CDRH Update

IVD Roundtable 6/7/2012

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Deputy Director

New Product Evaluation

OIVD

Summary

- 510(k) Reforms
- Guidances
- MDUFA III
- New News

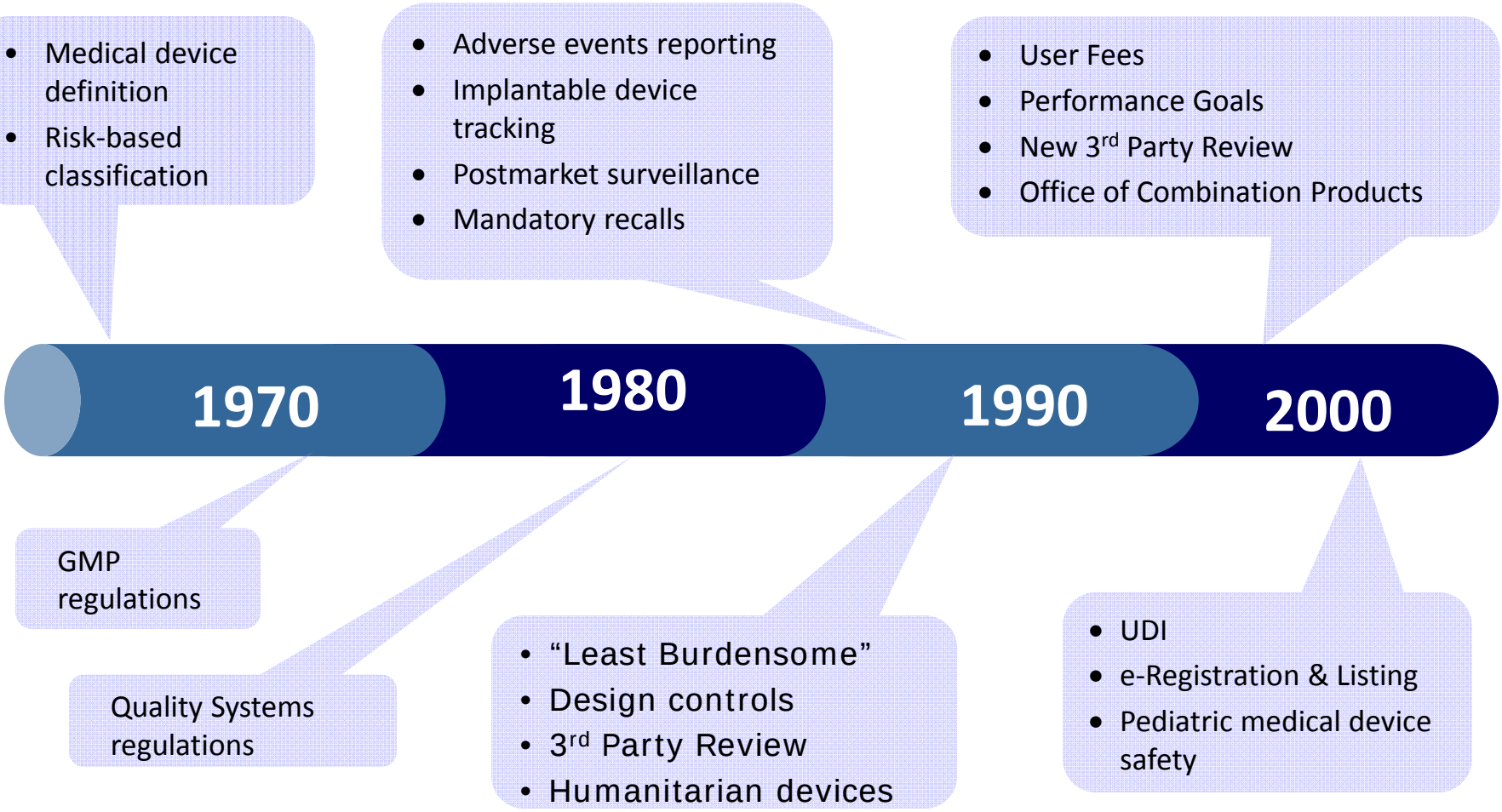
Innovation

Diagnostics

- **A test that can help detect ovarian cancer in a pelvic mass that is already known to require surgery**
- **Emergency use of diagnostic test in response to H1N1 outbreak in humans**
- **The first DNA test that identifies the two types of human papillomavirus that cause the majority of cervical cancers; a second wider-range DNA test that detects essentially all of the high-risk HPV types in cervical cell samples**
- **A more rapid test for the detection of influenza A/H5N1, a disease-causing subtype of the avian influenza A virus that can infect humans**
- **The first nucleic acid test for hepatitis B virus (HBV) that measures the amount of viral DNA (viral load) in a patient's blood**
- **A test that simultaneously detects and identifies 12 specific respiratory viruses; a test that detects four common respiratory viruses, including influenza in about 3 hours**
- **The first rapid blood test for the drug-resistant staph bacterium (MRSA)**
- **A test to help assess sensitivity to the blood-thinning drug warfarin**
- **The first quick test for malaria**
- **A test that helps in assessing the risk of tumor recurrence and long-term survival for patients with relatively high-risk breast cancer**
- **A companion diagnostic test to select metastatic melanoma patients with a BRAF mutation for therapy with the drug Zelboraf (vemurafinib)**
- **Glucose meter that attaches to the iPhone**
- **New tests to assess the prognosis of heart failure patients**

Regulating Medical Devices

New device legislation brings new challenges and opportunities for the regulatory system.



Regulatory Mandates

1968 Radiation Control for Health & Safety Act (RCHSA)
1976 Medical Device Amendment of 1976
1988 Clinical Laboratory Improvement Amendments (CLIA)
1990 Safe Medical Devices Act (SMDA)
