

Agenda

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

510(k) Workshop

Introduction

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

Our Mission

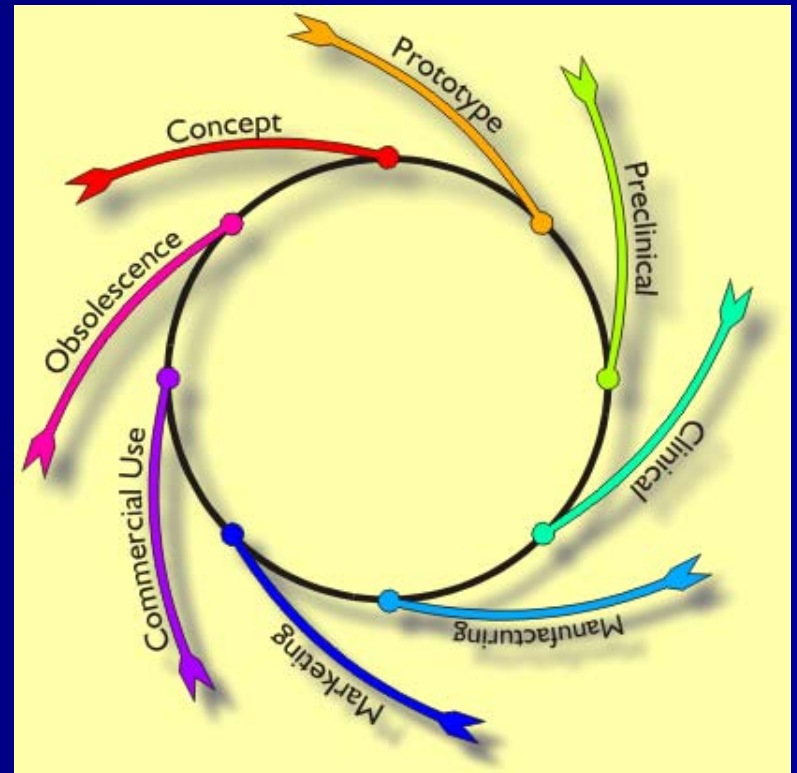


Getting safe and effective devices to market as quickly as possible...

