Agenda for Quarterly Meeting on MDUFMA / MDUFA Performance
9:00 – 11:00, Thursday, October 30, 2008
Room 020B, 9200 Corporate Blvd.

Welcome

- Welcome. Introductions, highlights from FY 2008. *Kate Cook, CDRH.*

FDA MDUFMA / MDUFA Performance — Actions through Sept. 30, 2008

- Reports on decision goals for the FY 2003 – FY 2008 cohorts.
    - CBER report: *Bob Yetter, CBER.*
    - CDRH report: *Donna-Bea Tillman, CDRH-ODE*.
    - Data on total review times (time with FDA plus time with the company) from receipt / filing to final decision for 510(k)s, PMAs and panel-track supplements, expedited PMAs and expedited panel-track supplements, and 180-day PMA supplements. Combined CBER and CDRH data. *Donna-Bea Tillman.*
    - De-identified review performance data for the branch with the shortest average review times and the branch with the longest average review times for 510(k)s, 180-day supplements, and real-time supplements. CDRH only. *Donna-Bea Tillman*.

Qualitative Update on Finances

- Update on FY 2008, FY 2008 Supplemental, and FY 2009 appropriations. *Patric Baumgartner, CDRH-OMO.*

- FY 2008 user fee receipts, compared with expectations. *Helio Chaves, FDA-OFM.*
    - Summary of overall fees collections and refunds made through September 30, with comparison to the statutory target of $48,431,000.
    - Amounts attributable to —
        - application / reporting fees, and
        - establishment registration fees.
    - Changes in user fee processing for FY 2009.

Overview of Medical Device Guidance Issued During FY 2008 Q4

- Overview of FY 2008. *Annette Marthaler, CDRH-OCD*
- Summary of guidance documents issued during the fourth quarter. *Donna-Bea Tillman, CDRH-ODE; Alberto Gutierrez, CDRH-OIVD; Bob Yetter, CBER*.

Guidance Initiatives for FY 2009

- FDA's plans for medical device guidance to be issued during FY 2009. *Annette Marthaler, CDRH-OCD.*

The Role of the Matrix at CDRH

- An overview of the role of, and our expectations for, matrix operations at CDRH. *Jonathan Sackner-Bernstein, CDRH-OCD.*

Training

- FY 2008 MDUFA-related training — *Joanne Choy, CDRH-OCER-Staff College.*

OIVD Initiatives

- Overview of key OIVD initiatives and accomplishments relating to MDUFA commitments. *Alberto Gutierrez, CDRH-OIVD.*

GAO and Congressional Oversight Relating to FDAAA

Update on recent GAO studies and FDA reports to Congress. *Phil Dejardins, CDRH-OCD.*

- GAO studies required by FDAAA —
    - GAO has completed their study of the 510(k) premarket notification process required by section 225 of FDAAA, but has not yet completed their final report. The report was due to Congress September 27, 2008.
    - On September 26, 2008, GAO issued a report, *Health-Care Associated Infections in Hospitals: Number Associated with Medical Devices Unknown, but Experts Report Provider Practices as a Significant Factor*; this report was required by section 229 of FDAAA. The report is available at: www.gao.gov/new.items/d081091r.pdf

Update on the Third-party Inspection Program

- Effects of 2007 amendments and status of our guidance revisions. *Bill Sutton, CDRH-OCER-DSMICA.*

IT

- FY 2008 IT accomplishments, plans for FY 2009 — *Paul Fisher, CDRH-OCD.*

Discussion

- General discussion, questions from industry.
- Set date for next update. Target: January 26 – 30, 2009 (no sooner than three weeks following close of FY 2009 Q1).

FY 2008 Medical Device User Fee Collections

As of September 30, 2008

Source	FY 2008 Authorized	FY 2008 Fee Revenues				Surplus (Deficit)
		Receipts	Refunds	Net	% of Expected	
Establishment Registration Fees[1]	$ 21,751,500	$ 23,708,410	$ 82,771	$ 23,625,639	108.6%	$ 1,874,139
Application / Reporting Fees[2]	$ 26,679,500	$ 26,037,989	$ 1,254,536	$ 24,783,453	92.9%	$ (1,896,047)
Uncategorized[3]		$ 322,154	$ -	$ 322,154		$ 322,154
Total[4]	$ 48,431,000	$ 49,746,399	$ 1,337,307	$ 48,731,246	100.6%	$ 300,246

Notes:

1. The Authorized revenues shown for Establishment Registration fees assume 12,750 establishments will register and pay the fee. During FY 2008, 13,849 establishments registered and paid the fee.
2. The Authorized revenues shown for Application / Reporting Fees represents the difference between total authorized fee revenues and the amount shown for authorized Establishment Registration revenues.
3. Nearly all of these amounts are believed to be attributable to establishment registration fees.
4. Total FY 2008 authorized fee revenues are specified in section 738(h)(3) of the FD&C Act.

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

FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
$21,620,549	$ 25,309,853	$31,801,091	$34,567,188	$26,893,394

Medical Device Guidance Documents
Issued During FY 2008

During FY 2008, FDA issued 38 medical device guidance documents.

Fourth Quarter (July 2008 – September 2008) — 11 Publications

Draft Guidance for Industry and FDA Staff - Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence — 09/19/2008
Available at http://www.fda.gov/cdrh/ode/guidance/1636.pdf

Guidance for Industry and FDA Staff - Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers — 09/09/2008
Available at http://www.fda.gov/cdrh/ode/guidance/560.pdf

Guidance for Industry and FDA Staff - Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment — 08/21/2008
Available at http://www.fda.gov/cdrh/osel/guidance/1685.pdf

Guidance for Industry - Medical Device Tracking; Guidance for Industry and FDA Staff — 08/15/2008
Available at http://www.fda.gov/cdrh/comp/guidance/169.pdf

Guidance for Industry and FDA Staff: Clinical Study Designs for Catheter Ablation Devices for Treatment of Atrial Flutter — 08/05/2008
Available at http://www.fda.gov/cdrh/ode/guidance/1678.pdf

Draft Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and FDA Staff - Humanitarian Device Exemption (HDE) Regulation: Questions and Answers — 08/05/2008
Available at http://www.fda.gov/cdrh/ode/guidance/1668.pdf

Guidance for Industry, FDA, and Foreign Governments - FY 2009 Medical Device User Fee Small Business Qualification and Certification — 08/01/2008
Available at http://www.fda.gov/cdrh/mdufma/guidance/2009.pdf

Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Bone Sonometers — 07/16/2008
Available at http://www.fda.gov/cdrh/ode/guidance/1547.pdf

Guidance for Industry and FDA Staff - Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves — 07/11/2008
Available at http://www.fda.gov/cdrh/comp/guidance/1141.pdf

Guidance for Industry and FDA Staff - Surveillance and Detention Without Physical Examination of Condoms — 07/11/2008

