Agenda for Quarterly Meeting on MDUFMA / MDUFA Performance
May 14, 2012

Welcome. *Barbara Zimmerman, CDRH-ODE*.

Guidance Development

- FDA issued 5 medical device guidance documents during the 2nd quarter. *Barbara Zimmerman, CDRH-ODE*; *Kate Cook, CBER; Don St. Pierre, CDRH-OIVD*

FDA MDUFMA / MDUFA Performance — Actions through March 31, 2012

- Reports on all decision goals for the FY 2008 - FY 2012 cohorts.
    - CBER: *Kate Cook, CBER.*
    - CDRH: *Barbara Zimmerman, CDRH.*

CLIA Waiver Review Times

- Report on qualitative goals and number of pending waiver requests. *Don St. Pierre,* CDRH-OIVD.

CDRH Information Technology (IT) Update

- Report on CDRH IT. *Scott McCall*, CDRH-OCD

CDRH Staff Training Update

- Report on CDRH staff training. *Jacqueline Woodard*, CDRH-OCER

CDRH Registration and Listing

- Report on registration and listing. *Dave Gartner*, CDRH-OC

Qualitative Update on Finances and Use of Resources – 2nd Quarter of FY 2012

- User fee receipts through the 2nd quarter of FY 2012. *David Miller,* FDA-OFM.
- Update on budget requests and appropriations. *Noni Buchanan,* CDRH-OMO.

Discussion

- Set date for next meeting, following close of Q3. Target Date: 8/1/2012 at 10:00 am.

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Medical Device Guidance Documents
Issued through 2nd Quarter FY 2012
Through March 31, 2012

A comprehensive list of guidances can be found at the following:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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Second Quarter (January 2012- March 2012)

1. Guidance for Industry and FDA Staff - Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications, CDRH-ODE, OIVD (3/28/12).
2. Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Full Field Digital Mammography System, CDRH-OSEL/DIAM/OIVD/DRD (3/27/12).
3. Draft Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of Mycobacterium tuberculosis Complex in Respiratory Specimens, CDRH-OIVD (3/19/12).
4. Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: Norovirus Serological Reagents, CDRH-OIVD (3/9/12).
5. Draft Guidance for Industry and Food and Drug Administration Staff - Medical Device Classification Product Codes, CDRH, CBER (1/3/12).

First Quarter (September 2011- December 2011)

6. Draft Guidance for Industry and Food and Drug Administration Staff - CDRH Appeals Processes, OCD (12/27/11).
7. Draft Guidance for Industry and Food and Drug Administration Staff - The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], ODE (12/27/11).
8. Guidance for Industry and Food and Drug Administration Staff - Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices, OIVD (12/20/11).
9. Draft Guidance for Industry and Food and Drug Administration Staff - Evaluation of Sex Differences in Medical Device Clinical Studies, OCD (12/19/11).
10. Draft Guidance for Industry and Food and Drug Administration Staff - The Content of Investigational Device Exemption (IDE) and Premarket Applications for Artificial Pancreas Device Systems, ODE (12/6/11).
11. Guidance for Industry and Food and Drug Administration Staff - Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses, OIVD (11/28/11).
12. Draft Guidance for Industry and Food and Drug Administration Staff - Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies, CDRH (11/10/11).
13. Draft Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: In Vitro Diagnostic Devices for Yersinia spp. Detection, OIVD (11/7/11).
14. Draft Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: External Pacemaker Pulse Generator, ODE (10/17/11).

15. Draft Guidance for Industry and Food and Drug Administration Staff - De Novo Classification Process (Evaluation of Automatic Class III Designation), ODE (10/3/11).

Quarterly Update on
Medical Device Performance Goals
— CBER Performance Data —

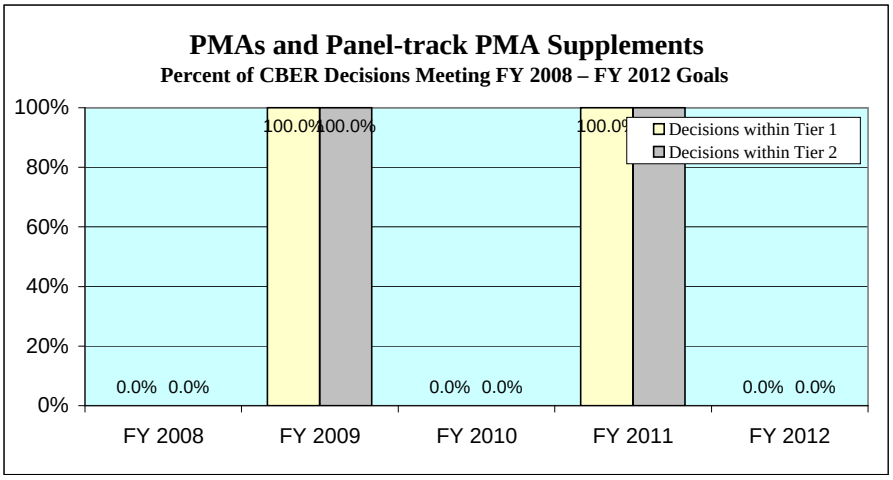
Actions through 31 March 2012

Data on FY 2008 – FY 2012 Cohorts

Actions through 31 March 2012

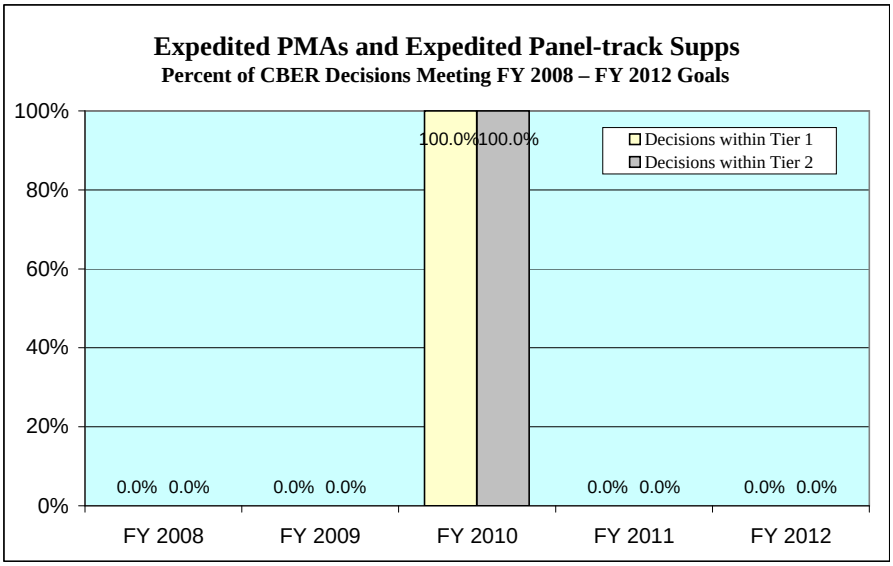
PMAs and Panel-track Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	0	2	0	1	1
Total FDA Decisions	0	2	0	1	0
Percent within Tier 1 goal (180 days)	--	100.0%	--	100.0%	0.0%
Tier 1 goal — *Percent within 180 days*	*60%*	*60%*	*60%*	*60%*	*60%*
Percent within Tier 2 goal (295 days)	--	100.0%	--	100.0%	0.0%
Tier 2 goal — *Percent within 295 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	Open



