U.S. FOOD & DRUG ADMINISTRATION

FY2017 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 FY2017.

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 FY2017

- FDA maintained the overall number of QS surveillance inspections in FY2017.
- In FY2017, FDA issued 14% more 483s and there was a 10% increase in the number of 483 observations.
  - Observations in all QS areas increased in FY2017. The most notable increases were in the two areas most frequently observed, Production and Process Controls (P&PC) and Corrective and Preventive Actions (CAPA).
- The number of WLs dropped by 56% from 75 WL in FY2016 to 33 WLs in FY2017.
  - Citations in all QS areas decreased in FY2017 between 31 - 57%.

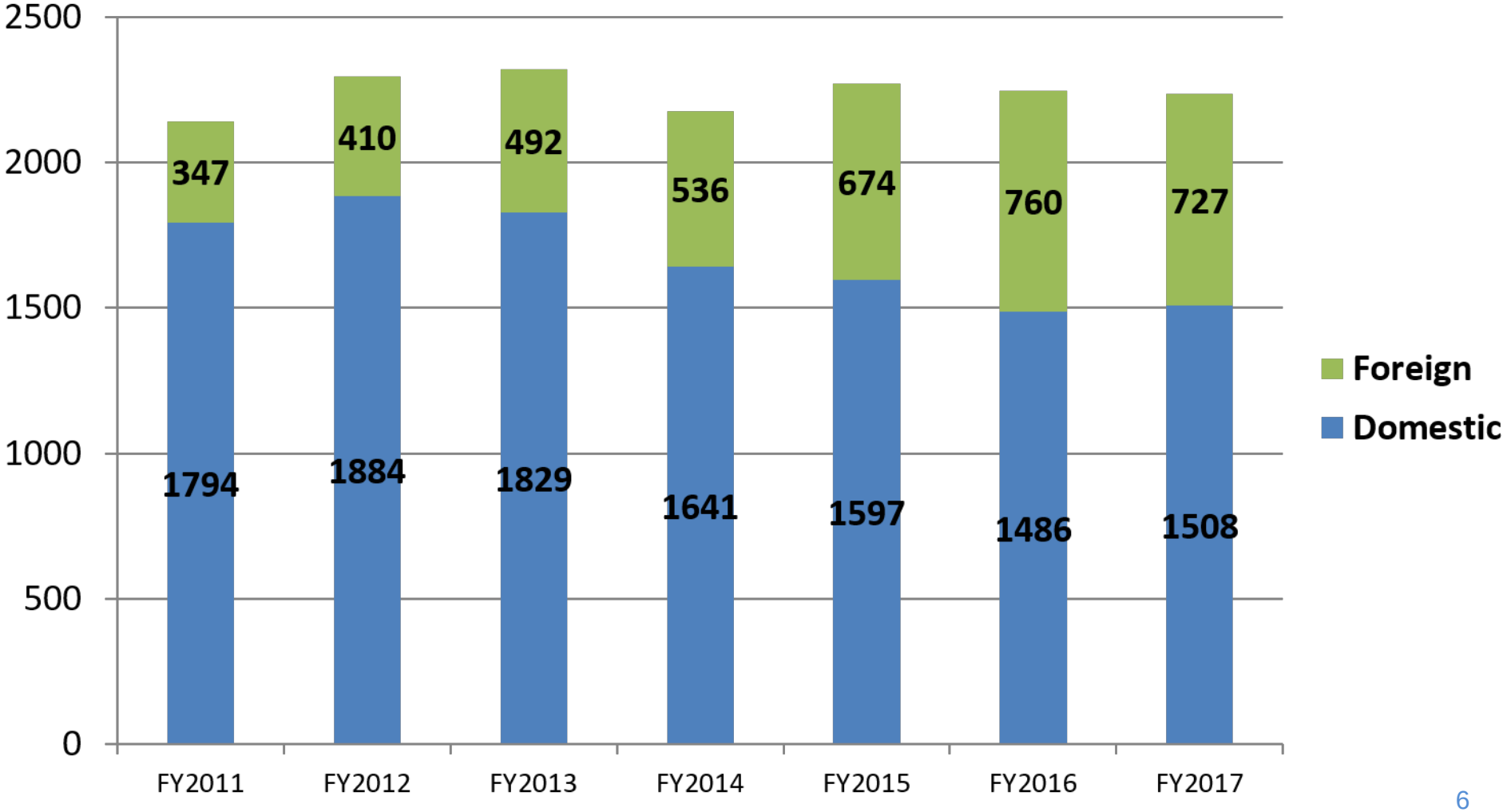
NOTE: Beginning in FY2017 this annual data analysis uses FY (Oct 1 – Sep 30) to display year to year trends. Prior years' analyses used CY.