Available at http://www.fda.gov/cdrh/comp/guidance/1139.pdf

Guidance for Industry and FDA Review Staff - Intravascular Administration Sets Premarket Notification Submissions [510(k)] — 07/11/2008

Available at http://www.fda.gov/cdrh/ode/guidance/1189.pdf

Third Quarter (April 2008 – June 2008) — 9 Publications

FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Performance Assessment - Guidance for Industry and FDA Staff — 06/30/2008

Available at http://www.fda.gov/cdrh/mdufma/guidance/1218.pdf

Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Full Field Digital Mammography System — 05/30/2008

Available at http://www.fda.gov/cdrh/ode/guidance/1616.pdf

Guidance for Industry and FDA Staff: Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification (510(k)) — 05/30/2008

Available at http://www.fda.gov/cdrh/ode/guidance/1617.pdf

Draft Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters — 05/30/2008

Available at http://www.fda.gov/cdrh/ode/guidance/1608.pdf

Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Plasmodium Species Antigen Detection Assays — 05/20/2008

Available at http://www.fda.gov/cdrh/oivd/guidance/1646.pdf

Guidance for Industry and FDA Staff: Administrative Procedures for CLIA Categorization — 05/07/2008

Available at http://www.fda.gov/cdrh/oivd/guidance/1143.pdf

Guidance for Industry and FDA Staff: Hemodialysis Blood Tubing Sets – Premarket Notification [510(k)] Submissions — 04/23/2008

Available at http://www.fda.gov/cdrh/ode/guidance/1649.pdf

Guidance for Industry and FDA Staff: Investigational Device Exemptions (IDEs) for Devices Indicated for Nocturnal Home Hemodialysis — 04/15/2008

Available at http://www.fda.gov/cdrh/ode/guidance/1650.pdf

Guidance for Industry and FDA Staff: Preparation and Review of Investigational Device Exemption Applications (IDEs for Total Artificial Discs — 04/11/2008

Available at http://www.fda.gov/cdrh/ode/guidance/1637.pdf

Second Quarter (January 2008 – March 2008) — 11 Publications

Guidance for Industry: Coronary Drug-Eluting Stents— Nonclinical and Clinical Studies — 03/27/2008
Available at http://www.fda.gov/cdrh/ode/guidance/6255.pdf

Guidance for Industry: Coronary Drug-Eluting Stents - Nonclinical and Clinical Studies
(Companion to above, providing additional and more detailed guidance) — 03/27/2008
Available at http://www.fda.gov/cdrh/ode/guidance/6255comp.pdf

Expedited Review of Premarket Submissions for Devices - Guidance for Industry and FDA Staff — 02/29/2008
Available at http://www.fda.gov/cdrh/mdufma/guidance/108.pdf

Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements — 02/28/2008
Available at http://www.fda.gov/cdrh/ode/guidance/1655.pdf

Guidance for Industry: Container and Closure System Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products — 02/25/2008
Available at http://www.fda.gov/cber/gdlns/contain.pdf

Draft Guidance for Industry and FDA Staff: Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Influenza Viruses — 02/15/2008
Available at http://www.fda.gov/cdrh/oivd/guidance/1638.pdf

Guidance for Industry and FDA Staff: Coronary and Carotid Embolic Protection Devices - Premarket Notification [510(k)] Submissions — 02/15/2008
Available at http://www.fda.gov/cdrh/ode/guidance/1658.pdf

Guidance for Industry and FDA Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices — 01/30/2008
Available at http://www.fda.gov/cdrh/oivd/guidance/1171.pdf

Guidance for Industry and FDA Staff - Medical Glove Guidance Manual — 01/22/2008
Available at http://www.fda.gov/cdrh/ocer/guidance/1661.html

Guidance for Industry and FDA Staff - The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations — 01/08/2008
Available at http://www.fda.gov/cdrh/comp/guidance/1566.pdf

Guidance for Industry and FDA Staff - The Review and Inspection of Premarket Approval Applications under the Bioresearch Monitoring Program — 01/08/2008
Available at http://www.fda.gov/cdrh/comp/guidance/1602.pdf

First Quarter (October 2007 – December 2007) — 7 Publications

Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements — 12/28/2007

This edition superseded by revised guidance on 02/28/2008.

Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle — 11/29/2007

Available at http://www.fda.gov/cber/gdlns/autobldcell.pdf

Draft Guidance for Industry and FDA Staff: Impact-Resistant Lenses: Questions and Answers — 10/26/2007

Available at http://www.fda.gov/cdrh/dsmica/guidance/23.pdf

Draft Guidance for Industry and FDA Staff - In Vitro Diagnostic (IVD) Device Studies – Frequently Asked Questions — 10/25/2007

Available at http://www.fda.gov/cdrh/oivd/guidance/1587.pdf

Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Remote Medication Management System — 10/19/2007

Available at http://www.fda.gov/cdrh/ode/guidance/1621.pdf

Guidance for Industry and FDA Staff - Biological Indicator (BI) Premarket Notification [510(k)] Submissions — 10/04/2007

Available at http://www.fda.gov/cdrh/ode/guidance/1320.pdf

Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Electrocardiograph Electrodes — 10/04/2007

Available at http://www.fda.gov/cdrh/ode/guidance/1597.pdf

Documents the Center for Devices and Radiological Health is Considering for Development (FY09)

Introduction

On September 30, 2008, FDA published a Notice in the Federal Register directing the public to the list of guidance documents the Center for Devices and Radiological Health (CDRH) is considering for development in 2009. The Notice also advised the public of the location of a public docket to which comments may be submitted. (73 FR 56830)

This is the list of guidance documents CDRH is considering for development this year. CDRH plans to update this list every year. CDRH invites interested persons to submit comments on any or all of the guidance documents on the list to docket FDA-2007-N-0270. Comments may include draft language on the proposed topics and/or suggestions for new or different guidance documents. CDRH believes this docket is an important tool for receiving information from interested parties and for making information available to the public.

The list includes topics that currently have no guidance associated with them, topics where updated guidance may be helpful, and topics for which CDRH has already issued Level 1 drafts that may be finalized following review of public comments. This list of proposed guidance documents is not binding. CDRH is not required to issue every guidance document on the list and may issue guidance documents not on the list.

Current FDA and CDRH guidance documents can be found at http://www.fda.gov/cdrh/guidance.

html.

Why is CDRH posting a list of guidance documents it is considering for development?

During negotiations over the reauthorization of the Medical Device User Fee and Modernization Act (MDUFMA), FDA agreed to meet a variety of goals in return for additional funding from industry. The goals are quantitative and qualitative commitments intended to help get safe and effective medical devices to market more quickly. Among other things, FDA agreed to:

- annually post a list of the guidance documents FDA's Center for Devices and Radiological Health (CDRH) is considering for development; and
- provide stakeholders an opportunity to provide comments and/or draft language for those topics as well as suggestions for new or different guidances.

