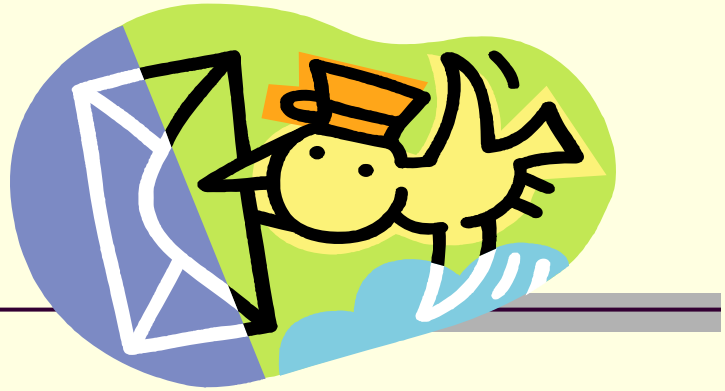
FDA Medical Device 2010 Quality System Data

Analysis of 2010 Warning Letter Cites

QS Regulation Cites 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
820.70	820.140	820.198	820.22		820.181
820.72	820.150		820.25		820.184
820.75	820.160				820.186
820.80	820.170				
820.86	820.200				
	820.250				

2010 Warning Letters



- Jan – Dec 2010

FDA issued 89 Warning Letters to medical device firms for QS/GMP deficiencies

QS subsystem	# WLs w/ cite	%
CAPA	81	91
P&PC	69	78
MGMT	43	48
DESIGN	49	55
DOC	33	37

