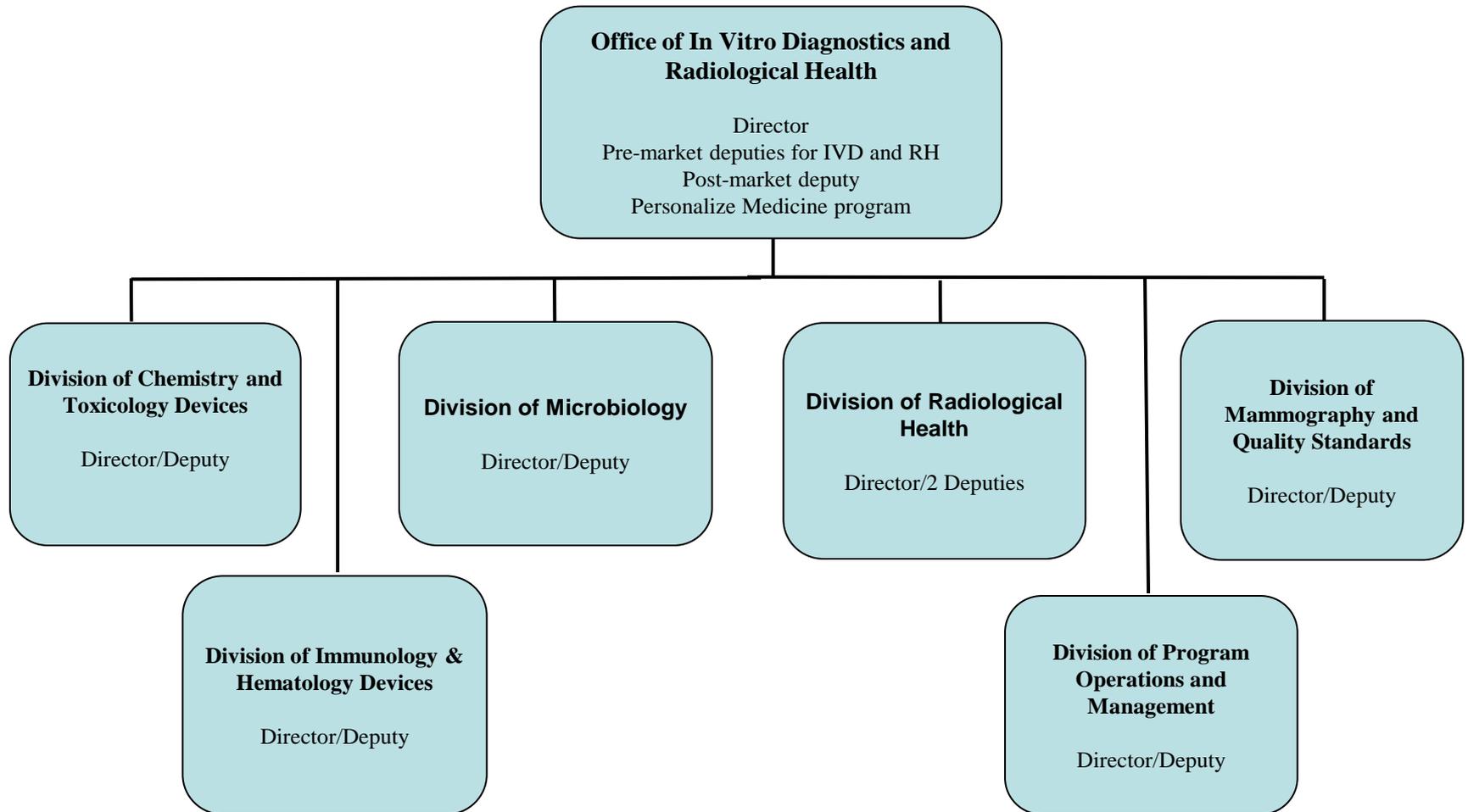




FDA Update

Alberto Gutierrez, PhD

Organizational Change





Organizational Change

- Increased the number of first line managers
- Re-focused the Office on total product life cycle regulation



MDUFA III

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



Submission Type		MDUFA III (2013-2017) - all in FDA Days except Average Total Time				
		FY13	FY14	FY15	FY16	FY17
510(k)s	Performance Goal	91% in 90 days	93% in 90 days	95% in 90 days	95% in 90 days	95% in 90 days
	Interaction Goal	65% in 60 days	75% in 60 days	85% in 60 days	95% in 60 days	95% in 60 days
	Average Total Time (shared)	135 days	135 days	130 days	130 days	124 days
Original PMAs & Panel Track Supplements (including Expedited)	Performance Goal (no panel mtg)	70% in 180 days	80% in 180 days	80% in 180 days	90% in 180 days	90% in 180 days
	Performance Goal (with panel mtg)	50% in 320 days	70% in 320 days	80% in 320 days	80% in 320 days	90% in 320 days
	Interaction	65% in 90 days	75% in 90 days	85% in 90 days	95% in 90 days	95% in 90 days
	Average Total Time (shared)	395 days	395 days	390 days	390 days	385 days
180 Day PMA Supplements	Performance Goal	85% in 180 days	90% in 180 days	90% in 180 days	95% in 180 days	95% in 180 days
	Interaction	65% in 90 days	75% in 90 days	85% in 90 days	95% in 90 days	95% in 90 days
Real Time PMA Supplements	Performance Goal	90% in 90 days	90% in 90 days	95% in 90 days	95% in 90 days	95% in 90 days
CLIA Waiver Applications	Dual CLIA/510(k)	90% in 210 days				
	CLIA (no panel)	95% in 180 days				
	CLIA (with panel)	95% in 330 days				

