Agenda for Quarterly Meeting on MDUFMA / MDUFA Performance
10:00 A.M., Tuesday, July 26, 2011

Welcome. *Barbara Zimmerman, CDRH-ODE.*

Guidance Development

- FDA issued 13 medical device guidance documents during the third quarter. *Barbara Zimmerman, CDRH-ODE*; *Kate Cook, CBER; Don St. Pierre, CDRH-OIVD*

FDA MDUFMA / MDUFA Performance — Actions through June 30, 2011

- Reports on all decision goals for the FY 2008 - FY 2011 cohorts.
    - CBER: *Kate Cook, CBER.*
    - CDRH: *Barbara Zimmerman, CDRH.*

CLIA Waiver Review Times

- Report on qualitative goals and number of pending waiver requests, *Natalia Comella*, CDRH-OIVD.

Qualitative Update on Finances and Use of Resources - 3rd Quarter of FY 2011

- User fee receipts through the 3rd Quarter of FY 2011, compared with expectations. *David Miller, FDA-OFM.*
- Update on Budget Requests and appropriations. *Jon Sauer*, CDRH-OMO.

CDRH Information Technology (IT) Update

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

CDRH Staff Training Update

- Report on CDRH staff training. Laura Stewart, CDRH-OCER

Discussion

- Questions from industry.
- Set date for next meeting, following close of Q4. Target Date: 10/26/2011.

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Medical Device Guidance Documents
Issued through 3rd Quarter FY 2011
Through June 30, 2011

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

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Third Quarter (March 2011- June 2011)

1. Draft Guidance for Industry and Food and Drug Administration Staff - The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Low Glucose Suspend (LGS) Device Systems, ODE (6/22/2011).

2. Draft Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Optimize Medical Device Design, ODE (6/22/2011).

3. ODE Draft Guidance for Industry and FDA Staff - Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of methicillin-resistant Staphylococcus aureus (MRSA) for Culture Based Devices, OIVD (6/15/2011).

4. Draft Guidance for Industry and FDA Staff - Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions, OIVD (6/1/2011).

5. Draft Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: In Vitro Diagnostic Devices for Bacillus spp. Detection, OIVD (5/18/2011).

6. Guidance for Industry and Food and Drug Administration Staff - Assembler's Guide to Diagnostic X-Ray Equipment, OCER (5/17/2011).

7. Draft Guidance for Industry and Food and Drug Administration Staff - Establishing the Performance Characteristics of In Vitro Diagnostic Devices for Chlamydia trachomatis and/or Neisseria gonorrhoea: Screening and Diagnostic Testing, OIVD (5/11/2011).

8. Draft Guidance for Industry and FDA Staff - Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, ODE (5/2/2011).

9. Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities, ODE (4/25/2011).

10. Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use, ODE (4/14/2011).

11. Guidance for Industry and FDA Staff - 30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75-Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes, OC (4/13/2011).

12. Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Ovarian Adnexal Mass Assessment Score Test System, OIVD (3/23/2011).

13. Guidance for Industry and FDA Staff - Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence, ODE (3/8/2011).

Second Quarter (January 2011- March 2011)

1. Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Ovarian Adnexal Mass Assessment Score Test System (3/23/2011).

2. Guidance for Industry and FDA Staff - Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence (3/8/2011).

3. Draft Guidance for Industry and FDA Staff - Recommended Warning for Surgeon's Gloves and Patient Examination Gloves that Use Powder (2/7/2011).

4. Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Contact Cooling System for Aesthetic Use (2/7/2011).

5. Electronic Source Documentation in Clinical Investigations (CDER/CBER/CDRH/OCPP) (1/6/2011).

6. Draft Guidance for Industry and Food and Drug Administration Staff - Establishing the Performance Characteristics of Nucleic Acid-Based In vitro Diagnostic Devices for the Detection and Differentiation of Methicillin-Resistant Staphylococcus aureus (MRSA) and Staphylococcus aureus (SA) (1/5/11).

7. Draft Guidance for Industry and Food and Drug Administration Staff - Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Antibodies to Borrelia burgdorferi (1/5/11).

First Quarter (October 2010 – December 2010)

1. Guidance for Industry and Food and Drug Administration Staff - Blood Lancet Labeling (11-29-10).

2. Draft Guidance for Industry and Food and Drug Administration Staff - Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Clostridium difficile (11-29-10).

3. The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #13 (11-16-10).

4. Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy (NPWT) (11-10-10).

5. Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin (11-10-10).

6. Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Full Field Digital Mammography System (11/5/10).