Does CDRH expect to complete the list?

Our experience over the years has shown that there are many reasons CDRH staff does not complete the entire annual agenda of guidances it undertakes. Staff are frequently diverted from guidance development to other activities, including review of premarket submissions or postmarket problems. In addition, the Center is required each year to issue a number of guidances it cannot know about in advance. These may involve newly identified public health issues as well as special control guidance documents that are necessary for the classification of de novo devices. It will be helpful, therefore, to receive comments that indicate the relative priority of different guidance topics to interested stakeholders. In addition, we intend to consider stakeholder feedback to the docket to help us prioritize our allocation of resources to specific guidance topics on the list.

How do I comment on this list or a particular guidance document?

FDA has established docket FDA-2007-N-0270 for comments on any or all of the proposed fiscal year 2009 guidance documents. FDA invites interested persons to submit comments, draft language on the proposed topics, and/or suggestions for new or different guidance documents. FDA believes this docket is an important tool for receiving information from interested parties and for making information available to the public.

Interested persons may submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Identify comments with docket number FDA-2007-N-0270. You may see received comments in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

What guidance documents is CDRH considering for development during fiscal year 2009?

CDRH is considering developing a variety of guidance documents in fiscal year 2009:

- Guidance Related to FDAAA
- Guidance on Postmarket Issues
- Device Specific Guidance
- Standards Related Guidance
- Cross-Cutting and Process Guidance

Specific topics are listed below:

Guidance Related to FDAAA

- Assay Migration Studies for IVDs
- Clinical Trials Using De-identified Leftover Specimens
- Disputes Concerning Payment or Refund of Medical Device User Fees
- Electronic Registration and Listing
- FDA and Industry Actions on Premarket Notification Submissions
- Inspection by Accredited Persons
- Tracking Pediatric Device Approvals
- User Fees and Refunds for Premarket Notification Submissions

Guidance on Postmarket Issues

- Electronic Medical Device Reporting
- Manufacturing Site Change Supplements
- Precedence on Enforcement Action Determinations

Device Specific Guidances

- Absorbable Hemostatic Devices
- Antimicrobial Susceptibility Tests
- Bacillus spp. Serological Reagents
- C. Difficile
- CAD Devices for Radiology
- Cardiac Allograft Gene Expression Profiling Test System
- Cervical Pillows for Obstructive Sleep Apnea
- Computerized Clinical Device Trials
- Contact Lens Care Products
- Coronary Drug Eluting Stents
- Dental Amalgam
- Dental Bone Grafting Materials
- Dental Mouthguards
- ECG Electrodes
- Electroconvulsive Therapy Devices
- Esophageal and Tracheal Prosthesis
- Flexible Sterilization Packaging and Rigid Sterilization Containers
- Full Field Digital Mammography
- Germicides Used to Reprocess Reusable Hemodialysis Systems

- Guidance on Instruments (IVD)
- Heart Valves - IDE and PMA Applications
- Hip Joint Replacement Systems
- Home Prothrombin Time
- Human Metapneumovirus (hMPV) Nucleic Acid Assays
- Human Papilloma Virus
- IDEs for Symptomatic Uterine Fibroid Devices
- Impact Resistant Lenses
- Infusion Pumps
- Invasive Portable Blood Glucose Monitoring Systems
- IVDs for Detection and Differentiation of Influenza Virus
- LASIK Patient Labeling
- Leeches
- Maggots
- Neurocognitive Assessment for Cardiovascualr Devices
- Nucleic Acid Assay for Detection and Differentiation of Influenza A Virus Subtypes
- Nucleic Acid Amplification Assays for the Detection of Enterovirus RNA
- Over the Counter (OTC) One-lead Electrocardiography (ECG) Devices
- Oxygen Regulators and Oxygen Conserving Devices
- Pacemaker Lead Adaptor 510(k) Submissions
- Pacing Leads
- Powered Muscle Stimulators
- Powered Wheelchairs
- PTCA (Percutaneous Transluminal Coronary Angioplasty) Devices
- Pulse Oximeters Submissions
- Radio-Frequency Wireless Technology in Medical Devices
- Respiratory Viral Panel Multiplex Nucleic Acid Assay
- Retina Prostheses – Preclinical and Clinical Studies
- Stereotaxic Devices
- Surgical Ablation Treatment of Atrial Fibrillation – clinical studies
- Therapeutic Drug Monitoring
- Tissue Expander
- Topical Oxygen Chamber for Extremities
- Vascular Grafts

Standards Related Guidances

- Use of IEC 60601-1 Third Edition in Applications
- Use of IEC Standard(s) for Ultrasound Therapy Systems
- Use of ISO 13485 Audits
- Use of ISO 14155 in Clinical Device Trials

Cross-Cutting and Process Guidance

- 510(k) Paradigm
- Adverse Event Reporting for IVDs
- Annual Reports for PMAs

- Bayesean Statistics
- CDRH Enforcement Discretion
- Electronic Premarket Statistical Data Submissions to CDRH
- Exports - General Guidance
- IVD Studies - General Guidance
- Live Case Presentations During IDE Clinical Trials
- Medical Devices that Include Antimicrobial Agents
- Modifications to PMA Devices
- Nucleic Acid Based In Vitro Diagnostic Devices for Detection of Microbial Pathogens
- Preamendment Status Determination
- Pre-IDE guidance for IVDs
- Premarket Review of Devices Labeled for Home Use
- Requests for Information Under Section 513(g)
- Research Use Only - General Guidance
- Reusable Medical Devices- Labeling for Reprocessing in Healthcare Facilities
- Risk Management Information in Premarket Submissions
- Sex Differences in Clinical Evaluation of Cardiovascular Devices
- Sterile Devices in Premarket Notification Submissions
- Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance

