



CDRH Good Guidance Practices

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What are GGP Best Practices?

- Practices that, when followed, will most often:
 - Produce high quality documents
 - Ensure appropriate participation from all external and internal sources
 - Make efficient use of FDA's and stakeholder's resources



Guidance Program Challenges

- Resources
 - Too few
 - Many other priorities
- Conflict
 - Internal/External
 - Legal constraints
 - Policy goals
- Process
 - Complexity
 - Legal constraints



Resources

2005 Study: 1 FTE per guidance

Title	ID	Lead Office	Office Div	Issued	Type	Office Hours	OCD Hours (incl. Z-tech)	RegsStaff Hours	Web Hours	PkIn Hours	Raw Hours	Revised Total Hours (time 1.43)	Office %	Other	Statistics
(16) Low Energy Ultrasound Wound Cleaner: Class II Special Controls	16	ODE	DGRND	11/7/2005	PRE-SCGD-DENOVO	214	1	2	2	17	236	337	64%	8 Z-tech	<div style="border: 1px solid black; padding: 5px;"> hours/FTE Yearly Inflation FY 05 Process Cost (w/Shared Serv) FY 08 Cost Module FTE support factor </div>
(19) CFTR Gene Mutation Detection Systems -- Class II Special Controls	19	OIVD	DMD	#####	PRE-SCGD-DENOVO	97	2	2	2	17	120	171	57%		
Novel Influenza A Viruses- Class II Special Controls	3	OIVD		3/22/2006	PRE-SCGD-DENOVO	324	8	95	2	67	496	709	46%		
Measurement System - Class II Special Controls	5	ODE	DCD	2/15/2006	PRE-SCGD-DENOVO	266	13	2	2	17	300	428	62%		
Simplex Virus Types 1 and 2 Serological Assays	10	OIVD	DMD	1/9/2006	PRE-SCGD	501	22	42	2	17	584	834	60%		
(13) Labeling for Male Condoms Made of Natural Rubber Latex - Class II Special Controls-Draft	13	OC		#####	PRE-SCGD	1993	290	270	2	138	2693	3850	52%		
(15) Tinnitus Masker Devices - Class II Special Controls - Draft	15	ODE	DOED	11/8/2005	PRE-SCGD	264	2	3	2	17	288	411	64%		
(23) AFP-L3% Immunological Test Systems - Class II Special Controls	23	OIVD		10/3/2005	PRE-SCGD	80	15	2	2	17	115	164	49%		
(6) Bone Sonometers - Class II Special Controls - Draft	6	ODE	DCD	2/15/2006	PRE-SCGD	519	14	174	2	17	726	1037	50%		
(8) Class II Special Controls - Hepatitis A Virus Serological Assays	8	OIVD		2/9/2006	PRE-SCGD	241	20	70	2	17	350	500	48%		
(9) Draft - Class II Special Controls - Intervertebral Body Fusion Device	9	ODE		2/9/2006	PRE-SCGD	1883	17	280	2	21	2203	3150	60%		
(22) Draft - Functional Indications for Implantable Cardioverter Defibrillators	22	ODE OC	DCD	10/6/2005	PREMARKET-POSTMARKET	291	35	90	2	133	551	787	37%	8 Z-tech	
(1) Tonometers - Premarket Notification [510(k)] Submissions	1	ODE	DCD	3/27/2006	PREMARKET	202	11	0	2	0	214	306	66%		
(12) Nucleic Acid Based In Vitro Diagnostic Devices for Detection of Microbial Pathogens - Draft	12	OIVD	DMD	12/8/2005	PREMARKET	465	2	70	2	21	560	800	58%		
(14) A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures	14	ODE	DCD	#####	PREMARKET	16	20	3	2	19	60	85	19%		
(2) Dental Curing Lights - Premarket Notification [510(k)] Submissions	2	ODE	DAGID	3/27/2006	PREMARKET	432	16	0	2	0	450	643	67%		
(20) Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions	20	ODE	DAGID	#####	PREMARKET	34	19	0	2	0	55	78	44%		
(7) Draft- Pharmacogenetic Tests and Genetic Tests for Heritable Markers	7	OIVD		2/9/2006	PREMARKET	254	25	70	2	21	372	531	48%		
(11) Exemption from Reporting and Recordkeeping Requirements for Low Power Laser Products (Laser Notice 54)	11	OCER	DMQ	1/6/2006	POST-RADH	335	17	0	2	0	354	506	66%		
(17) Performance Standard for High-Intensity Mercury Vapor Discharge Lamps (21 CFR 1040.30)	17	OCER	DMQ	11/6/2005	POST-RADH	167	27	0	2	0	196	280	60%		
(21) Compliance With Section 301 - Draft	21	OC		#####	POST-MDUFMA	460	18	180	2	50	710	1015	45%		
(4) Hospital Bed System	4	OSB/OCER		3/10/2006	POSTMARKET	5463	43	116	2	58	5682	8125	67%		

