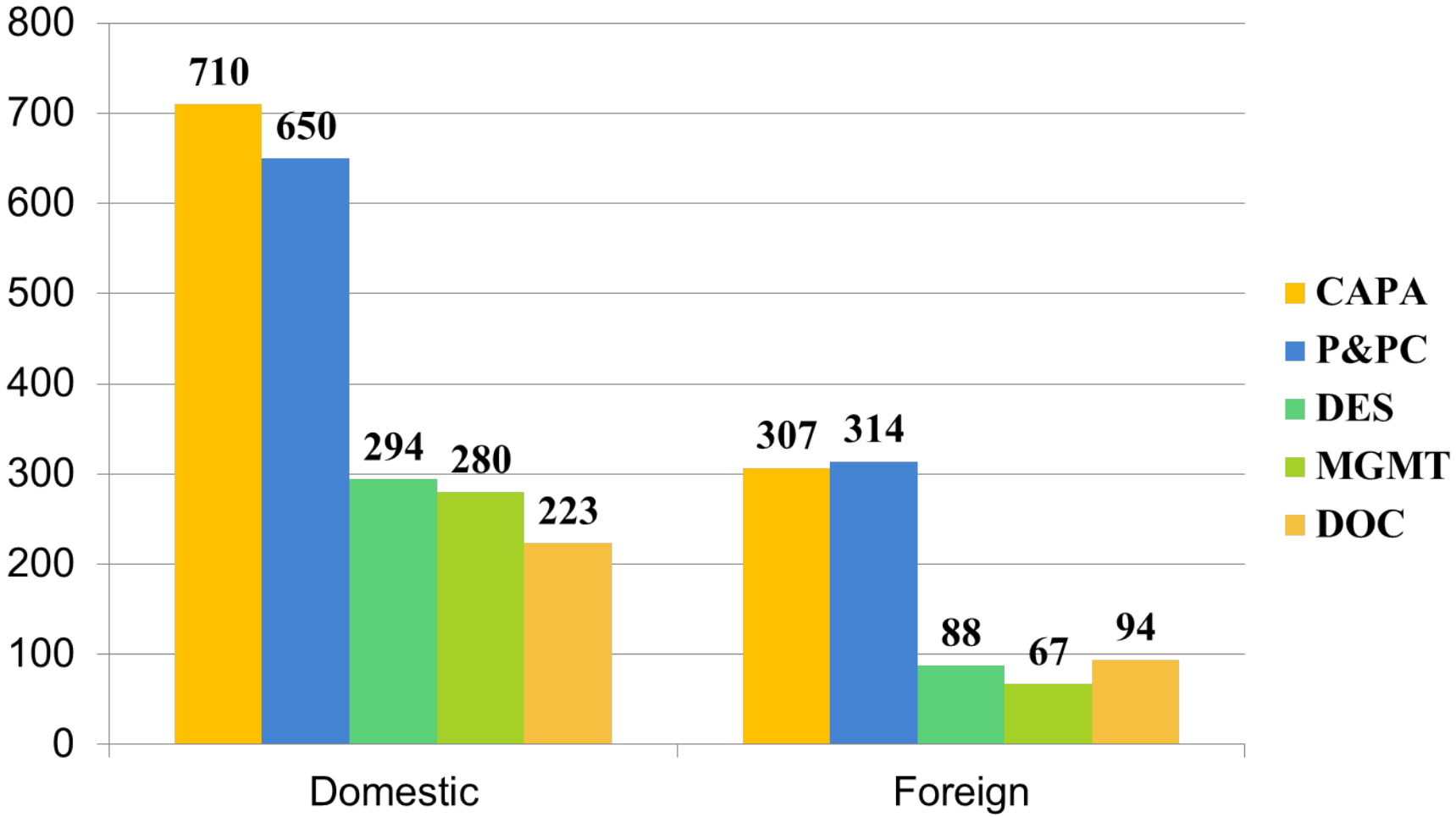


	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
P&PC	1287	1175	1141	1014	978	981	1131	1269	1303	1151	1197	1141	964
CAPA	1215	1150	1157	997	915	988	1125	1221	1258	1085	1148	1131	1017
DES	519	400	472	402	395	390	466	539	630	513	515	536	382
MGMT	825	667	657	588	540	442	546	582	583	425	497	378	347
DOC	470	428	365	358	320	304	388	487	469	367	383	339	317

