



OIR Update

IVD Roundtable

May 30, 2014

Don St.Pierre



Outline

- CDRH Priorities
- OIR – Organizational Update
- MDUFA III
- PMA / De novo Approvals
- Meetings
- Guidance
- Postmarket Update

CDRH 2014-2015 Priorities

- *Strengthen the Clinical Trial Enterprise*
 - Reduce cycles/Increase early feasibility & FIH
 - Expand interactions/Better PreSub utilization
- *Strike the Right Balance Between Premarket & Postmarket Data Collection*
 - EAP/Pre-Post Balance/LB considerations
- *Provide Excellent Customer Service*
 - Customer Survey/Staff Training



OIR Staff Training

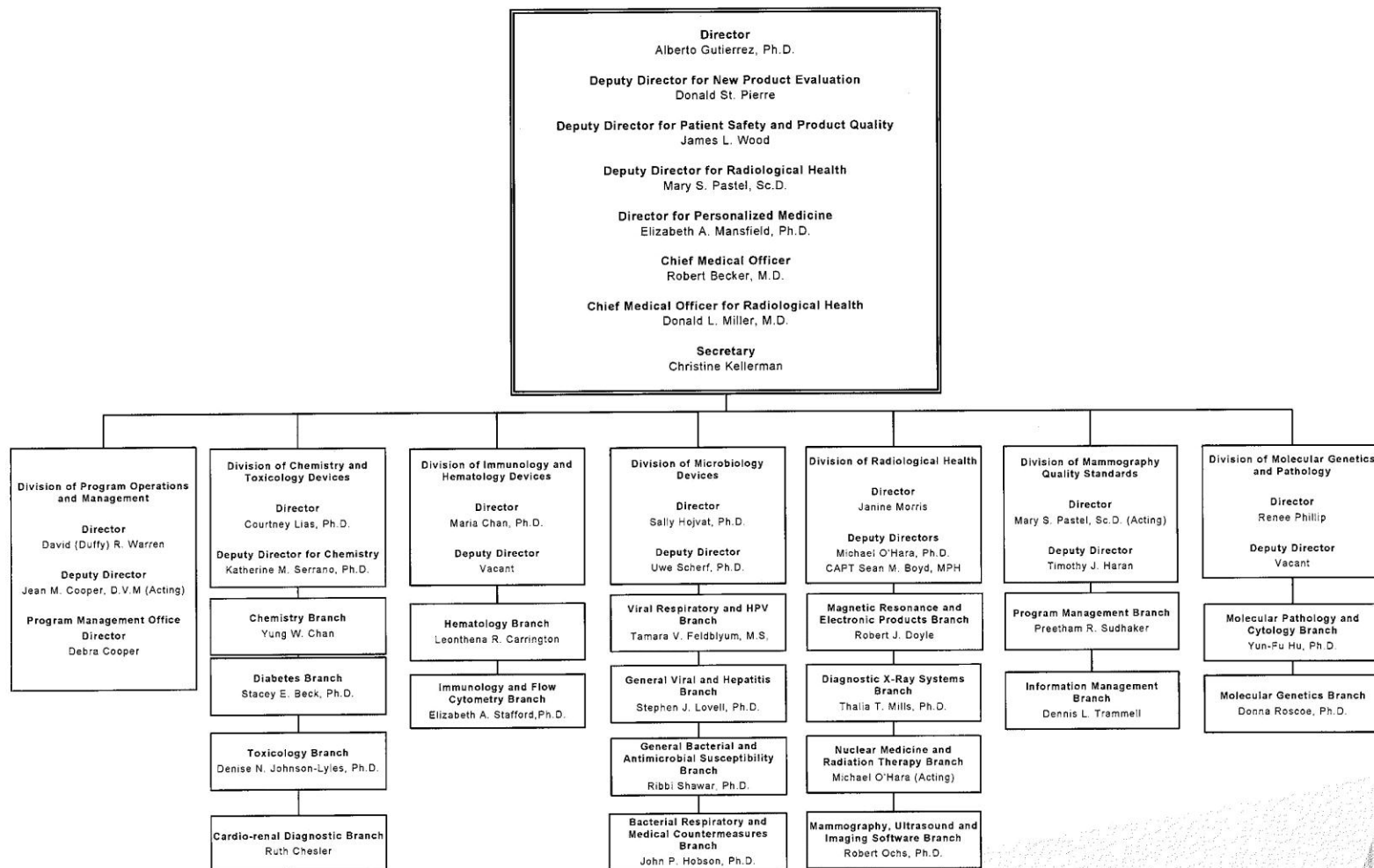
- Mentors
- Product Specialists
- Supervisory QC
- Internal training
- Working Group/Branch/Division/ Office mtgs
- Go-To Group
- DPOM
- Staff College – RCP, LRP, ELP, LEAD
- Travel / Conferences