Updated October 3, 2008

Role of the Matrix at CDRH

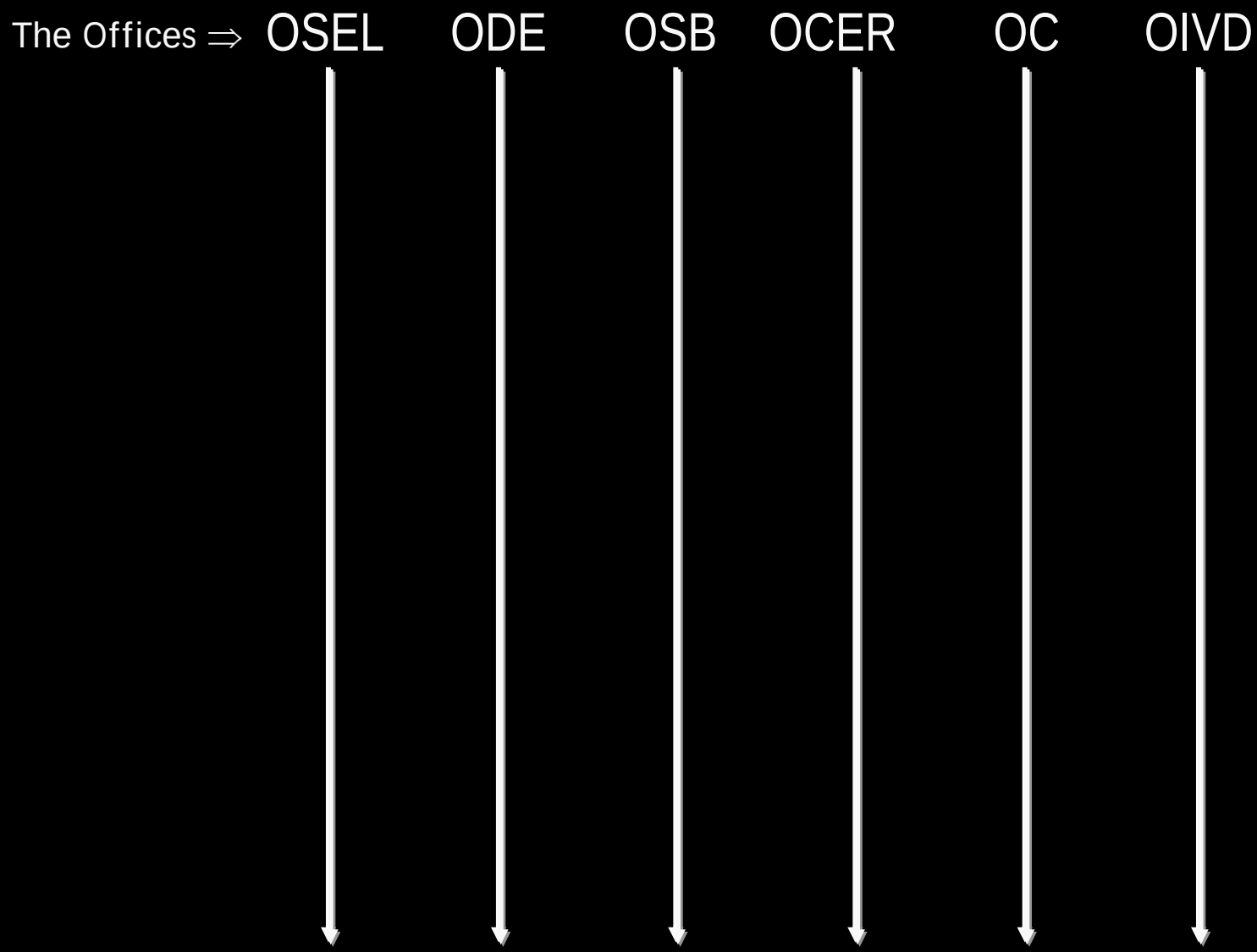
Jonathan Sackner-Bernstein, M.D.
Associate Director, Post Market Operations
Center for Devices and Radiological Health

October 2008

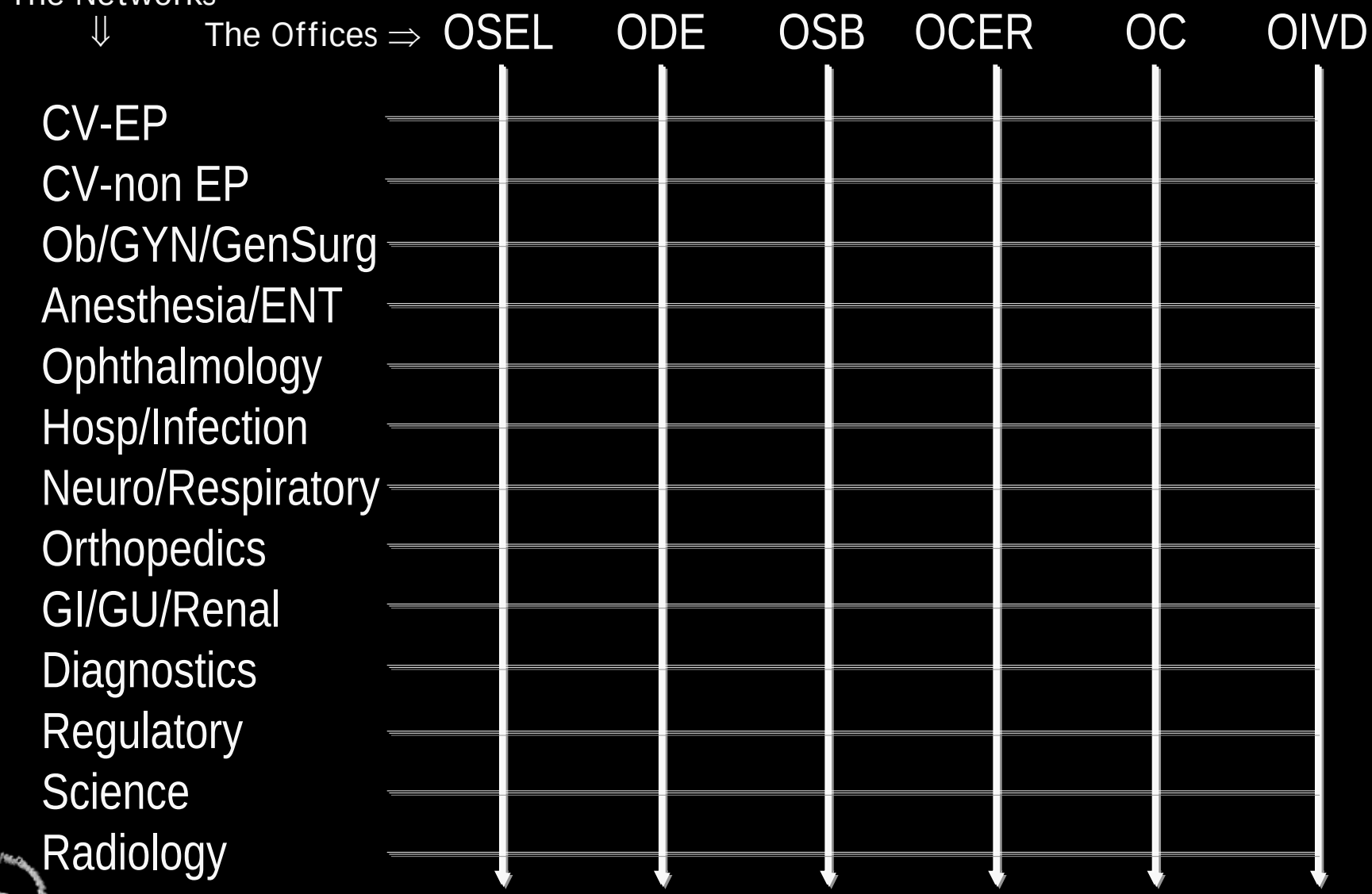
CDRH FY 2009 Priorities

- Develop and begin implementing a CDRH Import Safety Strategy
- Continue implementation of postmarket transformation, including successful integration of the Matrix into CDRH daily activities
- Improve product access through continued implementation of the Food and Drug Administration Amendments Act
- Successfully transition all CDRH operations to White Oak Campus
- Develop and implement a state-of-the-art knowledge management strategy that maximizes the potential of every CDRH employee and advances every aspect of the Center's mission

