OIR/OHT7 Update

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OHT7:Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration

FDA-Industry Roundtable Meeting
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Mission, Vision, & Shared Values

CDRH Mission

"…to protect and promote the public health…"

CDRH Vision

"Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world…"

CDRH Shared Values

Public Health Focus
Science-Based Decisions
Our People
Innovation
Transparency
Honesty and Integrity
Accountability

Patients are at the Heart of What We Do!

Key Office IVD Activities

- Premarket – Pre-submissions, Breakthrough Designations, CLIA Waiver Reviews and complexity determinations, 510(k), De Novo, PMA, EUA, IDE, and HDE
- Relevant Guidance Documents
- Third Party Review Program
- Surveillance
- Compliance
- Community Outreach

Highly Productive Office

In a typical year we receive…

- ~1800 Submissions
  - ~100 PMAs and PMA Supplements
  - >700 510(k)s
  - >1,000 Pre-Submissions
  - ~40 IDEs
  - + Plus multiple other types of submissions
- Surveillance
  - ~800,000 MDRs

EUAs in 2020

...2020 was far from typical.

As of 11/16/2020, 288 EUAs have been authorized for test kit manufacturers and commercial laboratories (223 molecular, 58 serology, 7 antigen)

Over 800 EUA submissions are currently in house.

Impact on non-COVID submissions

OIR by the numbers:

Over 310 Scientists & Engineers

- ~20 MDs
- ~150 PhDs
- ~40 Masters

CDRH by the numbers:

>90%

external customer satisfaction rating

We're proud of our talented, well-educated, and professional staff.

FY20 Hiring

OIR by the numbers:

59 External to CDRH hires

1 Internal to CDRH hire

1 Internal to OPEQ hire

61 Total new OIR staff

CDRH by the numbers:

282

external hires in FY20

OHT7: Office of In Vitro Diagnostics & Radiological Health (OIR)

Office Director: **Timothy Stenzel**
Deputy Director New Product Evaluation: **Donald St. Pierre**
Deputy Director Patient Safety & Product Quality: **Courtney Lias**
Deputy Director Radiological Health: **Robert Ochs**
Deputy Director Personalized Medicine: **Wendy Rubinstein**
Associate Director Programs & Performance: **Toby Lowe**
Associate Director Strategic Initiatives: Vacant
Associate Director for Regulatory Counsel: **Scott McFarland**
Associate Director for Medical Affairs: **Sara Brenner**
Chief Medical Officer for Radiological Health: **Donald Miller**
Associate Director for Operations: **Michelle Sutter**
OIR Immediate Office Staff:
Stacey Borenstein, Jennifer Campbell, Daniel Edelman, Dina Jerebitski, Rebecca Keenan, Marina Kondratovich, Ryan Lubert, Zivana Tezak, Vacant

Division of Chemistry and Toxicology Devices (DCTD)

Director – Kellie Kelm
Deputy – Marianela Perez-Torres (Acting)

Division of Immunology and Hematology Devices (DIHD)

Director – Lea Carrington
Deputy – Takeesha Taylor-Bell (Acting)

Division of Microbiology Devices (DMD)

Director – Uwe Scherf
Deputy – Steve Gitterman

Division of Molecular Genetics and Pathology (DMGP)

Director – Reena Philip
Deputy – Donna Roscoe (Acting)

Division of Mammography Quality Standards (DMQS)

Director – David Lee
Deputy – Preetham Sudhaker

Division of Program Operations and Management (DPOM)

Director – Rob Sauer
Deputy – Vacant

Division of Radiological Health (DRH)

Director – Thalia Mills
Deputy – Michael O'Hara
Deputy – LCDR David Dar (Acting)

FY2020 Highlights

Published FINAL Guidances for:

- ✓ "Recommendations for Dual 510(k) and CLIA Waiver by Application Studies" and "Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices"
- ✓ 510(k) Third Party Review Program
- ✓ "Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use"
- ✓ "Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised): Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff"

Notable Approvals:

- ✓ Approved the first liquid biopsy companion diagnostic that also uses next-generation sequencing (NGS) technology to identify patients with specific types of mutations of the epidermal growth factor receptor (EGFR) gene in a deadly form of metastatic non-small cell lung cancer (NSCLC)
- ✓ Approved first-of-its-kind automated insulin delivery and monitoring system for use in young pediatric patients aged 2 to 6 years with type 1 diabetes

FY2020 Highlights

COVID Response:

- ✓ Hosted over 34 webinars for 40,000+ participants from clinical labs and commercial manufacturers developing diagnostic tests for SARS-CoV-2
- ✓ Maintained an FAQ webpage relating to the development and performance of tests, and responded to over 292,000 inquiries about COVID-19
- ✓ Collaboration with the National Cancer Institute (NCI) to independently validate certain antibody tests
- ✓ Collaborative efforts with the National Institutes of Health (NIH) Rapid Acceleration of Diagnostics (RADx) initiative to speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing
- ✓ Established the COVID-19 Response In Vitro Diagnostics Shortages Team to help address potential device shortages that came with the increase of global demand and supply chain disruptions resulting from COVID-19
- ✓ Authorized the first serology test that detects neutralizing antibodies from recent or prior SARS-CoV-2 infection
- ✓ Authorized the first serology point-of-care (POC) test for COVID-19
- ✓ Authorized SalivaDirect COVID-19 diagnostic test, which uses a new method of processing saliva samples when testing for COVID-19 infection which does not require any special type of swab or collection device and does not require a separate nucleic acid extraction step
- ✓ Authorized the first COVID-19 diagnostic test for at-home use, a molecular, single-use test that can detect SARS-CoV-2 in individuals of all ages

FDA Becomes a Member of Collaborative Communities

- PGx - Standardizing Laboratory Practices in Pharmacogenomics (STRIPE) Initiative
  - The community aims to harmonize and optimize standards, practices, and resources related to pharmacogenetics testing that will improve access to safe, accurate, and reliable information about a patient's medication and drug-gene interactions.
- LiqBx - The International Liquid Biopsy Standardization Alliance (ILSA)
  - *Brings together complementary efforts around liquid biopsy standardization, focused on circulating tumor DNA (ctDNA), to promote its use as a broadly functional biomarker in cancer.*
- Diabetes - REducing SuiCide Rates Amongst IndividUals with DiabEtes (RESCUE)
- Digital Pathology Collaborative Community

More breakthroughs are coming to market through FDA

>370 designated devices

- 89 diagnostics

21 devices authorized to market

- 11 PMAs approved (4 IVDs)
- 5 510(k)s cleared
- 5 De Novos granted (3 IVDs)

MDIC

- SHIELD – Systemic Harmonization and Interoperability Enhancement for Lab Data
- Surrogate Samples - Establishing a foundation where surrogate samples can support product development with an initial focus on studies to support product submissions.
- POC Fingerstick - Developing and defining clear analytical validity study designs for Point of Care devices that use fingerstick capillary blood specimens.
- NGS Reference Samples - Developing reference samples that can be made available to the public to improve the accuracy, reliability and transparency of NGS-based oncology tests.
- Validity and Utility - Creating an evidence framework that test sponsors can use to make decisions on how to develop credible evidence of analytical and clinical validity and clinical utility.
- RWD/RWE - Building a framework for utilizing real-world data as a source of evidence that can be used to support regulatory and reimbursement decision-making for in vitro diagnostics.

Questions?

U.S. FOOD & DRUG
ADMINISTRATION