Trends in IVD Compliance and Inspections

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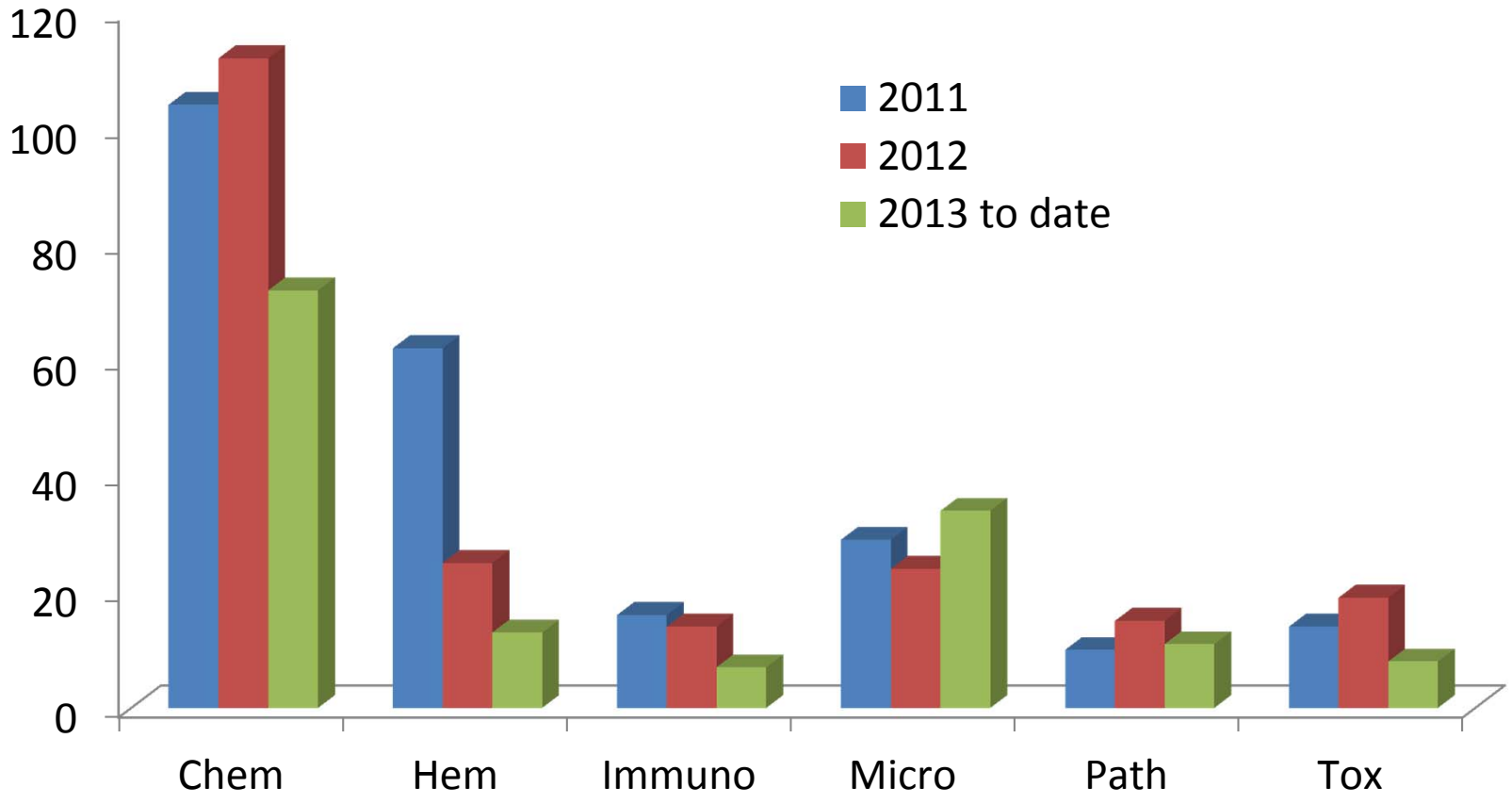
Outline of Presentation