1992 Mammography Quality Standards Act (MQSA)
1992 Medical Device Amendments
1997 Food & Drug Administration Modernization Act (FDAMA)
2002 Medical Device User Fee and Modernization Act (MDUFMA)
2005 Medical Device User Fee Stabilization Act (MDUFSA)
2007 Food and Drug Administration Amendments Act of 2007 (FDAAA)

Strategic Priorities/ 510(k) Reform

Outline of Initiatives and Action Items

- Establish Center Science Council (CSC)
- Assess Center Staffing Needs – **Reorg Pending**
- Enhance Training – LRP/RCP/LED
- Leverage External Experts (Network of Experts) (Draft SOP)
- “Assurance Case” Pilot Program
- Notice to Industry Letters

Outline of Initiatives and Action Items

- Improve the IDE Process
- **Unique Device Identification (UDI) System**
- 3rd Party Review
- Guidance/Regulation Development Process
- 510(k) Transfer of Ownership Regulation
- **Improve Medical Device Labeling**
- **Enforcement Discretion Guidance for certain IVDs and Radiology Devices (precursor to 510(k) exemption)**

Outline Initiatives and Actions Items

- Change in Reviewer SOP
- **Innovation Pathway**
- ODE - Corrective and Preventive Action (CAPA) System Pilot
- **OIVD – Triage Pilot**

Guidances

Published Program Guidance

- 510(k) Modifications Guidance
- Clinical Trials Guidance
- *De Novo* Guidance
- 510(k) Program Guidance
- Benefit-Risk Guidance (Final)
- Feasibility/First in Human Guidance
- IDE Decisions Guidance

Outline of Program Guidances Yet To Come

- Pre-Submissions Guidance (previously referred to as Pre-IDE)
- Refuse to Accept (RTA)
- Interactive Review and other communications
- Other MDUFA-Related Guidances

OIVD Guidances Yet To Come

- Class II Special Controls Guidance Document: Tryptase Test System
- Class II Special Controls Guidance Document: Dengue Virus Serological Reagents
- Establishing the Performance Characteristics of *In Vitro* Diagnostic Devices for the Detection of methicillin-resistant *Staphylococcus aureus* (MRSA) for Culture Based Devices (Final)
- LDT Guidances

……And finalization of any drafts that were published in the last couple of years.