Warning Letter Cites by QS Subsystem - 2010

CAPA	=	186
P&PC	=	168
MGMT	=	80
DESIGN	=	72
DOC	=	71
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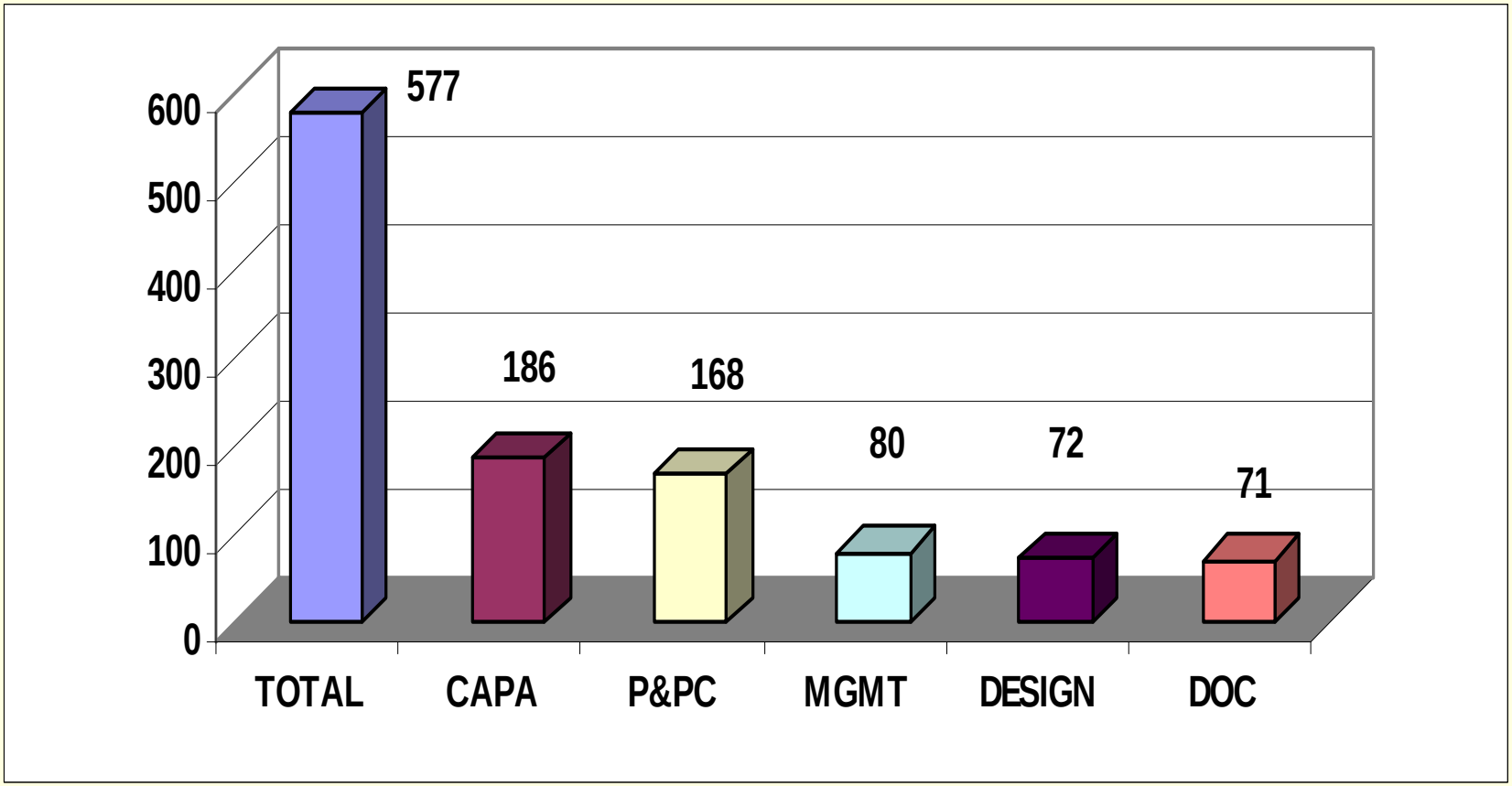
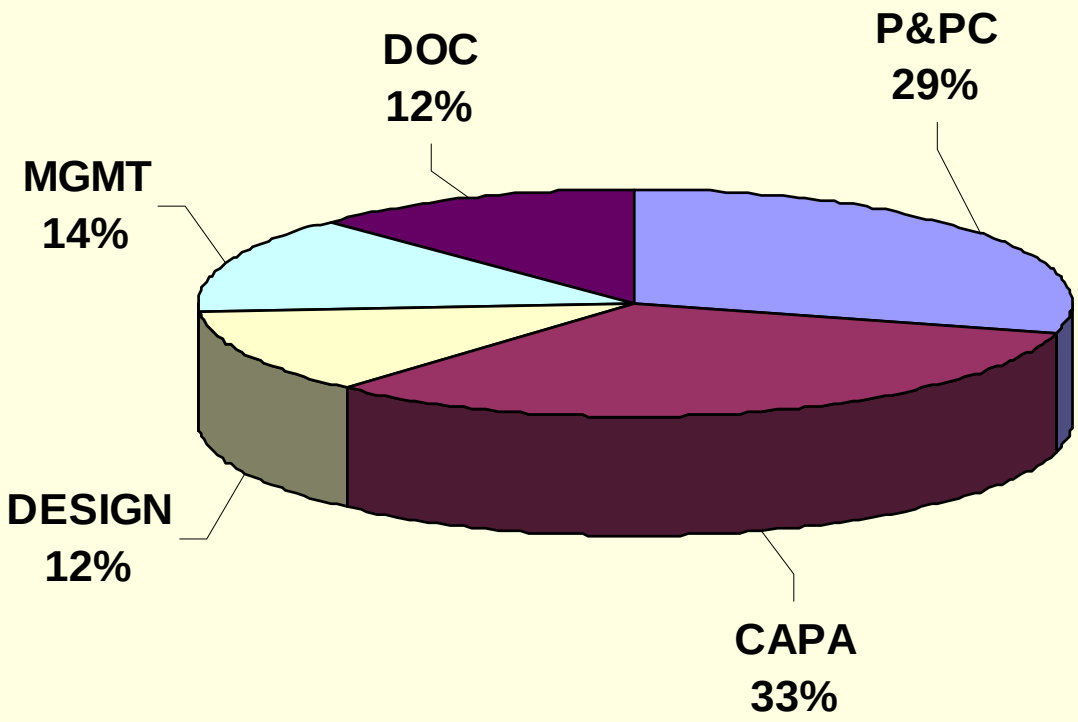
Total	**=**	**577**

Warning Letter Cites by QS Subsystem - 2010



Warning Letter Cites by QS Subsystem - 2010



Most Frequent QS Warning Letter Cites 2010

21 CFR 820.198(a)	42
21 CFR 820.100(a)	30
21 CFR 820.75(a)	28
21 CFR 820.22	26
21 CFR 820.184	21
21 CFR 820.20(c)	19
21 CFR 820.30(i)	18
21 CFR 820.90(a)	18
21 CFR 820.30(g)	17
21 CFR 820.50*	17

