

510(k) Workshop

Introduction

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Office of *In Vitro* Diagnostic Device
Evaluation and Safety (OIVD)
Center for Devices and Radiological Health

Agenda

- Mission/Vision
- Regulatory Programs
- OIVD Organizational Charts
- OIVD's Goals and Commitments

Our Mission

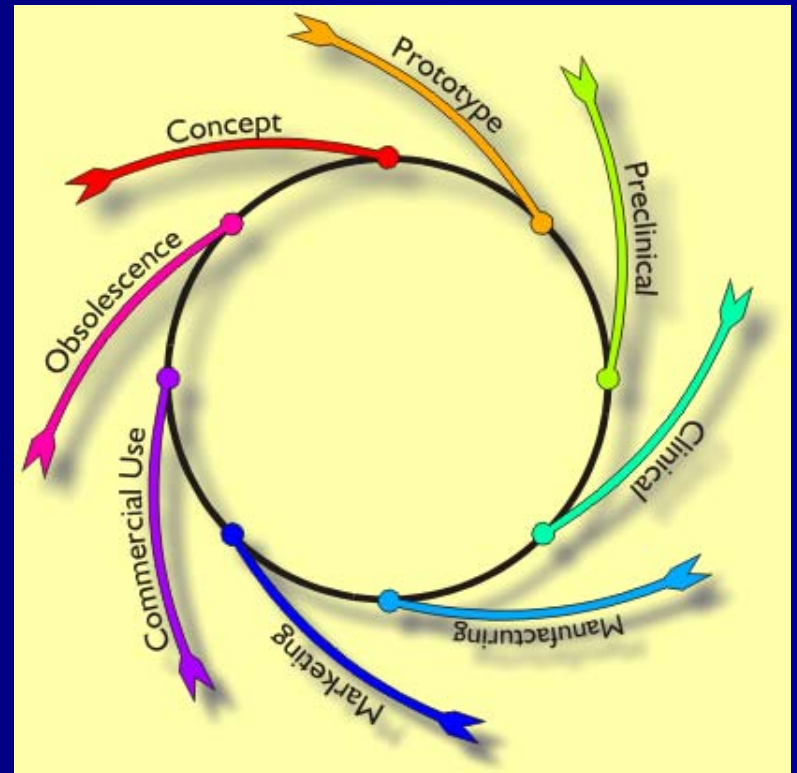


Getting safe and effective devices to market as quickly as possible...

... while ensuring that devices currently on the market remain safe and effective.

Our Vision

integrated
regulatory
oversight
throughout the
Total Product Life
Cycle



One Stop Shopping

- Single Organizational Unit
- Premarket/Compliance/Postmarket

and CLIA
categorization
to boot!



Premarket Programs

- Classification Information Request - 513(g)
- Investigational Device Exemption (IDE)
- Pre-IDE
- Premarket Notification (510(k))
- Premarket Approval (PMA)
- Humanitarian Device Exemption (HDE)

Premarket Submissions

- 510(k)
 - ◆ ~ 600 submissions per year
 - ◆ Substantial equivalence
 - ◆ Comparison to predicate device
- PMAs
 - ◆ 6 to 12 submissions per year
 - ◆ Safety and Effectiveness

OIVD Review

- More Interactive
- Least Burdensome
- Good Science!
 - Good Science!
 - Good Science!

Postmarket Programs

- Post-Market Studies
- Medical Device Adverse Event Reporting
- MedWatch
- MedSun and LabNet
- Other signals

Compliance Programs

- Registration and Listing
- GMP Inspections
- Bioresearch Monitoring Audits
- Enforcement Actions
 - Warning Ltrs, Untitled Ltrs, Recalls, etc.
- Import/Export