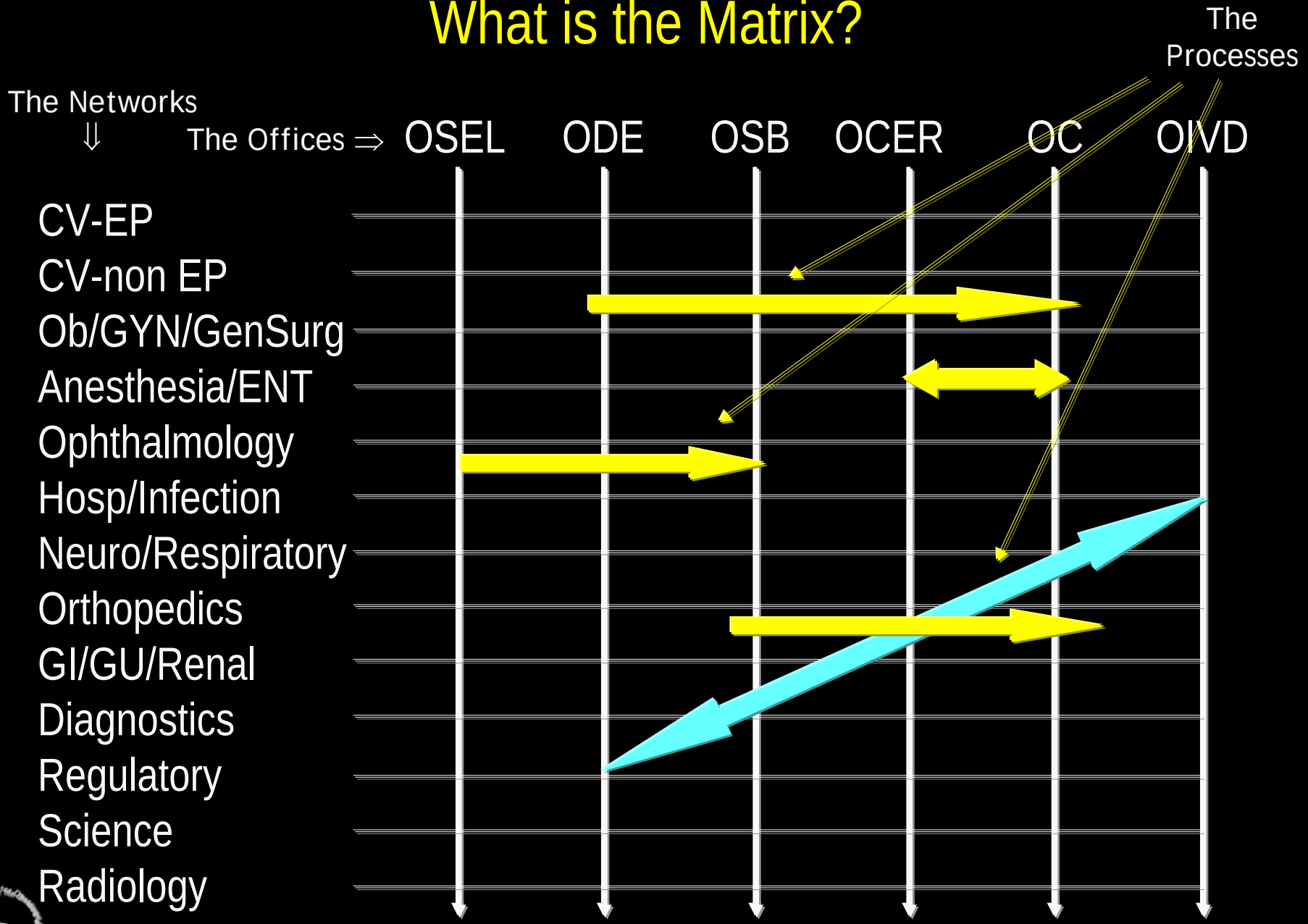
What is the Matrix?



What is the Matrix?



What is the Matrix?



Impact of the Matrix on CDRH and Stakeholders: Facilitation and a New Culture

- Protect
- Advance
- Inform

Impact of the Matrix on CDRH and Stakeholders: Facilitation and a New Culture

- Protect
  - OSCS-Heparin & Oxygenators for CABG
- Advance
  - JDRF – Artificial Pancreas
- Inform
  - Surgical Mesh – Use Specific Information

FY '08 Staff College Internal Training Summary Report

From 10/01/2007 to 09/30/2008

As of: **10/21/2008**

FY 2008 1st through 4th Quarter MDUFA-Related Training

FDA continues to invest in internal and external training opportunities supporting the medical device review process. CDRH's Staff College is a premier workforce development organization that designs and delivers training opportunities to meet the science, law, leadership and professional development needs of CDRH staff.

Table X attached provides a summary of internal training conducted between October 1, 2007 and September 30, 2008. The data shows 191 Staff College training courses and seminars focused on reviewer training, new scientific technologies, law, regulation and guidance updates or leadership and professional development designed to improve the device review process and support MDUFA goals and activities.

The remaining charts illustrate that 970 of the 1100 CDRH staff attended an average of 5 internal Staff College learning events representing approximately 23,000 contact hours. CDRH also had opportunities to attend other learning events with a focus on science and application review. Examples of these opportunities include:

- Office of Science and Engineering Laboratories Science Seminars;
- Office of Device Evaluation Vendor Days;
- Information Technology Training for Premarket and Postmarket Databases;
- Office of Compliance/Office of Surveillance and Biometrics/ODE Collaborative Reviewer;
- Advanced Biophotonics and Nanobiophotonics Seminar Series;
- Computerized Systems Used in Clinical Investigations (external training); and,
- Quality Systems Requirements and Industry Practices (external training).