FY2017 FDA Medical Device Inspection Data

- Source of data - FDA's Field Accomplishment and Compliance Tracking System (FACTS)

- Timeframe October 1, 2016 – September 30, 2017

Medical Device QS Surveillance Inspections



Top 10 Foreign Inspection Locations

Country Name	FY2016 # of Inspections
China	179
Germany	75
Japan	63
United Kingdom	51
Taiwan	41
Canada	33
Korea, Republic	29
France	28
Italy	26
Switzerland	24

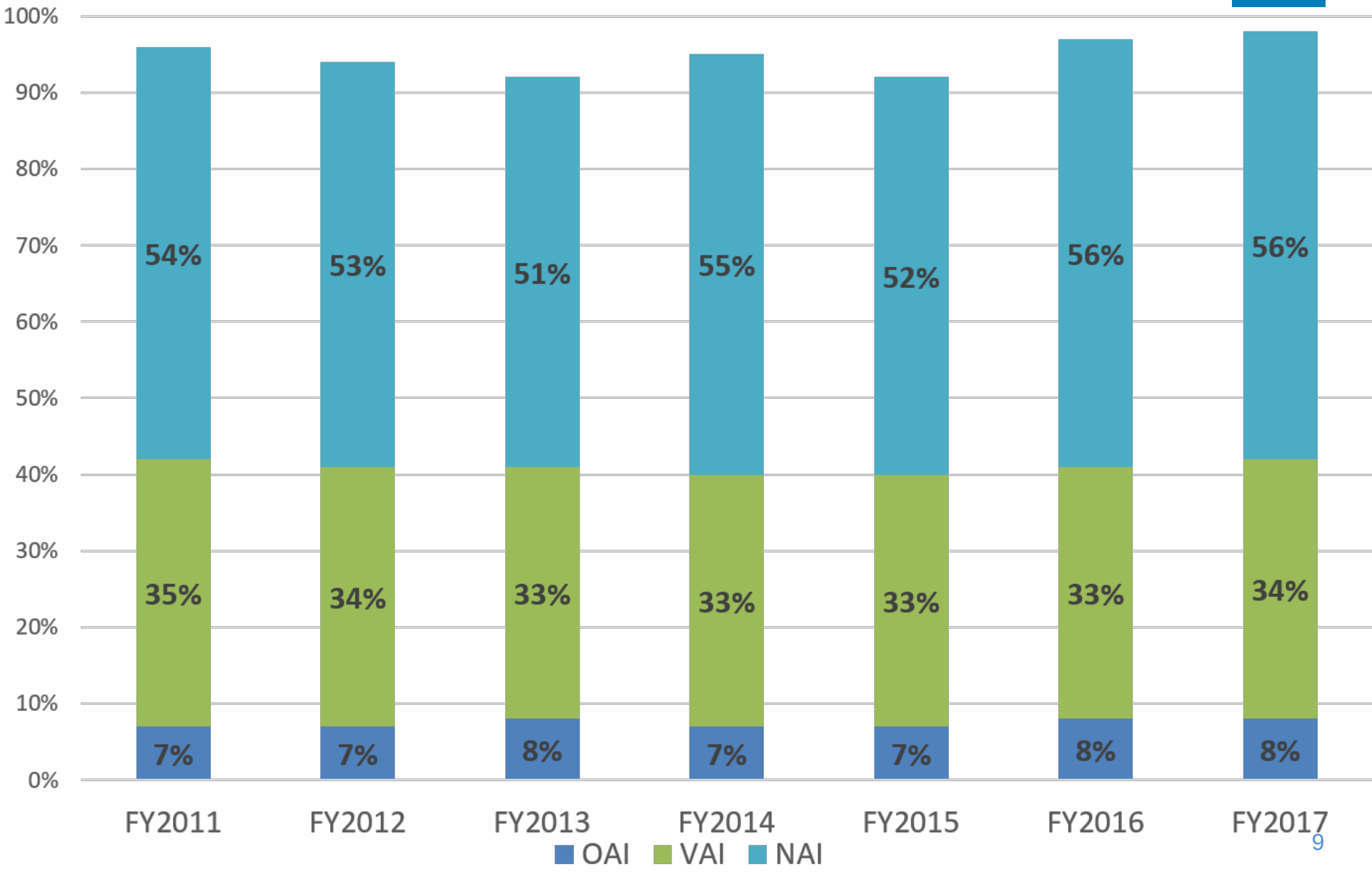
Country Name	FY2017 # of Inspections
China	135
Germany	106
United Kingdom	61
France	43
Canada	41
Japan	38
Switzerland	38
Korea, Republic	31
Italy	30
Taiwan	30

FDA Medical Device Inspection Data
Inspection Outcomes

- An inspection classification reflects the compliance status of the establishment at the time of the inspection, based on the observations documented.