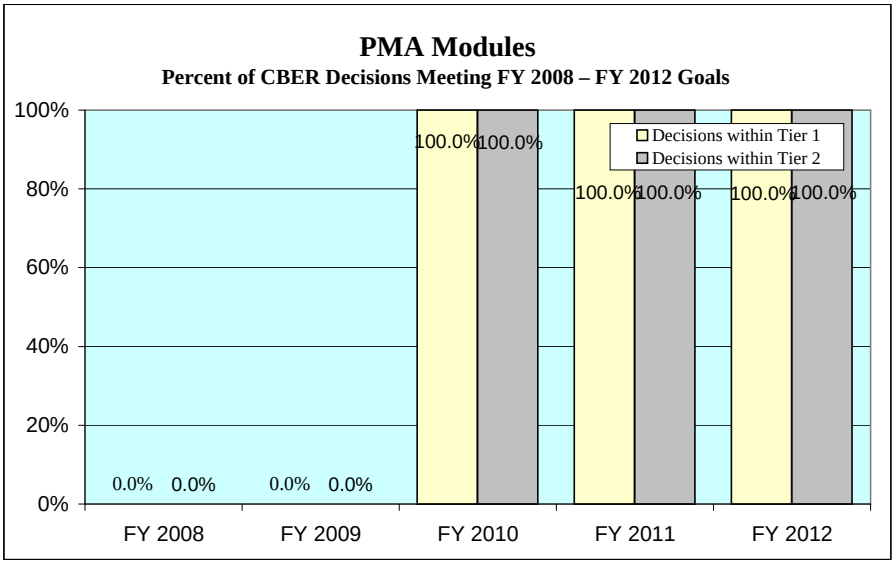
Expedited PMAs and Expedited Panel-track Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	0	0	1	0	0
Total FDA Decisions	0	0	1	0	0
Percent within Tier 1 goal (180 days)	--	--	100.0%	--	--
Tier 1 goal — *Percent within 180 days*	*50%*	*50%*	*50%*	*50%*	*50%*
Percent within Tier 2 goal (280 days)	--	--	100.0%	--	--
Tier 2 goal — *Percent within 280 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	Open



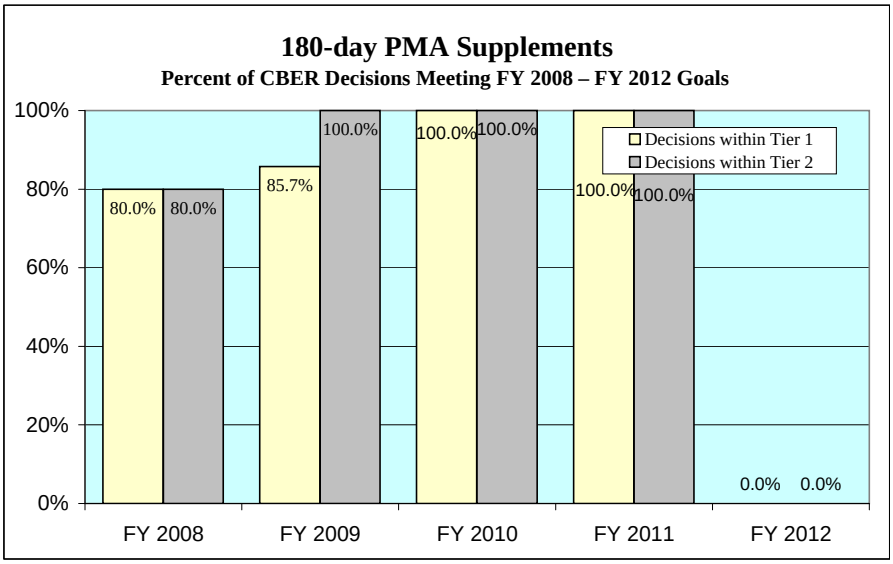
PMA Modules

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	0	0	1	5	3
MDUFMA Cohort	0	0	1	5	3
Total FDA Decisions	0	0	1	5	2
Percent within Tier 1 goal (90 days)	--	--	100.0%	100.0%	100.0%
Tier 1 goal — *Percent within 90 days*	*75%*	*75%*	*75%*	*75%*	*75%*
Percent within Tier 2 goal (120 days)	--	--	100.0%	100.0%	100.0%
Tier 2 goal — *Percent within 120 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	Open



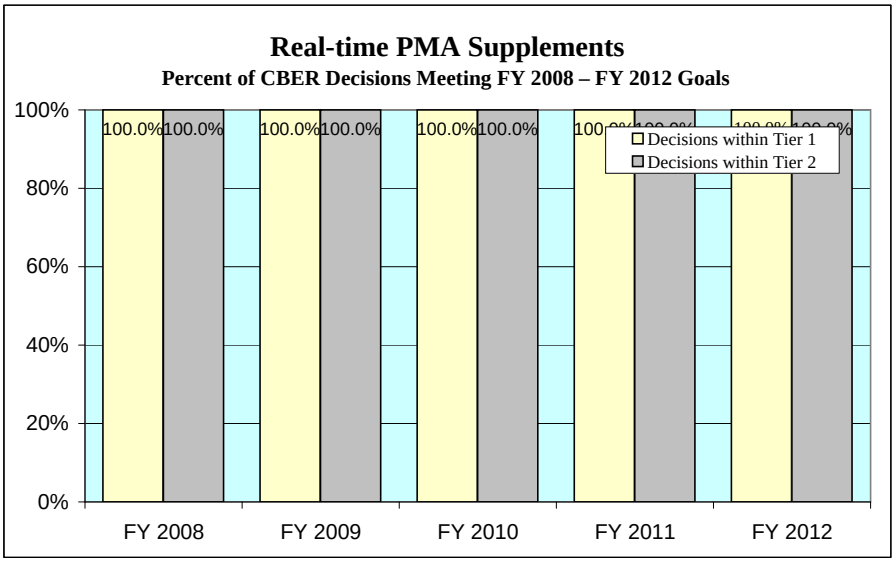
180-day PMA Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	5	7	7	9	6
Total FDA Decisions	5	7	7	9	0
Percent within Tier 1 goal (180 days)	80.0%	85.7%	100.0%	100.0%	--
Tier 1 goal — *Percent within 180 days*	*85%*	*85%*	*85%*	*85%*	*85%*
Percent within Tier 2 goal (210 days)	80.0%	100.0%	100.0%	100.0%	--
Tier 2 goal — *Percent within 210 days*	*95%*	*95%*	*95%*	*95%*	*95%*
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	Open



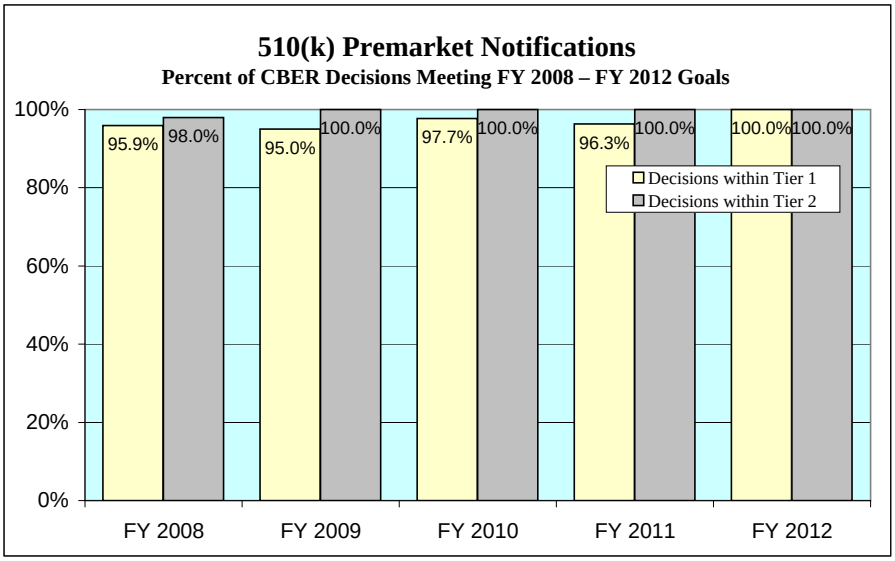
Real-time PMA Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	2	4	2	1	1
Total FDA Decisions	2	4	2	1	1
Percent within Tier 1 goal (60 days)	100.0%	100.0%	100.0%	100.0%	100.0%
Tier 1 goal — *Percent within 60 days*	*80%*	*80%*	*80%*	*80%*	*80%*
Percent within Tier 2 goal (90 days)	100.0%	100.0%	100.0%	100.0%	100.0%
Tier 2 goal — *Percent within 90 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	Open



