

# FY '10 Staff College Internal Training Summary Report

From 10/01/2009 to 03/31/2010



As of: 04/09/2010

## FY 2010 1<sup>st</sup> and 2<sup>nd</sup> Quarter 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. We began providing continuing medical education units for particular courses to enable Center medical officers opportunities to stay current in relevant knowledge for maintenance of continuing education requirements. To date, we have provided up to 72 CME's and continue to seek additional opportunities to provide more in upcoming courses.

Table X provides a summary of internal training conducted between October 1, 2009 and March 31, 2010. Ninety-six 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 757 of the 1264 CDRH staff attended an average of 2 internal Staff College learning events representing 15,934 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 Science and Engineering Laboratories Science Seminars
  - Office of Device Evaluation Vendor Days
  - Office of Compliance Internal Training
  - Office of Surveillance and Biometrics Internal Training

In addition to the formal internal and external training opportunities for staff, reviewers are given 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; and,
- Guidance Documents/Sample Reviews via the Image Database/Filing and Closeout Checklists.

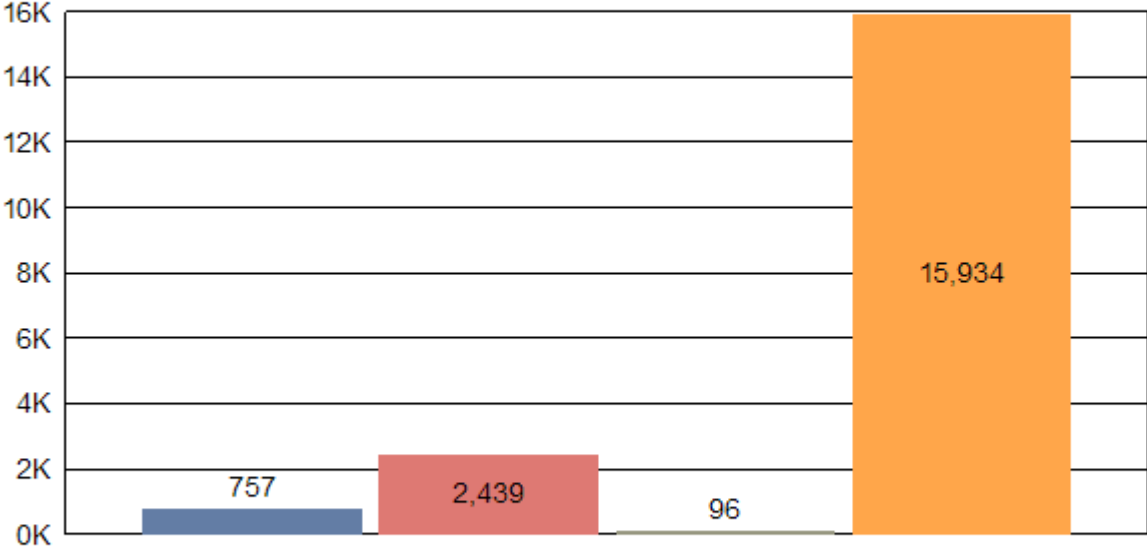
Table X: MDUFA FY 10 CDRH Staff College Internal Training

<i>Topical Area</i>	<i># of Learning Events</i>	<i>Total # of Participants</i>	<i>Examples of Training Conducted/Attended Between 10/1/09 - 3/31/10</i>
<i>Regulatory and Law (LAW)</i>	<b>19</b>	<b>504</b>	<ul style="list-style-type: none"> <li>• Reviewer Training 510(k) Essentials</li> <li>• Food and Drug Law</li> <li>• Medical Device Law</li> <li>• Deficiency Writing 4-Part Harmony in Practice</li> <li>• TPLC Data Integration and How to Use It</li> <li>• AAMI's Integrating Risk Management</li> </ul>
<i>Science (SCI)</i>	<b>30</b>	<b>1261</b>	<ul style="list-style-type: none"> <li>• Advanced Decision Analysis</li> <li>• Benefit-Risk Preferences for Regulatory Decision-making</li> <li>• Medical Device Epidemiology and Surveillance Systems</li> <li>• Finite Element Analysis for Lead Reviewers</li> <li>• Development of Closed Loop Drug Delivery Devices</li> <li>• Introduction to Biostatistics</li> <li>• Absolute Risk Prediction</li> <li>• Post-operative Adhesions Materials to Prevent Their Formation</li> </ul>
<i>Leadership Education and Development (LED)</i>	<b>10</b>	<b>143</b>	<ul style="list-style-type: none"> <li>• Critical Communication Skills: Teambuilding and Collaboration</li> <li>• Managing and Motivating People</li> <li>• FDA HR Practices for Managers and Supervisors</li> <li>• Fire Them Up!: Communication Skills for Managers</li> <li>• Leadership Skills for Non-managers</li> </ul>
<i>Professional Development (PRO)</i>	<b>37</b>	<b>531</b>	<ul style="list-style-type: none"> <li>• Critical Decision-making</li> <li>• Conflict Resolution</li> <li>• Effective Briefings</li> <li>• Advanced Facilitation Skills</li> </ul>

