2013 Annual FDA Medical Device Quality System Data

FDA Form 483 Observations

and

Warning Letter Citations

The Quality System (QS) regulation

- In Oct. 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 continued 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

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

2013 FDA Form 483 (483) Observations Data

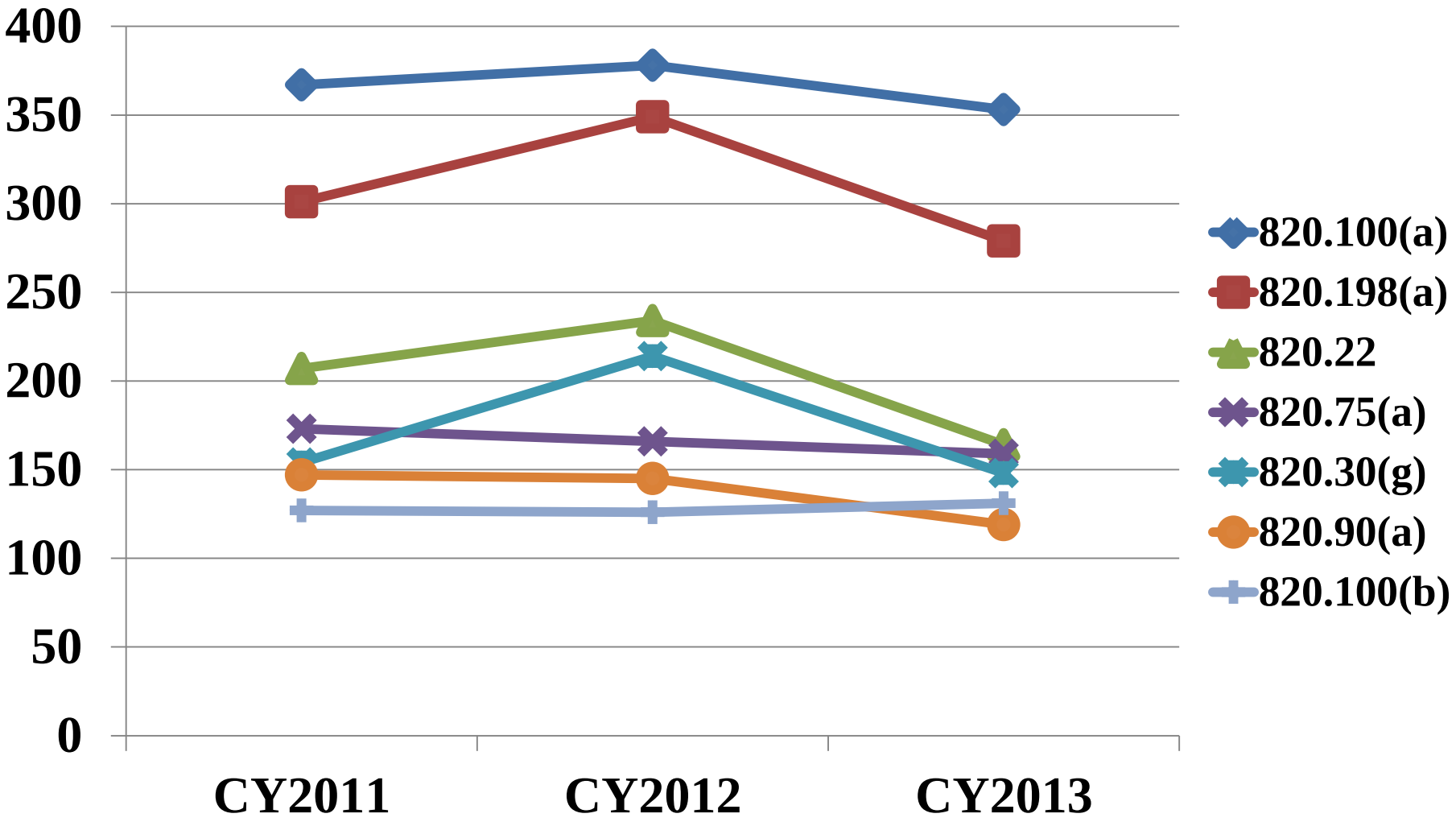
- Source of data - FDA's Turbo Establishment Inspection Reporting (EIR) Database
- Time frame 1/1/2013 to 12/31/2013
- **3534** FDA Form 483 observations cited for 21 CFR 820 (Quality System regulation*) deficiencies