Inspectional FDA Form 483s Issued CY2016



Domestic & Foreign Inspectional FDA Form 483 Observations (CY2016)



CY2016 Total 483 Observations

QS Subsystem	# of Observations	Percentage
CAPA	1017	34%
P&PC	964	32%
DES	382	13%
MGMT	347	11%
DOC	317	10%
	Total: 3027	**100%**

CY2016 483 Observations (Foreign/Domestic)

QS Subsystem	# of Domestic Observations	# of Foreign Observations
CAPA	710	307
P&PC	650	314
DES	294	88
MGMT	280	67
DOC	223	94
	2157	**870**

CY2016 Top CAPA Observations Domestic/Foreign

CFR #	# Domestic Observations	Percentage
21 CFR 820.100(a)	234	33%
21 CFR 820.198(a)	201	28%
21 CFR 820.90(a)	96	14%
21 CFR 820.100(b)	78	11%
21 CFR 820.198(c)	43	6%
21 CFR 820.198(e)	19	3%
21 CFR 820.198(b)	14	2%
21 CFR 820.90(b)(2)	12	2%
21 CFR 820.90(b)(1)	7	1%
21 CFR 820.198(d)	6	1%
Total:	710	100%

CFR #	# Foreign Observations	Percentage
21 CFR 820.100(a)	108	35%
21 CFR 820.198(a)	85	28%
21 CFR 820.90(a)	44	14%
21 CFR 820.100(b)	27	9%
21 CFR 820.90(b)(2)	13	4%
21 CFR 820.90(b)(1)	11	4%
21 CFR 820.198(e)	8	3%
21 CFR 820.198(c)	6	2%
21 CFR 820.198(b)	2	1%
21 CFR 820.198(d)	2	1%
21 CFR 820.198(f)	1	0%
Total:	307	100%

CY2016 Top P&PC Observations Domestic/Foreign

CFR #	# Domestic Observations	Percentage
21 CFR 820.50	98	15%
21 CFR 820.75(a)	84	13%
21 CFR 820.72(a)	45	7%
21 CFR 820.70(a)	35	5%
21 CFR 820.80(d)	33	5%
21 CFR 820.80(a)	31	5%
21 CFR 820.70(c)	28	4%
21 CFR 820.80(b)	28	4%
21 CFR 820.50(a)(1)	22	3%
21 CFR 820.80(e)	20	3%
21 CFR 820.50(a)	17	3%
21 CFR 820.50(a)(3)	15	2%
21 CFR 820.70(b)	14	2%

CFR #	# Foreign Observations	Percentage
21 CFR 820.75(a)	56	18%
21 CFR 820.70(a)	30	10%
21 CFR 820.50	19	6%
21 CFR 820.250(b)	18	6%
21 CFR 820.72(a)	18	6%
21 CFR 820.70(c)	16	5%
21 CFR 820.80(d)	14	4%
21 CFR 820.80(b)	13	4%
21 CFR 820.250(a)	9	3%
21 CFR 820.70(e)	9	3%
21 CFR 820.72(b)	9	3%
21 CFR 820.75(b)	9	3%
21 CFR 820.70(i)	8	3%

CY2016 Top P&PC Observations Cont'd Domestic/Foreign

CFR #	# Domestic Observations	Percentage
21 CFR 820.50(b)	14	2%
21 CFR 820.70(i)	13	2%
21 CFR 820.250(b)	11	2%
21 CFR 820.70(e)	11	2%
21 CFR 820.75(b)	11	2%
21 CFR 820.200(a)	10	2%
21 CFR 820.70(g)	10	2%
21 CFR 820.120	9	1%
21 CFR 820.50(a)(2)	9	1%
21 CFR 820.80(c)	8	1%
21 CFR 820.250(a)	7	1%
21 CFR 820.70(g)(1)	7	1%
21 CFR 820.75(c)	7	1%