Organizational Update

- Approx. 265 staff
- 6 management vacancies
 - 3 now / 3 later
- Still hiring to backfill vacancies

Office of In Vitro Diagnostics and Radiological Health (OIR)



MDUFA III status

- Quarterly reports
 - google – mdufma performance reports
 - Everything you wanted to know, but were afraid to ask
- So far all looks good....
- Independent Assessment

CY 2014 Original/PTS PMA Approvals

- Roche cobas HPV Test – P100020/S008
- Roche Elecsys HBeAg Immunoassay – P130015
- Dexcom G4 PLATINUM (Pediatric) Continuous Glucose Monitoring System – P120005/S002
- Qiagen *therascreen* KRAS RGQ PCR Kit– P110027



CY2014 Denovos

| | |
|---|---------|
| Affymetrix CytoScan® Dx Assay | K130313 |
| Prostate Immobilizer Rectal Balloon (Radiology) | K132194 |
| Quidel Lyra™ Direct HSV 1 + 2/VZV Assay | K133448 |
| Focus Simplexa™ HSV 1 & 2 Direct | K133621 |
| Quidel Lyra Direct Strep Assay | K133883 |



CY2014 OIR Guidances

- Administrative Procedures for CLIA Categorization (final)
- Class II Special Controls Guideline: John Cunningham Virus Serological Reagents (final)
- Blood Glucose Monitoring Systems for Prescription Point-of-Care Use (draft)
- Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use (draft)
- Surveying, Leveling, or Alignment Laser Products (draft)



Select CY2014 CDRH Guidances

- Premarket Assessment of Pediatric Devices (final)
- HDE Q&A (draft)
- PreSub Guidance (final)
- Q&A on eMDR (final)
- Annual Reports for PMAs (final)
- EAP (draft)
- Premarket/ Postmarket Balance (draft)
- Types of Communications (final)
- Voluntary Consensus Standards (draft)



Notable CY2014 Meetings

OIR

Advisory Panels: March 12 – HPV
 March 26 – Epigenomics
 March 27 – Exact Sciences

Public Workshop – Advancing Regulatory Science for High Throughput Sequencing Devices for Microbial Identification and Detection of Antimicrobial Resistance Markers

