Division of Clinical Laboratory Devices -- an update

DCLD Summary

- People
- Workload
- Performance
- Implementation of Least Burdensome Program
- Strategic Plan

People

- New Deputy Commissioner – Dr. Crawford
- Seasoned Chief Counsel – Dan Troy
- New Associate Director Science - Norris Alderson
- Seasoned Center Director – Dr. Feigal
- New Center Organization – Linda Kahan and Lillian Gill

People

- 60 FTEs
- New Genetics Hires
- No Growth

People -- Programs

- Premarket Review
- CLIA categorization
- Pharmacogenomics working group
- Bioterrorism initiatives
- TPLC initiative

510(k) Program

- Heart of workload
- 650 submissions
- Review times average 65 days (target 90)

Decreasing Workload

- Replacement reagent policy
- ASR policy
- Clarification in modification policy
- Business environment

PMA Program

- Variable workload
- Approved approximately 6
- Meeting all review targets

Protocol Review (pre IDE) Program

- Currently projected at 90/year
- High octane stuff
- 60 day reviews
- Multiple interactions

CLIA Review Program

- Active – more than 2000 determinations/year
- Remains program in evolution

FDAMA

- Improved market access
- Least burdensome pathways
- Premarket to postmarket balance
- Increased interaction with industry

Least Burdensome

- Appropriate questions
- Appropriate thresholds
- Non-academic pursuits

Least Burdensome

- Matter of law
- Matter of policy
- Matter of spirit

Least Burdensome

- Two Guidance Document
- Systems Approach – ensure appropriate process applied to use of regulatory tools
- Review Guidance

Least Burdensome

- Review changes are profound
- Parallel genetics initiative
- Shift to data summaries
- Shift to more focused labeling review
- Shift to use of clinical literature
- Shift to postmarket analysis

Strategic Plan -- Goals

- Mission related
- Total Product Life Cycle
- Knowledge Management

Total Product Life Cycle

- Cradle to grave
- Seamless oversight

Intellectual Appeal

- **Premarket review limitation**
- Outdated law
- Snapshot approach
- Impact of scale-up
- Impact of wide-use

Intellectual Appeal

- **Postmarket review strengths**
- Quality system regulations
- Require quality assessment
- Require process controls
- Require corrective actions
- Unrealized potential

Intellectual Appeal

- **Need for harmonization**
- IVD directive
- ISO labeling initiative
- Growing regulatory program in Canada

TPLC IVD Pilot

- Ideal target
- Stereotyped review issues
- Cadre of like minded scientists
- Engaged communities interested in partnering

Goals

- Increased transparency
- Expedited technology transfer
- Provide support and improvements application of ASRs
- Improve surveillance and use of surveillance

Core Mission

- Promote public health
- Apply good science
- Evolving program
- Relevant, focused, safe and effective