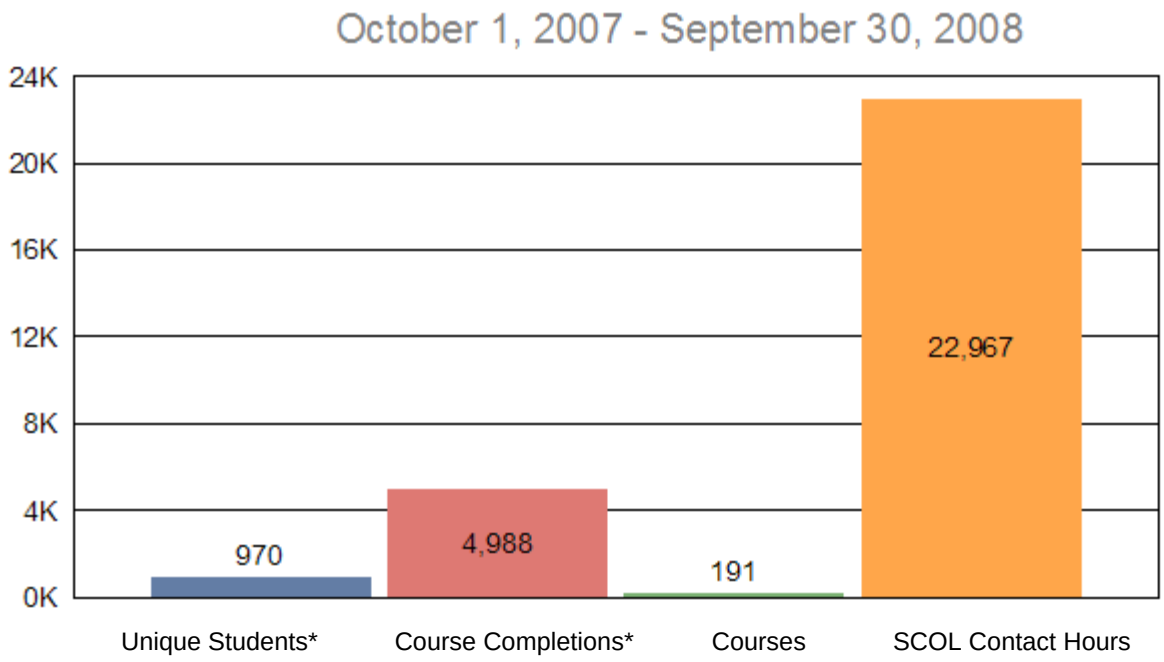
In addition to the formal internal and external training opportunities, that CDRH provides staff, reviewers are provided informal training to assist with the application review process. These opportunities include:

- An assigned mentor within the branch or division;
- 24x7 webcasts; relevant to reviewers;
- Guidance Documents;
- Sample Reviews via the Image Database; and,
- Filing & Closeout Checklists.

Table X: MDUFA FY 08 CDRH Staff College Internal Training

Topical Area	*# of Courses*	*Total # of Participants*	*Examples of Internal Training Conducted/Attended Between October 1, 2007 – September 30, 2008*
Science (SCI)	73	1,869	--The CDRH Software Education Program – Modules 3-6 (14 Modules Total) --CDRH Ophthalmic and ENT Network Education Series – Sessions 1-5 of 8 --Electromagnetic Compatibility – Lecture & Lab Tour --Statistics for Clinical Trials --Meet the Experts: Cardiovascular, Asymptomatic and Symptomatic Carotid Artery Stenosis --Clinical Update in Cardiology --History of Medical Devices --Epidemiology Grand Rounds --Finite Element Analysis --Neurology Grand Rounds --Atrial Fibrillation and Drug Therapies
Regulatory and Law (LAW)	34	1,226	--MDUFMA II: Performance Goals and Interactive Review Guidance Training --510(k) Essentials Hands-on Exercise --Deficiency Writing: 4-Part Harmony --Good Guidance Practices Refresher Course --Medical Device Law --Product Codes --Intro to Medical Device Software Risk --From Enforcement to Recalls and Beyond: The Office of Compliance Explained --Advanced Topics in Regulatory Issues
Leadership Education & Development (LED)	22	371	--Leadership Forum -Judgment – How Winning Leaders Make Great Calls -Human Resource Practices for Supervisors -Behavioral Based Interviewing --Leadership Readiness Program -Critical Conversations -Effective Presentations
Professional Development (PRO)	62	1,522	--Achieving Oral Communication --Speaking Under Fire --Organizational Awareness --Creating an Environment and Culture of Collaboration --Effective Facilitation --Building a Winning Scientific and Technical Team --Critical Thinking
TOTAL	**191**	**4,988**	

FY '08 Completion Summary Data for CDRH Staff College Internal Learning Events



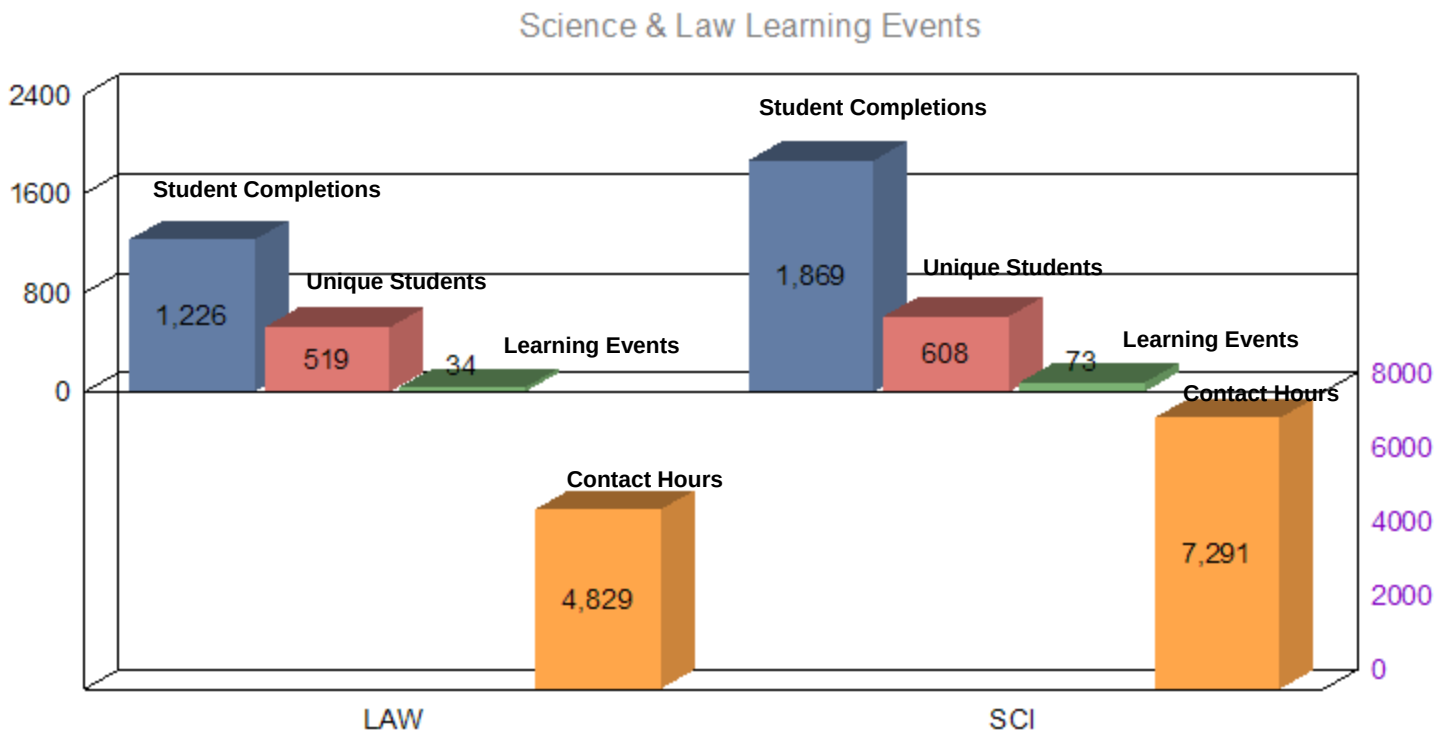
*Course Completions = Successful attendance in a Learning Event