Source			Hours		
Average	All	1138	Average SCGD	Excl. Condom & Body Fusion	510
Median	All	531	Median	Excl. Condom & Body Fusion	428
Standard Deviation	All	1777	Standard Deviation	Excl. Condom & Body Fusion	297
Average	Premarket	834	Average Premarket	Excl. Top 2 & Bottom 2	547
Median	Premarket	531	Median	Excl. Top 2 & Bottom 2	516
Standard Deviation	Premarket	991	Standard Deviation	Excl. Top 2 & Bottom 2	264
Average	SCGD	1054	Average	Excl. Top 2 & Bottom 2	604
Median	SCGD	500	Median	Excl. Top 2 & Bottom 2	518
Standard Deviation	SCGD	1248	Standard Deviation	Excl. Top 2 & Bottom 2	334
Average	Excl. Hosp Bed	820	Average	Excl. Hosp Bed	820
Median	Bed	518	Median	Bed	518
Deviation	Bed	937	Deviation	Bed	937



Resources: 2012 and 2013 data

2012 AND 2013 DATA

Estimate using CDRH Time Reporting data	EOY FY 2012 FTE	EOY F Y 2013 FTE
CDRH Time Reporting	42	44
Guidances Issued in FY	31	46
FTE/Guidance	1.3	.97

What We've Done: Process Improvement

- 2010: developed and piloted SOPs
- 2011: updated and finalized SOPs
- 2012: implemented guidance tracking system
- 2103: developed templates
- Increased Center-level staff working on guidance (but program remains thinly staffed relative to volume)



What We've Done: New Approaches

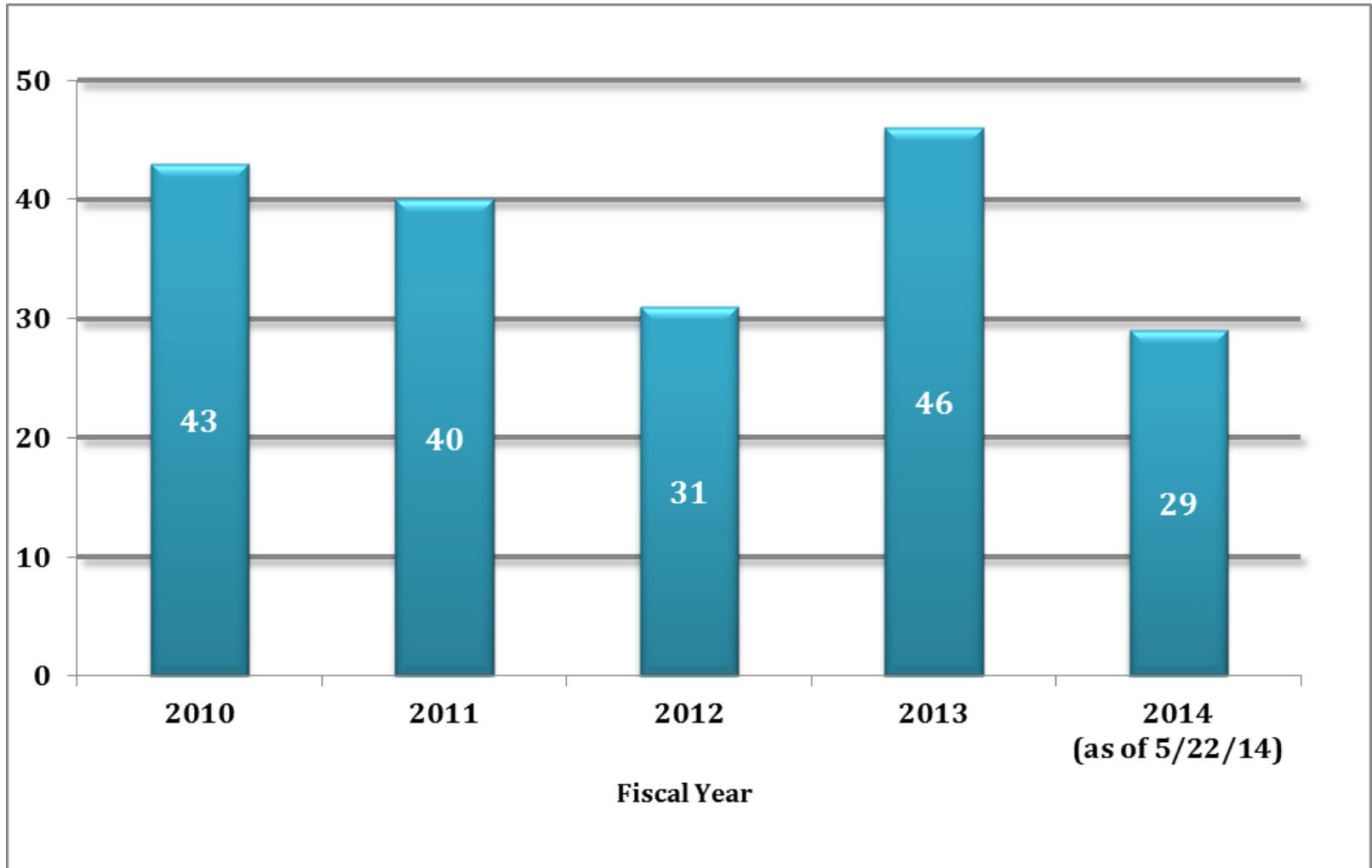
- New Approaches to Guidance:
 - “Leapfrog” guidance documents
 - Level I Immediately in Effect premarket guidance documents
 - Short-form guidance documents