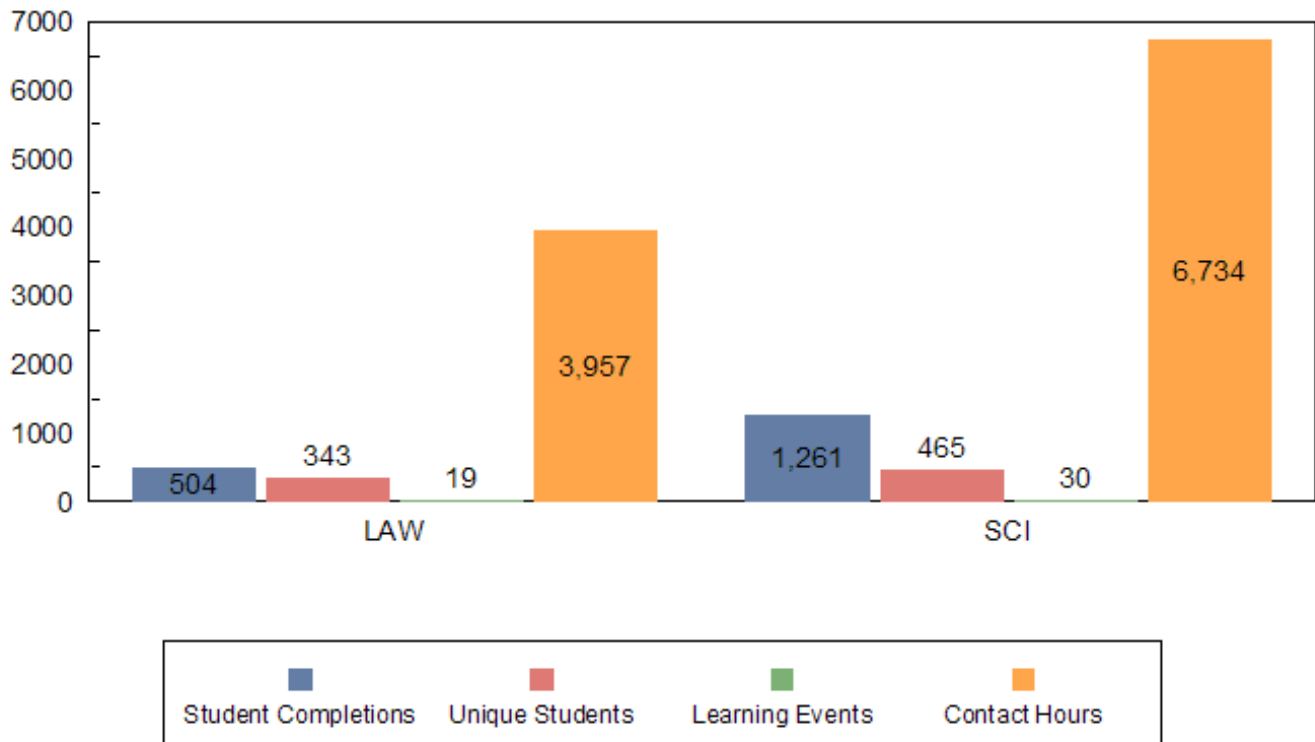
			<ul style="list-style-type: none"> <li>• Introduction to Interest-based Negotiations</li> <li>• Creativity and Innovation in Problem-solving</li> <li>• Dangerous Documents</li> </ul>
<b><i>TOTAL</i></b>	<b>96</b>	<b>*757</b> Unique participants	*Number represents unique students overall. Unique students equate to an individual being counted only once within the reporting time period.