... 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

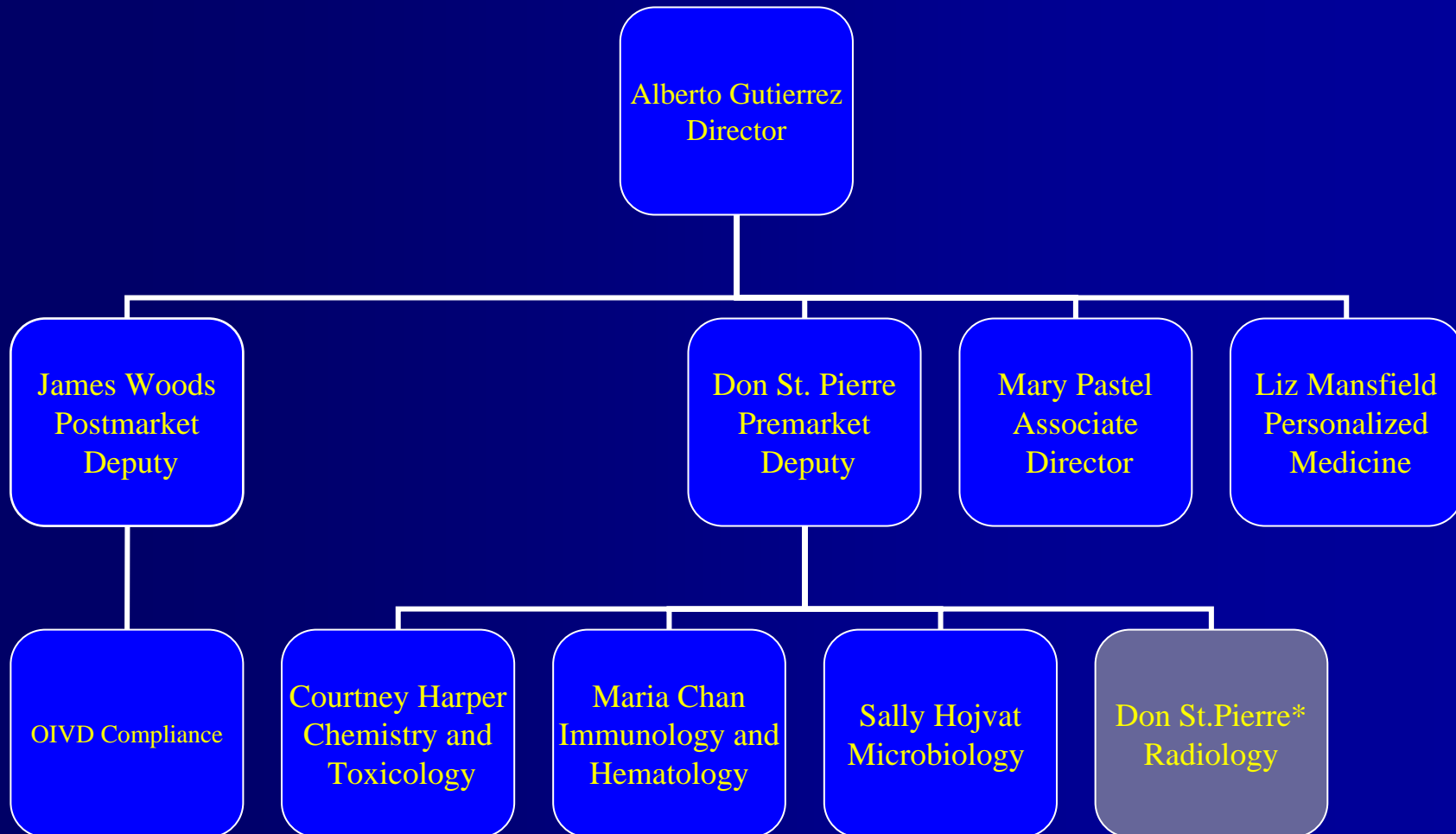
- High Complexity/Moderate Complexity and Waived
- Determination made based on expertise needed to perform the test
- Many High, Most Moderate, Few Waived