7. Guidance for Industry: Cellular Therapy for Cardiac Disease (11-4-10).

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

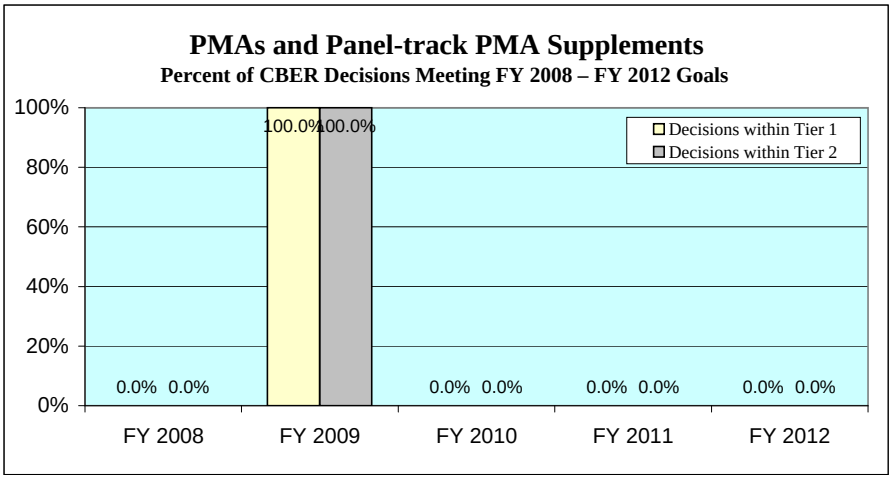
Actions through 30 June 2011

Data on FY 2008 – FY 2012 Cohorts

Actions through 30 June 2011

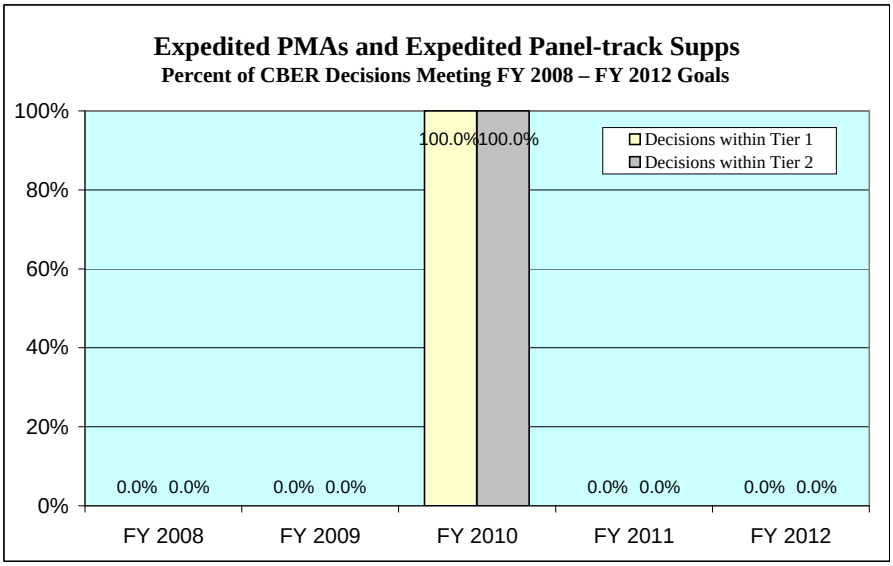
PMAs and Panel-track Supplements

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



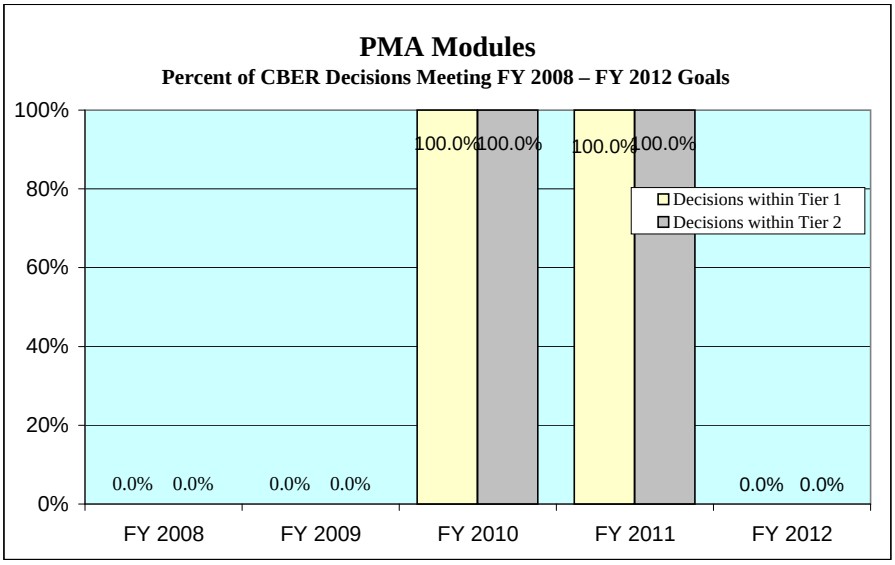
Expedited PMAs and Expedited Panel-track Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	0	0	1	0	—
Total FDA Decisions	0	0	1	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*	Open	—



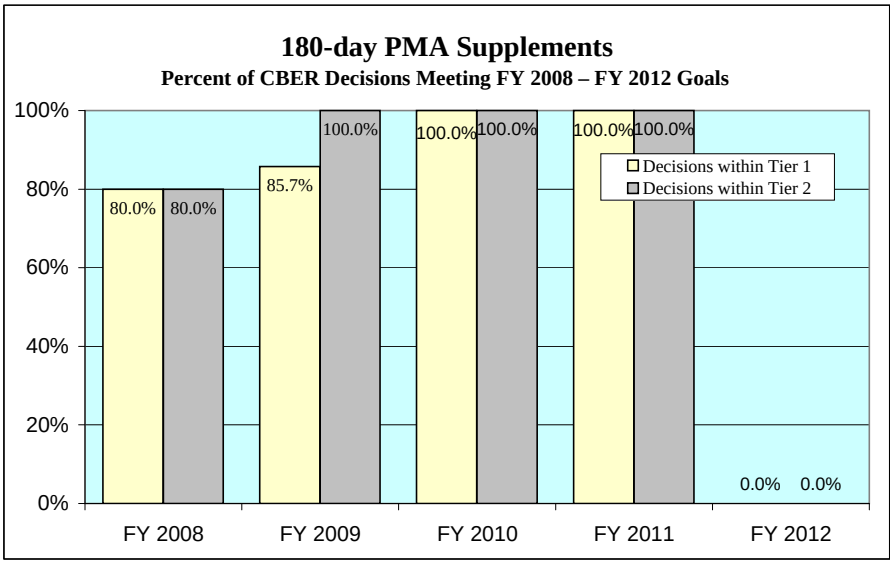
PMA Modules

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



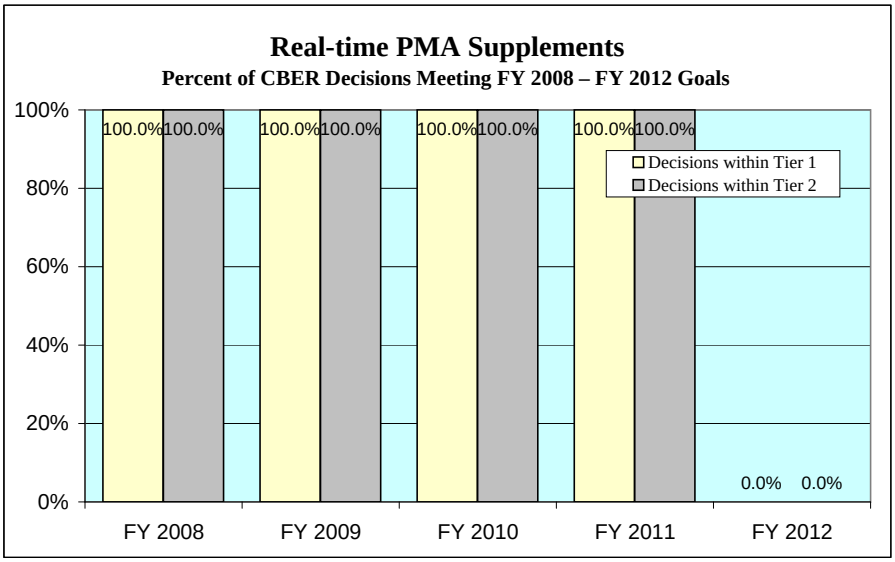
180-day PMA Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	5	7	7	7	—
Total FDA Decisions	5	7	7	1	—
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*	Open	—



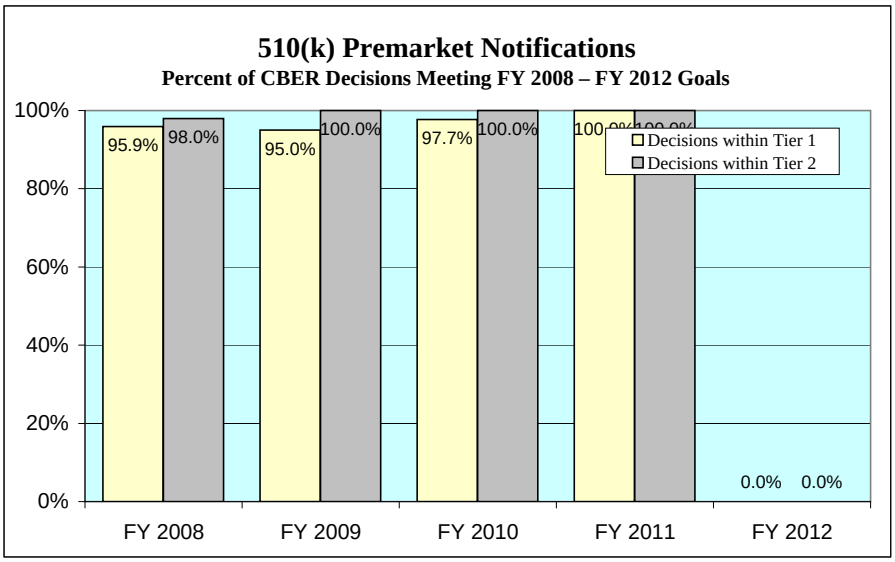
Real-time PMA Supplements

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



510(k)s

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Received to Date)	53	50	55	26	—
MDUFMA Cohort	49	41	48	25	—
Total FDA Decisions	49	40	43	9	—
Percent within Tier 1 goal (90 days)	95.9%	95.0%	97.7%	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%	—
Tier 2 goal — *Percent within 150 days*	*98%*	*98%*	*98%*	*98%*	*98%*
Cohort status	*Complete*	Open	Open	Open	—