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

2013 483 Observations Data

QS Subsystem	# of Observations	Percentage
CAPA	1085	31%
P&PC	1151	33%
MGMT	425	12%
DES	506	14%
DOC	367	10%
	Total: 3534	

Most Frequent QS 483 Observations



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: 1085	**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)

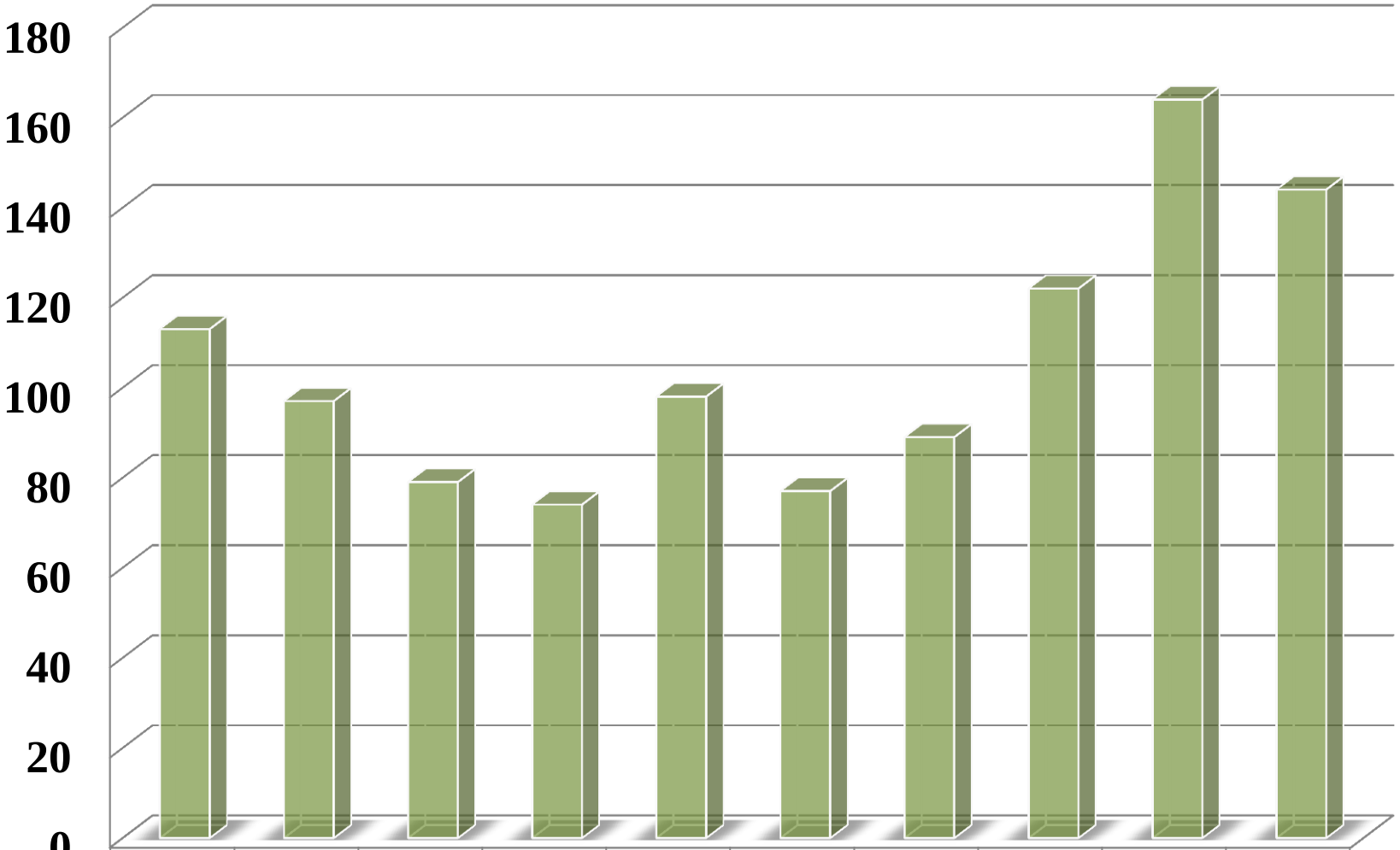
Observation (QS Regulation)	# of Observations	Percentage:
21 CFR 820.70(f)	2	0%
21 CFR 820.70(h)	2	0%
21 CFR 820.200(c)	1	0%
21 CFR 820.200(d)(6)	1	0%
21 CFR 820.70(a)(2)	1	0%
	Total: 1151	**100%**