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

QS Medical Device Inspection Outcomes



FY2017 QS Medical Device Inspections

Total Domestic Inspections	Total Foreign Inspections
1508	727

Domestic Inspection Outcomes		%	Foreign Inspection Outcomes		%
NAI	770	51%	NAI	344	47%
VAI	592	39%	VAI	313	43%
OAI	146	10%	OAI	70	10%

FY2017 Top Foreign OAI QS Medical Device Inspections

Country Name	FY2016 OAI Inspections
China	18
Germany	12
Korea, Republic	7
Japan	6
United Kingdom	6
Netherlands	5
Canada	4
Taiwan	4
France	3
Italy	3
Malaysia	3

Country Name	FY2017 OAI Inspections
China	13
Taiwan	7
Korea, Republic	6
Japan	5
Netherlands	5
South Africa	4
United Kingdom	4
France	3
India	3
Italy	3
Ireland	2

FDA Form 483 (483) Observations Data FY2017

- Source of data - FDA's Establishment Inspection Reporting Database
- Timeframe October 1, 2016 – September 30, 2017
- 976 (692 Domestic/284 Foreign) FDA Form 483s were issued in FY2017.
- 3,519 (2627 Domestic/892 Foreign) FDA Form 483 observations cited for 21 CFR 820 (Quality System regulation) deficiencies on FY2017.