- *IVD product recall trends*
- *IVD MDR recall by product code*
- *Trade complaint investigations*
- *Warning and Untitled Letters*

Total Number of Recalls by Product Area

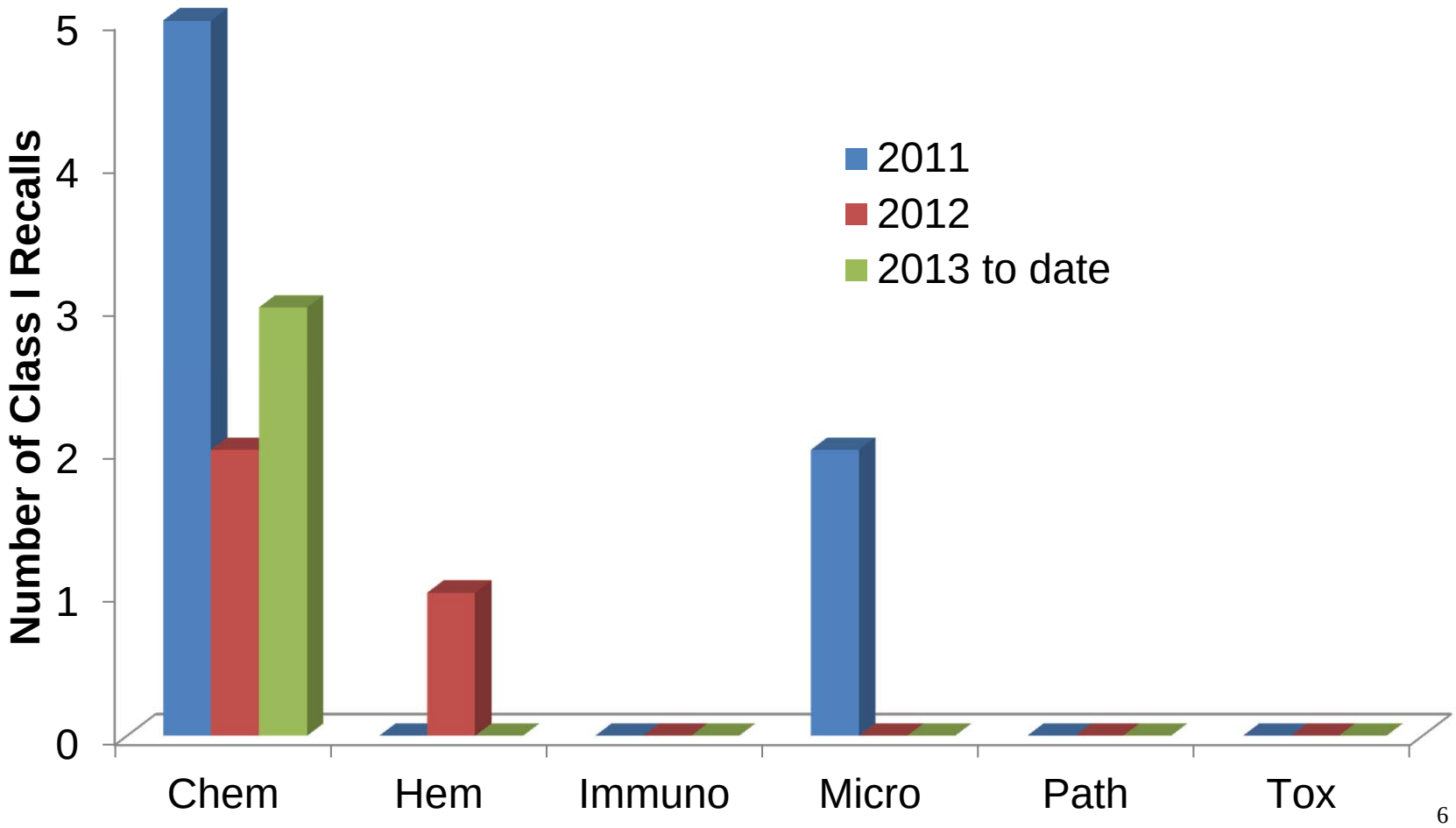


Classification of recalls

Class	Risk level	Risk to health	Probability
I	High	Serious adverse consequences or death	Reasonable probability
II	Medium	Serious adverse consequences or death	Remote
		Temporary/ medically reversible conditions	May cause
III	Low	Any health consequences	Not likely