FDA Warning Letter (WL) Citations

- Source of data - FDA's Warning letters
- Time frame 1/1/2013 to 12/31/2013
- **144** 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

CY2004-2013 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

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	

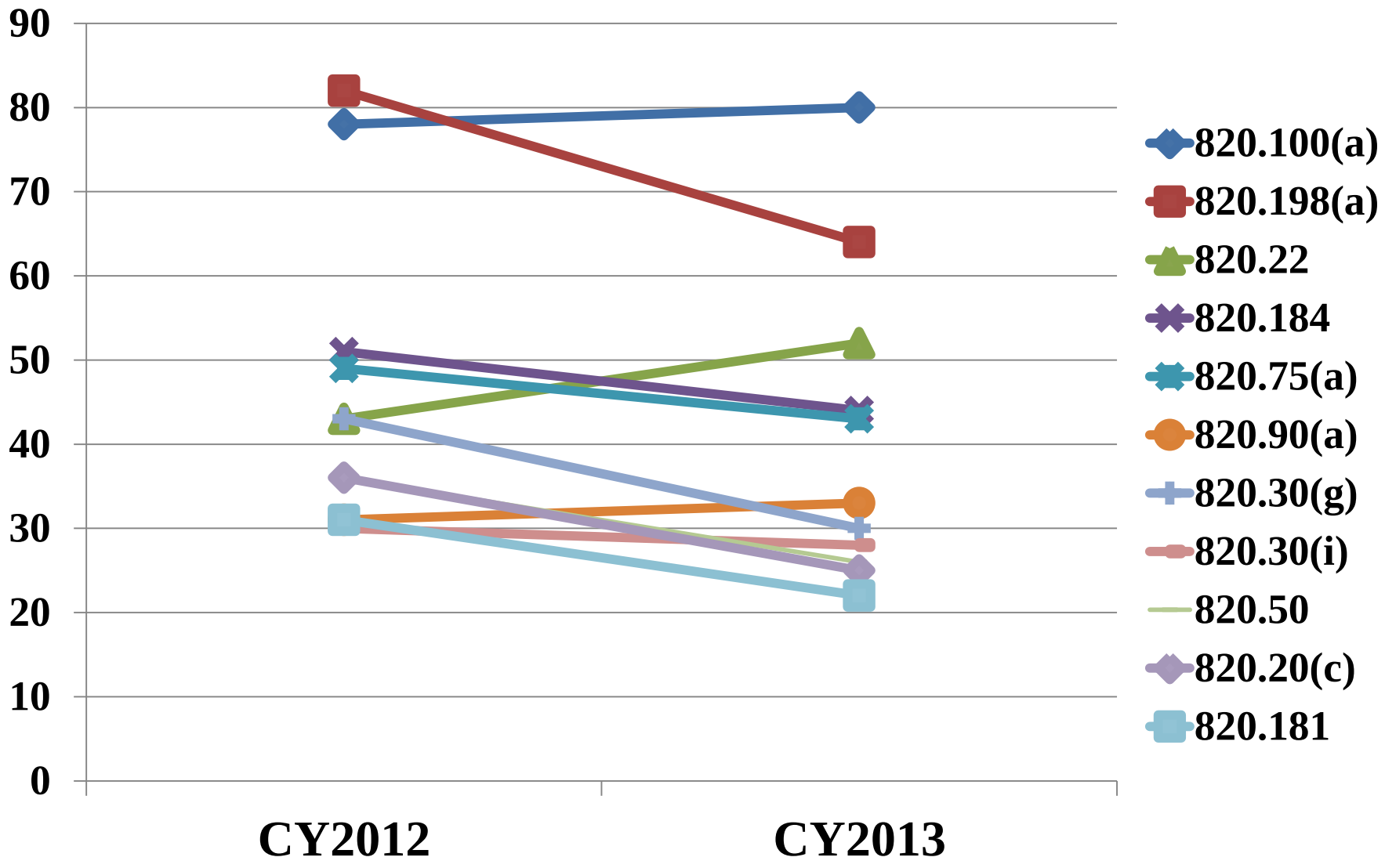
CY2013 Warning Letters

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