510(k)s

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Received to Date)	53	50	55	44	23
MDUFMA Cohort	49	40	45	38	22
Total FDA Decisions	49	40	43	27	7
Percent within Tier 1 goal (90 days)	95.9%	95.0%	97.7%	96.3%	100.0%
Tier 1 goal — *Percent within 90 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Percent within Tier 2 goal (150 days)	98.0%	100.0%	100.0%	100.0%	100.0%
Tier 2 goal — *Percent within 150 days*	*98%*	*98%*	*98%*	*98%*	*98%*
Cohort status	*Complete*	*Complete*	Open	Open	Open



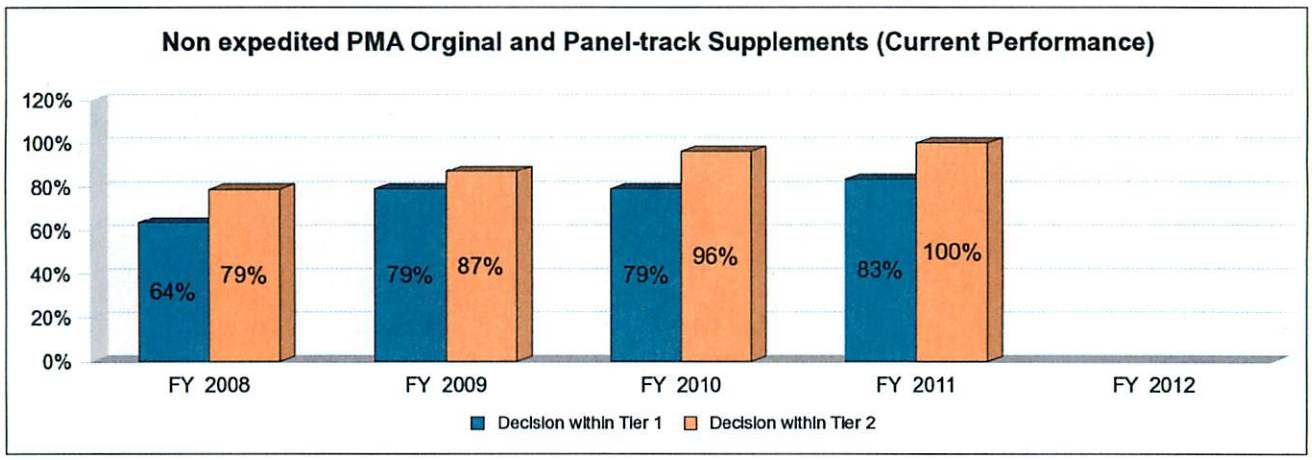
Quarterly Update on
Medical Device Performance Goals
---- CDRH Performance Data ----

Action through 31 March 2012

MDUFA II Quarterly (Non expedited PMA Orginal and Panel-track Supplements)

For Submissions Filed Between Year 2008 to 2012 as of 3/31/2012 11:59:00 PM

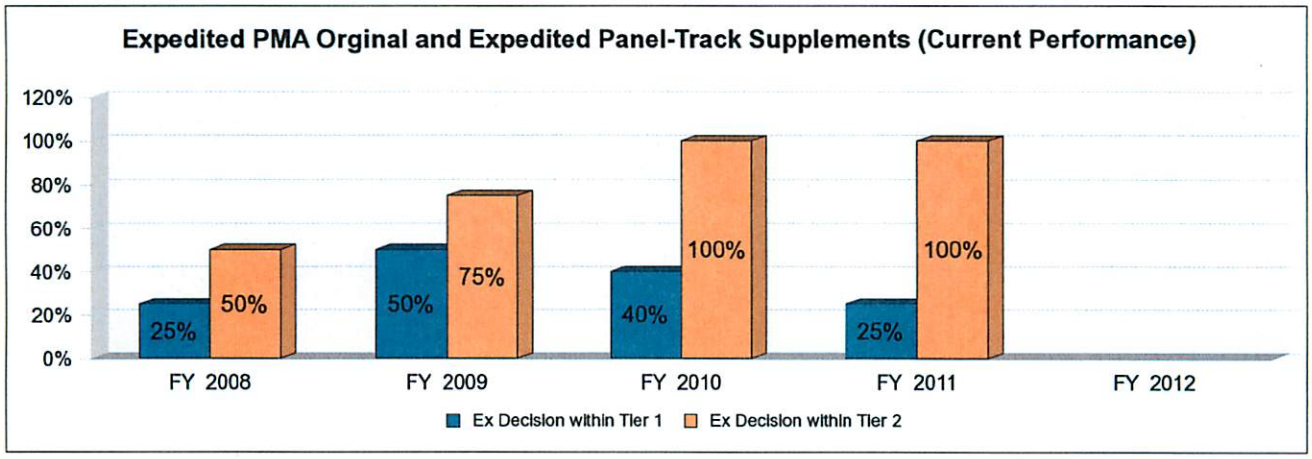
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	33	39	53	44	11
Total FDA Decision	33	38	52	30	0
Tier 1 goal -- Percent within 180 Days	*60%*	*60%*	*60%*	*60%*	*60%*
Goal met(yes/no/unknown)	yes	yes	yes	unknown	unknown
Pending Performance-Best Case	64%	77%	79%	82%	100%
Pending Performance-Worst Case	64%	77%	77%	57%	0%
Tier 2 goal -- Percent within 295 days	*90%*	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	no	no	yes	unknown	unknown
Pending Performance-Best Case	79%	85%	96%	98%	100%
Pending Performance-Worst Case	79%	85%	94%	68%	0%
Cohort status	Complete	Open	Open	Open	Open



MDUFA II Quarterly (Expedited PMA Orginal and Expedited Panel-Track Supplements)

For Submissions Filed Between Year 2008 to 2012 as of 3/31/2012 11:59:00 PM

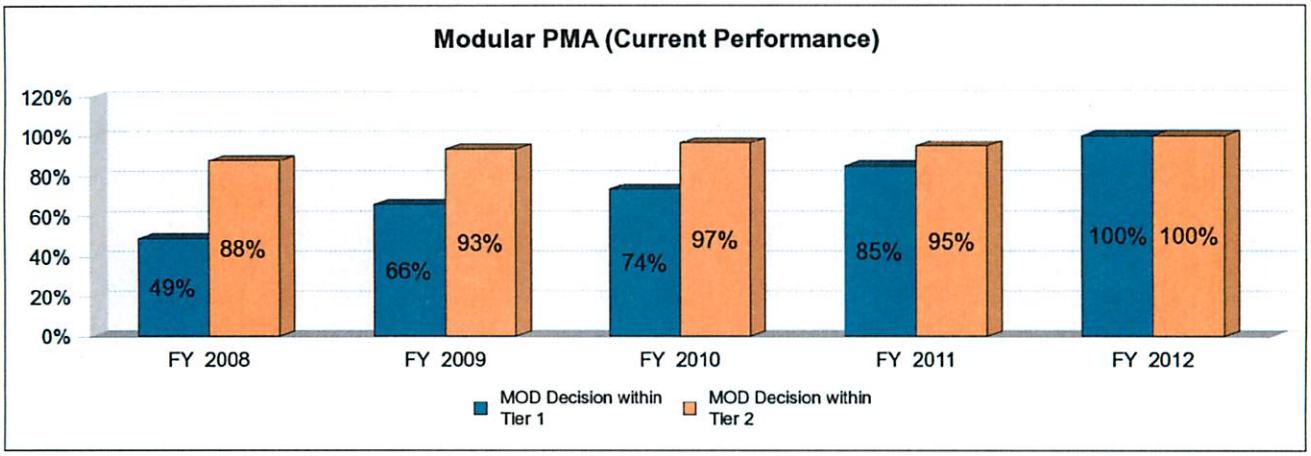
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	4	4	6	7	3
Total FDA Decision	4	4	5	4	0
Tier 1 goal -- Percent within 180 Days	*50%*	*50%*	*50%*	*50%*	*50%*
Goal met(yes/no/unknown)	no	yes	no	no	unknown
Pending Performance-Best Case	25%	50%	33%	43%	100%
Pending Performance-Worst Case	25%	50%	33%	14%	0%
Tier 2 goal -- Percent within 280 days	*90%*	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	no	no	no	unknown	unknown
Pending Performance-Best Case	50%	75%	83%	100%	100%
Pending Performance-Worst Case	50%	75%	83%	57%	0%
Cohort status	Complete	Complete	Open	Open	Open