CFR #	# Foreign Observations	Percentage
21 CFR 820.80(a)	8	3%
21 CFR 820.80(e)	8	3%
21 CFR 820.86	8	3%
21 CFR 820.50(a)(2)	6	2%
21 CFR 820.50(a)(1)	5	2%
21 CFR 820.70(b)	5	2%
21 CFR 820.120	5	2%
21 CFR 820.60	4	1%
21 CFR 820.70(d)	4	1%
21 CFR 820.80(c)	4	1%
21 CFR 820.200(a)	3	1%
21 CFR 820.50(a)	3	1%
21 CFR 820.50(a)(3)	3	1%

CY2016 Top P&PC Observations Cont'd Domestic/Foreign

CFR #	# Domestic Observations	Percentage
21 CFR 820.60	6	1%
21 CFR 820.86	6	1%
21 CFR 820.150	5	1%
21 CFR 820.160(a)	4	1%
21 CFR 820.70(g)(2)	4	1%
21 CFR 820.120(d)	3	0%
21 CFR 820.160(b)	3	0%
21 CFR 820.70(d)	3	0%
21 CFR 820.72(b)	3	0%
21 CFR 820.120(b)	2	0%
21 CFR 820.140	2	0%
21 CFR 820.170(b)	2	0%
21 CFR 820.200(d)	2	0%
21 CFR 820.75(b)(2)	2	0%
21 CFR 820.120(e)	1	0%
21 CFR 820.130	1	0%
21 CFR 820.170(a)	1	0%
21 CFR 820.200(b)	1	0%
21 CFR 820.200(c)	1	0%
21 CFR 820.70(f)	1	0%
Total	650	100%

CFR #	# Foreign Observations	Percentage
21 CFR 820.70(g)(1)	3	1%
21 CFR 820.70(g)(2)	3	1%
21 CFR 820.75(b)(2)	3	1%
21 CFR 820.120(b)	2	1%
21 CFR 820.70(f)	2	1%
21 CFR 820.70(g)	2	1%
21 CFR 820.120(d)	1	0%
21 CFR 820.140	1	0%
21 CFR 820.150	1	0%
21 CFR 820.200(d)	1	0%
21 CFR 820.75(c)	1	0%
Total	314	100%

CY2016 DES Observations

CFR #	# Domestic Observations	Percentage
21 CFR 820.30(g)	79	27%
21 CFR 820.30(i)	59	20%
21 CFR 820.30(a)	35	12%
21 CFR 820.30(f)	33	11%
21 CFR 820.30(c)	21	7%
21 CFR 820.30(e)	20	7%
21 CFR 820.30(j)	20	7%
21 CFR 820.30(d)	11	4%
21 CFR 820.30(h)	11	4%
21 CFR 820.30(b)	5	2%
Total:	294	100%

CFR #	# Foreign Observations	Percentage
21 CFR 820.30(g)	27	31%
21 CFR 820.30(f)	15	17%
21 CFR 820.30(i)	10	11%
21 CFR 820.30(a)	8	9%
21 CFR 820.30(e)	8	9%
21 CFR 820.30(j)	8	9%
21 CFR 820.30(d)	4	5%
21 CFR 820.30(h)	4	5%
21 CFR 820.30(c)	3	3%
21 CFR 820.30(b)	1	1%
Total:	88	100%

CY2016 DOC Observations

CFR #	# Domestic Observations	Percentage
21 CFR 820.184	101	45%
21 CFR 820.40	48	22%
21 CFR 820.181	38	17%
21 CFR 820.40(a)	13	6%
21 CFR 820.180	10	4%
21 CFR 820.40(b)	9	4%
21 CFR 820.180(b)	2	1%
21 CFR 820.186	2	1%
Total:	223	100%

CFR #	# Foreign Observations	Percentage
21 CFR 820.184	48	51%
21 CFR 820.181	14	15%
21 CFR 820.40	12	13%
21 CFR 820.40(a)	9	10%
21 CFR 820.40(b)	6	6%
21 CFR 820.180	2	2%
21 CFR 820.180(b)	2	2%
21 CFR 820.186	1	1%
Total:	94	100%