Most Frequent CY2013 QS Warning Letter Cites



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

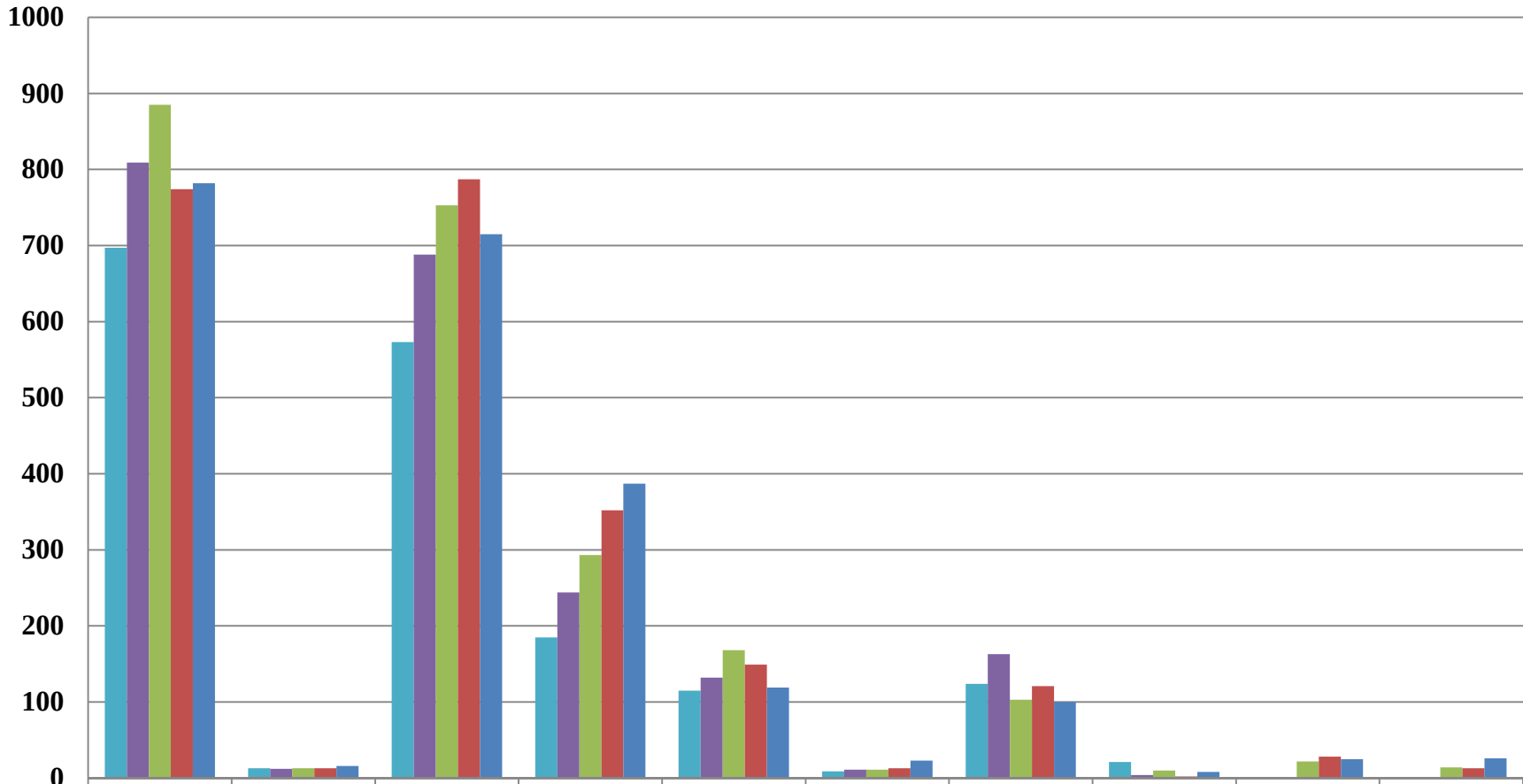
Medical Device Inspections

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

Medical Device Inspections CY2008-2013

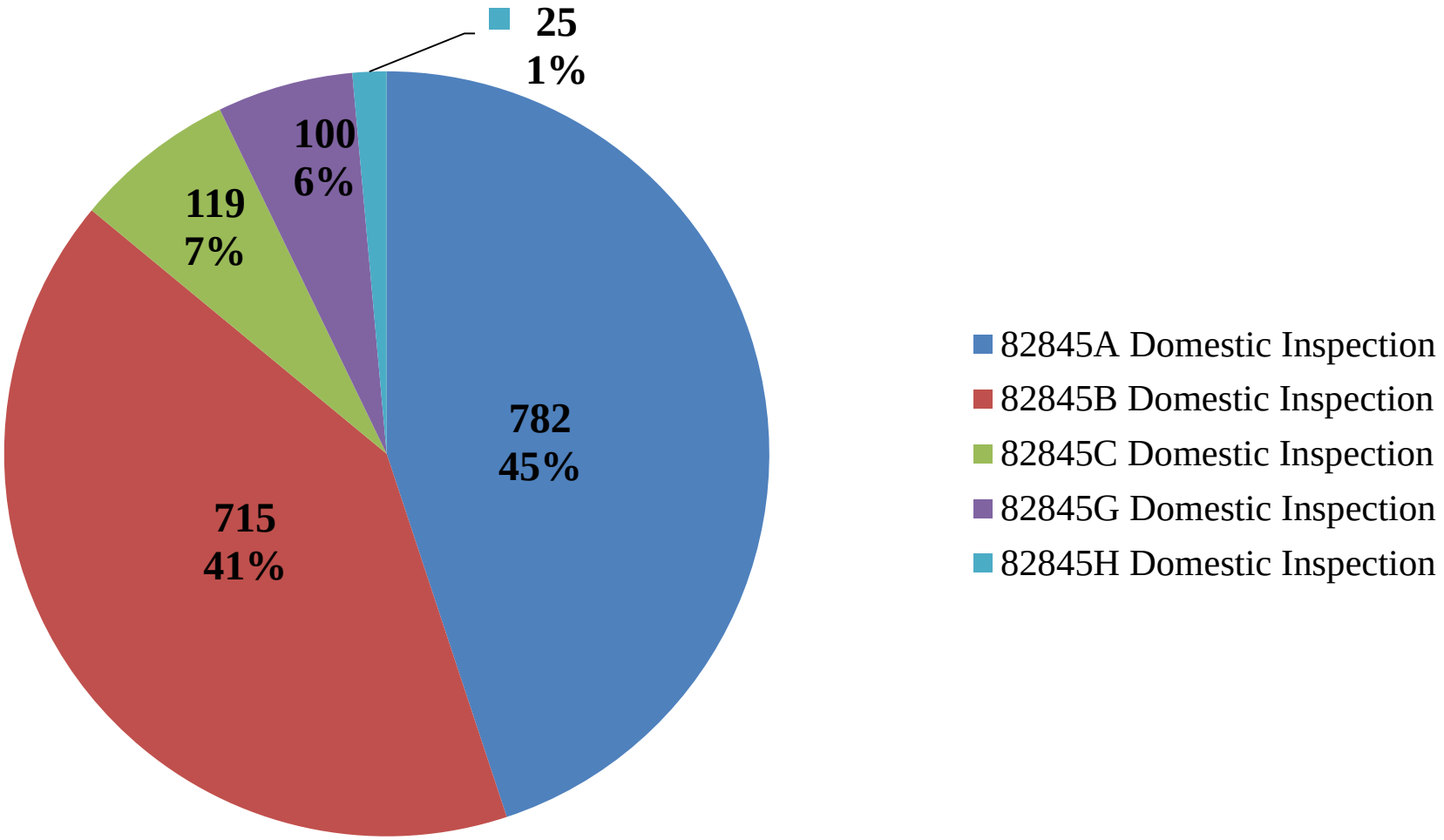
Year	Inspection Description	82845A	82845B	82845C	82845G	82845H	Sum:
2008	Domestic	515	604	100	104		**1323**
2008	Foreign	6	186	8	10		**210**
2009	Domestic	697	573	115	124		**1509**
2009	Foreign	13	185	9	21		**228**
2010	Domestic	809	688	132	163		**1792**
2010	Foreign	12	244	11	4		**271**
2011	Domestic	885	753	168	103	22	**1931**
2011	Foreign	13	293	11	10	14	**341**
2012	Domestic	774	787	149	121	28	**1859**
2012	Foreign	13	352	13	2	13	**393**
2013	Domestic	782	715	119	100	25	**1741**
2013	Foreign	16	387	23	8	26	**460**
	Sum:	**4535**	**5767**	**858**	**770**	**128**	**12058**