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 Regulations by Subsystem

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

P&PC Descriptions

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

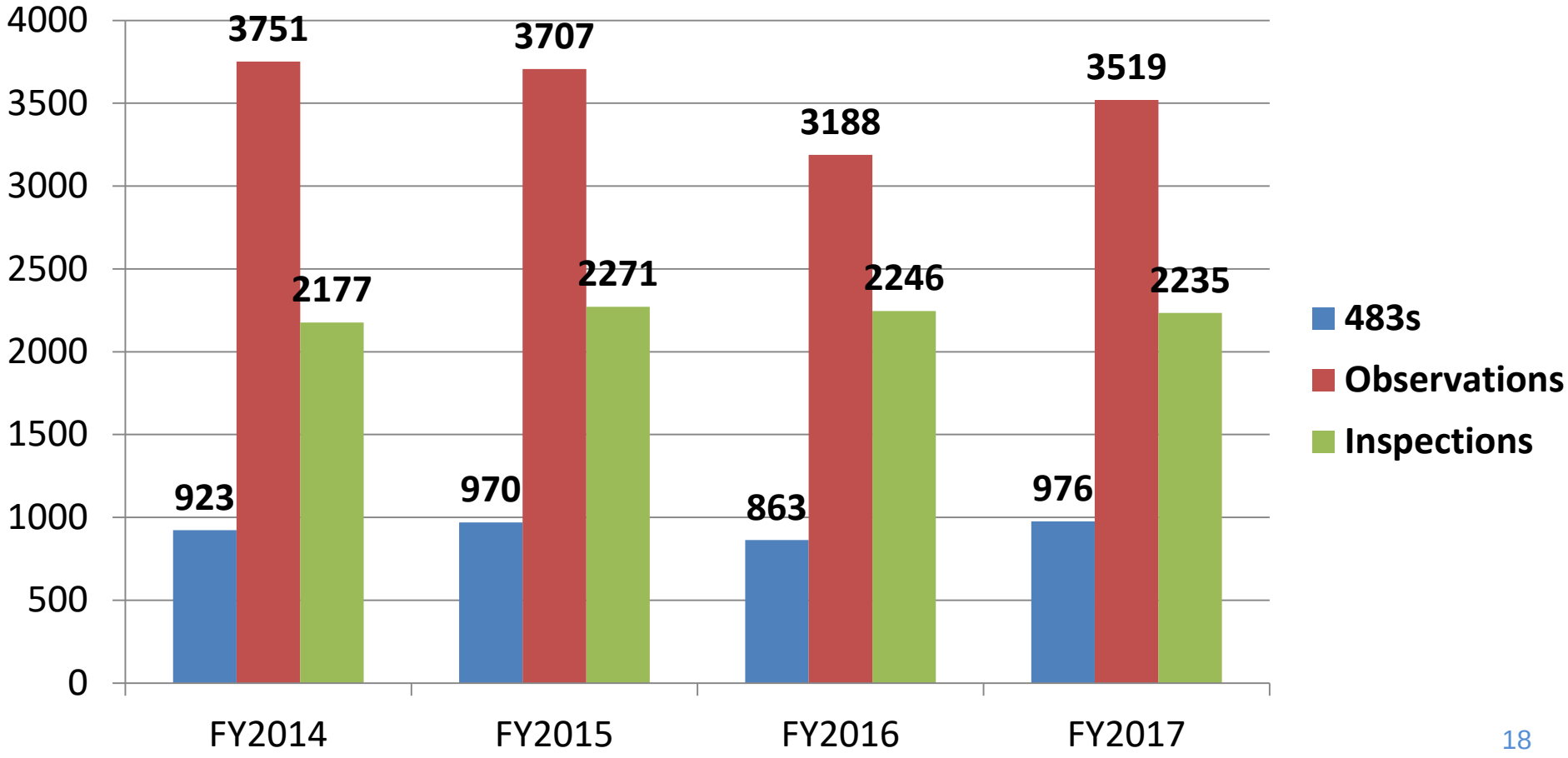
CAPA & MGMT Descriptions

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

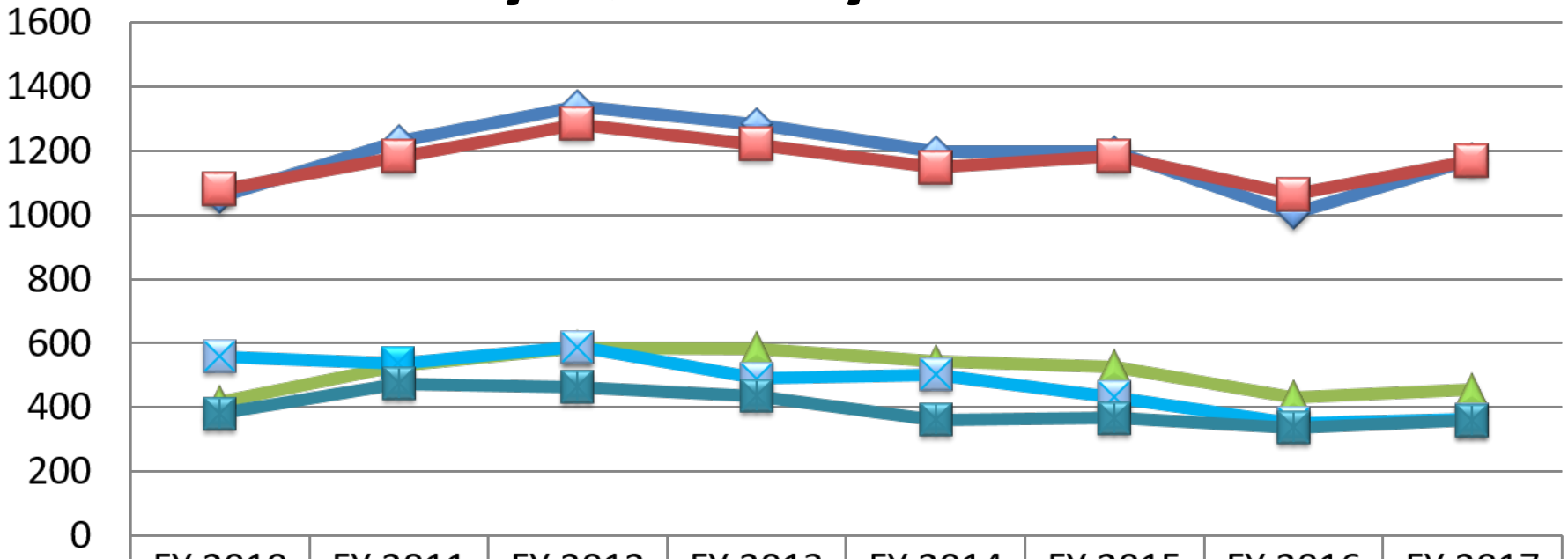
DES & DOC Descriptions

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 FDA Form 483s Issued, Inspectional Observations and Inspections