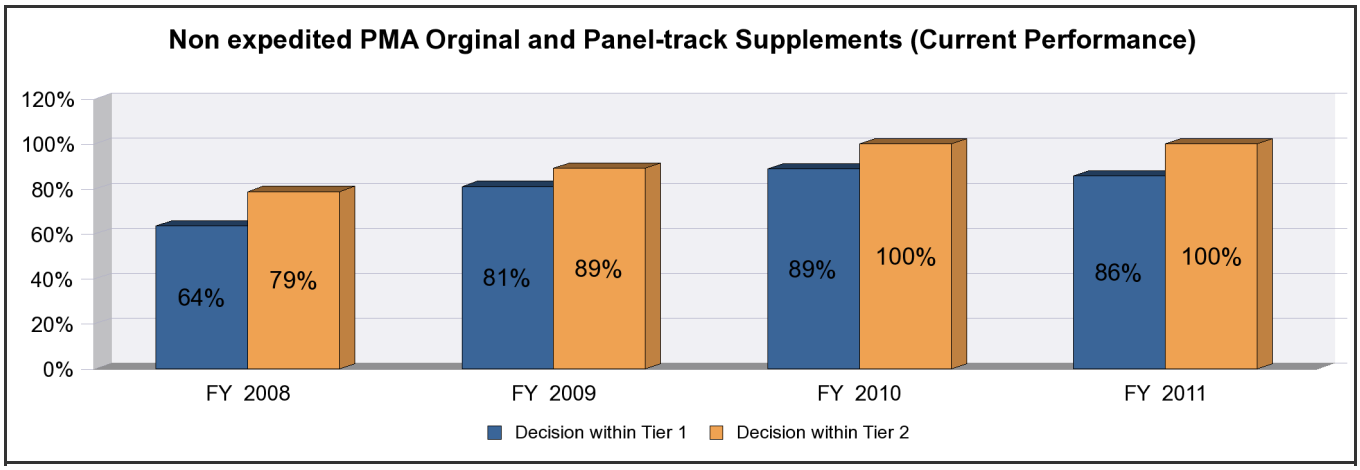
Quarterly Update on
Medical Device Performance Goals
---- CDRH Performance Data ----

Action through 30 June 2011

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

For Submissions Filed Between Year 2008 to 2011 as of 06/30/2011 11:59:00 PM

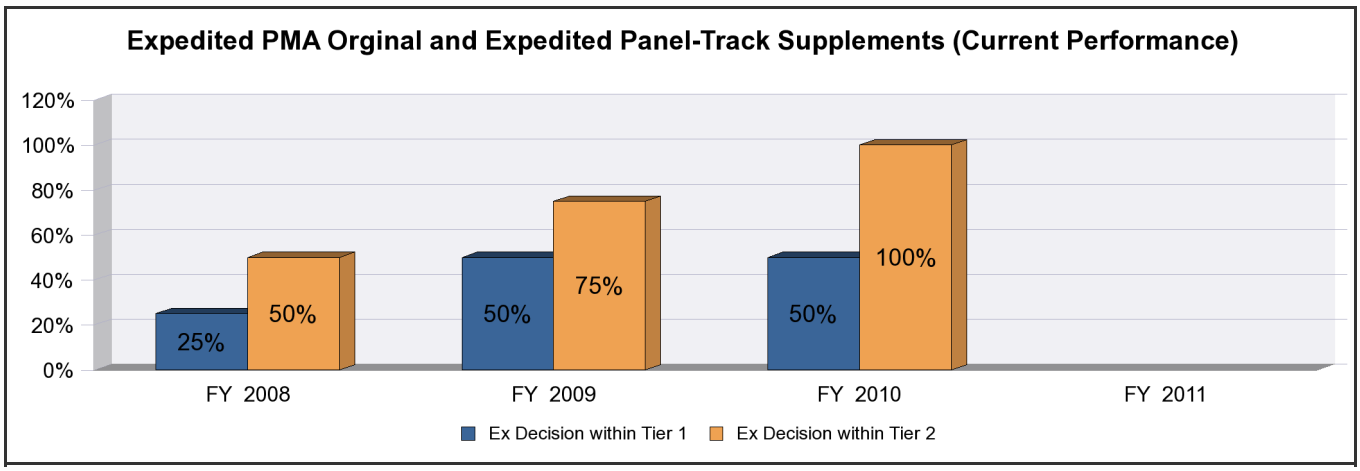
	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Filed to Date)	33	39	53	33
Total FDA Decision	33	37	36	7
Tier 1 goal -- Percent within 180 Days	*60%*	*60%*	*60%*	*60%*
Goal met(yes/no/unknown)	yes	yes	yes	unknown
Pending Performance-Best Case	64%	77%	87%	88%
Pending Performance-Worst Case	64%	77%	60%	18%
Tier 2 goal -- Percent within 295 days	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	no	no	unknown	unknown
Pending Performance-Best Case	79%	85%	96%	97%
Pending Performance-Worst Case	79%	85%	68%	21%
Cohort status	Complete	Open	Open	Open



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

For Submissions Filed Between Year 2008 to 2011 as of 06/30/2011 11:59:00 PM

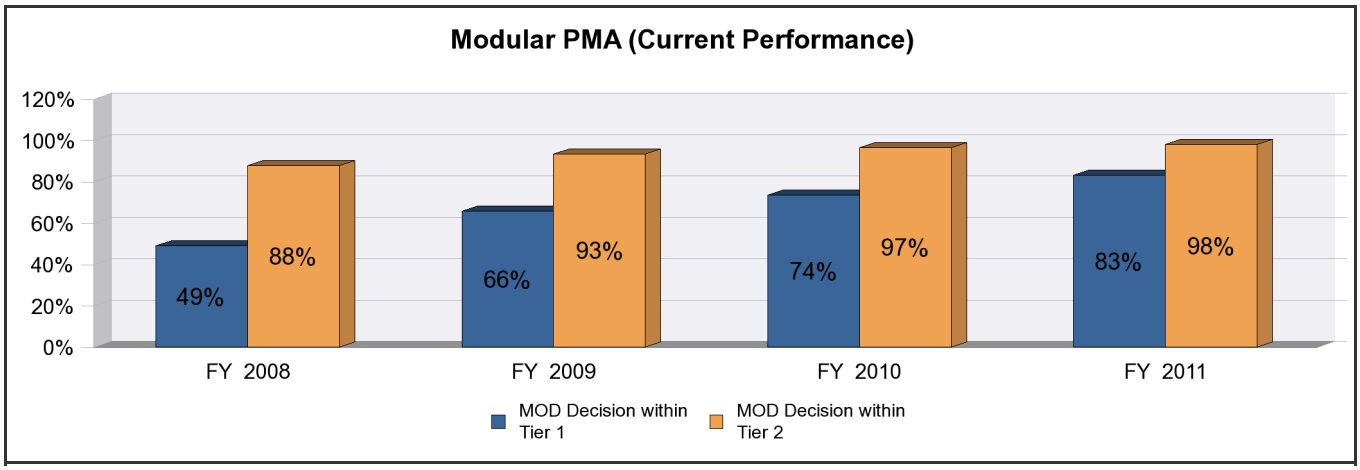
	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Filed to Date)	4	4	6	5
Total FDA Decision	4	4	4	0
Tier 1 goal -- Percent within 180 Days	*50%*	*50%*	*50%*	*50%*
Goal met(yes/no/unknown)	no	yes	unknown	unknown
Pending Performance-Best Case	25%	50%	67%	80%
Pending Performance-Worst Case	25%	50%	33%	0%
Tier 2 goal -- Percent within 280 days	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	no	no	unknown	unknown
Pending Performance-Best Case	50%	75%	100%	80%
Pending Performance-Worst Case	50%	75%	67%	0%
Cohort status	Complete	Complete	Open	Open



MDUFA II Quarterly (Modular PMA)