CY2016 MGMT Observations

CFR #	# Domestic Observations	Percentage
21 CFR 820.22	106	38%
21 CFR 820.20(c)	64	23%
21 CFR 820.25(b)	55	20%
21 CFR 820.20(e)	22	8%
21 CFR 820.20(b)	10	4%
21 CFR 820.20(a)	9	3%
21 CFR 820.25(a)	8	3%
21 CFR 820.20(d)	6	2%
Total:	280	100%

CFR #	# Foreign Observations	Percentage
21 CFR 820.22	29	43%
21 CFR 820.25(b)	19	28%
21 CFR 820.20(c)	13	19%
21 CFR 820.20(a)	2	3%
21 CFR 820.20(d)	2	3%
21 CFR 820.25(a)	2	3%
Total:	67	100%

FDA Warning Letter (WL) Citations

- Source of data - FDA's Warning Letters and FDA's Compliance Management System (CMS)
- Timeframe January 1, 2016 – December 31, 2016
- CY2016 - 57 Warning Letters with 21 CFR 820 (Quality System regulation*) deficiencies

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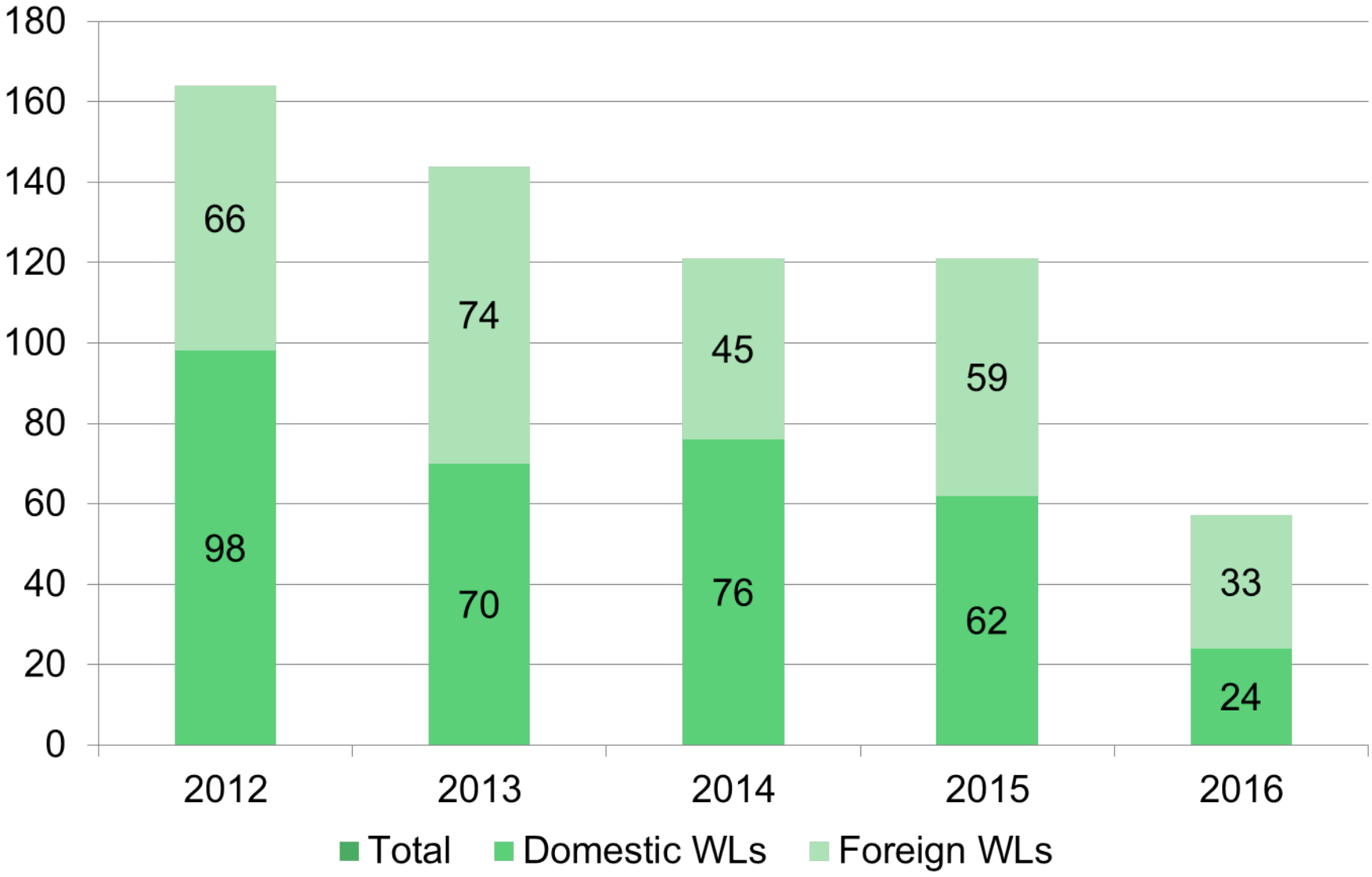
FDA Medical Device Warning Letters with Quality System Regulation Citations