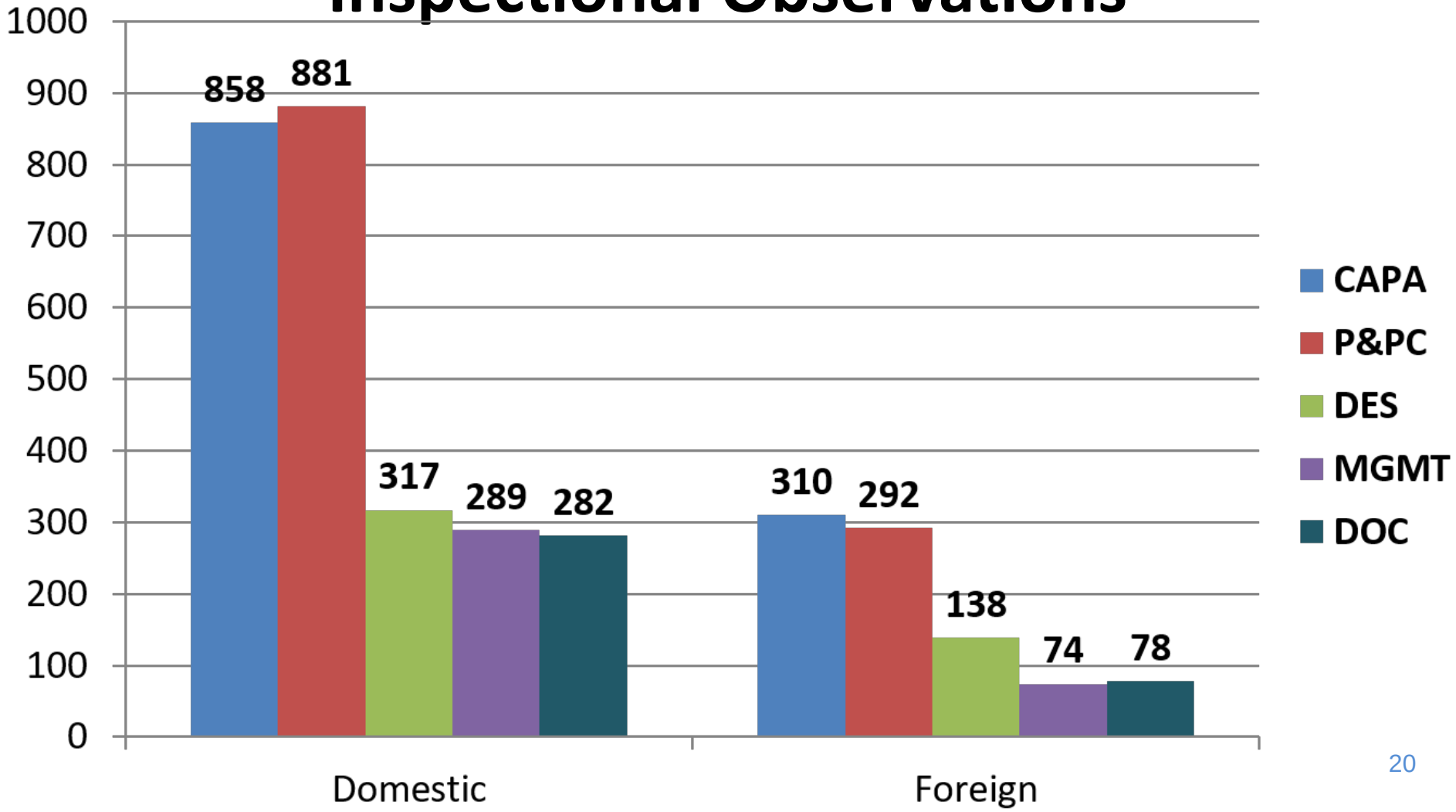


Inspectional FDA Form 483 Observations by QS Subsystem



	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
P&PC	1056	1229	1338	1283	1196	1197	1005	1173
CAPA	1079	1180	1282	1219	1148	1183	1063	1168
DES	417	528	587	584	542	527	432	455
MGMT	559	536	589	491	503	432	351	363
DOC	381	475	463	435	362	368	337	360

FY2017 Domestic & Foreign FDA Form 483 Inspectional Observations



FY2017 FDA Form 483 Observations

QS Subsystem	# of Observations	Percentage
P&PC	1173	34%
CAPA	1168	33%
DES	455	13%
MGMT	363	10%
DOC	360	10%
Total:	**3519**	**100%**

FY2017 FDA Form 483 Observations (Foreign and Domestic)

QS Subsystem	# of Domestic Observations	# of Foreign Observations
P&PC	881	292
CAPA	858	310
DES	317	138
MGMT	289	74
DOC	282	78
Total:	**2627**	**892**

FY2017 Top 10 P&PC 483 Observations Domestic and Foreign

CFR Number	# of Domestic Observations	Percentage
21 CFR 820.50	115	13%
21 CFR 820.75(a)	112	13%
21 CFR 820.72(a)	63	7%
21 CFR 820.70(a)	56	6%
21 CFR 820.80(d)	49	6%
21 CFR 820.80(b)	42	5%
21 CFR 820.80(a)	39	4%
21 CFR 820.70(i)	31	4%
21 CFR 820.70(c)	29	3%
21 CFR 820.50(a)(10)	27	3%

CFR Number	# of Foreign Observations	Percentage
21 CFR 820.75(a)	52	18%
21 CFR 820.70(a)	32	11%
21 CFR 820.50	24	8%
21 CFR 820.80(d)	18	6%
21 CFR 820.250(b)	14	5%
21 CFR 820.70(i)	14	5%
21 CFR 820.80(b)	13	4%
21 CFR 820.70(c)	11	4%
21 CFR 820.72(a)	11	4%
21 CFR 820.75(b)	9	3%

FY2017 CAPA 483 Observations Domestic and Foreign

CFR Number	# of Domestic Observations	Percentage
21 CFR 820.100(a)	295	34%
21 CFR 820.198(a)	252	29%
21 CFR 820.90(a)	121	14%
21 CFR 820.100(b)	73	8%
21 CFR 820.198(c)	38	4%
21 CFR 820.198(e)	27	3%
21 CFR 820.90(b)(2)	26	3%
21 CFR 820.198(b)	13	1%
21 CFR 820.198(d)	6	<1%
21 CFR 820.90(b)(1)	6	<1%
21 CFR 820.198(g)	1	<1%
	Total: 858	**100%**

CFR Number	# of Foreign Observations	Percentage
21 CFR 820.100(a)	108	34%
21 CFR 820.198(a)	75	24%
21 CFR 820.100(b)	46	14%
21 CFR 820.90(a)	40	12%
21 CFR 820.198(c)	14	4%
21 CFR 820.90(b)(2)	11	3%
21 CFR 820.198(e)	7	2%
21 CFR 820.90(b)(1)	5	1%
21 CFR 820.198(d)	3	<1%
21 CFR 820.198(b)	1	<1%
	Total: 310	**100%**