***General 820.50 cite only; does not include 820.50(a) and (b)**

CAPA Subsystem
2010 WL Cites

- 21 CFR 820.90 = 25
- 21 CFR 820.198 = 78
- 21 CFR 820.100 = 83

Total = 186

Warning Letters
CAPA Subsystem Data

Year	# WLs	# w/ CAPA cite	%
2010	89	81	91
2009	77	68	88
2008	98	86	88
2007	74	62	84
2006	79	69	87
2005	97	85	88
2004	113	89	79
2003	69	61	88

Design Control Subsystem
WL Cites 2010

21 CFR 820.30(i)	= 18	21 CFR 820.30(e)	= 3
21 CFR 820.30(g)	= 17	21 CFR 820.30(d)	= 3
21 CFR 820.30(a)	= 14	21 CFR 820.30	= 2
21 CFR 820.30(j)	= 6	21 CFR 820.30(b)	= 1
21 CFR 820.30(c)	= 4	21 CFR 820.30(h)	= 0
21 CFR 820.30(f)	= 4		

Total = 72

Warning Letters
Design Control Subsystem Data

Year	# WLs	# w/ DC cite	%
2010	89	49	55
2009	77	36	47
2008	98	54	55
2007	74	42	57
2006	79	47	60
2005	97	49	51
2004	113	57	50
2003	69	39	57

P&PC Subsystem WL Cites 2010

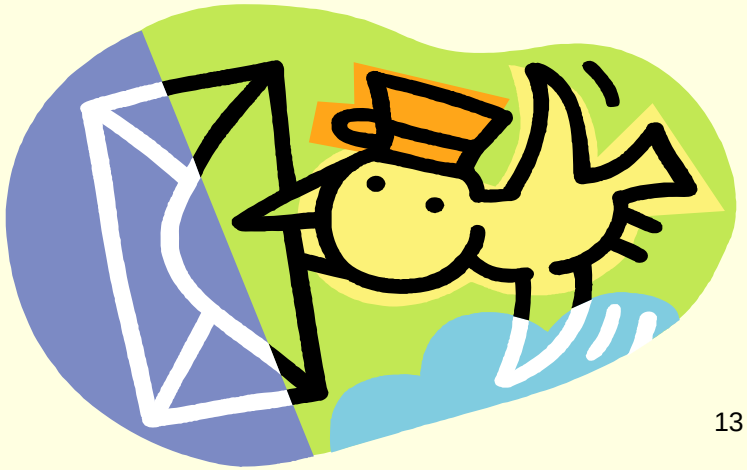
21 CFR 820.70	=	35	21 CFR 820.60	=	2
21 CFR 820.75	=	34	21 CFR 820.200	=	1
21 CFR 820.80	=	34	21 CFR 820.170	=	1
21 CFR 820.50	=	29	21 CFR 820.160	=	1
21 CFR 820.72	=	12	21 CFR 820.140	=	0
21 CFR 820.250	=	11	21 CFR 820.130	=	0
21 CFR 820.150	=	4	21 CFR 820.86	=	0
21 CFR 820.120	=	4			