MDUFA II Quarterly (Modular PMA)

For Submissions Filed Between Year 2008 to 2012 as of 3/31/2012 11:59:00 PM

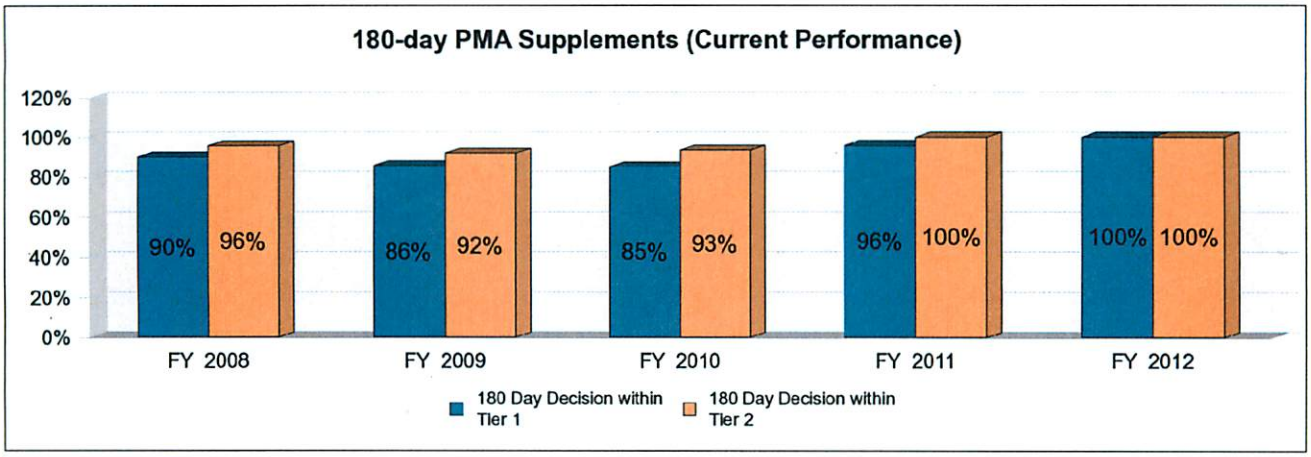
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Cycle Started)	57	90	104	85	24
Total FDA Decision	49	76	87	79	9
Tier 1 goal -- Percent within 90 Days	*75%*	*75%*	*75%*	*75%*	*75%*
Goal met(yes/no/unknown)	no	no	no	yes	unknown
Pending Performance-Best Case	49%	66%	74%	85%	100%
Pending Performance-Worst Case	49%	64%	74%	85%	41%
Tier 2 goal -- Percent within 120 days	*90%*	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	no	yes	yes	yes	unknown
Pending Performance-Best Case	88%	93%	97%	95%	100%
Pending Performance-Worst Case	88%	91%	97%	95%	41%
Cohort status	Complete	Open	Complete	Complete	Open



MDUFA II Quarterly (180-day PMA Supplements)

For Submissions Filed Between Year 2008 to 2012 as of 3/31/2012 11:59:00 PM

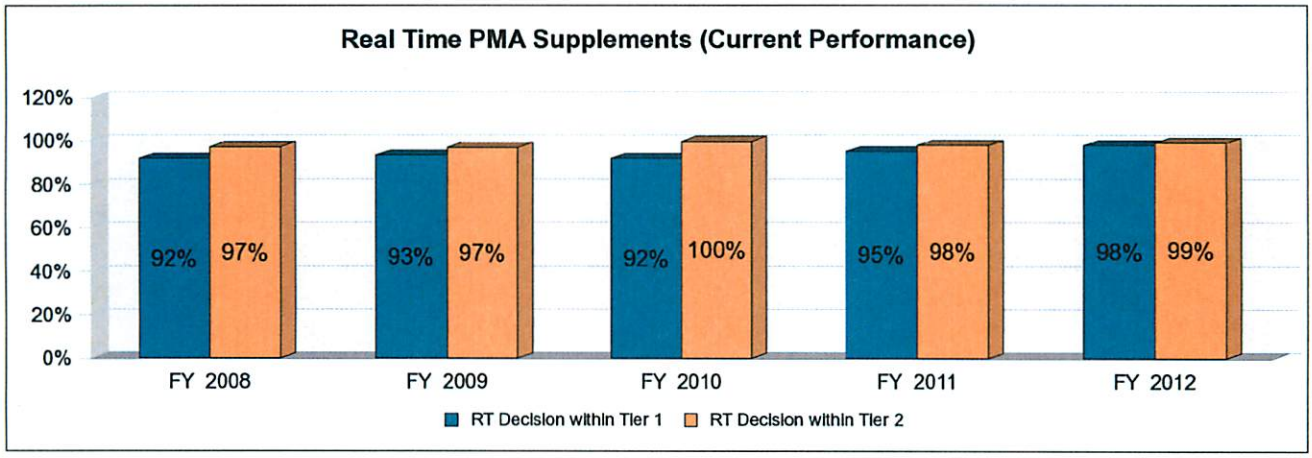
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	170	166	157	145	97
Total FDA Decision	160	159	134	115	9
Tier 1 goal -- Percent within 180 Days	*85%*	*85%*	*85%*	*85%*	*85%*
Goal met(yes/no/unknown)	yes	yes	no	unknown	unknown
Pending Performance-Best Case	89%	86%	84%	96%	100%
Pending Performance-Worst Case	89%	86%	83%	80%	9%
Tier 2 goal -- Percent within 210 days	*95%*	*95%*	*95%*	*95%*	*95%*
Goal met(yes/no/unknown)	yes	no	no	unknown	unknown
Pending Performance-Best Case	95%	92%	92%	99%	100%
Pending Performance-Worst Case	95%	92%	91%	84%	9%
Cohort status	Open	Complete	Open	Open	Open



MDUFA II Quarterly (Real Time PMA Supplements)