FY2017 DES 483 Observations Domestic and Foreign

CFR Number	# of Domestic Observations	Percentage
21 CFR 820.30(g)	93	29%
21 CFR 820.30(i)	60	18%
21 CFR 820.30(a)	42	13%
21 CFR 820.30(f)	40	12%
21 CFR 820.30(j)	28	8%
21 CFR 820.30(e)	15	4%
21 CFR 820.30(c)	10	3%
21 CFR 820.30(d)	9	2%
21 CFR 820.30(b)	7	2%
21 CFR 820.30(c)	7	2%
21 CFR 820.30(h)	6	1%
	Total: 317	**100%**

CFR Number	# of Foreign Observations	Percentage
21 CFR 820.30(g)	46	33%
21 CFR 820.30(f)	26	18%
21 CFR 820.30(i)	21	15%
21 CFR 820.30(e)	16	11%
21 CFR 820.30(c)	6	4%
21 CFR 820.30(a)	5	3%
21 CFR 820.30(b)	5	3%
21 CFR 820.30(c)	4	2%
21 CFR 820.30(h)	4	2%
21 CFR 820.30(j)	4	2%
21 CFR 820.30(d)	1	<1%
	Total: 138	**100%**

FY2017 MGMT 483 Observations Domestic and Foreign

CFR Number	# of Domestic Observations	Percentage
21 CFR 820.22	103	35%
21 CFR 820.20(c)	63	21%
21 CFR 820.25(b)	58	20%
21 CFR 820.20(e)	22	7%
21 CFR 820.20(b)	15	5%
21 CFR 820.20(a)	11	3%
21 CFR 820.25(a)	11	3%
21 CFR 820.20(d)	6	2%
	Total: 289	**100%**

CFR Number	# of Foreign Observations	Percentage
21 CFR 820.22	35	47%
21 CFR 820.25(b)	21	28%
21 CFR 820.20(c)	12	16%
21 CFR 820.20(b)	3	4%
21 CFR 820.20(d)	2	2%
21 CFR 820.25(a)	1	1%
	Total: 74	**100%**

FY2017 DOC 483 Observations Domestic and Foreign

CFR Number	# of Domestic Observations	Percentage
21 CFR 820.184	100	35%
21 CFR 820.40	77	27%
21 CFR 820.181	54	19%
21 CFR 820.40(a)	28	9%
21 CFR 820.40(b)	11	3%
21 CFR 820.186	5	1%
21 CFR 820.180	4	1%
21 CFR 820.180(b)	3	1%
	Total: 282	**100%**

CFR Number	# of Foreign Observations	Percentage
21 CFR 820.184	42	53%
21 CFR 820.40	15	19%
21 CFR 820.181	12	15%
21 CFR 820.40(a)	5	6%
21 CFR 820.180	2	2%
21 CFR 820.40(b)	2	2%
	Total: 78	**100%**