For Submissions Filed Between Year 2008 to 2011 as of 06/30/2011 11:59:00 PM

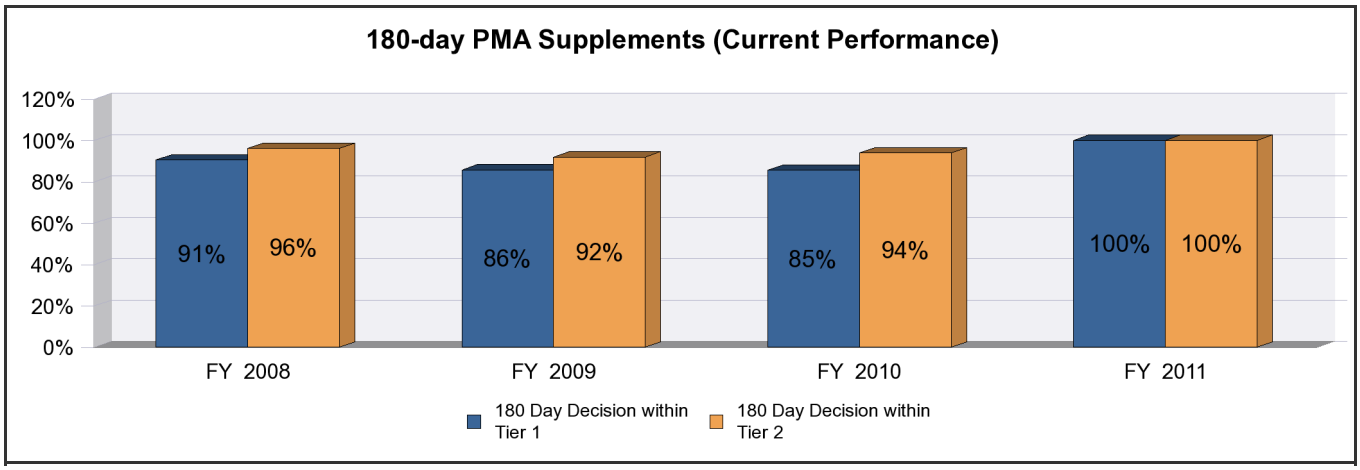
	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Cycle Started)	45	68	86	63
Total FDA Decision	49	76	87	47
Tier 1 goal -- Percent within 90 Days	*75%*	*75%*	*75%*	*75%*
Goal met(yes/no/unknown)	no	no	no	unknown
Pending Performance-Best Case	49%	66%	74%	86%
Pending Performance-Worst Case	49%	64%	74%	63%
Tier 2 goal -- Percent within 120 days	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	no	yes	yes	unknown
Pending Performance-Best Case	88%	93%	97%	98%
Pending Performance-Worst Case	88%	91%	97%	74%
Cohort status	Complete	Open	Complete	Open



MDUFA II Quarterly (180-day PMA Supplements)

For Submissions Filed Between Year 2008 to 2011 as of 06/30/2011 11:59:00 PM

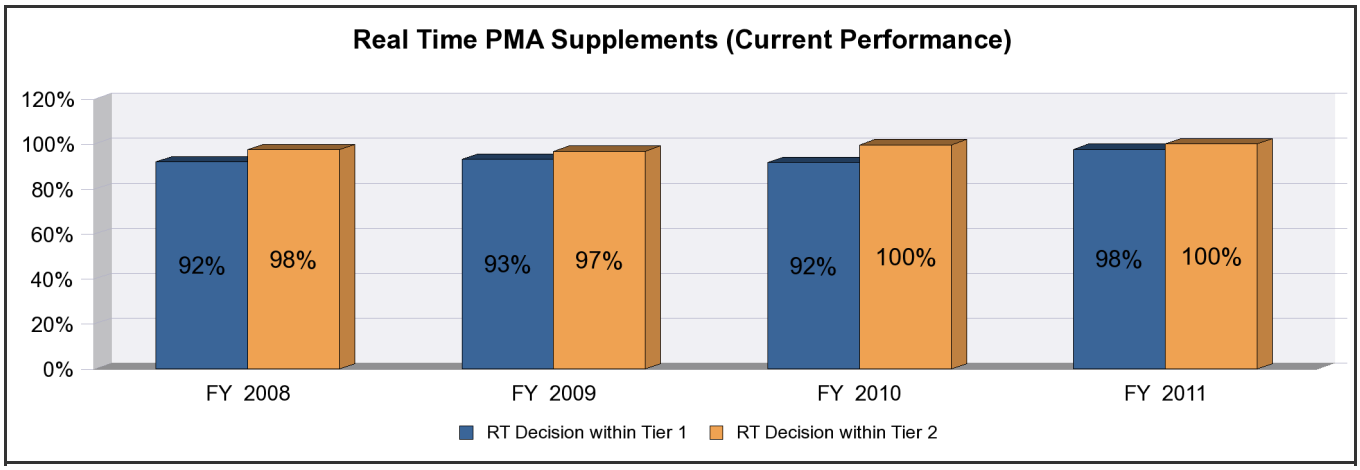
	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Filed to Date)	170	166	157	103
Total FDA Decision	160	161	131	49
Tier 1 goal -- Percent within 180 Days	*85%*	*85%*	*85%*	*85%*
Goal met(yes/no/unknown)	yes	yes	unknown	unknown
Pending Performance-Best Case	90%	85%	85%	88%
Pending Performance-Worst Case	90%	85%	74%	48%
Tier 2 goal -- Percent within 210 days	*95%*	*95%*	*95%*	*95%*
Goal met(yes/no/unknown)	yes	no	no	unknown
Pending Performance-Best Case	95%	91%	92%	88%
Pending Performance-Worst Case	95%	91%	81%	48%
Cohort status	Open	Open	Open	Open



MDUFA II Quarterly (Real Time PMA Supplements)

For Submissions Filed Between Year 2008 to 2011 as of 06/30/2011 11:59:00 PM

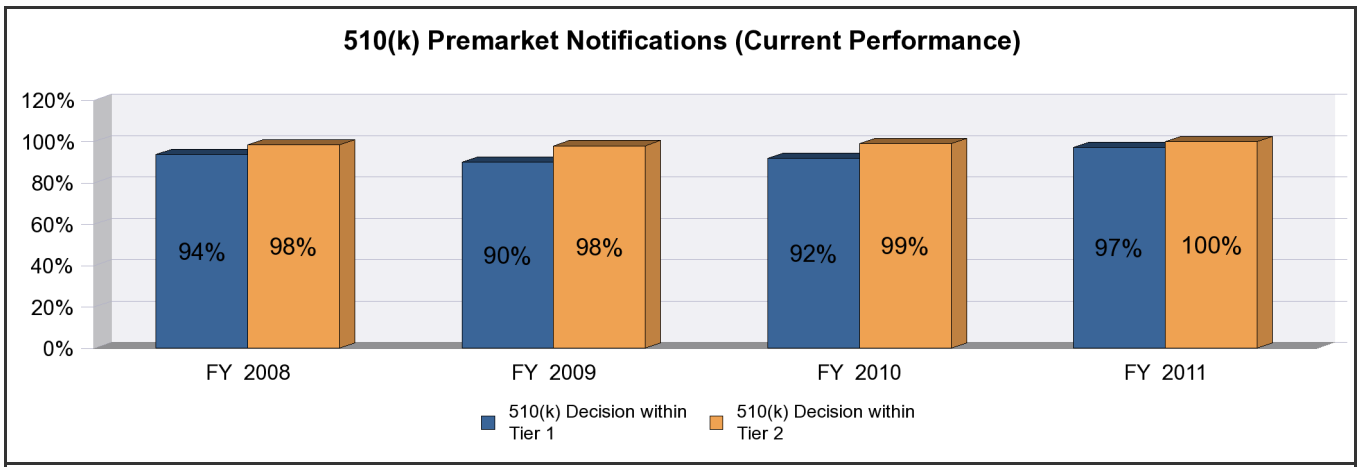
	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Filed to Date)	249	296	269	167
Total FDA Decision	241	280	257	126
Tier 1 goal -- Percent within 60 Days	*80%*	*80%*	*80%*	*80%*
Goal met(yes/no/unknown)	yes	yes	yes	unknown
Pending Performance-Best Case	92%	93%	91%	84%
Pending Performance-Worst Case	92%	93%	91%	77%
Tier 2 goal -- Percent within 90 days	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	yes	yes	yes	unknown
Pending Performance-Best Case	98%	97%	99%	87%
Pending Performance-Worst Case	98%	97%	99%	79%
Cohort status	Complete	Complete	Open	Open



MDUFA II Quarterly (510(k) Premarket Notifications)

For Submissions Received Between Year 2008 to 2011 as of 06/30/2011 11:59:00 PM

	FY 2008	FY 2009	FY 2010	FY 2011
Workload (Received to Date)	3,848	4,103	3,880	2,804
MDUFA Cohort	3,261	3,404	3,198	2,686
Total FDA Decision	3,259	3,392	2,983	1,172
Tier 1 goal -- Percent within 90 Days	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	yes	yes	unknown	unknown
Pending Performance-Best Case	94%	90%	92%	99%
Pending Performance-Worst Case	94%	90%	86%	42%
Tier 2 goal -- Percent within 150 Days	*98%*	*98%*	*98%*	*98%*
Goal met(yes/no/unknown)	yes	yes	unknown	unknown
Pending Performance-Best Case	98%	98%	99%	100%
Pending Performance-Worst Case	98%	98%	92%	44%
Cohort status	Open	Open	Open	Open