Non-OIR

Public Workshop – Health IT

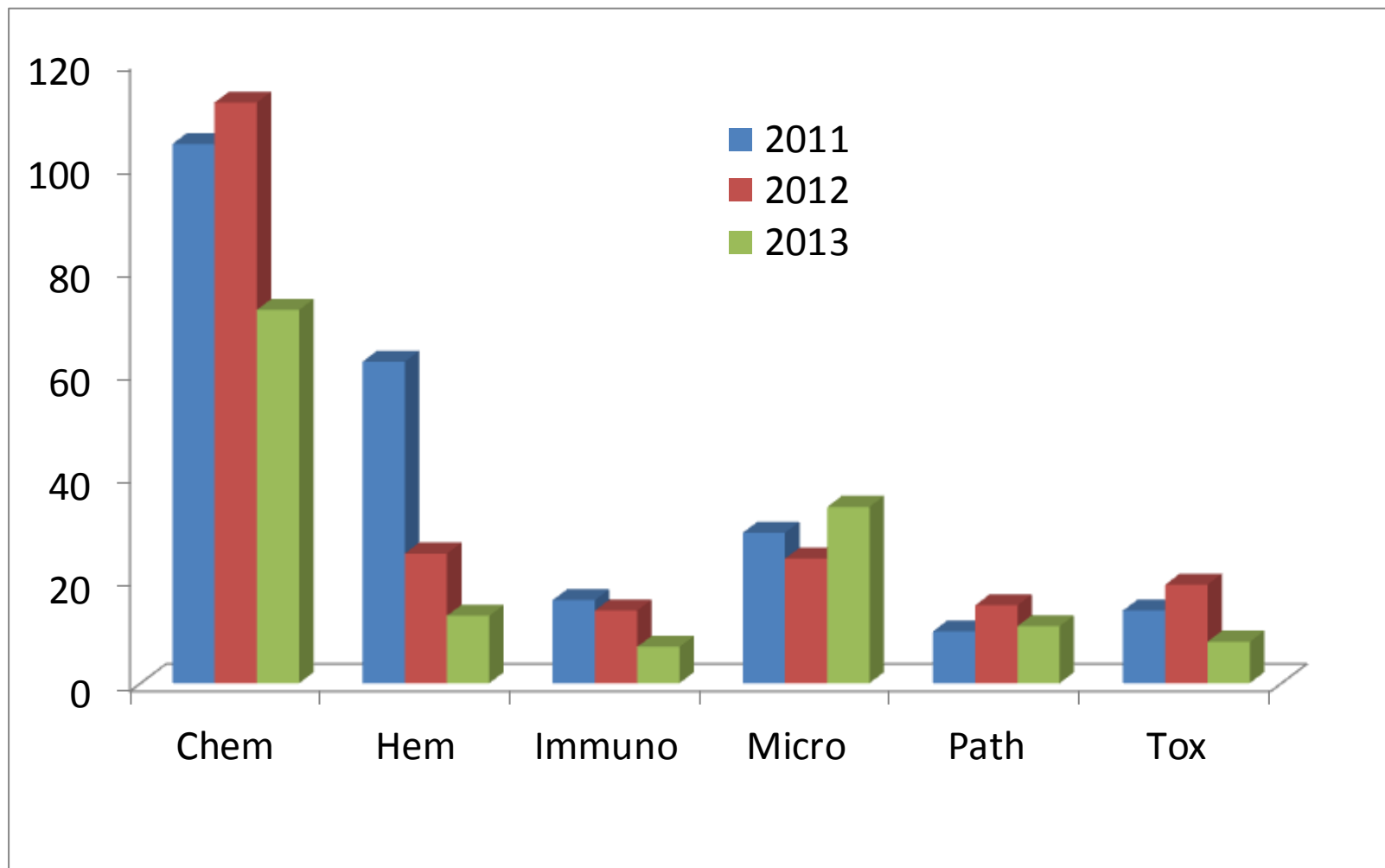
Upcoming Workshop – CDRH Guidance Development and Prioritization (June 5)