*Unique Students = Number of distinct students

Data date 10/21/2008

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

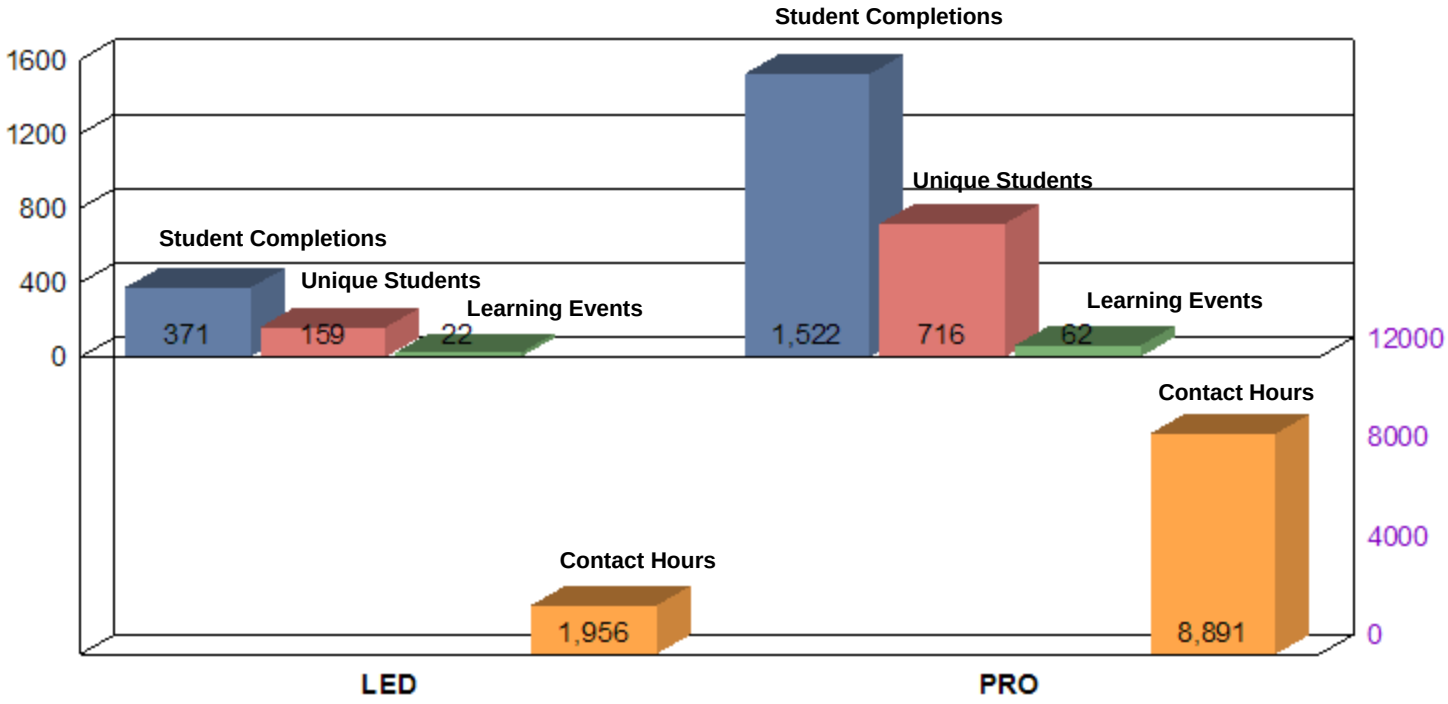
CDRH FY '08 Internal Training Summary October 1, 2007 - September 30, 2008



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

CDRH FY '08 Internal Training Summary October 1, 2007 - September 30, 2008

Leadership & Professional Development Learning Events

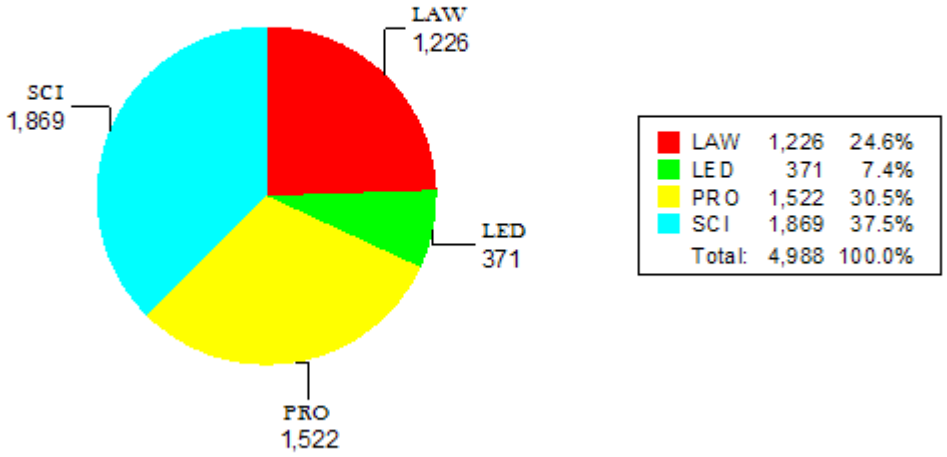


Key: LAW = Law & Policy, LED = Leadership,
PRO = Professional Development, SCI = Science

.