CLIA WAIVER BY APPLICATION WORKLOAD

FISCAL YR RECIEVED	RECOMMENDATION	TOTAL FDADAYS	TOTAL MFR DAYS	TOTAL DAYS
2008	APPR - Approved	61		61
		248	38	286
		248	38	286
		398		398
		398		398
	DENY - Denied	102		102
		129		129
		189		189
		199		199
		287		287
		320	424	744
	TH - Telephone Hold	136	1142	1278
2008 Total	12			
2009	APPR - Approved	204	64	268
		233		233
	DENY - Denied	285		285
		644	7	651
		740		740
	TH - Telephone Hold	33	867	900
		259	552	811
		518	90	608
2009 Total	8			
2010	APPR - Approved	77		77
	DENY - Denied	172		172
		105	106	211
		248		248
		266		266
	Under Review	441		441
		466		466
2010 Total	7			
2011	APPR - Approved	27		27
	Under Review	120		120
2011 Total	2			
Grand Total	29			

As of 7/20/11

FY 2011 Medical Device User Fee Collections[2]
As of June 30, 2011

Source	FY 2011 Authorized[1]	FY 2011 Fee Revenues				FY 2011 Surplus
		Receipts	Refunds	Net	% of Authorized	*cf.* Authorized
Establishment Registration Fee	$27,782,250	$34,264,237	$138,215	$34,126,022	122.8%	$6,343,772
Application / Reporting Fees	$34,077,750	$26,632,033	$109,445	$26,522,588	77.8%	-$7,555,162
Total	**$ 61,860,000**	$60,896,270	$ 247,660	**$ 60,648,610**	**98.0%**	**-$1,211,390**

[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
$21,620,549	$25,309,853	$31,801,091	$35,059,601	$28,726,239	$47,610,614	$53,631,621	$63,666,840

Notes:

1. The Authorized revenues shown for Establishment Registration fees assume 12,750 establishments will register and pay the fee of $2,179. 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. Total FY 2011 authorized fee revenues are specified in section 738(h)(3) of the FD&C Act.
2. Collections in this section are attributed to the authorized revenue ceiling for Cohort Year 11.
3. Collections in this section are attributed to the authorized revenue ceiling of the Cohort Year listed.

July 2011
MDUFA Stakeholder Meeting
Appropriation Update

FY 2011 Appropriations Update

- FDA is in the process of obligating funding for FY 2011 increases including the National Medical Device Registry, Nanotechnology, Pediatric Safety, and Medical Device Safety.
- FDA is working to address budget and hiring challenges due to the delayed FY 2011 Budget Resolution and the Center receiving FY 2011 funding levels late in the fiscal year (April).

FY 2012 Appropriations Update

The FY 2012 Agriculture Appropriations bill, H.R. 2112, passed the House on June 16 2011. Under H.R. 2112, the Agency's budget authority (BA) for FY 2012 is less than the FY 2011 Enacted level, with each Program taking a share of the reduction.

- H.R. 2112 still provides BA for the Device Program (CDRH and Field activities combined) at a level above the FY 2012 appropriation trigger for MDUFA.
- Under H.R. 2112, the legislatively mandated FY 2012 MDUFA collection level remains unchanged from the FY 2012 President's Budget. According to H.R. 2112, "$67,118,000 shall be derived from medical device user fees authorized by 21 U.S.C. 379j, and shall be credited to this account and remain available until expended".
- The FY 2012 MDUFA authorized collection level of $67,118,000 reflects an increase of $5,258,000 from the FY 2011 authorized collection level of $61,860,000.

Footnotes:
1. According to H.R. 2112, "$321,171,000 shall be for the Center for Devices and Radiological Health and for related field activities in the Office of Regulatory Affairs". The Device Program FY 2011 Enacted Budget is $359,781,000.
2. $321,171,000 reflects the Device Program's (CDRH/Field) BA and MDUFA dollars before adding fees from the MQSA indefinite UF program. The language does not separate Center and field funding levels. The reduction is entirely in Budget Authority dollars.

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)

July 26, 2011

Recent Accomplishments (2 of 2)

- **CSTAR** – Center Submission Tracking and Reporting
  - Established tracking mechanisms for Post Surveillance Studies (PSS)
  - Performed a Total Product Life Cycle (TPLC) data warehouse integration for premarket and postmarket data
    - http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm

FY '11 Staff College Internal Training Summary Report

From 10/01/2010 to 6/30/2011

As of: **07/19/2011**

FY 2011 *(Oct 1, 2010 – June 30, 2011)* MDUFA-Related Training

FDA continues to invest in internal and external training opportunities supporting the medical devices 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 medical device reviews grow 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 October 1, 2010 and June 30, 2011. One hundred thirty-four Staff College training courses and seminars were offered addressing reviewer training, new scientific technologies, law, regulation and guidance updates or leadership and professional development. This training was designed to improve the device review process and support MDUFA goals and activities. The remaining charts illustrate that 907 of the approximately 1400 CDRH staff attended an average of 3 internal Staff College learning events representing 20,087 contact hours.

CDRH staff also had opportunities to attend other learning events with a focus on science and application review. 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

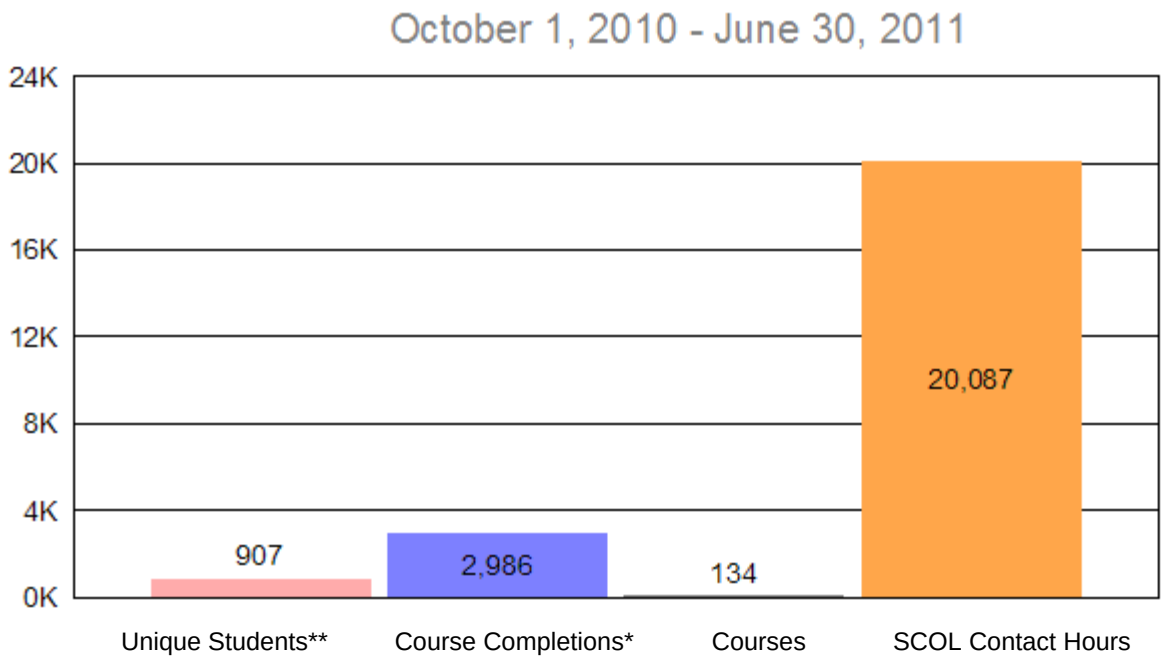
Table X: MDUFA FY 11 CDRH Staff College Internal Training