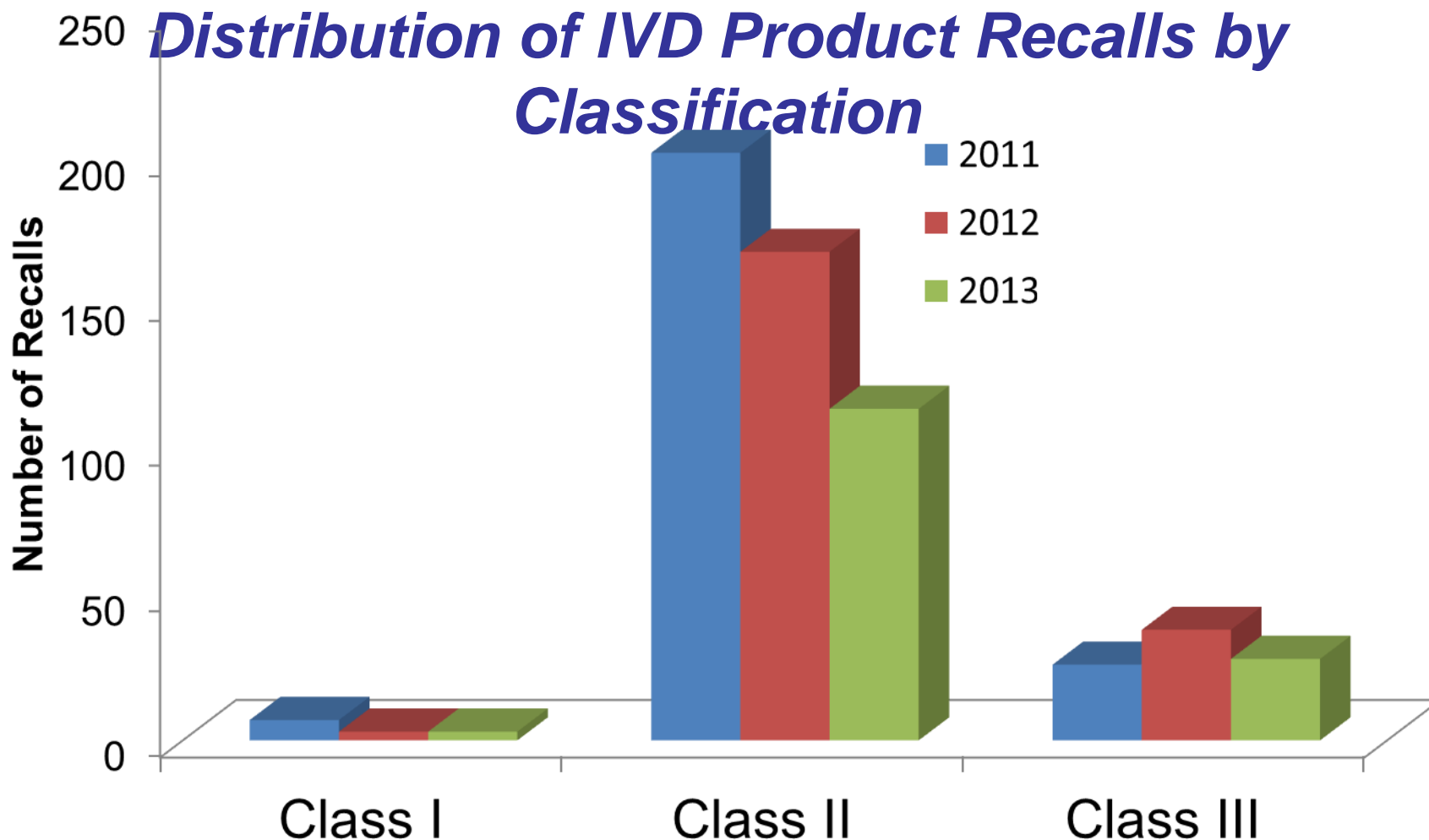


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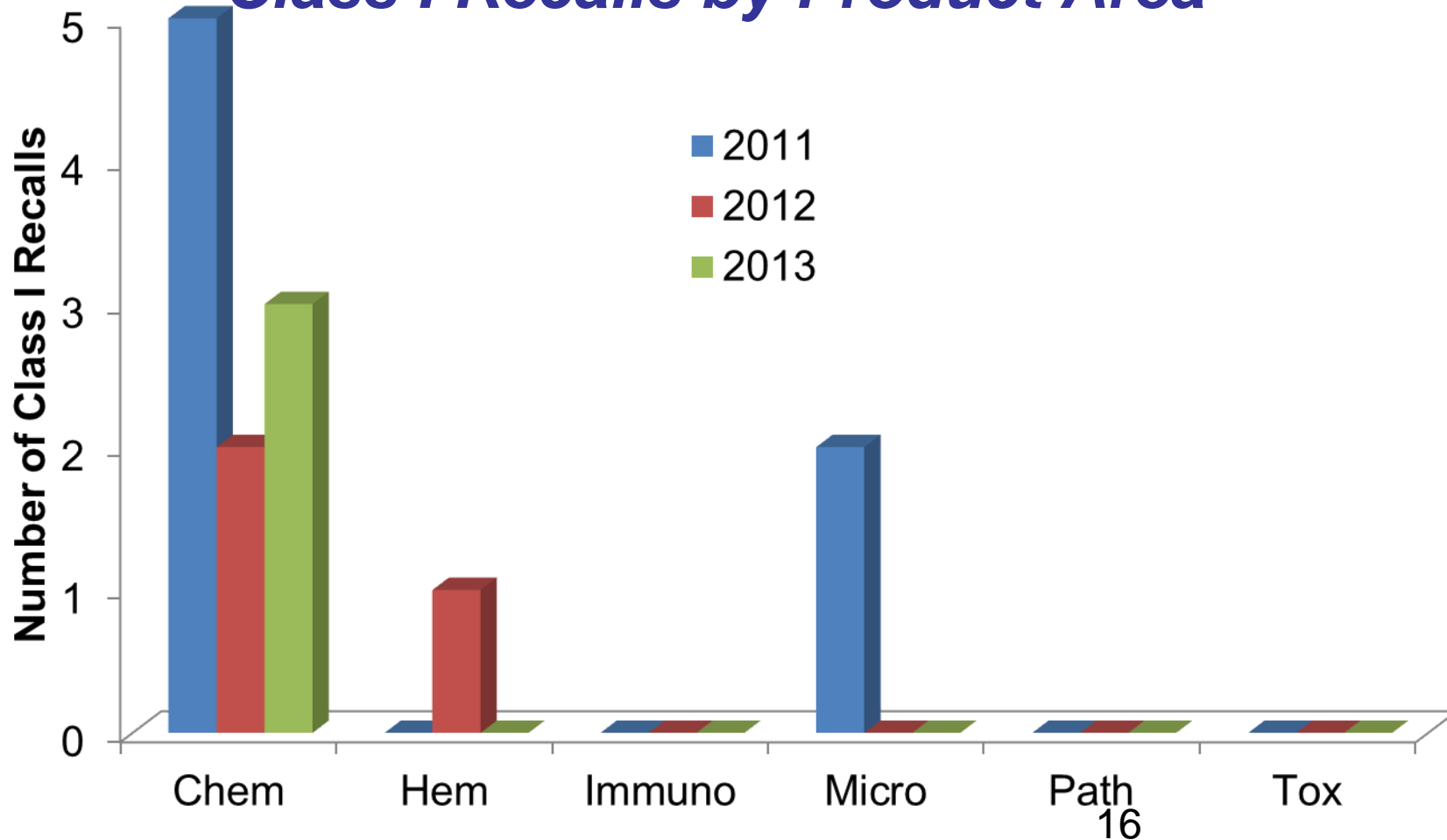
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Postmarket Update