CLIA Categorizations

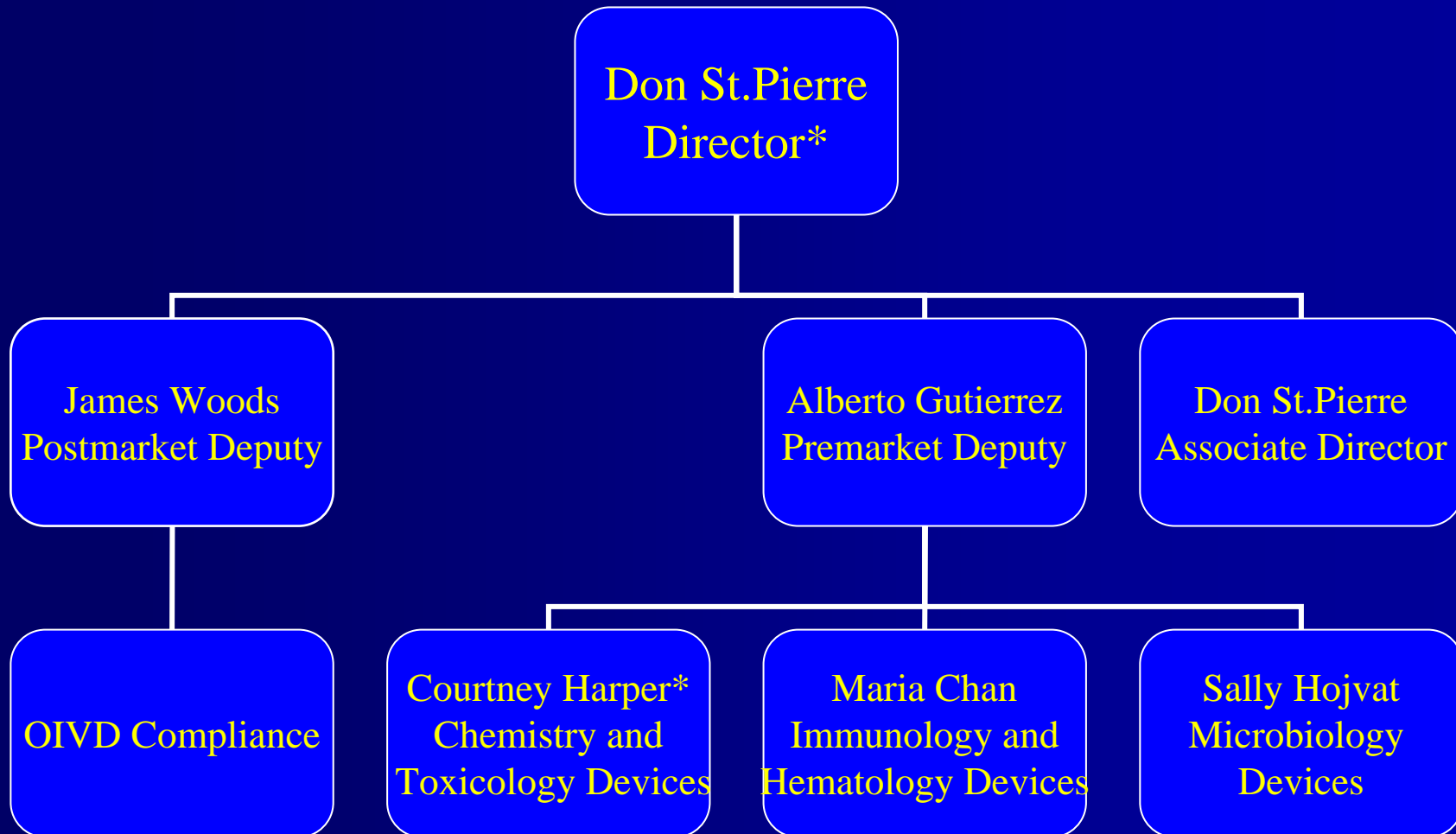
- High Complexity/Moderate Complexity and Waived
- Determination made based on expertise needed to perform the test
- Many High, Most Moderate, Few Waived

Program Implementation

- **Premarket:** Industry provides the evidence, FDA reviews and clears or approves
- **Postmarket:** Industry's responsibility, FDA monitors and provides guidance
- **Compliance:** FDA acts as policemen
- **CLIA:** Categorization performed after approval or clearance

OIVD Organizational Chart

*Acting



Division of Chemistry and Toxicology Devices

- General/Special Chemistry tests
- Cardiac Markers (i.e. Lipids/Cholesterol, CRP)
- Pregnancy tests
- Osteoporosis Markers
- Glucose tests
- Drugs of Abuse tests
- Therapeutic Drug Monitoring

Division of Immunology and Hematology Devices

- Allergy tests
- Autoimmune Assays
- Tumor Markers
- Hematology tests
- Cytology tests
- Coagulation tests

Division of Microbiology Devices

- Antimicrobial Susceptibility
- Bioterrorism Preparedness
- Sexually Transmitted Diseases
- Bacterial Identification
- Hepatitis
- Herpes
- Rubella
- Influenza