Topical Area	# of Learning Events	Total # of Participants	Examples of Training Conducted/Attended Between 10/1/10 – 6/30/11
Regulatory and Law (LAW)	25	626	• Basic Food and Drug Law Course • Four-Part Harmony: Deficiency Writing in Plain English • How to Write Clear and Concise 510(k) 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
Science (SCI)	40	1184	• Statistics for Diagnostic Devices • CREP: Diabetes Update • Regenerative Medicine Series - Nov. 8 • Bone Seminar Series 2011 • Human Factors for Medical Devices • Benefit: Risk Issues in Design, Monitoring, Analysis & Reporting • Introduction to Biostatistics
Leadership Education and Development (LED)	36	619	• CDRH Leadership Forum: A Case Study in Leadership (Thomas Jefferson) • LRP Critical Thinking & Creative Problem Solving • LRP: Sharpen Your Coaching Skills • LRP - Trust Based Leadership
Professional Development (PRO)	33	557	• Conflict Resolution • Championing Diversity • The Effective Facilitator • Nonverbal Communication • Precision Thinking and Problem Solving

Leadership Readiness Program (LRP) Graduates ROI Update 2011 (Includes iterations for Program Years 2006-2007, 2008-2009, and 2010/11)

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

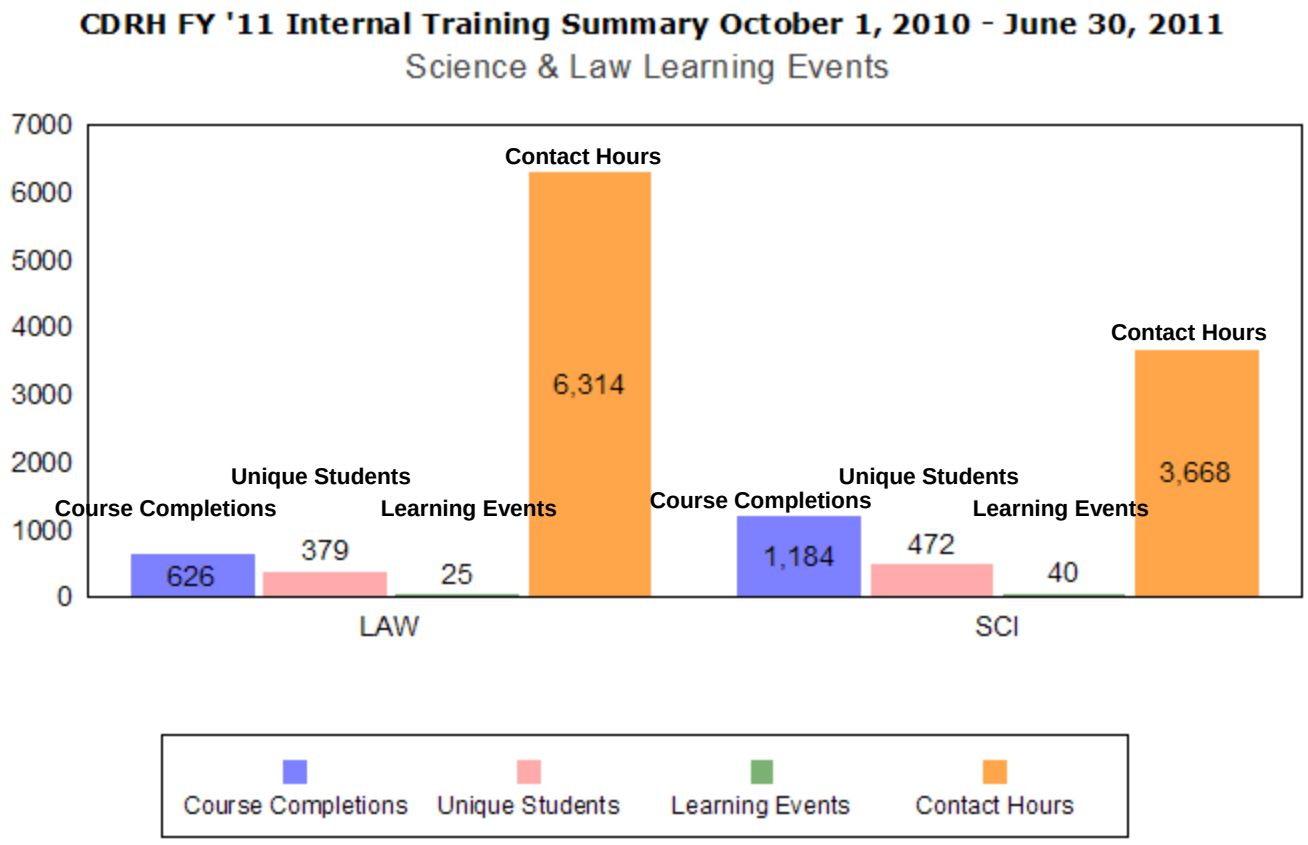
FY '11 Completion Summary Data for CDRH Staff College Internal Learning Events



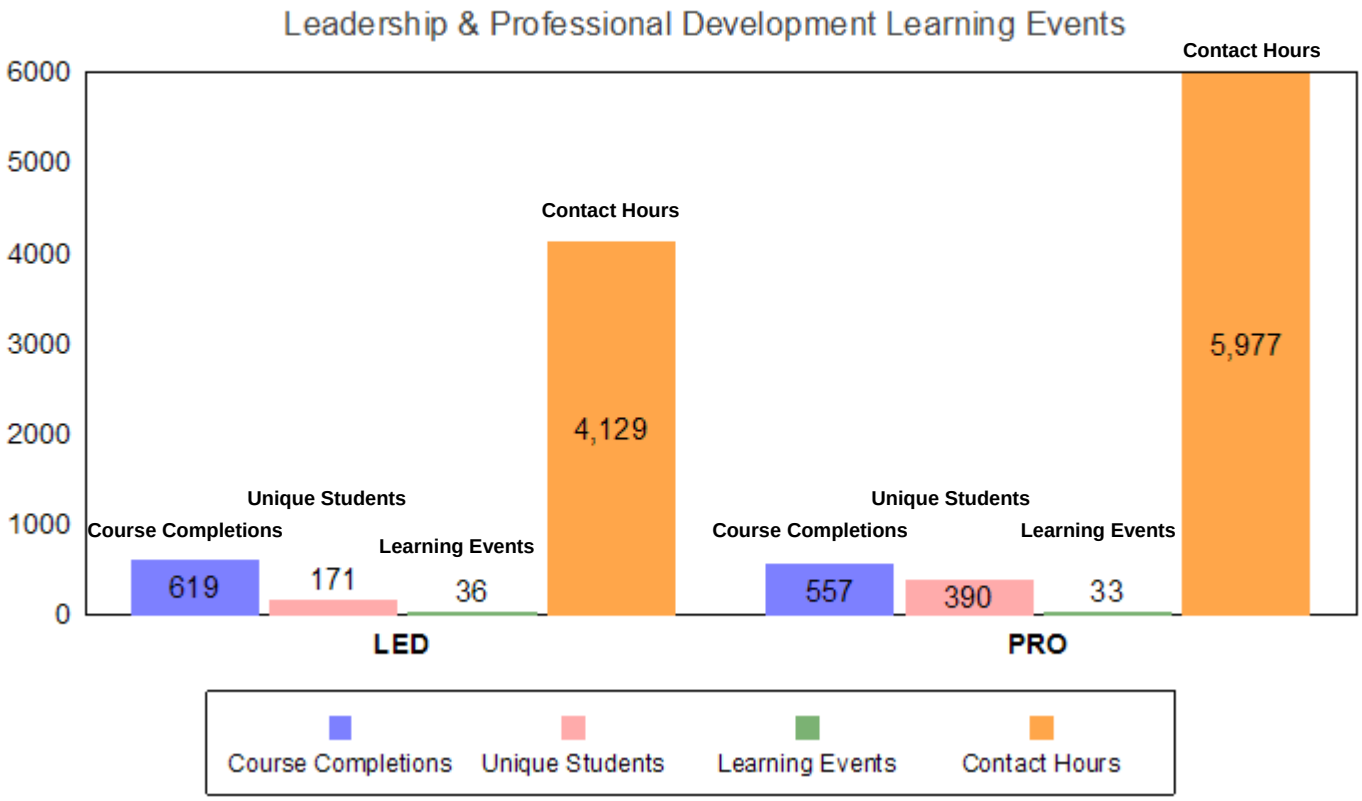
*Course Completions = Total number of students overall