Distribution of IVD Product Recalls by Classification

Class I Recalls by Product Area



IVD Recalls – Summary

- *Overwhelming majority of IVD recalls classified by OIR are Class II*
- *No significant year-to-year trends*
- *Most Class I recalls are in the Chemistry area*
- *Five of the Class I IVD recalls in the past 3 years were for product code NBW – OTC Glucose Test System*

IVD MDR reports – top ten product codes – total events in database

Product code and description	Total events
NBW - OTC glucose test system	78135
LFR - glucose test system	56272
CFR - glucose test system	33315
JJE - clinical chemistry analyzer	22418
GJS - prothrombin time test	7538
JPA - multipurpose system for coagulation testing	7399
MMI - troponin immunoassay	5943
JTC - Microtiter diluting and dispensing device	5915
KSZ - Automated blood grouping antibody test system	5250
GKZ - Automated differential cell counter	3843
CGA - Glucose test system	1658

IVD MDR reports – top ten product codes – total death reports in database

Product code and description	Total death reports
NBW - OTC glucose test system	60
CFR - glucose test system	30
OYA – insulin pump to be used with invasive glucose sensor	29
JPA - multipurpose system for coagulation testing	24
GKT - Automated blood cell separator	24
LFR - Glucose test system	16
GJS - prothrombin time test	12
JJE - clinical chemistry analyzer	9
CHL - Blood gases and blood pH electrode measurement	7
CGA - Glucose test system	6

MDR and death reports for IVD devices - summary

- *Glucose test systems (especially OTC) account for the largest number of MDRs and death reports.*
- *Other devices with a significant rate of both MDR reports and death reports include multipurpose coagulation devices and prothrombin time tests.*
- *Year-to-year trends were not analyzed.*

Investigation of Trade Complaints

- *Sources:*
  - *industry*
  - *professional groups*
  - *concerned individuals*
  - *FDA personnel*

Trade Complaint Investigations: Typical Outcomes

- *Firm agrees to website or labeling changes*
- *Firm agrees to a submission*
- *Referred to District or other Center*
- *No further action required*

