FDA Update

Office of In Vitro Diagnostics and Radiological Health (OIR)

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CLIAC November 5, 2014

Outline

- OIR – Organizational Update
- CDRH Priorities
- MDUFA III
- PMA / De novo Approvals
- Meetings
- Guidance
- Other

Organizational Update

285 staff

{~2/3 IVD (1/3 Rad Health); ~40% ≤ 3yrs}

DCTD – Chemistry Toxicology - 45

DMD – Microbiology - 52

DIHD – Immunology Hematology - 32

DMGP – Molecular Genetics and Pathology - 32

CDRH 2014-2015 Priorities

- ***Strengthen the Clinical Trial Enterprise***
  - Reduce cycles/Increase early feasibility & FIH
  - Expand interactions/Better PreSub utilization
- ***Strike the Right Balance Between Premarket & Postmarket Data Collection***
  - EAP/Pre-Post Balance/LB considerations
- ***Provide Excellent Customer Service***
  - Customer survey/*Staff Training*

OIR Staff Training

- Mentors
- Product Specialists
- Supervisory QC
- Internal training
- Working Group/Branch/Division/Office mtgs
- Go-To Group
- DPOM
- Staff College
- Travel / Conferences

MDUFA III status

- Quarterly reports
  - google – mdufma performance reports
  - Everything you wanted to know, but were afraid to ask
- So far looking pretty good
- Independent Assessment

CY 2014 PMA Approvals IVDs

- Roche cobas HPV Test – P100020/S008
- Roche Elecsys HBeAg Immunoassay – P130015
- Dexcom G4 PLATINUM (Pediatric) Continuous Glucose Monitoring System – P120005/S002
- Qiagen *therascreen* KRAS RGQ PCR Kit– P110027
- Siemens Advia Centaur HBsAgII – P110041
- Exact Science Cologuard – P130017

CY2014 Denovos

Affymetrix CytoScan® Dx Assay	K130313
Euroimmun Anti-PLA2R IFA	K132379
Quidel Lyra™ Direct HSV 1 + 2/VZV Assay	K133448
Focus Simplexa™ HSV 1 & 2 Direct	K133621
Quidel Lyra Direct Strep Assay	K133883

Notable CY2014 OIR Meetings

Advisory Panels: March 12 – HPV
March 26 – Epigenomics
March 27 – Exact Sciences

Public Workshop (April 1) – Advancing Regulatory Science for High Throughput Sequencing Devices for Microbial Identification and Detection of Antimicrobial Resistance Markers

CY2014 OIR Guidances

- **Final Guidances**:
  - Administrative Procedures (CLIA); Companion Dx; Multiplex
- **Class II Special Controls Guidelines:**
  - John Cunningham Virus; Dengue; TB; Tryptase

CY2014 OIR Guidances

- **Drafts:**
  - LDT Guidances
  - Blood Glucose Monitoring Systems for Prescription Point-of-Care Use; Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use
  - EGR1 Gene FISH Test System
  - Surveying, Leveling, or Alignment Laser Products; Policy Clarification for Certain Fluoroscopic Equipment

CY2014 CDRH Guidances

- GUDID
- UDI
- MDDS
- 510(k) Benefit/Risk (draft)
- Evaluation of SE in 510(k)s
- Appeals
- Premarket Assessment of Pediatric Devices
- HDE Q&A (draft)
- PreSub Guidance
- Q&A on eMDR

CY2014 CDRH Guidances

- Annual Reports for PMAs
- EAP (draft)
- Premarket/ Postmarket Balance (draft)
- Types of Communications
- Voluntary Consensus Standards (draft)
- Home Use
- Denovo (draft)
- FDA Decisions for IDEs
- Custom Devices

EUAs / CLIA Waiver

- 2014 Ebola Virus Emergency Use Authorization

- CLIA (CY2014)
  - 7 Approval Decisions
  - 3 Dual Pre-Subs
  - 1 Dual 510(k)/CLIA Waiver Submission

Thanks

ACRONYM LIST

OIR	Office of In Vitro Diagnostic and Radiological Health
CDRH	Center for Devices and Radiological Health
MDUFA III	Medical Device User Fee Amendments 2012
PMA	Premarket Approval
DCTD	Division of Chemistry and Toxicology Devices
DMD	Division of Microbiology Devices
DIHD	Division of Immunology and Hematology Devices
DMGP	Division of Molecular Genetics and Pathology
DPOM	Division of Program Operations and Management
GUDID	Global Unique Device Identification Database
UDI	Unique Device Identification
MDDS	Medical Device Data Systems
HDE	Humanitarian Device Exemption
eMDR	Electronic Medical Device Reporting
EAP	Expanded Access Programs
IDE	Investigational Device Exemption