**Unique Students = Number of distinct students

Data date 7/19/2011


CDRH FY '11 Internal Training Summary October 1, 2010 - June 30, 2011
Science & Law Learning Events
7000
6000
5000
4000
3000
2000
1000
0
Course Completions
626
Unique Students
379
Learning Events
25
Contact Hours
6,314
LAW
Course Completions
1,184
Unique Students
472
Learning Events
40
Contact Hours
3,668
SCI
Course Completions
Unique Students
Learning Events
Contact Hours

CDRH FY '11 Internal Training Summary October 1, 2010 - June 30, 2011



FY’ 11 Total Unique Students attending Internal Learning Events by Office, Quarter and Cumulatively

Offices	Q1	Q1 & Q2	Q1,Q2&Q3
OC	52	88	117
OCD	18	28	31
OCER	44	71	100
ODE	167	233	266
OIVD	67	86	97
OMO	23	36	49
OSB	52	81	119
OSEL	49	92	128
FY’ 11 Total Unique Student Count	472	715	907

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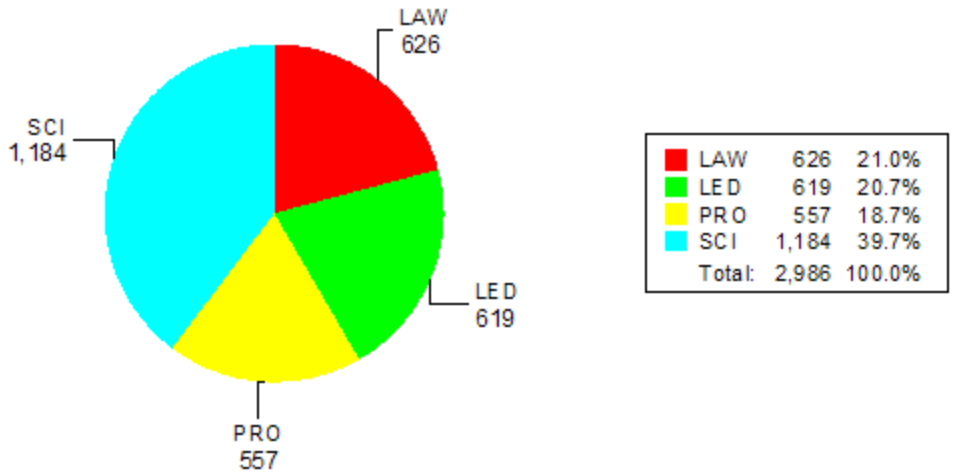
CDRH Total Distribution FY 11 October 1, 2010 - June 30, 2011

Student Course Completions by Category*



*Course Completions = Successful attendance in a Learning Event

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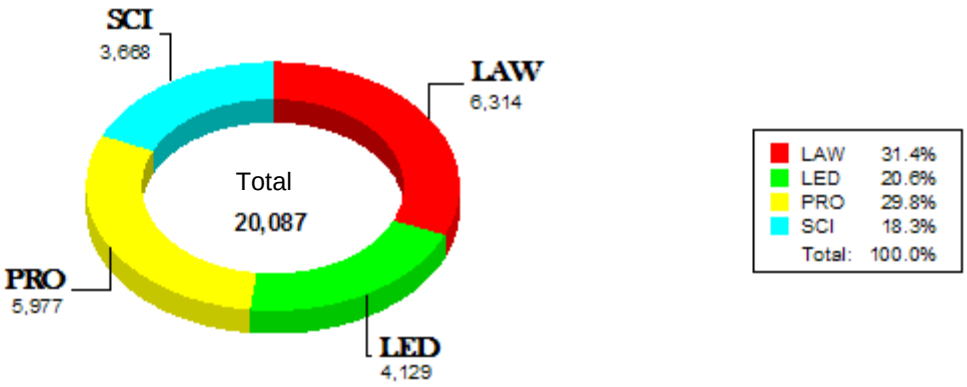
CDRH Total Distribution FY 11 October 1, 2010 - June 30, 2011

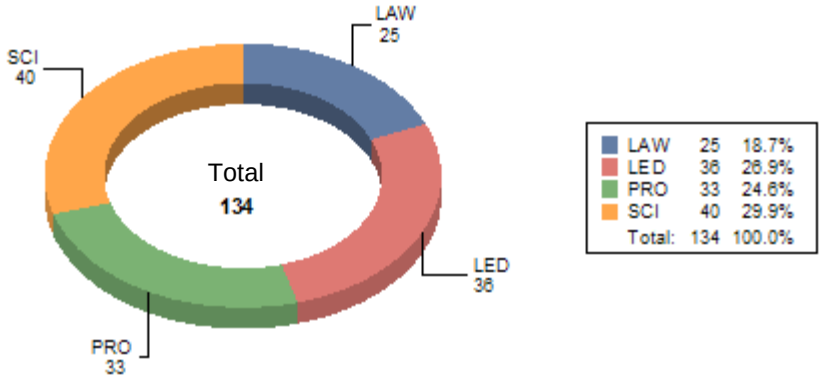
Contact Hours by Category



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

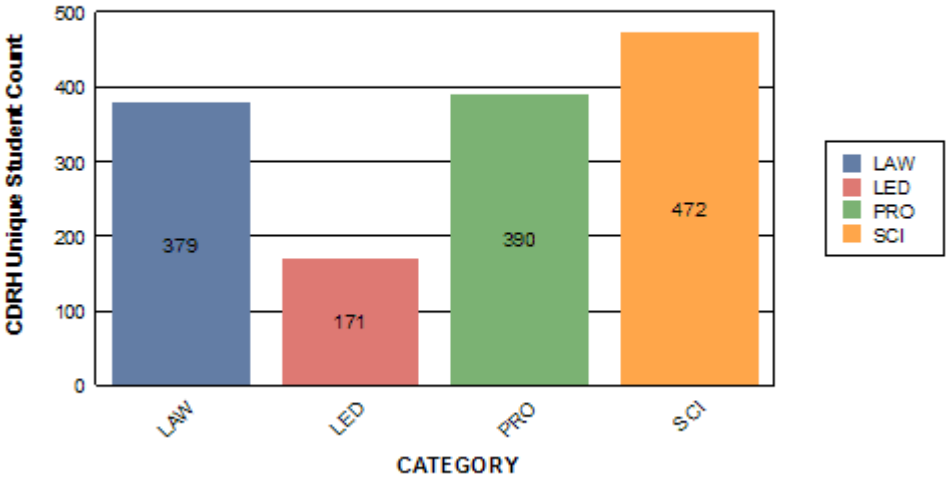
CDRH Total Distribution FY 11 October 1, 2010 - June 30, 2011