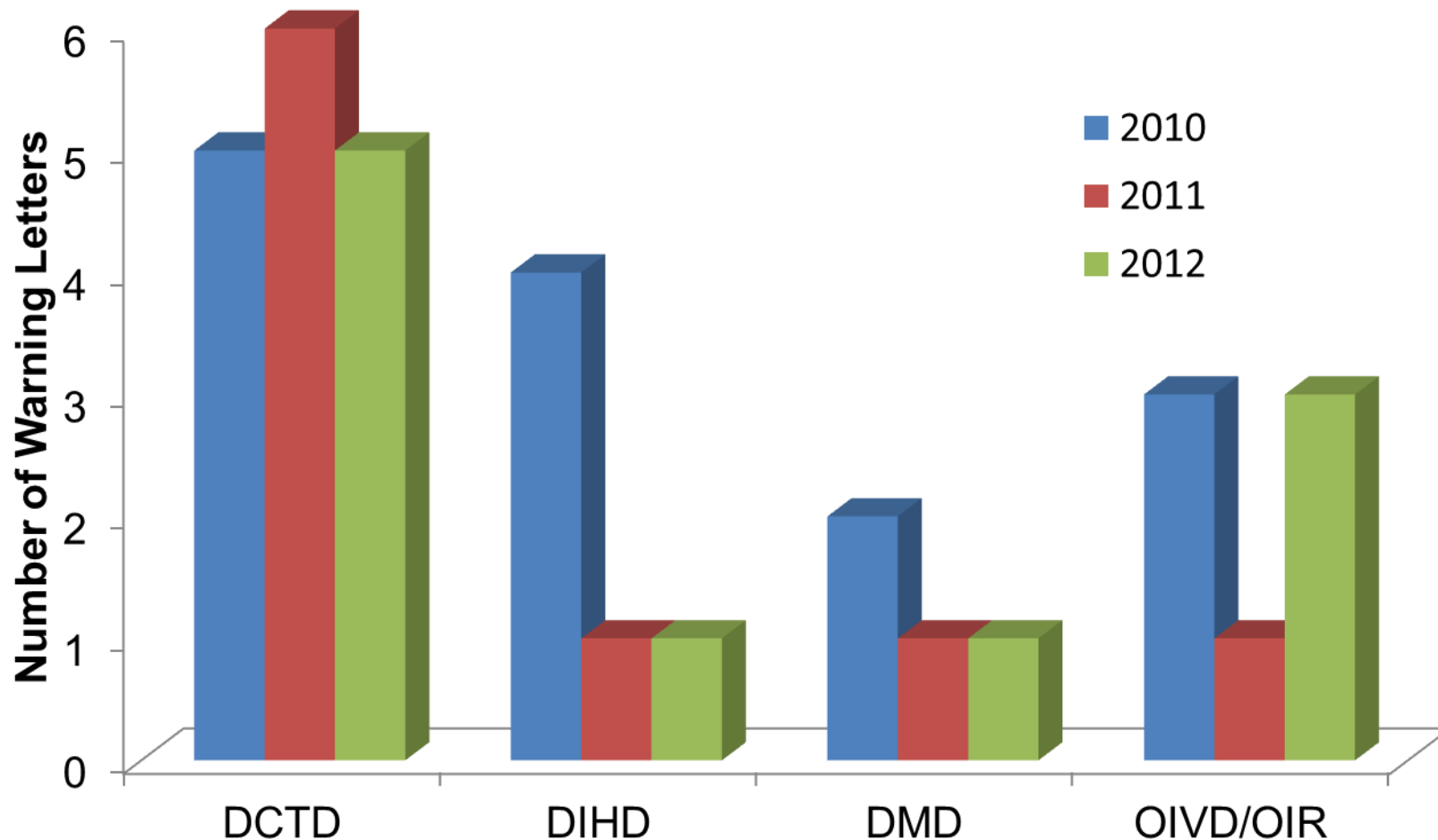
Class I Recalls by Product Area