Key Points of MDUFA III

- Shared Outcome Goal – Total Time
- 1 Tier System
- No Submission Left Behind
- Refuse to Accept policy
- Substantive Interaction goals
- PMAs separated: panel vs no panel

Key Points of MDUFA III

- Resources allocated to support a reorganization

- Commitment letter posted

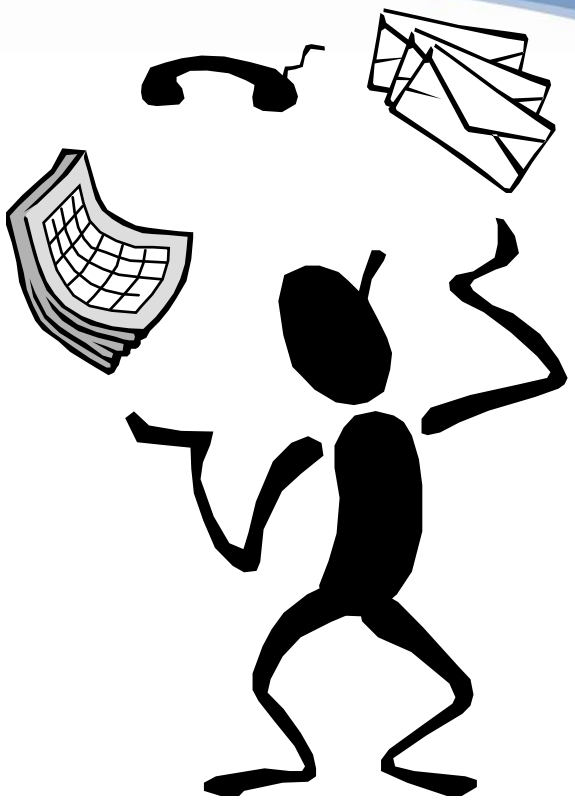
  http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf

New News

- Holds for 180 days Maximum then delete
  - Premarket program (ODE and OIVD)
- Special 510(k) Conversions
  - 1st 4 months of CY2012
  - 26 IVD specials received
  - 7 converted from special to traditional (1 for IFU issue, 4 for technology, and 2 for other)
  - SE to conversion rates in ODE

Old New News

- Artificial Pancreas moved from ODE to OIVD as the lead
- Oversight of the Third Party Review Program moved from ODE to OIVD



When in doubt, just ask:

Email or phone

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Triage Pilot – 1st month Metrics

- Total number of 510(k)s accepted into Quick Review Triage Pilot: 8/59; 13% of Traditional 510(k)s; from 8 sponsors
- All Quick Reviews cleared between 10-50 days
- Reasons for Rejection (>100% due to multiple reasons):
  - Program (extensive consults; division experience): 53%
  - TPLC: 7%
  - Known Quality: 50%
    - Missing data/documentation: 24%
    - Performance data: 13%
    - Predicate &/or IFU: 9%
    - didn't follow guidance: 4%

May prelims: 13%, ½ completed, 15-28 days

Triage Congratulations

- Abbott
- Bio-rad
- ChemTron
- Cliniqa
- Copan Flock
- Halifax
- Kamiya
- Meridian BioScience
- Optoacoustics
- Roche
- Siemens

Proposed OIVD Reorg

(beginning FY2013?)

- Office of In Vitro Diagnostics and Radiological Health (OIR)
  - Division of Chemistry and Toxicology (DCTD)
  - Division of Immunology and Hematology (DIHD)
  - Division of Microbiology (DMD)
  - Division of Program Operations and Management (DPOM)
  - Division of Radiological Health (DRH)
  - Division of Mammography Quality Standards (DMQS)

Big changes

- Adding branches
  - Consistent with the rest of the Center
  - More manageable (~ 10/branch)
- Adding Post-market Radiology (from OC and OSB)
- Adding all RH (from OCER)
- Adding MQSA (from OCER)

DCTD

- Chemistry Branch
- Diabetes Branch
- Toxicology Branch
- Cardio-Renal Branch

DIHD

- Hematology Branch
- Immunology and Flow Cytometry Branch
- Molecular Pathology and Cytology Branch
- Immunology/Hematological Genetic Disorders Branch

DMD

- Viral Respiratory and HPV Branch
- General Viral and Hepatitis Branch
- General Bacterial and Antimicrobial Susceptibility Branch
- Bacterial Respiratory and Medical Countermeasures Branch

DPOM

- Program Operations Team
- Management Operations Team

DRH

- Magnetic Resonance and Electronic Products Branch
- Diagnostic X-Ray Systems Branch
- Nuclear Medicine and Radiation Therapy Branch
- Mammography, Ultrasound and Software Branch

DMQS

- Program Management Branch
- Information Management Branch

Reorg Challenges

- Management training
- Concurrent MDUFA III changes
- Premarket program changes

What would be important for you to know?