For Submissions Filed Between Year 2008 to 2012 as of 3/31/2012 11:59:00 PM

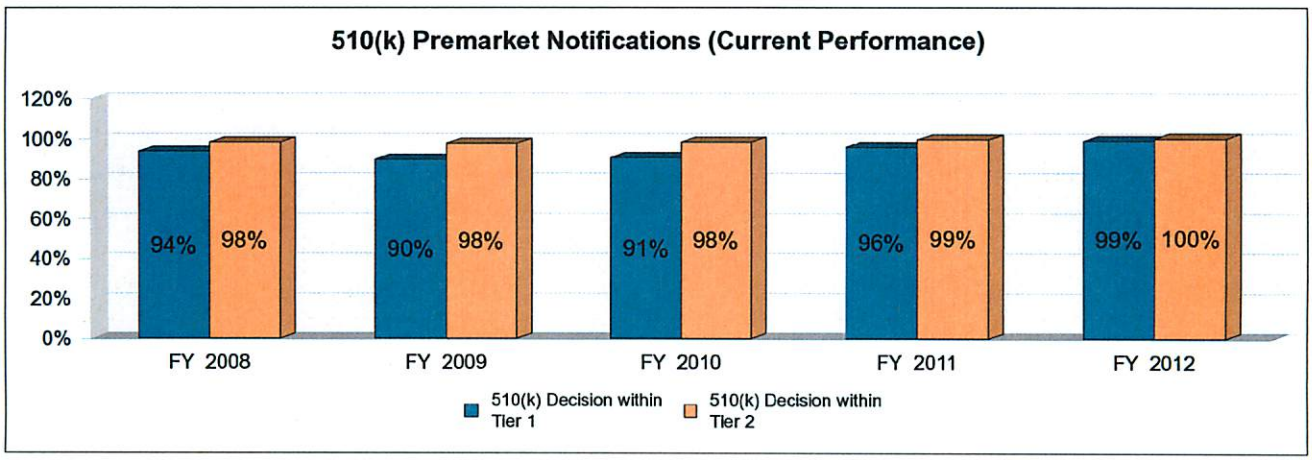
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	249	296	269	245	133
Total FDA Decision	241	280	257	235	88
Tier 1 goal -- Percent within 60 Days	*80%*	*80%*	*80%*	*80%*	*80%*
Goal met(yes/no/unknown)	yes	yes	yes	yes	unknown
Pending Performance-Best Case	92%	93%	92%	95%	97%
Pending Performance-Worst Case	92%	93%	92%	95%	67%
Tier 2 goal -- Percent within 90 days	*90%*	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	yes	yes	yes	yes	unknown
Pending Performance-Best Case	97%	97%	100%	98%	98%
Pending Performance-Worst Case	97%	97%	100%	98%	67%
Cohort status	Complete	Complete	Complete	Complete	Open



MDUFA II Quarterly (510(k) Premarket Notifications)

For Submissions Received Between Year 2008 to 2012 as of 3/31/2012 11:59:00 PM

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Received to Date)	3,848	4,103	3,880	3,833	1,932
MDUFA Cohort	3,259	3,403	3,147	3,348	1,902
Total FDA Decision	3,258	3,398	3,135	2,881	594
Tier 1 goal -- Percent within 90 Days	*90%*	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	yes	yes	yes	unknown	unknown
Pending Performance-Best Case	94%	90%	91%	96%	100%
Pending Performance-Worst Case	94%	90%	90%	82%	31%
Tier 2 goal -- Percent within 150 Days	*98%*	*98%*	*98%*	*98%*	*98%*
Goal met(yes/no/unknown)	yes	yes	yes	unknown	unknown
Pending Performance-Best Case	98%	98%	98%	100%	100%
Pending Performance-Worst Case	98%	98%	98%	86%	31%
Cohort status	Open	Open	Open	Open	Open



CLIA WAIVER BY APPLICATION WORKLOAD April 2012

FISCAL YR RECIEVED	RECOMMENDATION	TOTAL FDA DAYS	TOTAL MFR DAYS	TOTAL DAYS
2008	Approved	61		61
		248	38	286
		248	38	286
		398		398
		398		398
	Denied	102		102
		129		129
		189		189
		199		199
		287		287
		320	424	744
	Telephone Hold	136	1408	1544
2008 Total	12			
2009	Approved	204	64	268
		233		233
	Denied	285		285
		644	7	651
		740		740
	Telephone Hold	33	1133	1166
		259	818	1077
		518	356	874
2009 Total	8			
2010	Approved	77		77
		162	212	374
	Denied	172		172
		248		248
		266		266
	Under Review	732		732
2010 Total	6			
2011	Approved	27		27
		165	87	252
	Request For Additional Information	95	109	204
		95	109	204
	Under Review	216	98	314
2011 Total	5			
2012	Approved	24		24
	Denied	57		57
		147		147
	Under Review	69		69
2012 Total	4			
Grand Total	35			

U.S. Department of Health & Human Services

U.S. Food and Drug Administration

MDUFA Quarterly Performance: Information Technology (IT) Update

Scott McCall

IT Program Manager

Office of the Center Director (CDRH)

April 18, 2012

CDRH's IT Investments

- **CeSub** – Center Electronic Submission (CeSub) Business Process Automation
  - Electronic Document Repository
  - Electronic Submissions
  - Adverse Event Reporting
- **CSTAR** – Center Submission Tracking and Reporting
  - Premarket Review
  - Reporting Data Warehouse

Recent Accomplishments (1 of 2)

- **MDUFA III** – Planning, analysis, and design for IT system changes in support of the MDUFA reauthorization
- **CeSub** – Center Electronic Submission (CeSub) Business Process Automation
  - Established the IT infrastructure to support the ISO 13485 Voluntary Audit Report Submission Pilot Program Guidance
  - Modernized desktop-based CD loading programs to web-based applications to improve functionality and reliability
  - Enabled the mandatory logging onto CeSub applications using the Personal Identity Verification (PIV) card in accordance with Homeland Security Presidential Directive 12 (HSPD-12)

Recent Accomplishments (2 of 2)

- **CSTAR** – Center Submission Tracking and Reporting
  - 510(k) Interactive Review
    - Added a reminder flag for reviewers to confirm if the review as interactive
    - Enabled the bulk upload of interactive review log entries via spreadsheet
  - CLIA
    - Created new CLIA reports within the reporting data warehouse
    - Provided a new mechanism to enter multiple CLIA categorization records simultaneously
  - Reengineered how the Center Tracking System (CTS) loads data to reduce the initial logon time from 30 seconds to 5 seconds
  - Enhanced the ability to choose which types of email notifications that reviewers receive from CTS
  - Enabled the mandatory logging onto CSTAR applications using the PIV card

Staff College Internal Training Summary Report

From 07/01/2011 to 3/31/2012

As of: **04/18/2012**

4th Qtr FY11 -2nd Qtr FY 12 MDUFA-Related Training
(July 1, 2011 – March 31, 2012)

FDA continues to invest in internal and external training opportunities supporting the pre-market review process. CDRH's Staff College is a workforce development organization that designs and delivers internal training opportunities to meet the professional needs of FDA staff. As the pre-market review process grows increasingly complex, training must keep pace with these advancements. Staff College is committed to leveraging internal and external resources to enhance the training provided to Center staff.

Table X provides a summary of internal training conducted between July 1, 2011 and March 31, 2012. Two hundred and fifty eight Staff College training courses (including online courses) and seminars were offered addressing reviewer training, scientific technologies, law, regulation and guidance updates in addition to leadership and professional development. This training was designed to improve the review process and support MDUFA goals and activities. The charts provided in this training summary illustrate that 848 of the approximately 1400 CDRH staff attended an average of 4 internal Staff College learning events representing 13,473 contact hours.

CDRH staff also had opportunities to attend other learning events. Examples of these opportunities include:

- Office Specific Training
  - Office of Device Evaluation Site Visits
  - Office of Compliance Internal Training
  - Office of Surveillance and Biometrics Internal Training

Table X: MDUFA 4th Qtr FY11 -2nd Qtr FY 12 CDRH Staff College Internal Training

Topical Area	# of Learning Events	Total # of Participants	Examples of Training Conducted/Attended Between 7/1/11 – 3/31/12
Regulatory and Law (LAW)	159	1148	• Basic Food and Drug Law Course • Four-Part Harmony: Deficiency Writing in Plain English • How to Write Effective Premarket Consulting Reviews • Medial Device Law Course • CDRH Guidance Development: How to use the new SOP • TPLC Data Integration and Linking to Additional Information • Clinical Trial Design - Scales in Medical Device Regulation • Online Reviewer training courses (ex. Essentials of a Review) • Reviewer Certification Program (RCP) – Cohort 1 (Sept '11) and Cohort 2 (Jan '12) • Freedom of Information Training
Science (SCI)	57	1848	• Statistics for Diagnostic Devices • Clinical Reviewers Education Program (CREP): Diabetes Update • Regenerative Medicine Series - • Bone Seminar Series 2011 • Human Factors for Medical Devices • Benefit: Risk Issues in Design, Monitoring, Analysis & Reporting • Introduction to Biostatistics • Introduction to Public Health • Risk Communication
Leadership Education and Development (LED)	15	248	• Effective Supervision for Scientist/Technical Staff • Leading in a Telework Environment • Leadership Readiness Program (LRP) Critical Thinking & Creative Problem Solving • LRP: Sharpen Your Coaching Skills • LRP - Trust Based Leadership • Effective Communication as a Leader
Professional Development (PRO)	27	374	• Building High Performing Teams • Effective Communication Skills for Technical and Scientific Professionals • Decision-making and Critical Thinking Techniques for Results • Briefing and Presentation • Conflict Resolution • Championing Diversity • The Effective Facilitator • Nonverbal Communication • Precision Thinking and Problem Solving
New Employee Orientation	2	82	• New Employee Orientation – Discover the Mission, Embrace the Vision.