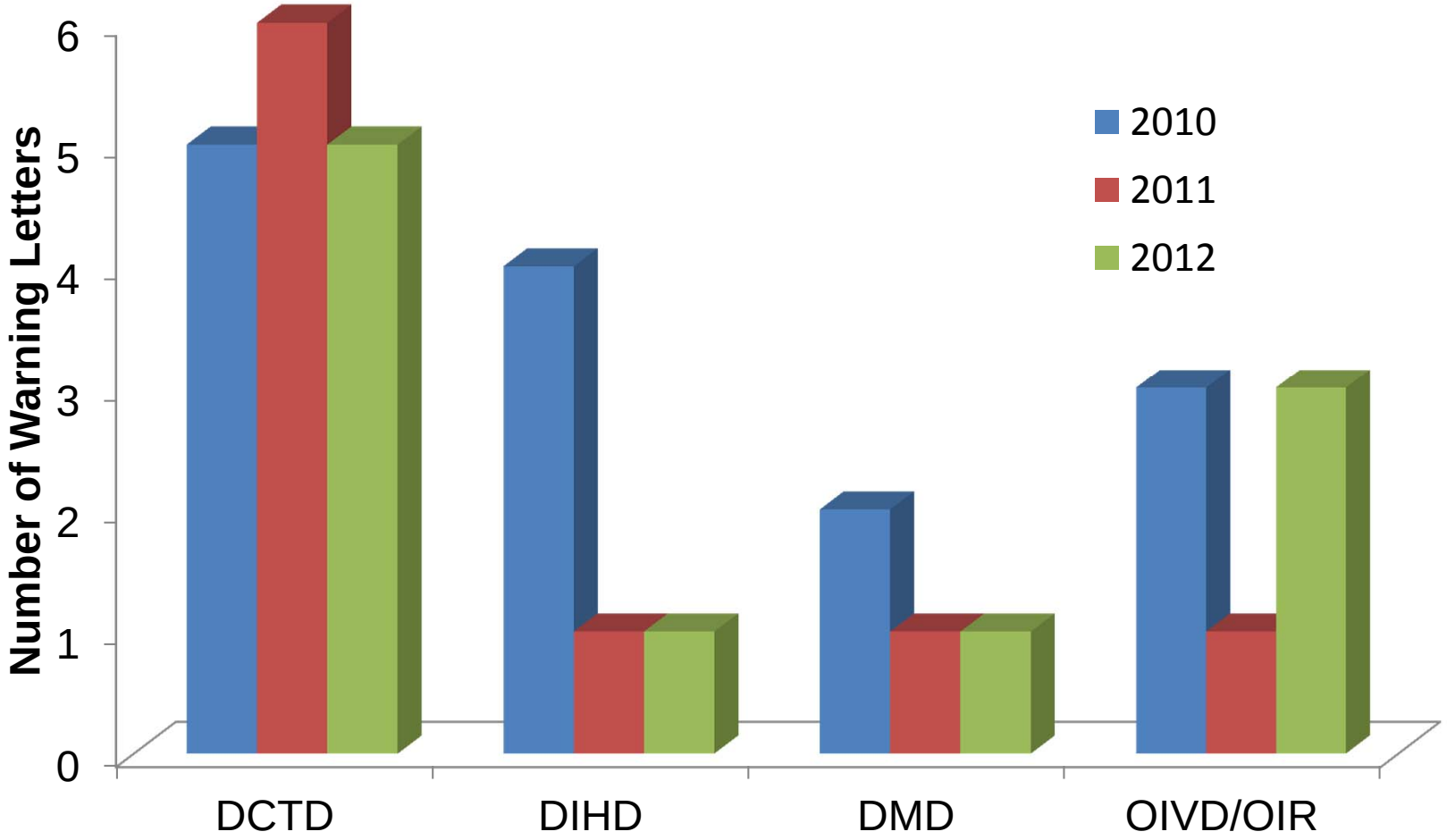
IVD Warning and Untitled Letter Data - caveats

- *Most WL and UL for domestic firms issued by the District - data not readily available for CDRH*
- *Direct reference authority for District for domestic firms initiated in 2011 (for Quality System violations)*
- *Data based on entries in the agency-wide Compliance Management System*

