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

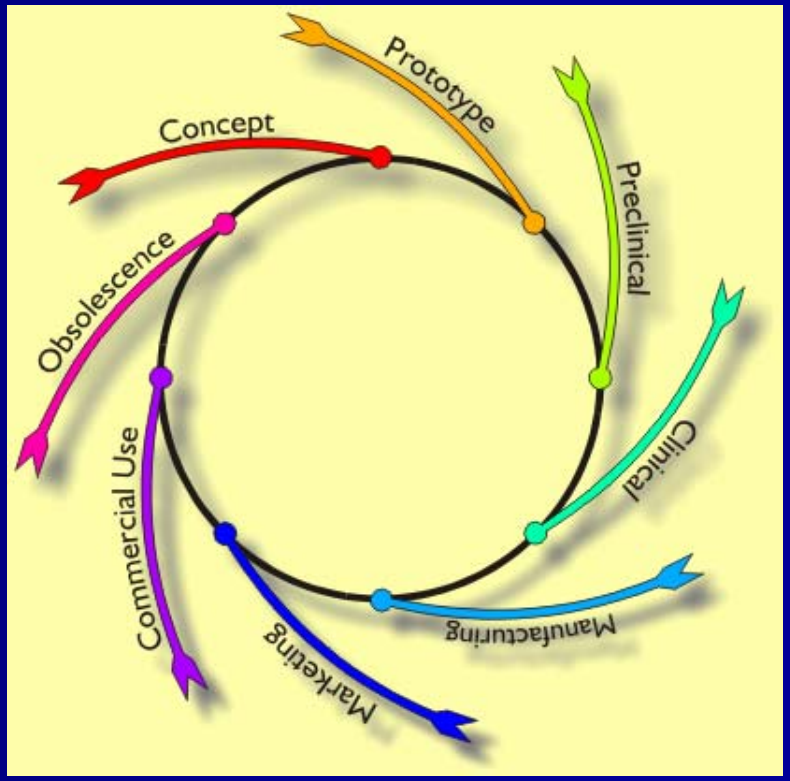
Our Mission

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)
- EUA/ pre-EUA

Premarket Submissions

- 510(k)
  - ~ 800 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

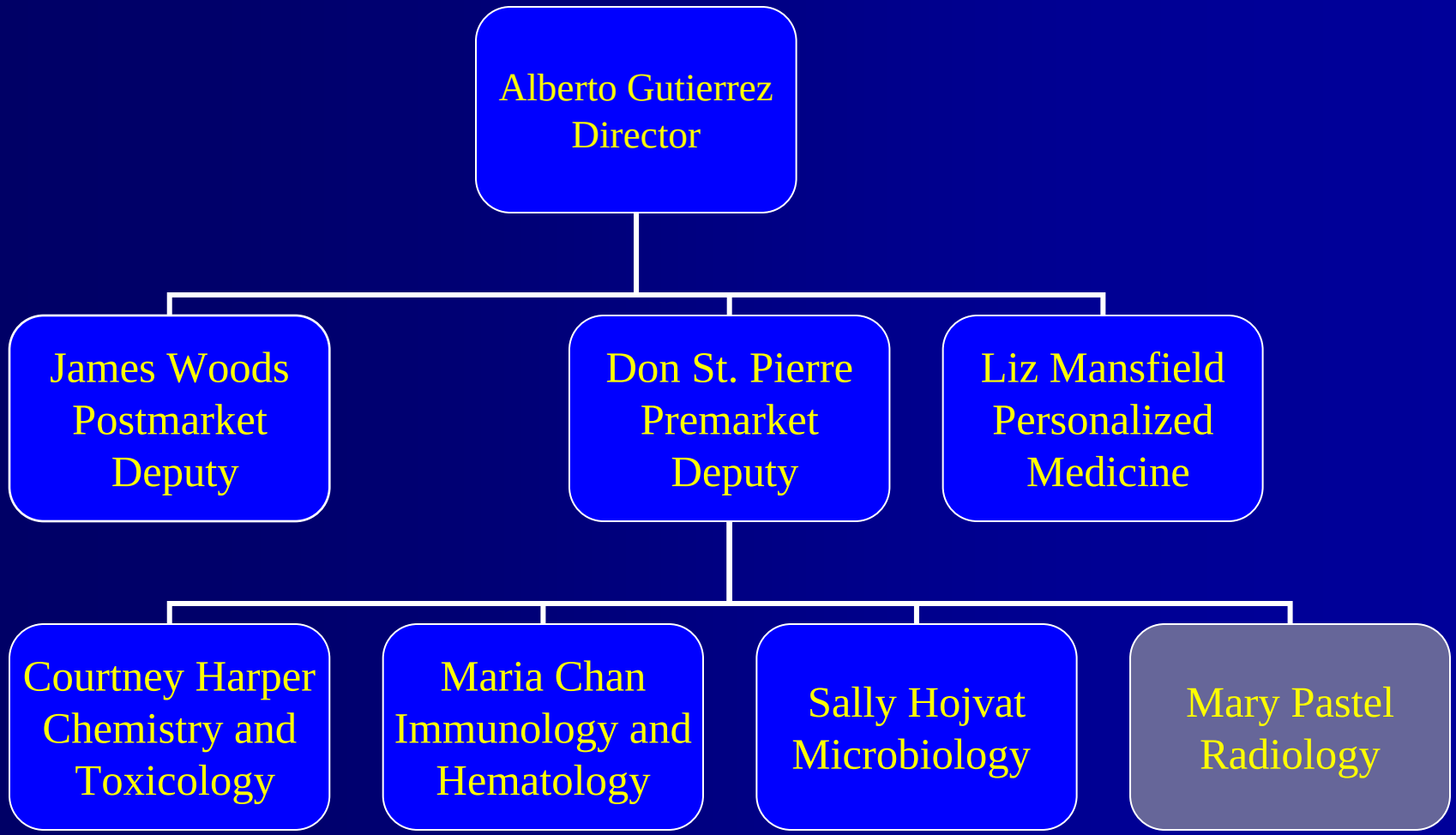
- High Complexity/Moderate Complexity and Waived
- Determination made based on expertise needed to perform the test
- Many High, Most Moderate, Few Waived

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



Organizational Change

- Uwe Scherf
  - Deputy Director Microbiology
- Reena Philip
  - Deputy Director Immunology Hematology
- Carol Benson
  - Deputy Director Chemistry Toxicology
- Michael O’Hara
  - Deputy Director Radiology

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 > 200,000 labs

Multi-tasking Workforce

~ 150 dedicated scientists, managers & support staff doing TPLC regulation to promote and protect public health

- Premarket Applications (~1,300/yr)
- Compliance Actions (~150/yr)
- MDR Surveillance (~10,000/yr)
- CLIA Determinations (~2,000/yr)
- *Industry Issues – ???*

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 RUOs
- 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

Thank You

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