*Please note that the NEE category data has been incorporated under the Professional Development category within the subsequent data charts.

Leadership Readiness Program (LRP) Graduates ROI Update 2012
(Includes iterations for Program Years 2006-2007, 2008-2009, 2010-2011 and 2012/13)

LRP Program Year	Number LRP Participants Enrolled/	Number LRP Participants Completed
2006-2007	OIVD=3 ODE =13 Total = 16*	OIVD = 3 ODE = 12 Total = 15
2008-2009	OIVD=3 ODE = 10 Total = 30**	OIVD = 3 ODE = 10 Total = 29**
2010-2011	OIVD = 3 ODE = 9 Total = 20**	OIVD = 3 ODE = 8 Total = 19**
Sub total	**OIVD=9** **ODE =33** **Total = 66****	**OIVD = 9** **ODE = 30** **Total = 63****

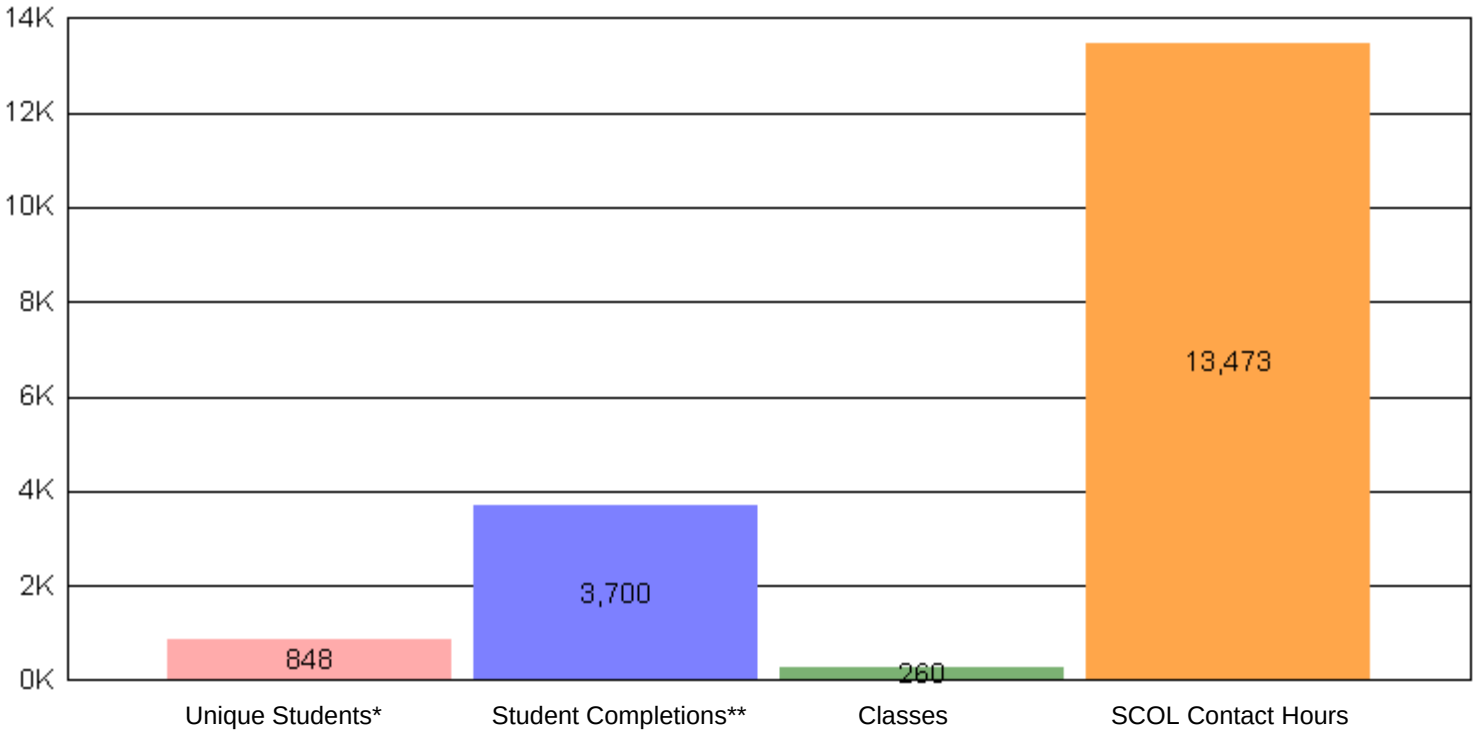
* This total represents LRP participants from ODE and OIVD. The 2006-2007 LRP consisted of participants from ODE and OIVD only.

** This total represents LRP participants from all CDRH Offices

Note: The 2012-2013 LRP Program will begin June 2012.