Year	# WL's
2016	**57**
2015	121
2014	121
2013	144
2012	164
2011	122
2010	89
2009	77
2008	98
2007	74
2006	79
2005	97
2004	113
2003	69
2002	42

Domestic & Foreign WLs with Quality System (CFR 820) Citations (CY2016)



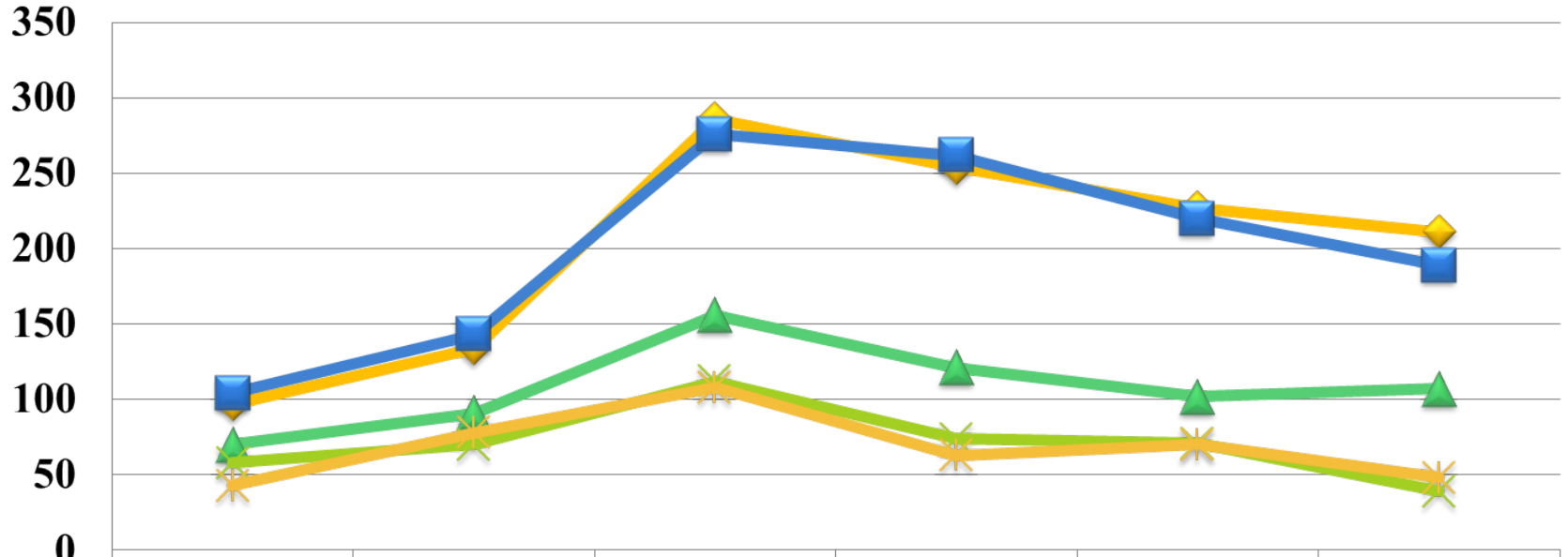
CY16 Foreign and Domestic WLs with QS (CFR 820) Citations