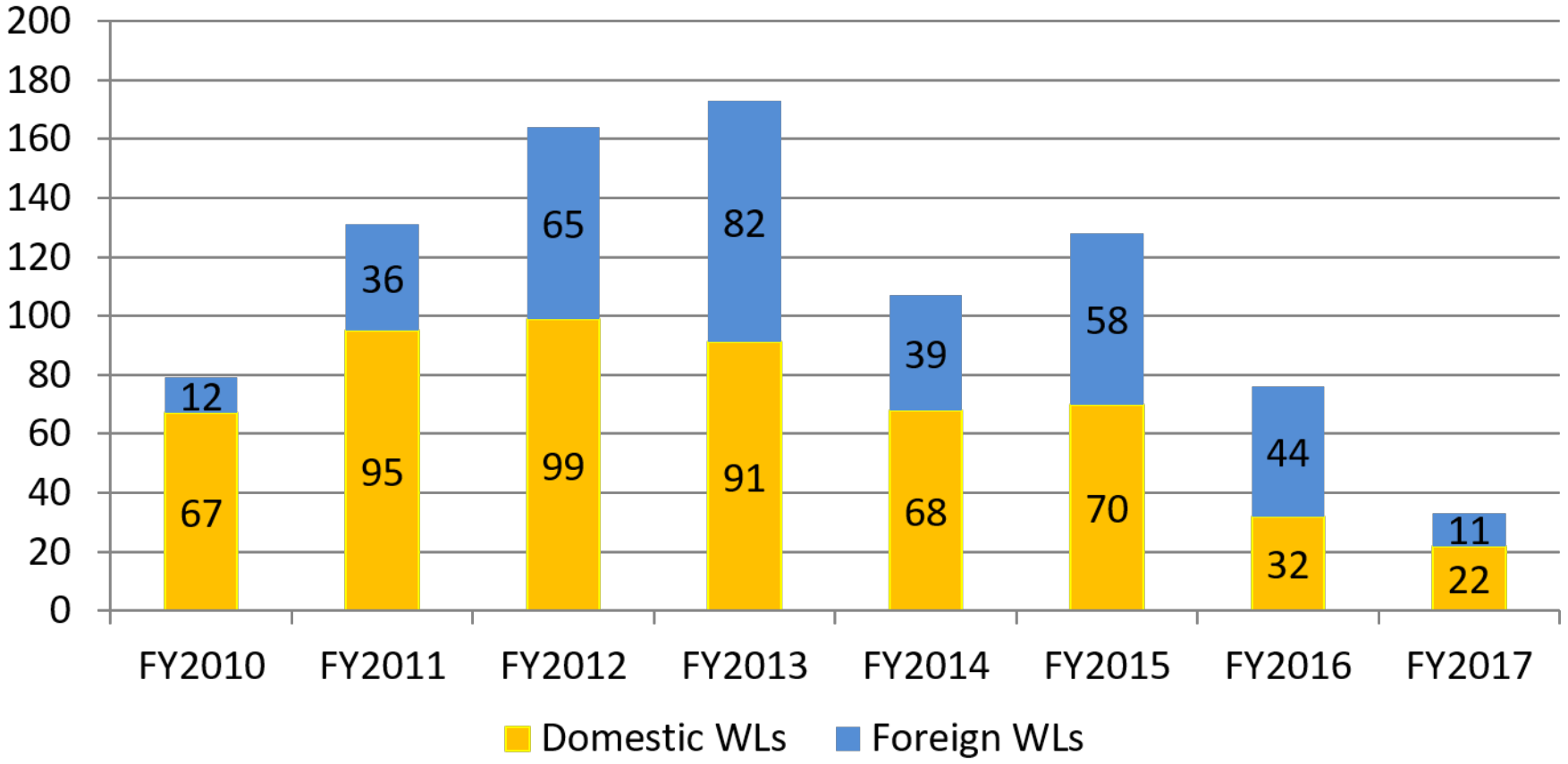
FDA Warning Letter (WL) Citations

- Source of data - FDA's Warning Letters and FDA's Compliance Management System (CMS)
- Timeframe October 1, 2016 – September 30, 2017
- FY2017 - 33 Warning Letters with 21 CFR 820 (Quality System regulation) deficiencies

FDA Medical Device Warning Letters with Quality System Regulation Citations

FY	# WL's
FY2017	**33**
FY2016	75
FY2015	128
FY2014	107
FY2013	172
FY2012	163
FY2011	131
FY2010	79

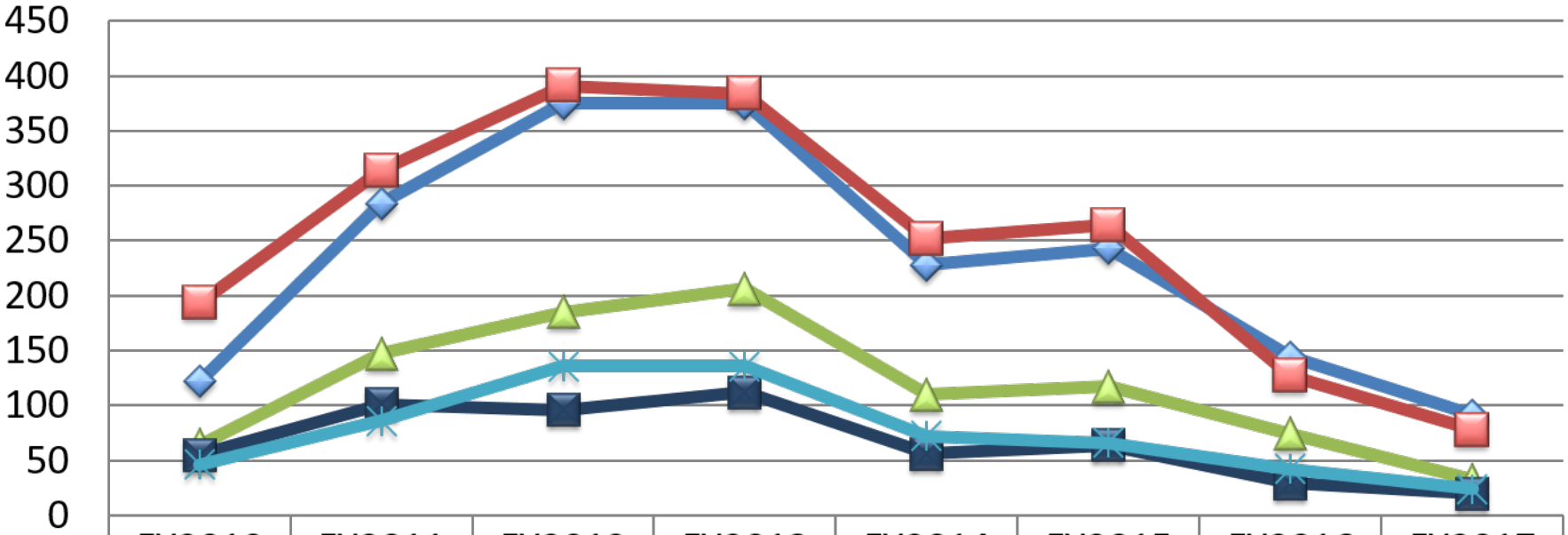
Domestic and Foreign WLs with Quality System (CFR 820) Citations