**FY '10 Completion Summary Data for CDRH Staff College Internal Learning Events**

October 1, 2009 - March 31, 2010

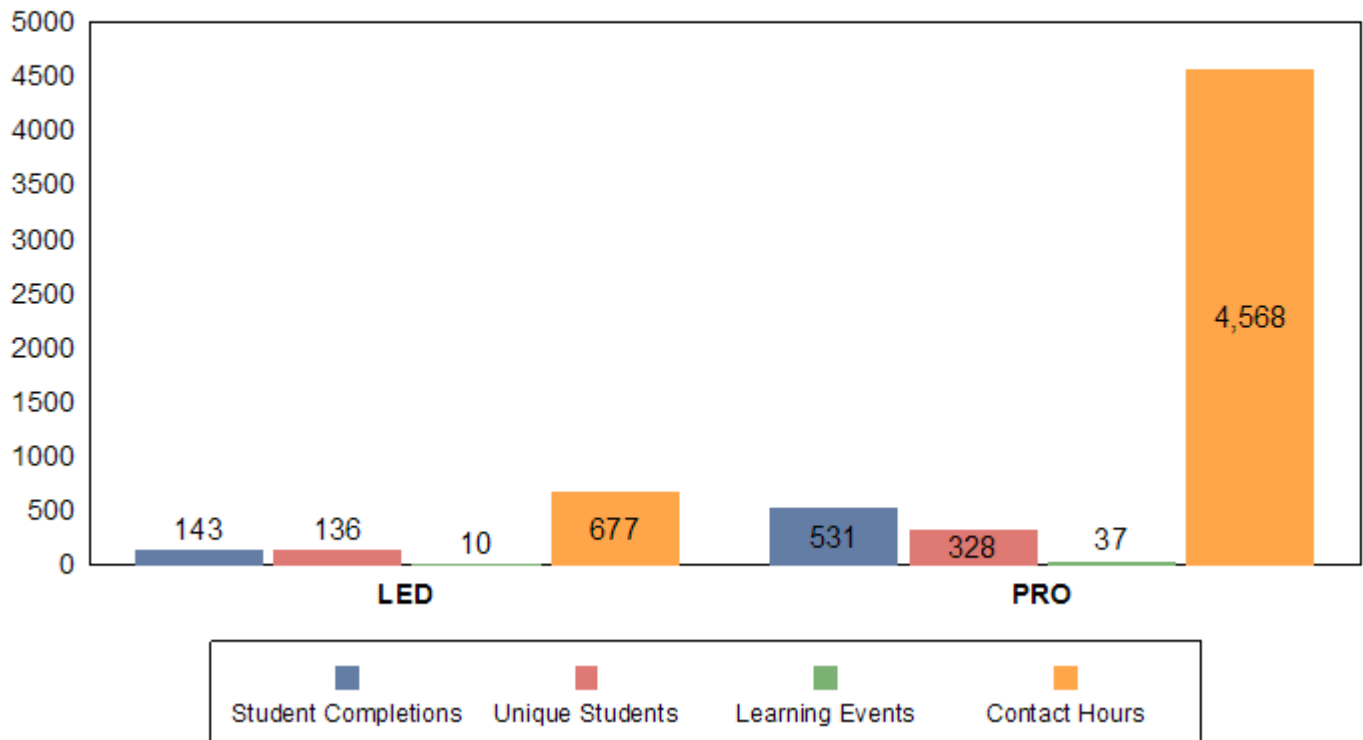


**CDRH FY '10 Internal Training Summary October 1, 2009 - March 31, 2010**  
Science & Law Learning Events



### CDRH FY '10 Internal Training Summary October 1, 2009 - March 31, 2010

#### Leadership & Professional Development Learning Events



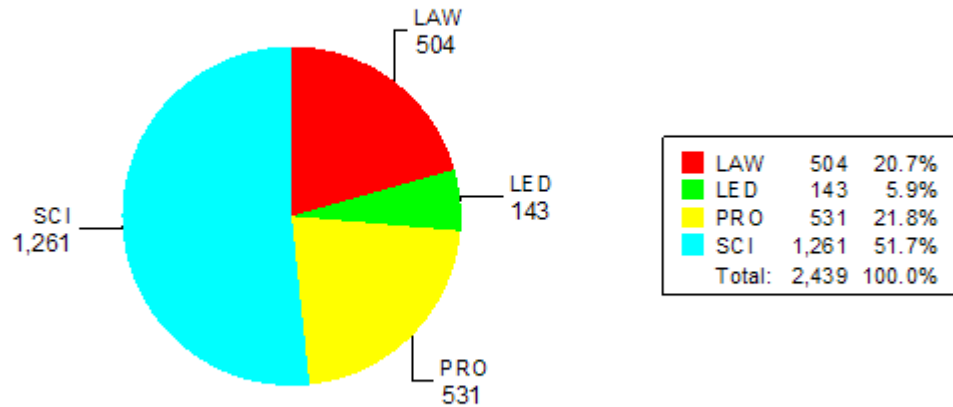
FY' 10 Total Unique Students attending Internal Learning Events by Office, Quarter and Cumulatively

<b>Offices</b>	<b>Q1</b>	<b>Q1 &amp; Q2</b>	<b>Q1,Q2&amp;Q3</b>	<b>Q1,Q2,Q3&amp;Q4</b>
<b>OC</b>	53	85		
<b>OCD</b>	14	24		
<b>OCER</b>	48	77		
<b>ODE</b>	172	244		
<b>OIVD</b>	55	74		