Completion Summary Data for CDRH Staff College Internal Classes

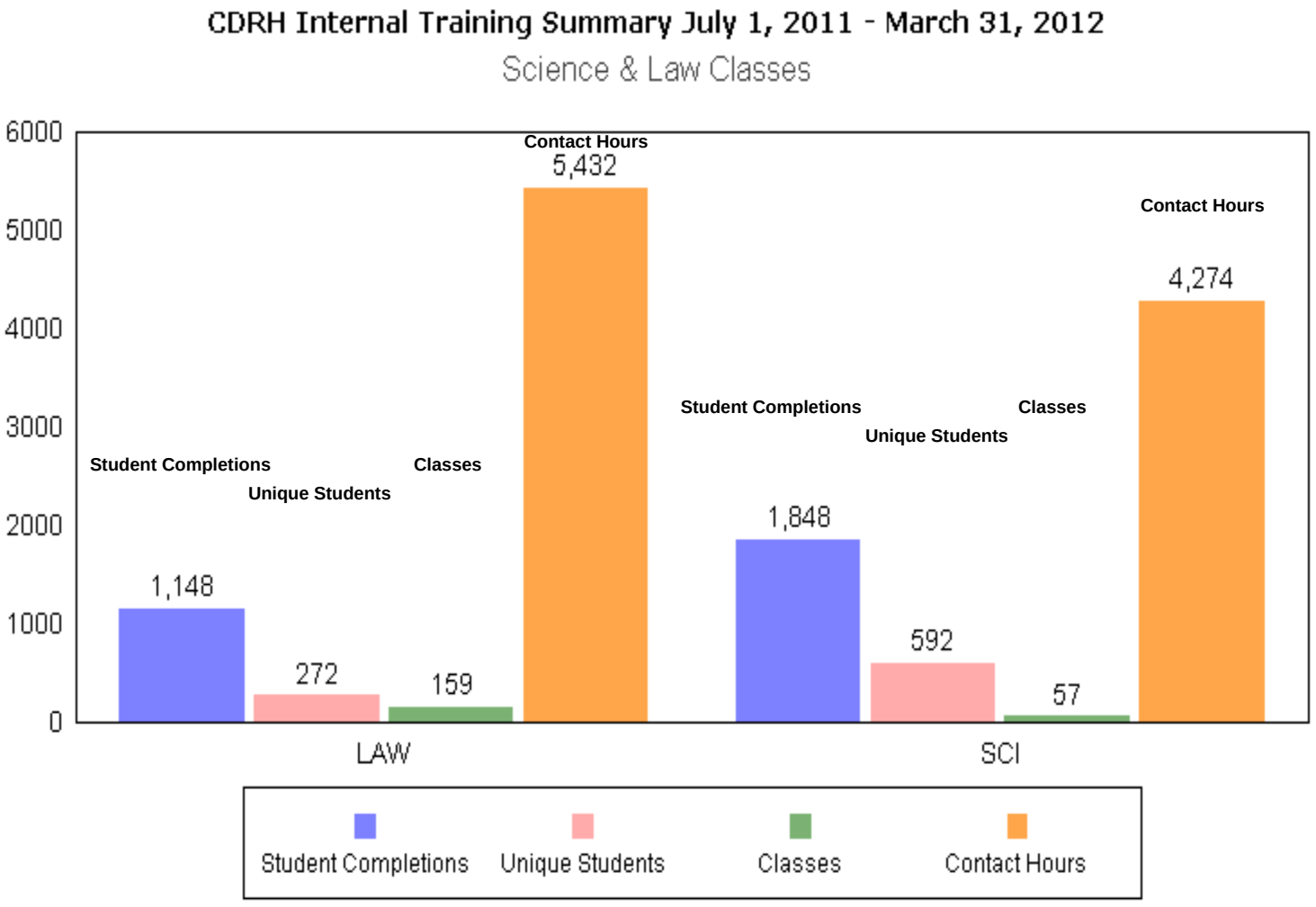
July 1, 2011 - March 31, 2012



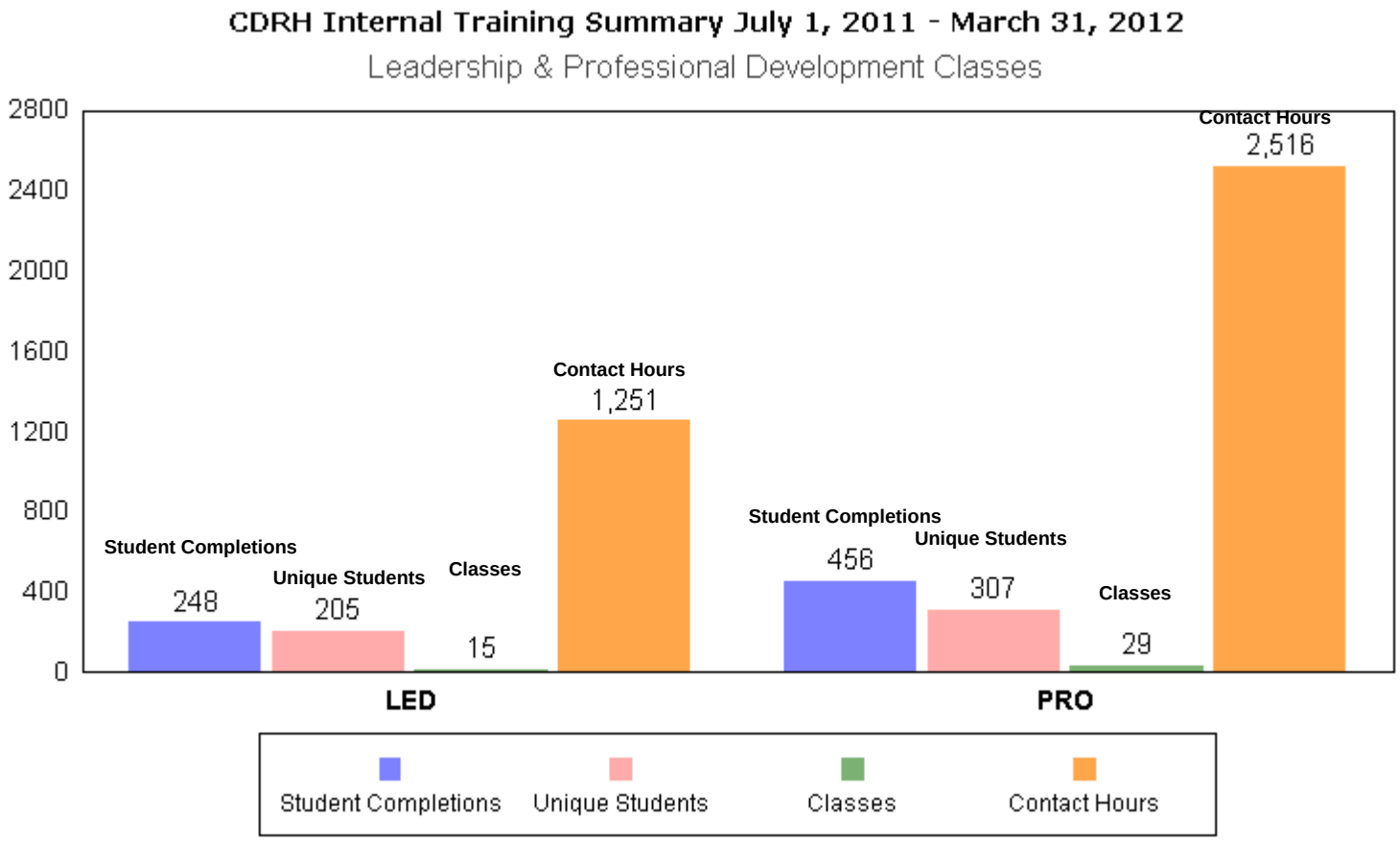
*Unique Students: This data represents the number of students who participated in at least one training class. During July 1, 2011 - March 31, 2012, 848 of the approximately 1400 Center staff (61%) participated in training.

**Student Completions: This data represents the total number of successful class completions.

Data Prepared: 4/18/2012



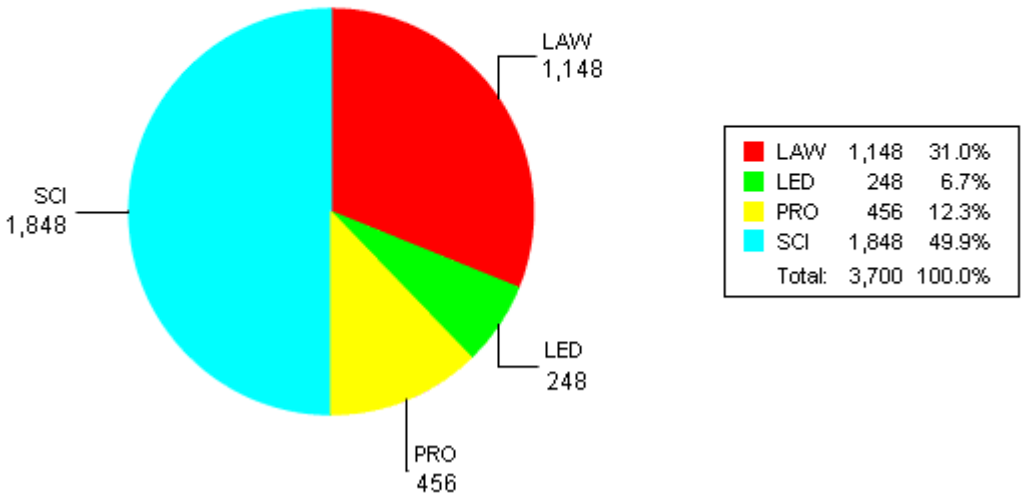
Unique LAW Students: 272 = 19% of Center Staff
Unique SCI Students: 592 = 42% of Center Staff



Unique LED Students: 205 = 15% of Center Staff
Unique PRO Students: 307 = 22% of Center Staff