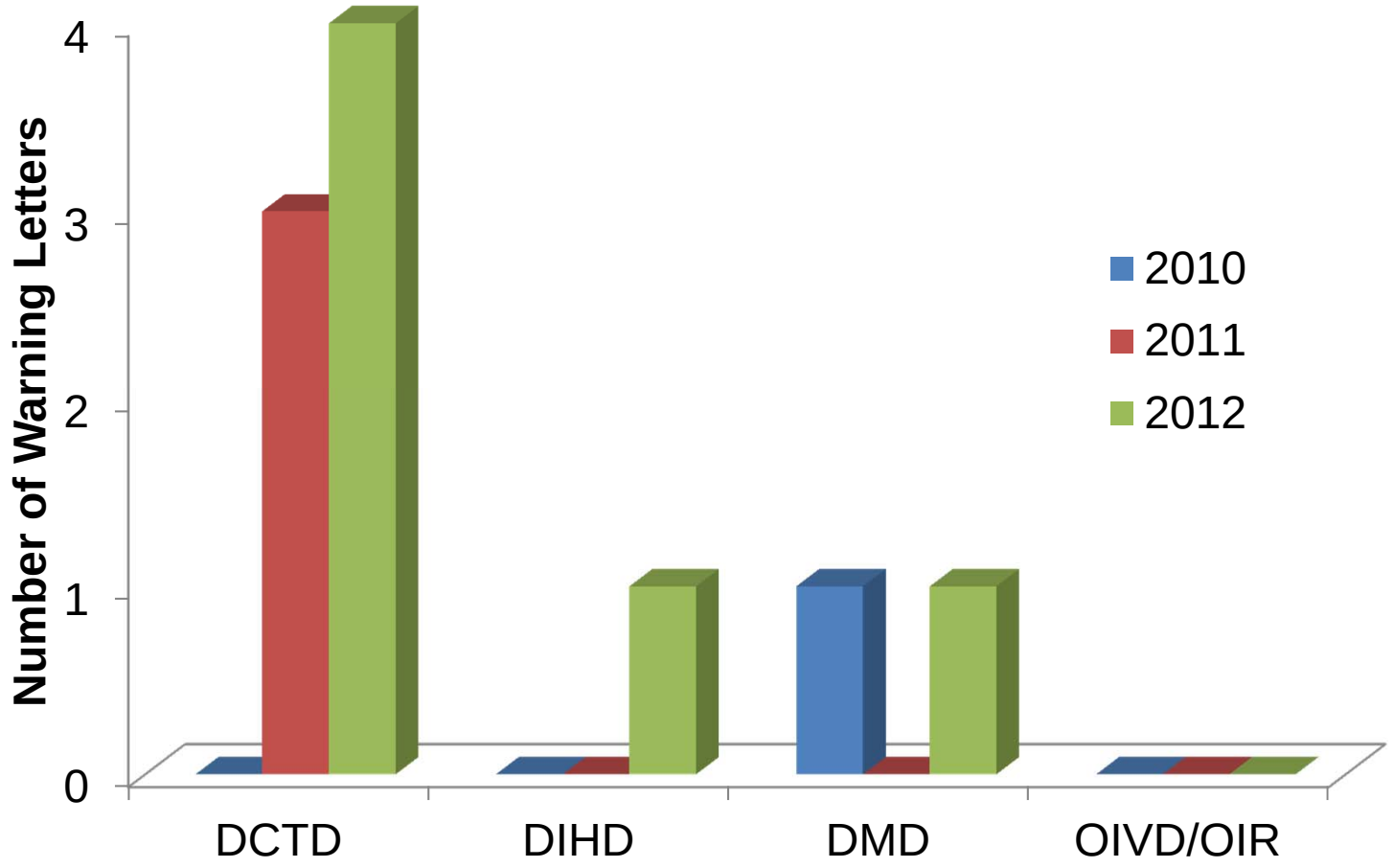
IVD Warning and Untitled Letter Data – primary subtypes