World of IVDs

Industry

- \$10-15 Billion industry for raw materials
- \$30-50 Billion for testing
- 10 Billion lab tests in > 170,000 labs

Multi-tasking Workforce

- ~ 100 dedicated scientists, managers & support staff doing TPLC regulation to promote and protect public health
- Premarket Applications (~1,000/yr)
- Compliance Actions (~150/yr)
- MDR Surveillance (~10,000/yr)
- CLIA Determinations (~2,000/yr)
- *Industry Issues – more than all the rest*

Challenges

- Increasing public expectation
- Explosive growth of new technologies
- Increasing health and safety threats
- Addressing special needs of segments of population (baby boomer, elderly)
- Increasing number of U.S. manufacturers using foreign clinical trials
- Regulating US products - int'l market
- Increasing vol./diversity of imports

IVD Hot Topics

- ASRs, laboratory developed tests (home brew), and multivariate index assays
- Personalized medicine, drug/device co-development, critical path, biomarkers, companion Dx, & combination products
- Genetic Testing
- Biothreat diagnostics/inter-agency activities/pandemic flu
- CLIA Waiver
- Electronic Submissions (Turbo 510(k))
- More Postmarket (including QSR and LabNet)

OIVD's Goals

- Public health impact throughout the total product life cycle
- Consumer protection in a global marketplace
- Knowledge that makes a difference
- Communication with stakeholders
- A workforce for the future

OIVD Regulatory Commitment

- Early collaboration with developers/future applicants
- Encourage coordination across disciplines
- Provide input on evaluation protocols & study design
- Encourage guidance, diagnostic algorithms and standards
- Education – users, clinicians, public

OIVD Website

www.fda.gov/cdrh/oivd

The screenshot shows a web browser window displaying the FDA's Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) website. The browser's address bar shows the URL www.fda.gov/cdrh/oivd. The website header includes the FDA logo, the text "U.S. Food and Drug Administration", and the Department of Health and Human Services logo. Below the header, the text "CENTER FOR DEVICES AND RADIOLOGICAL HEALTH" is displayed, along with navigation links for "FDA Home Page", "CDRH Home Page", "Search", and "A-Z Index". A "Questions?" link is also present.

The main content area features a large heading: "Office of In Vitro Diagnostic Device Evaluation and Safety" with the OIVD logo to the right. Below this, a welcome message reads: "Welcome to the Office of In Vitro Diagnostic Device (OIVD) Evaluation and Safety Web Site". A link to "Receive OIVD Updates by Email" is provided.

The website is organized into several sections:

- Regulatory Assistance:** Includes links for "New CeSub Turbo 510(k) eSubmissions", "Code of Federal Regulations (CFR)", "Overview of IVD Regulation", "Guidance Documents", "IVD Standards", "FDA Advisory Committees", "Device Advice", "Medical Device User Fees (MDUFMA)", "Manufacturer Certification Programs", "Enforcement Letters to Industry", "Find a Predicate Device", and "Decision Summaries".
- Home and Lab Tests:** Includes links for "New Reporting Glucose Device Problems", "Rapid Lead Screening Test", "Glossary of Terms", "Home-Use Tests", "Lab Tests", "Safety Tips for Laboratorians", "Recalls", and "Find All FDA-Approved Home & Lab Tests".
- About Us:** Includes links for "Office Information", "Mission", and "Expertise".
- In Vitro Device News (Updated 01/30/2008):** Lists recent news items such as "FDA Publishes Final Guidance Document on CLIA '88 Waiver Applications", "FDA Joins NIH in Awareness Campaign for Hemoglobin A1c Testing", "OIVD eConference: OIVD's Shortcuts on the Critical Path to the Market, February 19, 2008", "OIVD Conducts the Annual 510(k) Workshop on April 22-23, 2008", and "FDA Publishes a New Guidance Document".

On the left side, there is a search bar for OIVD, a "Home" button, and a "Regulatory Assistance" section with links to "Home & Lab Tests" and "About Us". Below these are "Quick Links" for "New OIVD Products (since 1/1/2008)", "All OIVD Products", "510(k) Database", "PMA Database", "CLIA Database", "Home use/OTC tests", "IVD Guidances", "IVD Standards", and "CeSub Turbo 510(k)".

The browser's taskbar at the bottom shows the Windows start button, several open Internet Explorer windows, and the system clock indicating 5:56 PM.

Thank You

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