Staff College Learning Events by Category



CDRH Total Distribution FY 11 October 1, 2010 - June 30, 2011

Unique Student Count by Category*



*Unique Students = Number of distinct students

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

SCOL classes from 10/01/2010 to 6/30/2011

CAT	CLASS_NAME	HOURS
LAW	Basic Food and Drug Law Course	35.00
LAW	Unique Device Identification: Foundation for Health Informatics Init	2.00
LAW	Master the Technical Sentence	4.00
LAW	Four-Part Harmony: Deficiency Writing in Plain English	7.50
LAW	How to Write Clear and Concise 510(k) Reviews	7.50
LAW	How to Write Effective Consulting Reviews	3.00
LAW	Medial Device Law Course	18.00
LAW	CDRH Guidance Development: How to use the new SOP	2.00
LAW	Basic Food and Drug Law Course	35.00
LAW	T2 Series - Technology Transfer (T2) 101	2.50
LAW	Federal Acquisition Certification (FAC) COTR Refresher	7.00
LAW	T2 Series - Cooperative Research and Development Agreement (CRADA) 101	2.50
LAW	Medical Device Law Course	20.00
LAW	T2 Series - GRANTS 101	6.00
LAW	How to Write Deficiencies in Four-Part Harmony: Plain Writing Workshop	6.50
LAW	How to Write Clear & Concise 510(k) Reviews: A Plain Writing Workshop	6.50
LAW	How to Write Effective Pre-market Consulting Reviews	3.00
LAW	Medical Device History	10.00
LAW	TPLC Data Integration and Linking to Additional Information	1.00
LAW	TPLC Data Integration and Linking to Additional Information	1.00
LAW	TPLC Data Integration and Linking to Additional Information	1.00
LAW	TPLC Data Integration and Linking to Additional Information	1.00
LAW	Clinical Trial Design - Scales in Medical Device Regulation	2.00
LAW	Master the Technical Sentence	4.00
LAW	How to Write Deficiencies in 4-Part Harmony: A Plain Writing Workshop	6.50
LED	CDRH Leadership Forum: A Case Study in Leadership (Thomas Jefferson)	14.00
LED	LRP: Negotiation and Influencing	21.00
LED	CDRH Leadership Forum: Effective Supervision of Scientists & Technical	14.00
LED	CDRH Leadership Forum: FDA HR Practices for Managers and Supervisors	14.00
LED	LRP: Effective Presentations	14.00
LED	LRP: Project Management	21.00
LED	LRP: Sharpen Your Coaching Skills	3.00
LED	CDRH Leadership Forum: Introduction to Situational Leadership	3.00
LED	Using Personal Wellness to Enhance Productivity	3.00
LED	LRP: Myers-Briggs Type Indicator	3.00
LED	LRP Mentoring Mid-point Energizer	3.00
LED	LRP: True North Session	3.00
LED	LRP Budget Briefing: Understanding the Center Budget	3.00
LED	LRP Employee & Labor Relations	4.00
LED	LRP - Trust Based Leadership (LRP Mentors)	3.00
LED	LRP Ethics of Leadership	7.50
LED	LRP - Master & Peer Review Process	3.00
LED	LRP True North Session March 15, 2011	3.00
LED	LRP - Introduction to Situational Leadership	7.00
LED	LRP Kitchen Krunch (March 18, 2011)	4.00
LED	CDRH Leadership Forum: Employee and Labor Relations for Managers	2.50

SCOL classes from 10/01/2010 to 6/30/2011		
LED	LRP Critical Thinking & Creative Problem Solving	7.00
LED	CDRH Leadership Form - Lincoln: Vision and Purpose	7.00
LED	Employee Relations Overview - OCER	1.00
LED	LRP Kitchen Krunch (April 1, 2011)	4.00
LED	LRP - Personnel Practices: So You Want to be a Supervisor	7.00
LED	LRP Leadership, Managership & Chickenship	3.00
LED	LRP True North Session April 11, 2011	3.00
LED	CDRH Leadership Forum - Delegation and Motivation	3.50
LED	LRP G.R.A.C.E. at Work: A New Social Contract for the Workplace	14.00
LED	LRP : A Day in the Life-Real Life Survival Skills	3.00
LED	CDRH Leadership Forum - Delivering Effective Feedback	7.00
LED	LRP Gettysburg Battleground Leadership Tour	7.00
LED	LRP True North Close Out session	3.00
LED	LRP 360 Feedback After Action Review	2.00
PRO	7 Habits for Highly Effective People	14.00
PRO	Speaking Under Fire	14.00
PRO	Effective Communication Skills for Scientific and Technical Profession	14.00
PRO	Thrift Savings Plan	3.00
PRO	Teamwork and Collaboration	7.00
PRO	CDRH New Employee Orientation	3.00
PRO	Pre-Retirement Seminar (FERS Employees Only)	21.00
PRO	Managing Projects and Priorities	7.00
PRO	Get Control of Meetings - Webinar	1.50
PRO	Pre-Retirement Seminar (CSRS Employees Only)	21.00
PRO	Precision Thinking and Problem Solving	7.00
PRO	ASHI Adult CPR/AED	3.00
PRO	AHA Healthcare Provider Course	7.00
PRO	Successful Planning for Your Mid-Career Goals	7.00
PRO	Pre-Retirement Seminar (FERS Employees Only)	21.00
PRO	Championing Diversity	7.00
PRO	NonVerbal Communication	7.00
PRO	Working at the Speed of Trust - For Associates	7.00
PRO	ASHI Adult CPR/AED	3.00
PRO	ASHI First Responder Recertification	14.00
PRO	Emotional Intelligence	3.00
PRO	The Effective Facilitator	21.00
PRO	Mid-Career Retirement Planning (FERS)	14.00
PRO	Contracting Officer's Representative Course	40.00
PRO	Story Telling for Non-Supervisors	7.00
PRO	AHA Healthcare Provider Course	4.00
PRO	7 Habits of Highly Effective People	14.00
PRO	Conflict Resolution	7.00
PRO	Speaking for Success: Pronunciation Improvement For Non-Native English	21.00
PRO	Thrift Savings Plan	7.00
PRO	Focus: Achieving Your Highest Priorities	7.00
PRO	Effective Listening and Memory Development	7.00
PRO	Get Control of Meetings - Webinar	1.50
SCI	Current 510(k) Sterility Review Practices	2.00
SCI	CBER & CDRH 9th Annual Best Practices Interactive Workshop for IVD	7.25

SCOL classes from 10/01/2010 to 6/30/2011		
SCI	Statistics for Diagnostic Devices	2.50
SCI	Statistics for Diagnostic Devices	2.50
SCI	CREP: Diabetes Update	3.00
SCI	Statistics for Diagnostic Devices	2.50
SCI	2010 Scientific Seminar	2.00
SCI	Statistics for Diagnostic Devices	2.50
SCI	2010 Scientific Seminar	2.00
SCI	Statistics for Diagnostic Devices	2.50
SCI	OC Journal Club - Review of Court Case Involving Medical Device Firms	1.00
SCI	Regenerative Medicine Series - Nov. 8	1.50
SCI	Statistics for Diagnostic Devices	2.50
SCI	2010 Scientific Seminar	2.00
SCI	Basic Respiratory Drug Delivery : Technologies and Frontiers	3.50
SCI	Bone Seminar Series 2011	1.00
SCI	Current 510(k) Sterility Review Practice - Part 1	1.00
SCI	Regenerative Medicine Seminar Series - Feb. 4, 2011	2.50
SCI	Current 510(k) Practices in Sterility Review - part 2	1.00
SCI	Laparoscopic Treatment of Vaginal Agenesis	1.50
SCI	Bone Seminar Series 2011	1.00
SCI	WEBINAR: Steam Sterilization Process Risk Assessment	1.00
SCI	Regenerative Medicine Seminar Series	1.00
SCI	CDRH Science Sharing Seminar - Tissue Imaging in Pathology	1.00
SCI	Bone Seminar Series 2011	1.00
SCI	CDRH Science Sharing Seminar - Tissue Imaging in Pathology	1.00
SCI	Human Factors for Medical Devices	11.00
SCI	CDRH Science Sharing Seminar - Electrical Activity in the Heart	1.00
SCI	Introduction to Biostatisics	24.00
SCI	Bone Seminar Series 2011	1.00
SCI	CDRH Science Sharing Seminar - Using Medicare Claims in Epidemiology	1.00
SCI	CDRH Science Sharing Seminar - Using Quantitative Decision Analysis	1.00
SCI	An Overview of Comparative Effectiveness Research	1.50
SCI	Comparative Effectiveness Research Tutorial	4.00
SCI	Cancer Screening: A Clash Between Intuition and Science	1.50
SCI	CDRH Science Sharing Seminar - 5/16/11 - Diagnostic Ultrasound	1.00
SCI	Benefit:Risk Sess1 Issues in Design, Monitoring, Analysis & Reporting	1.50
SCI	Benefit:Risk-Sess2 - Issues in Design, Monitoring, Analysis & Reportin	2.00
SCI	CDRH Science Sharing Seminar - 6/13/11 - Innovative Optical Methods	1.00
SCI	CDRH Science Sharing Seminar - 6/27/11 - Fluids, Goops, Solids	1.00