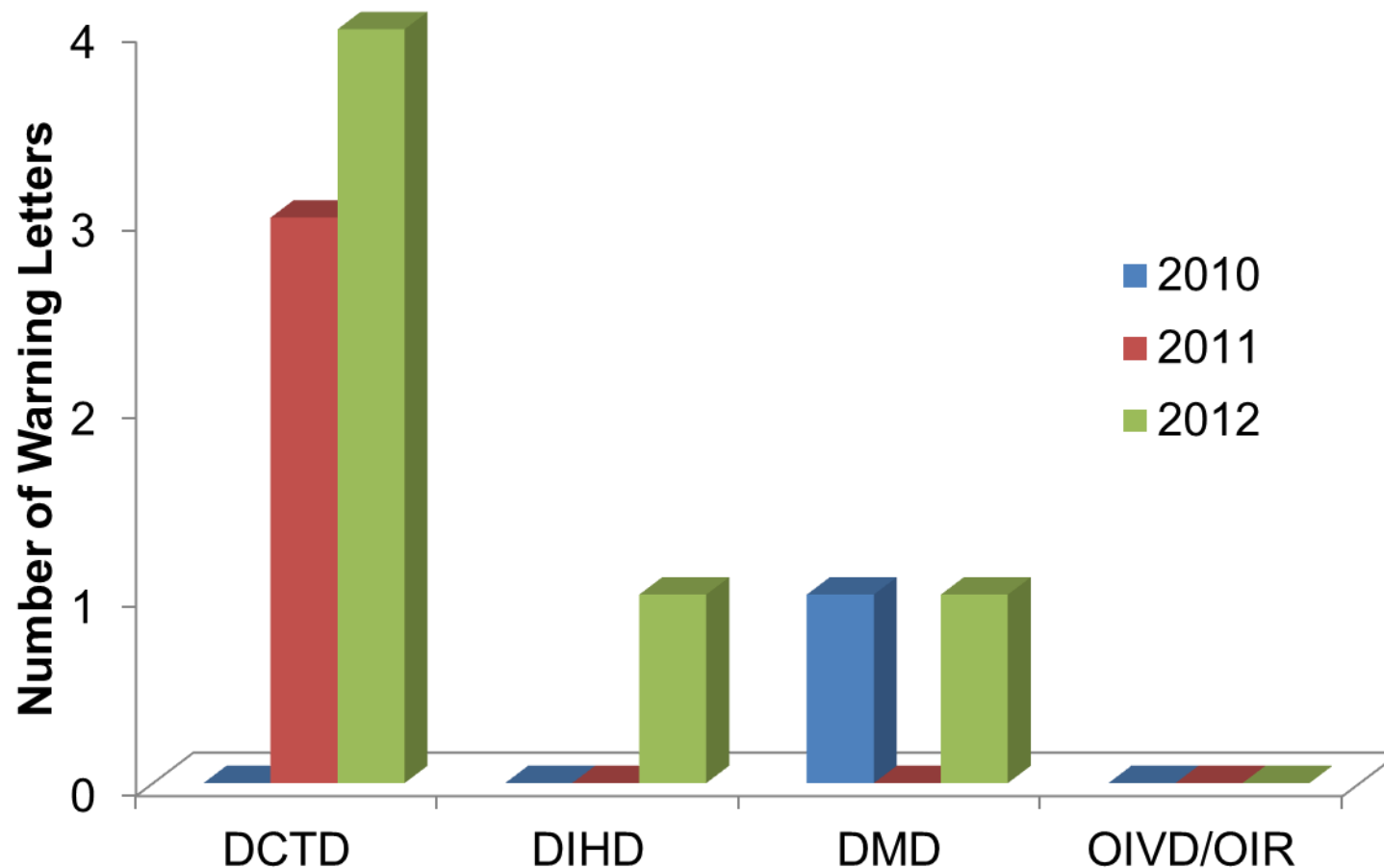
IVD Warning and Untitled Letter Data – primary subtypes

