Office of In Vitro Diagnostics

- One organizational unit to regulate all IVDs through their Total Product Life Cycle using Knowledge Management
- One stop shopping
- Regulation from common technical base
Office of In Vitro Diagnostics

- Goal – to better connect
  - Premarket review
  - Compliance/Enforcement actions
  - Postmarket monitoring
Office of In Vitro Diagnostics

- Three divisions support all technical decision making
- Compliance in matrix form
- MDR analysts are embedded in divisions
- Cross hires with postmarketing and research groups
- Total regulatory staff now about 85 FTE
Multi-Tasking Work Force

- Premarket Review -- 650 actions/ year
- Compliance Actions – 130 to 150/ year (range from recalls to enforcement letters to seizures)
- MDR surveillance – 10,000 reports/ year
CLIA Initiatives

- Waiver guidance
  - Expected summer 2005
  - Tri-agency effort
  - Build off of CLIAC recommendations
CLIA Initiatives

- Re-delegation of authority
- Tri-agency agreement
- SOPs in place
Current CLIA

- 2000 classifications per year
- Waived – 8 %
- Moderate – 80%
- High – 12%
Current CLIA -- good news

- New tracking system
- Personnel well trained in process
Current CLIA -- bad news

- Lack of guidance produces regulatory uncertainty for both sponsors and FDA
- Lack of guidance produces problem reviews for FDA and sponsors
Other Initiatives -- the OIVD Web Page

- Primary goal is transparency
- Standardized review template posted
- Public compliance actions posted
- Laboratory safety information posted
Other Initiatives -- the OIVD Web Page

- Recent face lift -- new tranquil blue look
- Try it, you may like it

www.fda.gov/cdrh/oivd
Guidance Document Development

- Son (daughter) of Multiplex
- Joint Drug and Diagnostic
- Future documents in area of genomics/genetics
- Current revision of older documents
Turbo 510(k)

- First three submissions
- Others in pipeline
- Move toward paperless and streamlined future
Refinement of Review Tools

- Promotion of Pre-IDEs (protocol reviews)
- Use of expedited reviews for new technologies
- Use of de novos for some cutting edge technologies (allows automatic down-classification of devices which by default would be class III)
Fruit of This Labor

Rapid introduction of new technologies such as

- West Nile antibody testing
- Tandem Mass Spec for Inborn Errors of Metabolism
- Affymetrix Reader/ Roche P450 AmpliChip
Loose Ends -- ASRs/Home brews

- Awkward product specific queries
- Ongoing compliance evaluation, issues, and actions
- Issues of non-parity and non-congruity between CLIA and FDA processes unresolved
ASRs/Home brews

- FDA commitment to work toward clarity
- AdvaMed Developed Q and A’s now being shared with professional groups; basis for possible future guidance
Loose Ends -- Informed Consent

- Discussion of issue is both hierarchial and broad
- Multiple players within and outside CDRH
- Increased appreciation of non-congruence between HHS (common) rule and FDA requirements
Loose Ends -- Informed Consent

- Clear work plan
- Move toward guidance or changes in regulation if appropriate
- Unclear time line
- High level HHS interest in harmonization
Future Goals

- Continue to re-balance programs to reflect Total Product Life Cycle regulation
- Better coordination of patient safety efforts
- Clarify or develop clearer regulatory positions
Critical Path

- Generated out of the Office of Commissioner
- Available on web page
- Focused on improving flow of new technology from research bench to clinical bed side
Critical Path

- Not IVD specific (more drug focused)
- Does refer explicitly to Biomarkers
- As valuable diagnostic tools
- As valuable tools to assist in drug development
Critical Path

- Does resonate with IVD industry
- Weighed in with comments to docket
- Weighed in at last IVD Round Table
- Model for IVDs may be somewhat different than for therapeutic products
Critical Path for Medical Product Development*
Concept Model for IVD Roundtable Discussion

Model Presented in FDA Report

Basic Research
Prototype Design, Discovery
Preclinical Studies
Clinical Development Phase 1
Clinical Development Phase 2
Clinical Development Phase 3
FDA Filing Approval Launch

Basic Research - fundamental understanding of the biology and disease
Prototype/Design & Discovery - creates or selects molecules
Preclinical/translational Research - drives discovery to clinical evaluation, pre-IND
Clinical Development/Critical Path - proves safety/utility/effectiveness, improves R&D process, establish tools, scale-up, IND
FDA Filing - final application review, approval, postmarket activities

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* From: Innovation/Stagnation, FDA report on Challenge and Opportunity on the Critical Path to New Medical Products, March 2004
Sheri Hall, BD & Andrea Casper, OCD
FDA/Industry IVD Roundtable, 11/10/04
Regulation May Not Be Only or Predominant Obstacle

- Science – nuanced and complex; methods and materials poorly standardized
- Economic – competing choices, disincentives, patents, and conflicting cultures
- Legal and social issues
OIVD Goals

- Wisely use existing regulatory tool box
- Ensure review transparency and clear labeling
- Meet the letter and spirit of the law to have a “least burdensome” review threshold
- Proactively partner in translational phase of product development
OIVD

- Unique product line
- Unique organizational program
- Unique policy challenges
OIVD

- Government partners (NIH, CDC, CMS, HRSA)
- Professional partners
- Industry partners
OIVD

- Right resources
- Right regulatory support
- Right communication
- Potential for success or interesting failures
Concerns

- Translating work products into reality
- Finding the right balance
- Keeping our eye on the ball
Winning Hand

- Passionate cadre of innovative scientists
- Regulate an industry with imagination, energy, verve and healthy competitive spirit
- Clear public health vision
- Public commitment to good science