<b>OMO</b>	9	36		
<b>OSB</b>	90	127		
<b>OSEL</b>	53	90		
<b>FY-10 Total Unique Student Count</b>	<b>494</b>	<b>757</b>		



CDRH Total Distribution FY 10 October 1, 2009 - March 31, 2010

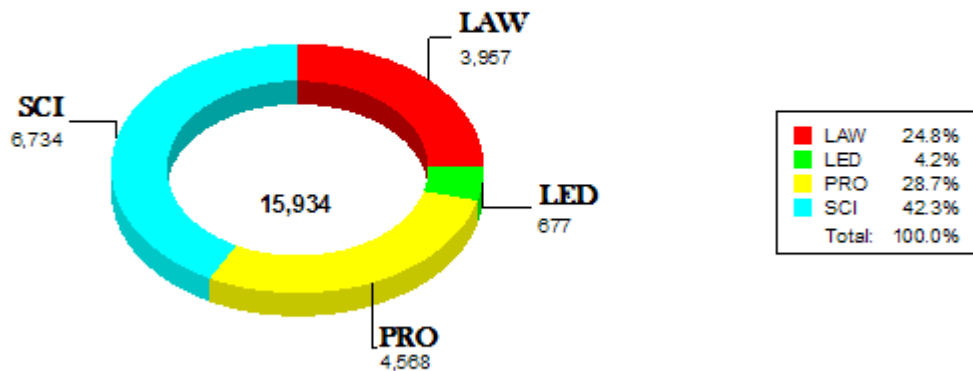
### Student Course Completion by Category\*



\*Course Completions = Successful attendance in a Learning Event

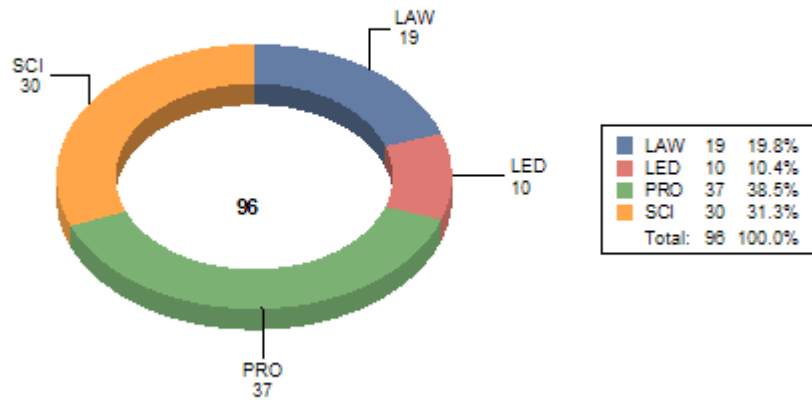
CDRH Total Distribution FY 10 October 1, 2009 - March 31, 2010

### Contact Hours by Category



PRO - Professional Development, SCI - Science

CDRH Total Distribution FY 10 October 1, 2009 - March 31, 2010  
**Staff College Learning Events by Category**



CDRH Total Distribution FY 10 October 1, 2009 - March 31, 2010

**Unique Student Count by Category\***