Country	# of WLs
USA	24
United Kingdom	6
China	6
Germany	4
Korea (the Republic of)	4
Canada	3
France	3
Taiwan	2
Argentina	1
Greece	1
India	1
Italy	1
Philippines	1
Total:	**57**

CY16 WL Citations

QS Subsystem	# of Citations	Percentage
P&PC	211	36%
CAPA	189	32%
DES	107	18%
DOC	48	8%
MGMT	39	7%
Total:	**594**	**100%**

WL Citations by QS Subsystem (CY2011-CY2016)



	2011	2012	2013	2014	2015	2016
P&PC	97	134	286	254	227	211
CAPA	104	143	276	262	220	189
DES	70	91	156	121	102	107
MGMT	58	70	112	74	71	39
DOC	43	78	108	63	70	48

CY2016 Top 10 Most Frequent QS WL Citations

WL Citation	QS Subsystem	CY2016 # of Citations	Percentage of all Citations
21 CFR 820.100(a)	CAPA	57	10%
21 CFR 820.198(a)	CAPA	39	7%
21 CFR 820.90(a)	CAPA	30	5%
21 CFR 820.30(g)	DES	27	5%
21 CFR 820.75(a)	P&PC	25	4%
21 CFR 820.22	MGMT	23	4%
21 CFR 820.72(a)	P&PC	22	4%
21 CFR 820.184	DOC	21	4%
21 CFR 820.50	P&PC	20	3%
21 CFR 820.30(i)	DES	19	3%
	Total of All Citations:	**594**	

CY2016 CAPA QS Subsystem WL Citations

CFR #	# Domestic Observations	Percentage
21 CFR 820.100(a)	16	27%
21 CFR 820.198(a)	11	19%
21 CFR 820.90(a)	7	12%
21 CFR 820.198(c)	4	7%
21 CFR 820.20(c)	4	7%
21 CFR 820.198	3	5%
21 CFR 820.100(a)(1)	2	3%
21 CFR 820.100(a)(4)	2	3%
21 CFR 820.100(b)	2	3%
21 CFR 820.90(b)(2)	2	3%
21 CFR 820.100	1	2%
21 CFR 820.198(a)(3)	1	2%
21 CFR 820.198(b)	1	2%
21 CFR 820.198(e)	1	2%
21 CFR 820.90	1	2%
21 CFR 820.90(b)(1)	1	2%
Total:	59	100%

CFR #	# Foreign Observations	Percentage
21 CFR 820.100(a)	41	32%
21 CFR 820.198(a)	28	22%
21 CFR 820.90(a)	23	18%
21 CFR 820.90(b)(1)	6	5%
21 CFR 820.90(b)(2)	5	4%
21 CFR 820.198(a)(3)	4	3%
21 CFR 820.20(c)	4	3%
21 CFR 820.100(a)(1)	3	2%
21 CFR 820.198(e)	3	2%
21 CFR 820.100	2	2%
21 CFR 820.100(a)(4)	2	2%
21 CFR 820.100(a)(5)	2	2%
21 CFR 820.198	2	2%
21 CFR 820.198(a)(1)	1	1%
21 CFR 820.198(c)	1	1%
21 CFR 820.198(e)(2)	1	1%
21 CFR 820.90	1	1%
21 CFR 820.90(b)	1	1%
Total:	130	100%

CY2016 Design Control QS Subsystem WL Citations

CFR #	# Domestic Observations	Percentage
21 CFR 820.30(g)	9	24%
21 CFR 820.30(i)	8	22%
21 CFR 820.30(f)	4	11%
21 CFR 820.30	3	8%
21 CFR 820.30(j)	3	8%
21 CFR 820.30(a)	2	5%
21 CFR 820.30(e)	2	5%
21 CFR 820.30(h)	2	5%
21 CFR 820.30(a)(1)	1	3%
21 CFR 820.30(b)	1	3%
21 CFR 820.30(c)	1	3%
21 CFR 820.30(d)	1	3%
Total:	37	100%