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

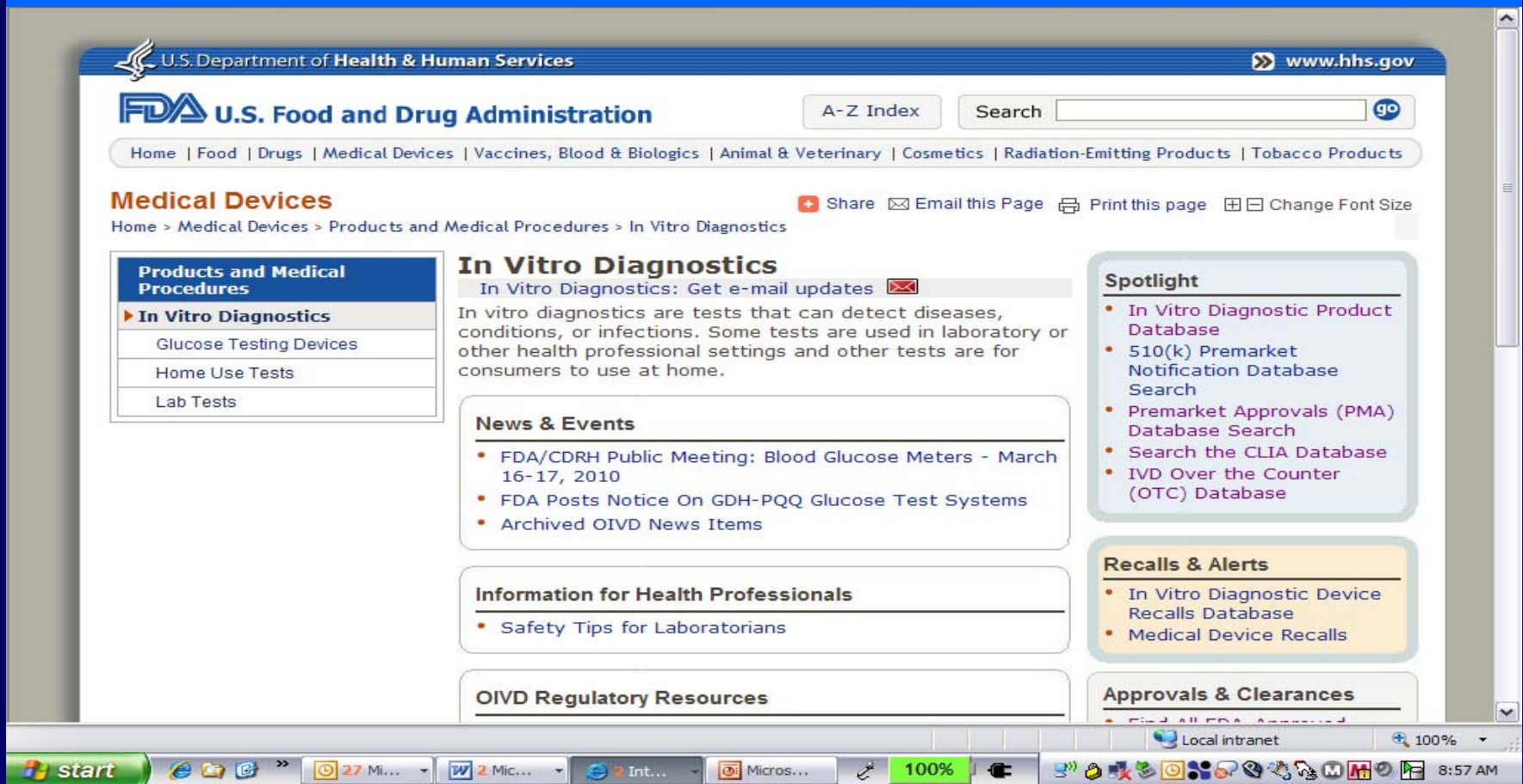
- Public health impact throughout the total product life cycle
- Consumer protection in a global marketplace
- Knowledge that makes a difference
- Communication with stakeholders
- A workforce for the future

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/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/default.htm



The screenshot shows the FDA's In Vitro Diagnostics (OIVD) website. The header includes the U.S. Department of Health & Human Services logo and the FDA logo. The main navigation bar lists various FDA categories, with 'Medical Devices' being the active section. The left sidebar contains a 'Products and Medical Procedures' menu with 'In Vitro Diagnostics' selected. The main content area is titled 'In Vitro Diagnostics' and includes a description of the tests, a 'News & Events' section with recent announcements, an 'Information for Health Professionals' section with safety tips, and 'OIVD Regulatory Resources'. On the right, there are three boxes: 'Spotlight' with links to various databases, 'Recalls & Alerts' with links to recall databases, and 'Approvals & Clearances'.

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration

A-Z Index Search go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

Medical Devices Share Email this Page Print this page Change Font Size

Home > Medical Devices > Products and Medical Procedures > In Vitro Diagnostics

Products and Medical Procedures

- In Vitro Diagnostics**
- Glucose Testing Devices
- Home Use Tests
- Lab Tests

In Vitro Diagnostics

In vitro diagnostics: Get e-mail updates

In vitro diagnostics are tests that can detect diseases, conditions, or infections. Some tests are used in laboratory or other health professional settings and other tests are for consumers to use at home.

News & Events

- FDA/CDRH Public Meeting: Blood Glucose Meters - March 16-17, 2010
- FDA Posts Notice On GDH-PQQ Glucose Test Systems
- Archived OIVD News Items

Information for Health Professionals

- Safety Tips for Laboratorians

OIVD Regulatory Resources

Spotlight

- In Vitro Diagnostic Product Database
- 510(k) Premarket Notification Database Search
- Premarket Approvals (PMA) Database Search
- Search the CLIA Database
- IVD Over the Counter (OTC) Database

Recalls & Alerts

- In Vitro Diagnostic Device Recalls Database
- Medical Device Recalls

Approvals & Clearances

Find All FDA Approved

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Thank You

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