CDRH Total Distribution FY 08 October 1, 2007 - September 30, 2008

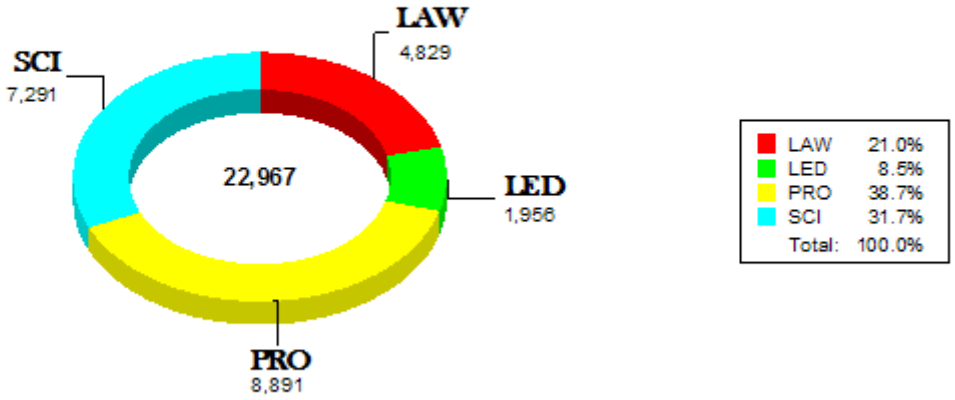
Student Course Completion by Category*



*Course Completions = Successful attendance in a Learning Event

CDRH Total Distribution FY 08 October 1, 2007 - September 30, 2008

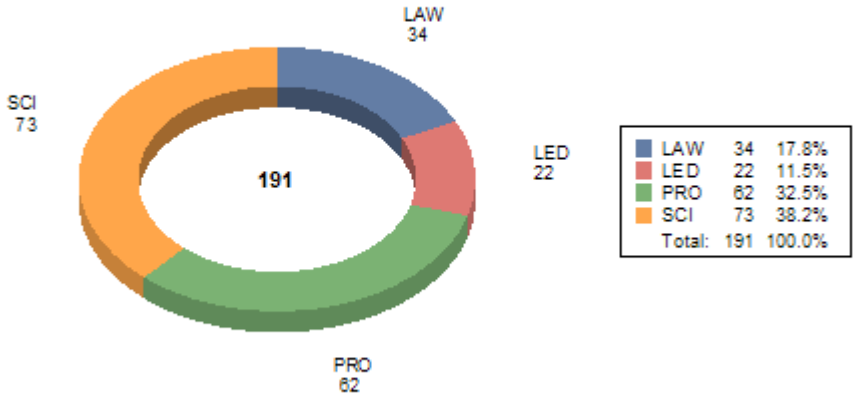
Contact Hours by Category



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

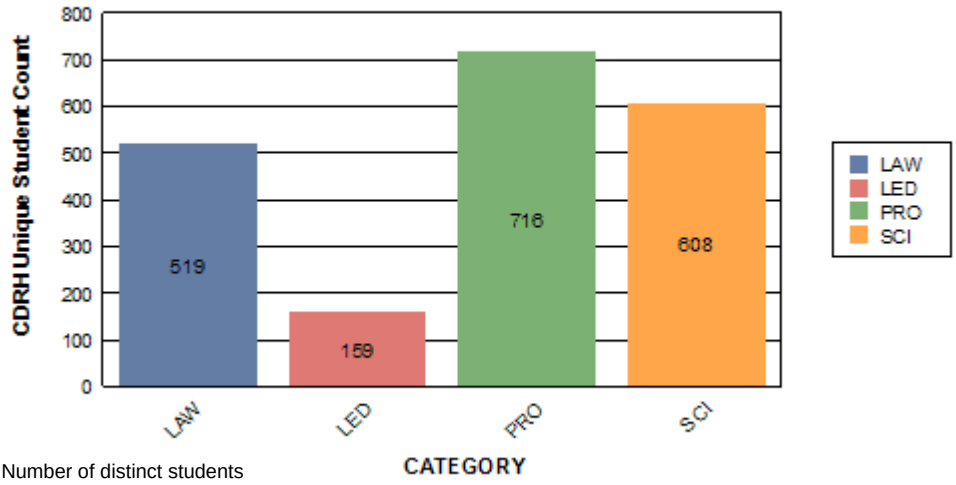
CDRH Total Distribution FY 08 October 1, 2007 - September 30, 2008

Staff College Learning Events by Category



CDRH Total Distribution FY 08 October 1, 2007 - September 30, 2008

Unique Student Count by Category*



*Unique Students = Number of distinct students

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

FDAAA of 2007
MDUFMA II

Update Accredited Persons (AP) Inspection Program

October 30, 2008

Bill Sutton

Deputy Director

Division of Small Manufacturers, International and Consumer Assistance (DSMICA)

Accredited Persons (AP) Inspection Program

UPDATE October 2008

- **Authorized under MDUFMA of 2002**
- ***Amended by FDAAA of 2007***
  (FDAAA changes in Yellow)

Background

- FD&C act requires that FDA inspect manufacturers of Class II and III devices at least once every two years.
- FDA's ability to conduct biennial inspections has diminished with decreasing resources and the significant growth of the device industry.

Background (cont.)

- MDUFMA amended Section 704 of the FD&C act to authorize FDA-accredited third parties to perform certain biennial inspections in lieu of FDA.
- ***FDAAA streamlines the MDUFMA third party amendments.***
- API program is voluntary and offers eligible manufacturers the option of being inspected by an AP, for a fee, or by FDA.

Background (cont.)

- **FDA granted accreditation to 17 of 23 organizations that applied.**
- **16 organizations are currently active.**
- **8 Accredited Persons have at least 1 auditor that is eligible to conduct independent inspections.**
- **http://www.fda.gov/cdrh/ap-inspection/ap-inspection.html#list**

Is My Establishment Eligible?

- Most recent inspection is NAI or VAI.
- Produces at least one device marketed in the U.S. and at least one device intended to be marketed in a foreign country.
- AP you wish to use is recognized by at least one foreign country where device is to be sold.

Primary Features of the Program

- Process for inspection
  - Eligible establishment selects AP from list
  - Negotiates fee (not FDA funded)
  - *Notifies FDA that they plan to use a specific AP*
  - *No FDA denial or requests for compliance data within 30 days = permission to use the AP*
  - AP assesses quality system & determines compliance
  - AP prepares/submits report to FDA
  - FDA makes final classification

Notification to FDA, Office of Compliance (CDRH or CBER)

- *State intention to use an AP to conduct establishment inspection.*
- *Provide date of the last inspection and the inspection classification.*
- *Identify the AP intended to be used.*
- *Certify that the establishment produces at least one domestically marketed device, and one device exported to a country that recognizes the AP intended to be used.*

Current Guidance Documents

- **Oct. 4, 2004 – Implementation by Inspection of Accredited Persons. Guidance for Third Party Organizations *(Revision In Process)***
- **Sept. 15, 2005 – Request for Inspection by Accredited Persons *(Revision In Process)***
- **http://www.fda.gov/cdrh/ap-inspection/apguidance.html**

AP Inspections Conducted

- 79 Total 3P Joint Inspections
  - 32 under the U.S./EC MRA
  - 47 under the AP for Inspection Program
- 15 Total Independent Inspections:
  - 7 in U.S.
  - 8 in Foreign Counties

Next Steps

- Div. of Field Investigations will continue to work with District Offices to schedule training inspections.
- FDA will continue to promote this program.
- AP for Inspection Homepage at: http://www.fda.gov/cdrh/ap-inspection/ap-inspection.html

Questions?

Division of Small Manufacturers, International and Consumer Assistance (DSMICA)

- www.fda.gov/cdrh/industry/support/
- Email: DSMICA@FDA.HHS.GOV
- Fax: 240-276-3151
- Phone: 240-276-3150 or 800-638-2041