What We've Done: Supplemental Processes

- Opened public docket *before* draft
 - Guidance specific (custom devices)
 - All guidances (annual prioritization)
- Workshops and Panels
 - Device Specific
 - Policy-related
- Pilot programs (before *and* after draft)
- Formal and informal discussions at conferences, meetings, etc.
- Stakeholder calls, webinars



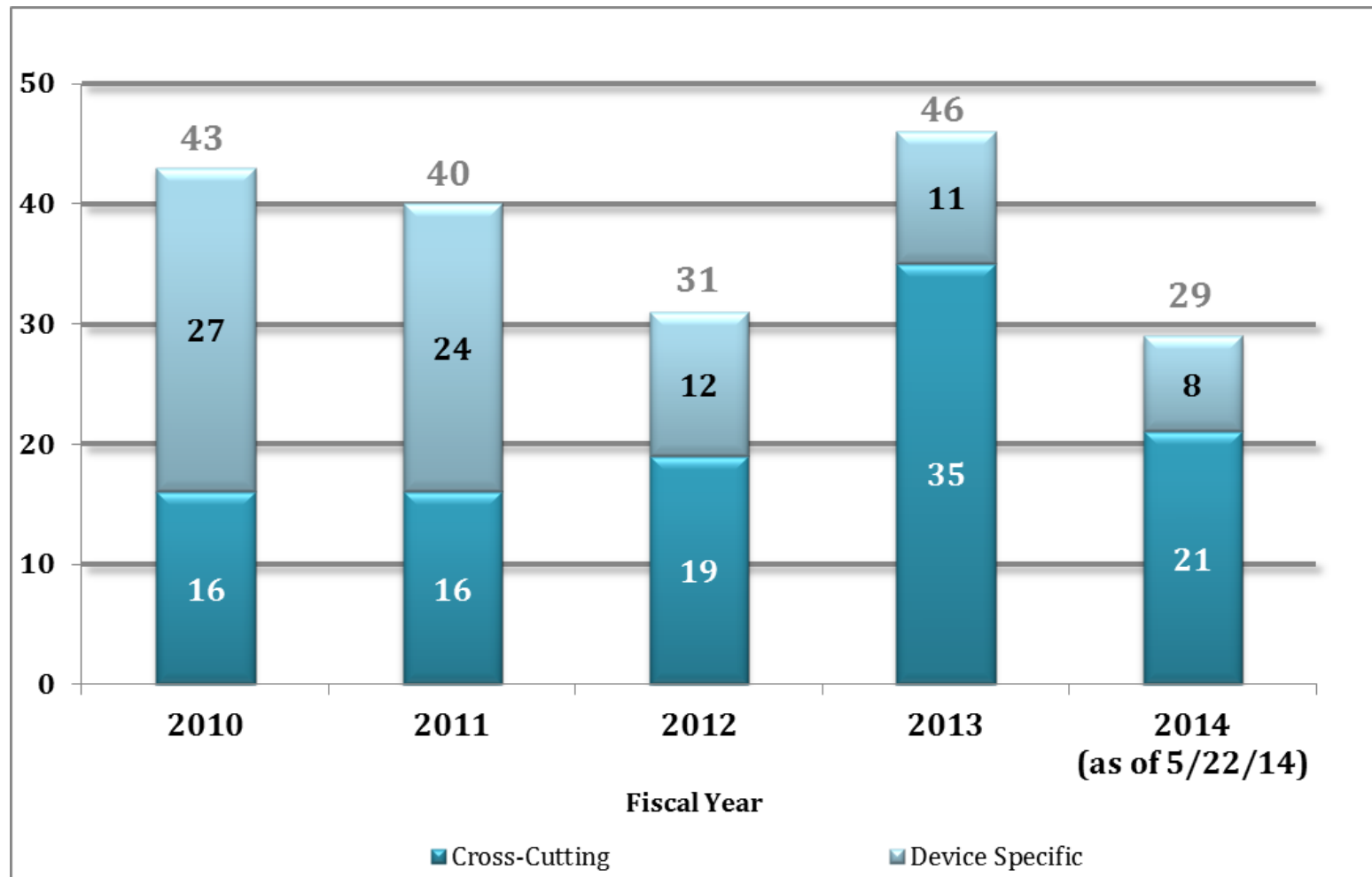
Issued Guidances





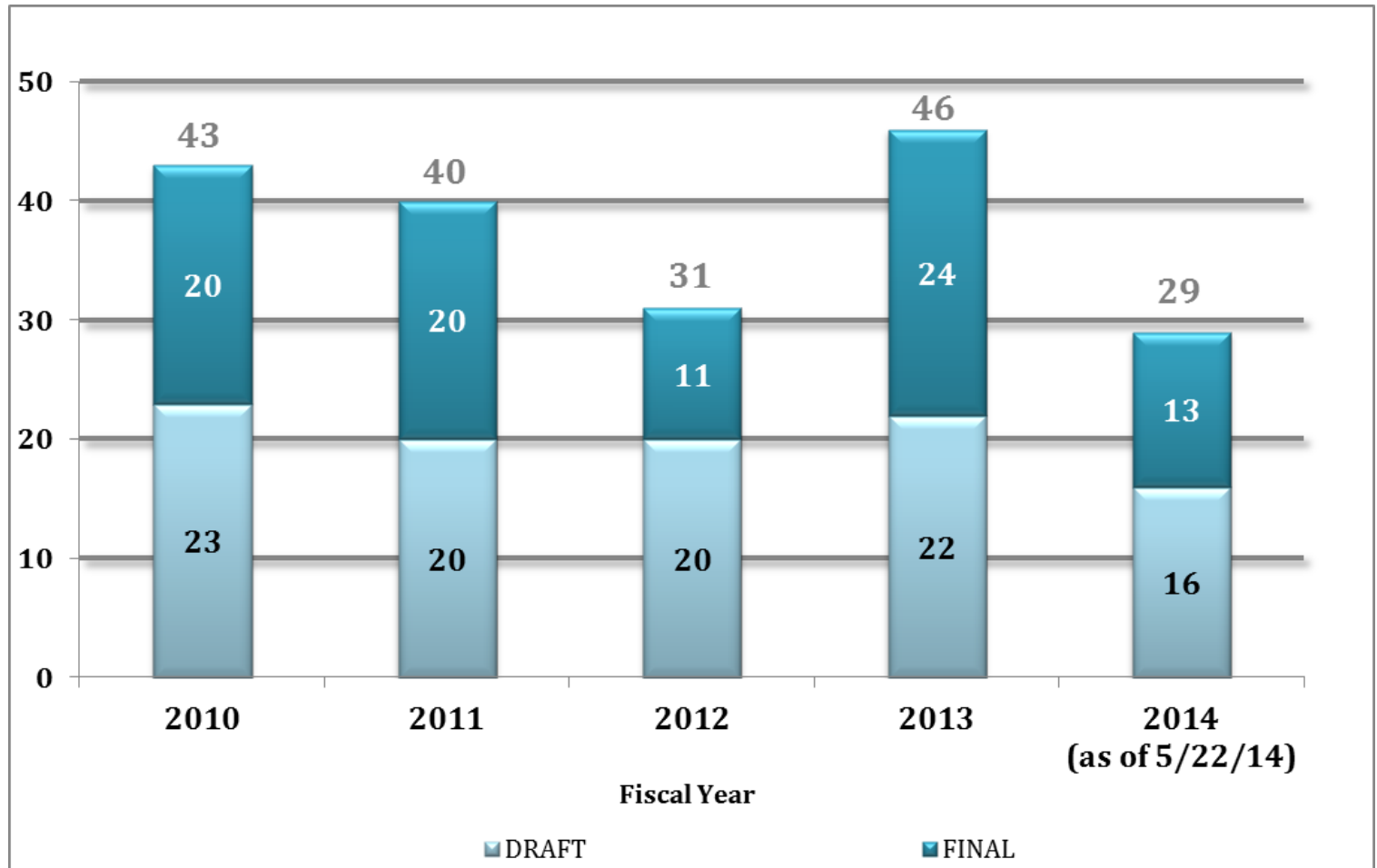
Issued Guidances

(Cross Cutting and Device Specific)





Issued Guidances (Draft and Final)





Days to Issue a Final Guidance (From Draft to Final)