Medical Device Inspections CY2008-2013

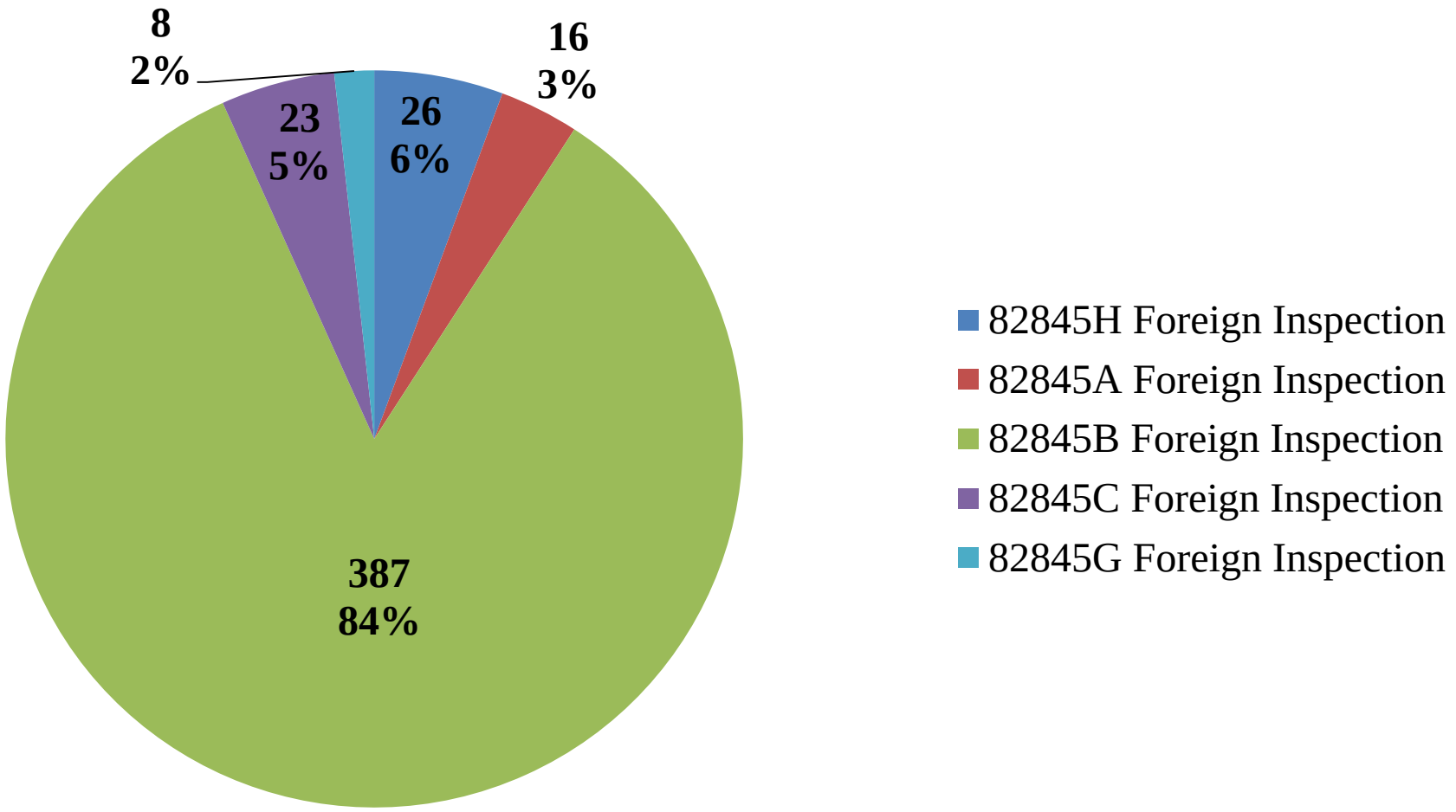


	Domestic Inspection 82845A	Foreign Inspection 82845A	Domestic Inspection 82845B	Foreign Inspection 82845B	Domestic Inspection 82845C	Foreign Inspection 82845C	Domestic Inspection 82845G	Foreign Inspection 82845G	Domestic Inspection 82845H	Foreign Inspection 82845H
2009 Inspections	697	13	573	185	115	9	124	21		
2010 Inspections	809	12	688	244	132	11	163	4		
2011 Insepctions	885	13	753	293	168	11	103	10	22	14
2012 Inspections	774	13	787	352	149	13	121	2	28	13
2013 Inspections	782	16	715	387	119	23	100	8	25	26

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

Contact Information

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