FY2017 WL Citations by QS Subsystem

QS Subsystem	# of Citations	Percentage
P&PC	91	37%
CAPA	78	32%
DES	32	13%
DOC	24	10%
MGMT	20	8%
Total:	**245**	**100%**

WL Citations by QS Subsystem



	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017
P&PC	122	284	375	375	228	243	144	91
CAPA	193	314	391	384	252	264	127	78
DES	64	147	185	206	110	117	74	32
MGMT	55	101	96	112	56	64	29	20
DOC	46	86	136	136	72	66	42	24

FY2017 Most Frequent QS WL Citations

WL Citation	QS Subsystem	# of Citations
21 CFR 820.100(a)	CAPA	24
21 CFR 820.198(a)	CAPA	13
21 CFR 820.75(a)	P&PC	13
21 CFR 820.90(a)	CAPA	11
21 CFR 820.22	MGMT	10
21 CFR 820.30(g)	DES	10
21 CFR 820.181	DOC	8
21 CFR 820.184	DOC	8
21 CFR 820.25(b)	MGMT	8
21 CFR 820.70(a)	P&PC	8

FY2017 P&PC WL Citations

WL Citation	# of Domestic Citations	Percentage
21 CFR 820.75(a)	7	11%
21 CFR 820.72(a)	5	8%
21 CFR 820.80(d)	5	8%
21 CFR 820.50	4	6%
21 CFR 820.50(a)	4	5%
21 CFR 820.70(a)	3	5%
21 CFR 820.80(a)	3	5%
21 CFR 820.80(e)	3	5%
21 CFR 820.50(a)(1)	2	3%
21 CFR 820.50(a)(2)	2	3%

WL Citation	# of Foreign Citations	Percentage
21 CFR 820.75(a)	6	18%
21 CFR 820.70(a)	4	15%
21 CFR 820.70(c)	4	12%
21 CFR 820.72(a)	3	9%
21 CFR 820.80(d)	2	6%
21 CFR 820.150	1	3%
21 CFR 820.170(a)	1	3%
21 CFR 820.50	1	3%
21 CFR 820.60	1	3%
21 CFR 820.70(e)	1	3%

FY2017 CAPA WL Citations

WL Citation	# of Domestic Citations	Percentage
21 CFR 820.100(a)	15	30%
21 CFR 820.198(a)	8	16%
21 CFR 820.90(a)	7	14%
21 CFR 820.198(c)	4	8%
21 CFR 820.20(c)	4	8%
21 CFR 820.100(b)	2	4%
21 CFR 820.90	2	4%
21 CFR 820.100	1	2%
21 CFR 820.100(a)(1)	1	2%
21 CFR 820.100(a)(4)	1	2%

WL Citation	# of Foreign Citations	Percentage
21 CFR 820.100(a)	9	31%
21 CFR 820.198(a)	5	17%
21 CFR 820.90(a)	4	14%
21 CFR 820.198	2	7%
21 CFR 820.198(a)(3)	2	7%
21 CFR 820.20(c)	2	7%
21 CFR 820.90(b)(1)	2	7%
21 CFR 820.100(b)	1	3%
21 CFR 820.198(a)(1)	1	3%
21 CFR 820.198(e)	1	3%

FY2017 DES WL Citations

WL Citation	# of Domestic Citations	Percentage
21 CFR 820.30(g)	8	40%
21 CFR 820.30(f)	3	15%
21 CFR 820.30(j)	3	15%
21 CFR 820.30(a)	2	10%
21 CFR 820.30(i)	2	10%
21 CFR 820.30(c)	1	5%
21 CFR 820.30(h)	1	5%

WL Citation	# of Foreign Citations	Percentage
21 CFR 820.30(f)	3	25%
21 CFR 820.30(a)	2	17%
21 CFR 820.30(e)	2	17%
21 CFR 820.30(g)	2	17%
21 CFR 820.30	1	8%
21 CFR 820.30(c)	1	8%
21 CFR 820.30(h)	1	8%

FY2017 MGMT WL Citations

WL Citation	# of Domestic Citations	Percentage
21 CFR 820.22	5	50%
21 CFR 820.25(b)	4	40%
21 CFR 820.20(b)	1	10%

WL Citation	# of Foreign Citations	Percentage
21 CFR 820.22	5	50%
21 CFR 820.25(b)	4	40%
21 CFR 820.22(c)	1	10%

FY2017 DOC WL Citations

WL Citation	# of Domestic Citations	Percentage
21 CFR 820.181	6	35%
21 CFR 820.184	6	35%
21 CFR 820.40	3	18%
21 CFR 820.40(a)	2	12%

WL Citation	# of Foreign Citations	Percentage
21 CFR 820.181	2	29%
21 CFR 820.184	2	29%
21 CFR 820.184(c)	1	14%
21 CFR 820.40	1	14%
21 CFR 820.40(b)	1	14%

Contact Information

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