MDUFA III – What to Expect

- A lot of internal changes for staff to learn
- More Touch Points (after RTA screening, after SI, after MMD, during IR)
- Electronic correspondence, digitally signed (won't have to wait for the mailman)
- Less review cycles to reach a final decision (more decisive which means less flexible)
- A better documented/tracked database (better performance data available to stakeholders which means a more formalized process)

MDUFA III status

- 1st quarter (10/1 – 12/31)
 - mostly beta testing new IT systems and processes
- 2nd quarter (1/1 – 3/31)
 - Fingers crossed

PMA Approvals

- Abbott's ARCHITECT AFP Assay
 - Aid in monitoring nonseminomatous testicular cancer
 - Aid in the detection of fetal open neural tube defects
- Gen-Probe's APTIMA® HPV 16 18/45 Genotype Assay

PMA Approvals

- Dexcom's G4 PLATINUM Continuous Glucose Monitoring System
- Qiagen's therascreen® KRAS RGQ PCR Kit
 - Identification of CRC patients for treatment with Erbitux® (cetuximab)
- Roche's COBASo AmpliPrep/COBAS® TaqMan® CMV Test
 - Aid in the management of solid-organ transplant patients who are undergoing anti-CMV therapy

PMA Approvals

- Beckman's Access Hybritech p2PSA on the Access Immunoassay Systems
 - Used in combination with Access Hybritech (total) PSA and Access Hybritech free PSA to calculate the Beckman Coulter Prostate Health Index (phi), an In Vitro Diagnostic Multivariate Index Assay (IVDMIA)
- Leica's BONDTM ORACLETM HER2 IHC System
 - Companion diagnostic to Herceptin

PMA Approvals

- Abbott's ARCHITECT HBsAg Qualitative Assay
- Otsuka's pediatric BreathTek UBT for H. pylori Kit
- Gen-Probe's PROGENSA® PCA3 Assay
- Siemens' ADVIA Centaur Anti-HBs2 (aHBs2) Assay
- Roche's Elecsys Anti-HBc IgM Immunoassay

De Novo Downclassifications

- Ferriscan R2-MRI Analysis System
 - Intended to measure liver iron concentration to aid in the identification and monitoring of non-transfusion dependent thalassemia patients receiving therapy with deferasirox.
- Luminex's xTAG® Gastrointestinal Pathogen Panel (GPP)
 - A gastrointestinal microorganism multiplex nucleic acid-based assay is a qualitative *in vitro* diagnostic device intended to simultaneously detect and identify multiple gastrointestinal microbial nucleic acids extracted from human stool specimens.

De Novo Downclassifications

- VERIGENE® Gram Positive Blood Culture Nucleic Acid Test
 - A qualitative, multiplexed *in vitro* diagnostic test for the simultaneous detection and identification of potentially pathogenic gram-positive bacteria which may cause bloodstream infection.
- CDC's Dengue Virus (DENV) RNA target sequence
- Phadia's ImmunoCAP Tryptase
 - Aid in the clinical diagnosis of patients with a suspicion of systemic mastocytosis

De Novo Downclassifications

- Focus Diagnostics' STRATIFY JCV™ Antibody ELISA
 - Detection of antibodies to John Cunningham virus in human serum or plasma. It is intended for use in conjunction with other clinical data, in multiple sclerosis and Crohn's disease patients receiving natalizumab therapy, as an aid in risk stratification for progressive multifocal leukoencephalopathy development

Guidances

- Special Controls : Norovirus Serological Reagents
- Special Controls : Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of Mycobacterium tuberculosis Complex in Respiratory Specimens
- Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications
- The Pre-Submission Program and Meetings with FDA Staff (draft)



Guidances

- FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals
- FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals
- Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices
- The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems



Guidances

- eCopy Program for Medical Device
- Acceptance and Filing Reviews for Premarket Approval Applications (PMAs)
- Refuse to Accept Policy for 510(k)s
- Accreditation and Reaccreditation Process for Firms under the Third Party Review Program (draft)

Notable Panel Meetings

- Clinical Study Design and Performance of Hospital Glucose Sensors, June 25, 2012
- Clinical Flow Cytometry in Hematologic Malignancies, February 25-26, 2013

Glucose Meter Polemic

- Glucose Meter public meeting March 2010.
 - “Not to be used for patients who are critically ill”

The ACCU-CHEK Inform II Test strip is for use with the ACCU-CHEK Inform II meter to quantitatively measure glucose (sugar) in venous whole blood, arterial whole blood, neonatal heelstick, or fresh capillary whole blood samples drawn from the fingertip as an aid in monitoring the effectiveness of glucose control.

- “the performance of this system has not been evaluated in the critically ill.”



Thanks