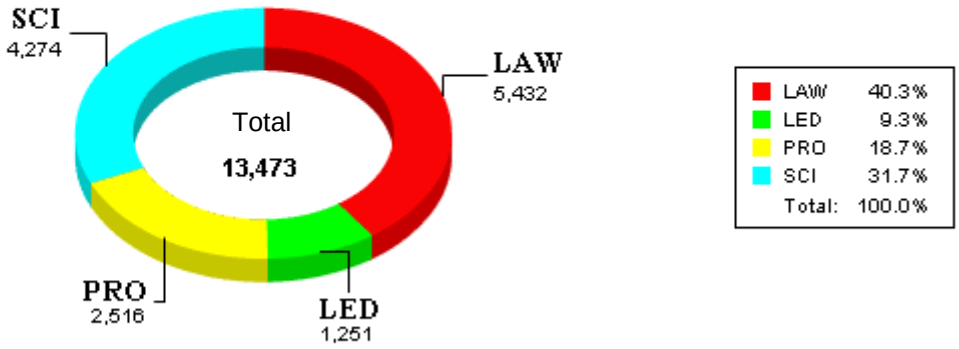
CDRH Total Distribution July 1, 2011 - March 31, 2012

Student Completions by Category*

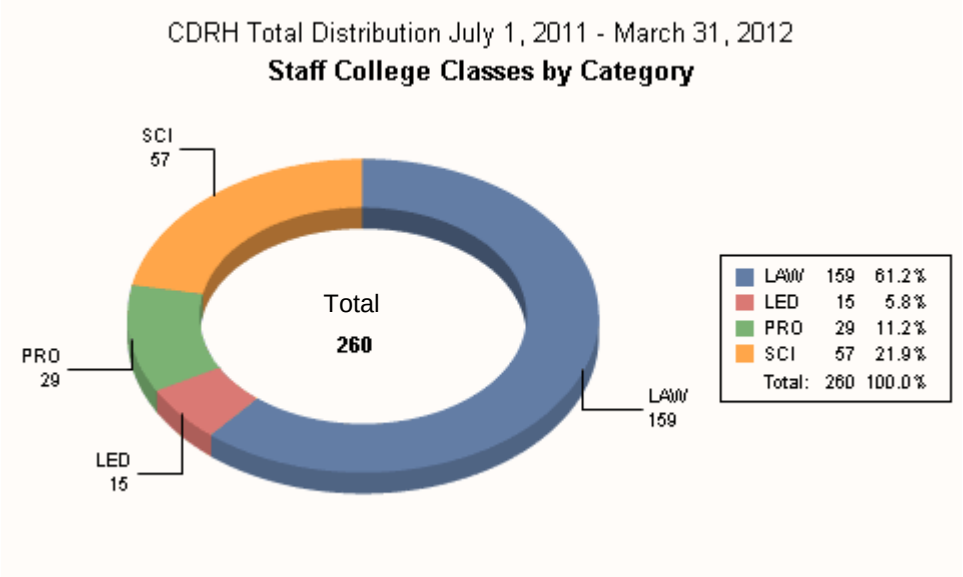


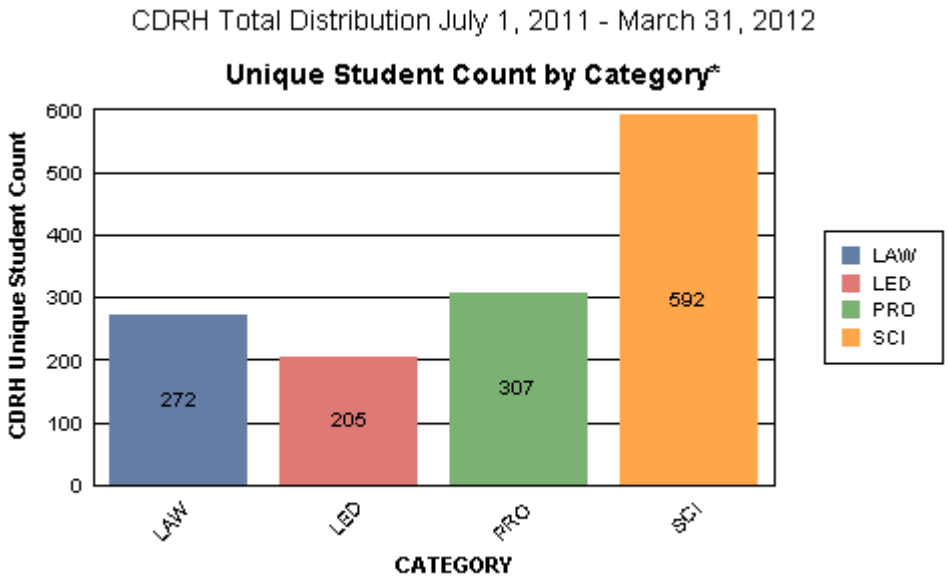
CDRH Total Distribution July 1, 2011 - March 31, 2012

Contact Hours by Category



Key: LAW = Law and Policy, LED = Leadership, PRO = Professional Development, SCI = Science





Key: LAW = Law and Policy, LED = Leadership, PRO = Professional Development, SCI = Science

Establishments by Establishment Type

		Domestic	Foreign	Total
1	Manufacturer	5125	7323	12448
2	Contract Manufacturer	286	662	948
3	Contract Sterilizer	20	41	61
4	Specification Developer	1501	322	1823
5	Reprocessor of Single Use Devices	13	1	14
6	U.S. Manufacturer of Export Only Devices	110		110
7	Repackager/Relabeler	1807	422	2229
8	Remanufacturer	65	86	151
9	Foreign Exporter		1203	1203
10	Initial Distributor/Importer	4977		4977
	Unknown	2		2
	Total:	**13906**	**10060**	**23966**

FY 2012 Medical Device User Fee Collections[2]
As of March 31, 2012

Source	FY 2012 Authorized[1]	FY 2012 Fee Revenues				FY 2012 Surplus
		Receipts	Refunds	Net	% of Authorized	*cf.* Authorized
Establishment Registration Fe	$25,869,750	$32,005,306	$34,914	$31,970,392	123.6%	$6,100,642
Application / Reporting Fees	$31,735,250	$17,350,506	$24,410	$17,326,096	54.6%	-$14,409,154
Total	**$ 57,605,000**	$ 49,355,812	$ 59,324	**$ 49,296,488**	**85.6%**	**-$8,308,512**

[3]Comparison:
Medical Device User Fee Collection in Prior Years
Excludes Unearned Fees, Includes Refunds

FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011
$21,620,549	$25,309,853	$31,801,091	$35,059,601	$28,726,239	$47,536,312	$53,565,502	$63,415,185	$64,891,167

Notes:

1. The Authorized revenues shown for Establishment Registration fees assume 12,750 establishments will register and pay the fee of $2,029. The Authorized revenues shown for Application / Reporting Fees represents the difference between the Total authorized fee revenues and the amount shown for authorized Establishment Registration revenues. The calculation for the total FY 2012 authorized fee revenues is specified in the FY 2012 FR Notice for publishing fees.

2. Collections in this section are attributed to the authorized revenue ceiling for Cohort Year 12.
3. Collections in this section are attributed to the authorized revenue ceiling of the Cohort Year listed.

FY 2012 Appropriations Update

Public Law 112-55, the Fiscal Year 2012 Agriculture, Commerce/Justice/Science (CJS), and Transportation/Housing and Urban Development (THUD) Appropriations bill, also known as the "Mini-bus," included the following funding for the Devices Program:

- Provides $322.672 million in budget authority for the Devices Program. CDRH is expected to receive $241.475million.
- Includes $20.038 million for the Medical Countermeasures Initiative. CDRH is expected to receive approximately $3 million of this funding.

FY 2013 Appropriations Update

The FY 2013 budget request for the Devices Program is $386,766,000. The request includes an additional $723,000 for CDRH in support of the Medical Countermeasures Initiative.