- *Quality Systems and MDR violations*
- *Promotion and advertising violations*
- *Lack of 510(k) clearance or PMA approval*

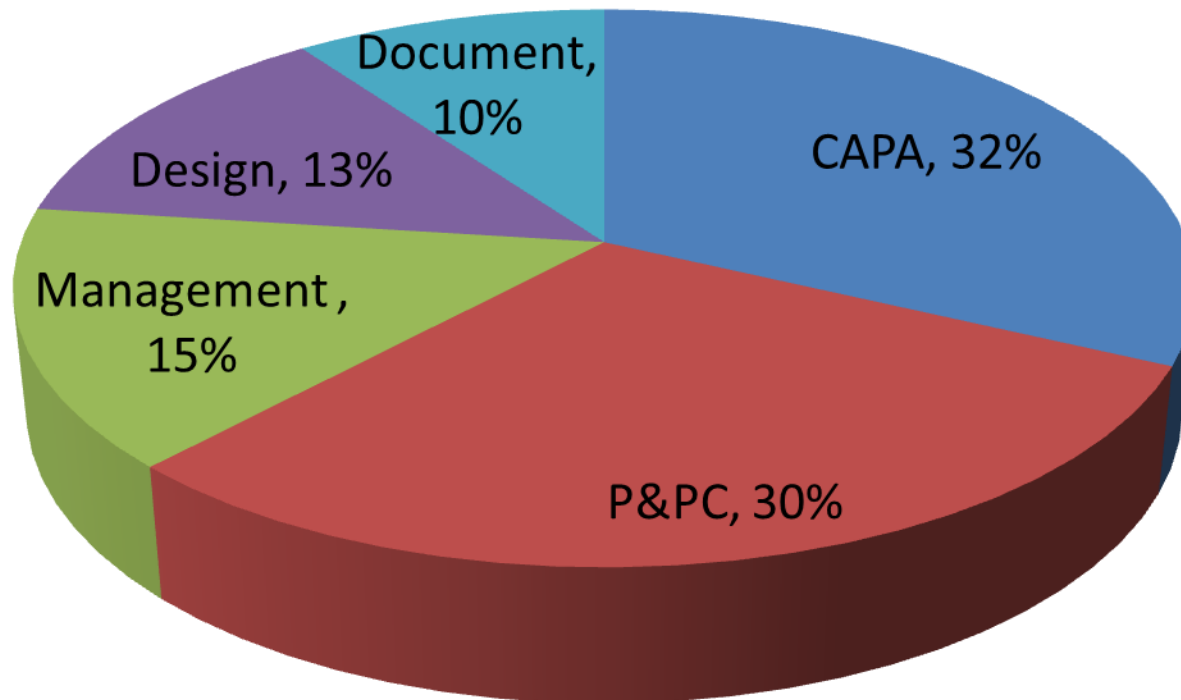
Domestic Untitled and Warning Letters Issued by OIVD/OIR – by Product Area



Foreign Untitled and Warning Letters Issued by OIVD/OIR – by Product Area



Analysis of 2010 FDA 483 Observations*



****source: AAMI Corrective and Preventative Action, Requirements and Industry Practice course, 2011***



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Thanks