CFR #	# Foreign Observations	Percentage
21 CFR 820.30(g)	18	26%
21 CFR 820.30(f)	12	17%
21 CFR 820.30(e)	11	16%
21 CFR 820.30(i)	11	16%
21 CFR 820.30(a)	6	9%
21 CFR 820.30(c)	5	7%
21 CFR 820.30(h)	5	7%
21 CFR 820.30(j)	2	3%
Total:	70	100%

CY2016 P&PC QS Subsystem WL Citations

CFR #	# Domestic Observations	Percentage
21 CFR 820.50	7	13%
21 CFR 820.75(a)	7	13%
21 CFR 820.80(d)	6	11%
21 CFR 820.72(a)	5	9%
21 CFR 820.80(a)	4	7%
21 CFR 820.250(b)	3	5%
21 CFR 820.75	3	5%
21 CFR 820.80(e)	3	5%
21 CFR 820.50(a)	2	4%
21 CFR 820.70(a)	2	4%
21 CFR 820.70(b)	2	4%
21 CFR 820.160(a)	1	2%
21 CFR 820.200(a)	1	2%
21 CFR 820.50(a)(1)	1	2%
21 CFR 820.50(b)	1	2%
21 CFR 820.70	1	2%
21 CFR 820.70(c)	1	2%
21 CFR 820.70(g)(1)	1	2%
21 CFR 820.70(i)	1	2%
21 CFR 820.72(b)(1)	1	2%
21 CFR 820.75(b)	1	2%
21 CFR 820.80	1	2%
Total:	55	100%

CFR #	# Foreign Observations	Percentage
21 CFR 820.75(a)	18	12%
21 CFR 820.72(a)	17	11%
21 CFR 820.50	13	8%
21 CFR 820.70(c)	13	8%
21 CFR 820.70(a)	12	8%
21 CFR 820.70(i)	10	6%
21 CFR 820.80(d)	9	6%
21 CFR 820.200(a)	7	4%
21 CFR 820.80(b)	7	4%
21 CFR 820.70(e)	6	4%
21 CFR 820.75(b)	6	4%
21 CFR 820.250(b)	4	3%
21 CFR 820.72(b)	4	3%
21 CFR 820.50(a)(2)	3	2%
21 CFR 820.80(a)	3	2%
21 CFR 820.120	2	1%
21 CFR 820.200(d)	2	1%
21 CFR 820.250(a)	2	1%
21 CFR 820.50(a)	2	1%
21 CFR 820.70(g)	2	1%
21 CFR 820.120(b)	1	1%
21 CFR 820.140	1	1%
21 CFR 820.150(a)	1	1%

CY2016 P&PC QS Subsystem WL Citations Continued

CFR #	# Foreign Observations	Percentage
21 CFR 820.200(b)	1	1%
21 CFR 820.50(a)(1)	1	1%
21 CFR 820.60	1	1%
21 CFR 820.70(b)	1	1%
21 CFR 820.70(d)	1	1%
21 CFR 820.70(g)(1)	1	1%
21 CFR 820.75	1	1%
21 CFR 820.80	1	1%
21 CFR 820.80(c)	1	1%
21 CFR 820.80(e)	1	1%
21 CFR 820.86(a)	1	1%
Total:	156	100%

CY2016 MGMT QS Subsystem WL Citations

CFR #	# Domestic Observations	Percentage
21 CFR 820.22	11	79%
21 CFR 820.20(a)	1	7%
21 CFR 820.20(b)	1	7%
21 CFR 820.5	1	7%
Total:	14	100%

CFR #	# Foreign Observations	Percentage
21 CFR 820.22	12	48%
21 CFR 820.25(b)	8	32%
21 CFR 820.5	5	20%
Total:	25	100%

CY2016 DOC QS Subsystem WL Citations

CFR #	# Domestic Observations	Percentage
21 CFR 820.184	8	53%
21 CFR 820.181	5	33%
21 CFR 820.40	1	7%
21 CFR 820.40(a)	1	7%
Total:	15	100%

CFR #	# Foreign Observations	Percentage
21 CFR 820.184	13	39%
21 CFR 820.181	9	27%
21 CFR 820.40	8	24%
21 CFR 820.184(c)	1	3%
21 CFR 820.184(e)	1	3%
21 CFR 820.40(b)	1	3%
Total:	33	100%

Contact Information

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