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

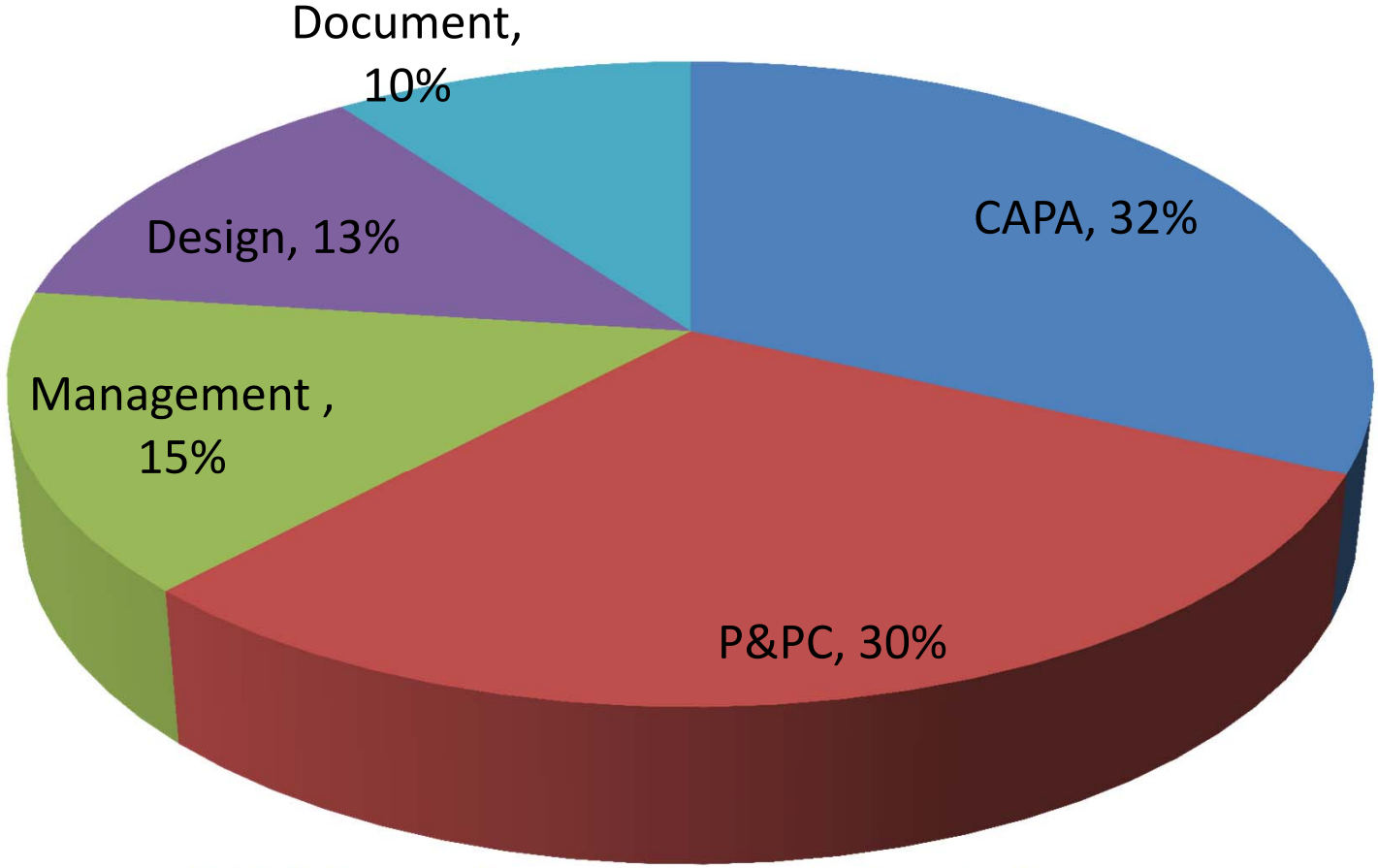
Domestic Untitled and Warning Letters Issued by OIVD/OIR – by Product Area



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

IVD Warning Letter Data - Summary

- *Foreign inspection oversight increasing – 6 foreign UL/WL issued by OIR/DIHD for 2013 to date*

- *In 2010, CAPA and P&PC were responsible for the largest number of FDA-483 cites– this is likely to continue*

Guidance documents – 510(k) device modifications

Deciding When to Submit a 510(k) for a Change to an Existing Device

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm

Guidance for Industry and FDA Staff; Replacement Reagent and Instrument Family Policy

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm079185.htm

Class II Special Controls Guidance Document: Instrumentation for Clinical Multiplex Test Systems - Guidance for Industry and FDA Staff

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077819.htm

Guidance documents – PMA device modifications

Quality System Information for Certain Premarket Application Reviews; Guidance for Industry and FDA Staff

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070897.htm

Guidance for Industry and FDA Staff: Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089360.pdf

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

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080192.htm

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Thank you!

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