Total = 168

Numbers include cites from all subparts of the listed regulation

Warning Letters with Process Validation Cites 2010

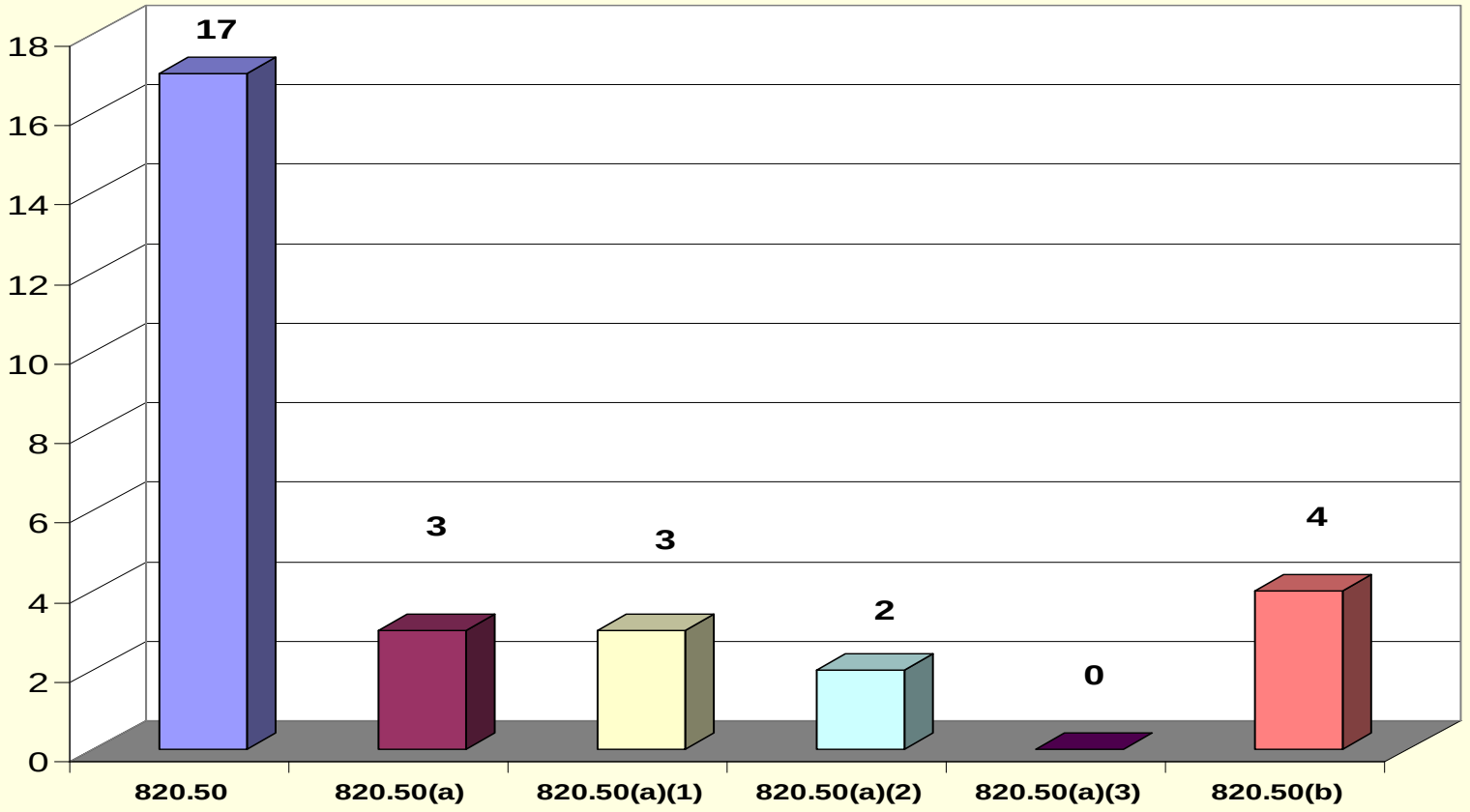
- **89** Warning Letters issued in 2010 to medical device manufacturers for QS/GMP deficiencies
- **36** WLs (40%) contained citations for deviations from 21 CFR 820.75(a)-(c), 70(b), and 70(i)
- **36** WLs had a 21 CFR 820.75(a)-(c) cite
- **7** WLs had a 21 CFR 70(i) cite
- **4** WLs had a 70(b) cite



Warning Letter Data
Process Validation Cites
21 CFR 820.75(a)-(c)

Year	# WLs	# w/ PV cite	%
2010	89	33	37
2009	77	27	35
2008	98	28	29
2007	74	24	32
2006	79	27	34
2005	97	39	40
2004	113	33	29
2003	69	24	35
2002	42	23	55

Warning Letter Cites – 2010 Purchasing Controls



Purchasing Controls
WL Cites

	2009	2010
820.50	12	17
820.50(a)	4	3
820.50(a)(1)	5	3
820.50(a)(2)	0	2
820.50(a)(3)	3	0
820.50(b)	4	4
Total Cites	27	29

Management Control Subsystem
WL Cites 2010

- 21 CFR 820.5 = 1
- 21 CFR 820.25 = 16
- 21 CFR 820.22 = 26
- 21 CFR 820.20 = 37

Total = 80

Document Control Subsystem
WL Cites 2010

- 21 CFR 820.180 = 2
- 21 CFR 820.181 = 20
- 21 CFR 820.40 = 22
- 21 CFR 820.184 = 27

Total = 71