



U.S. Food and Drug Administration
Protecting and Promoting Public Health



OIR Update

Donald J. St. Pierre

Deputy Director for New Product Evaluation

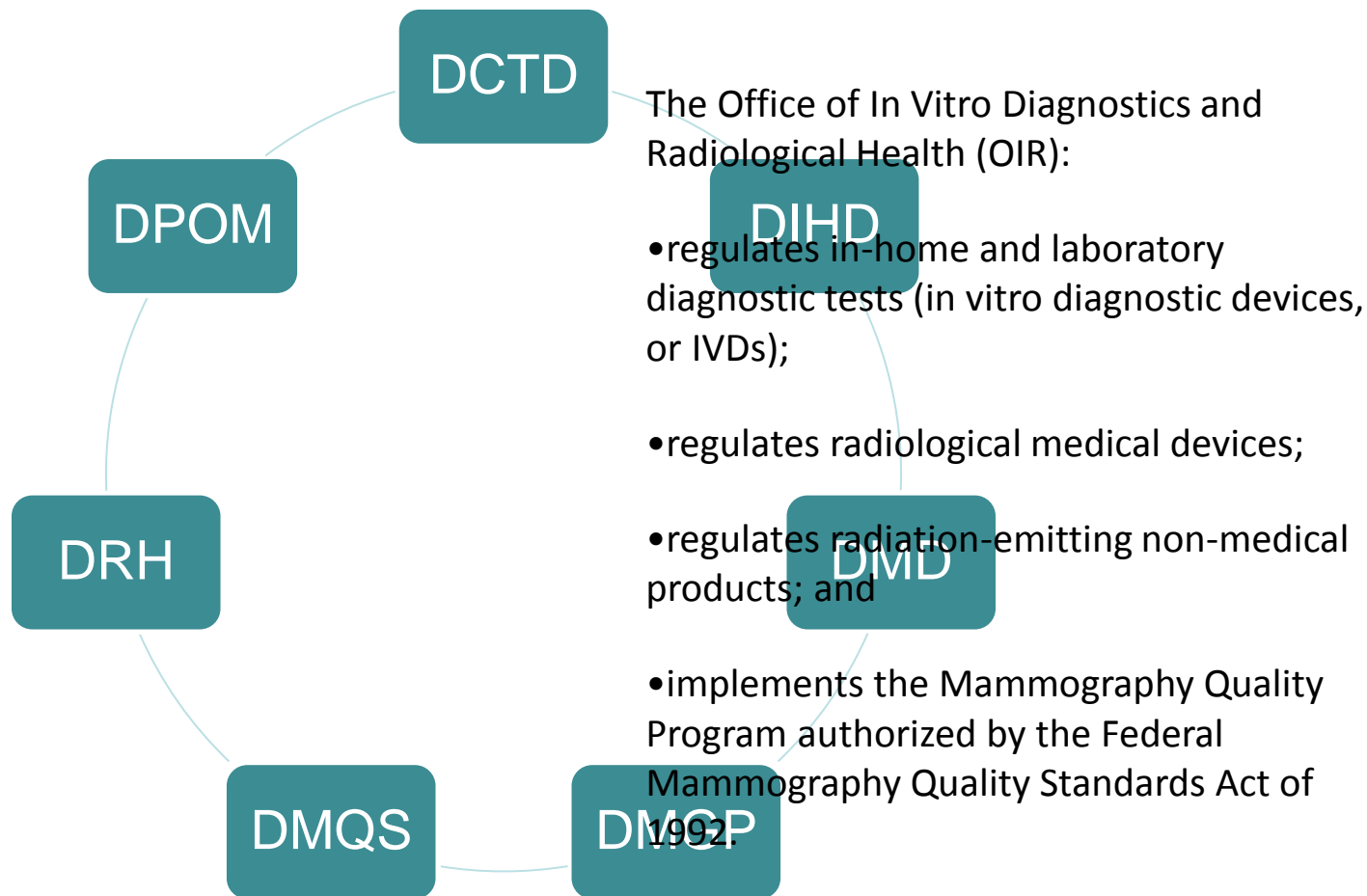
Office of *In Vitro* Diagnostics and Radiological Health (OIR)

June 2, 2016

IVD Roundtable

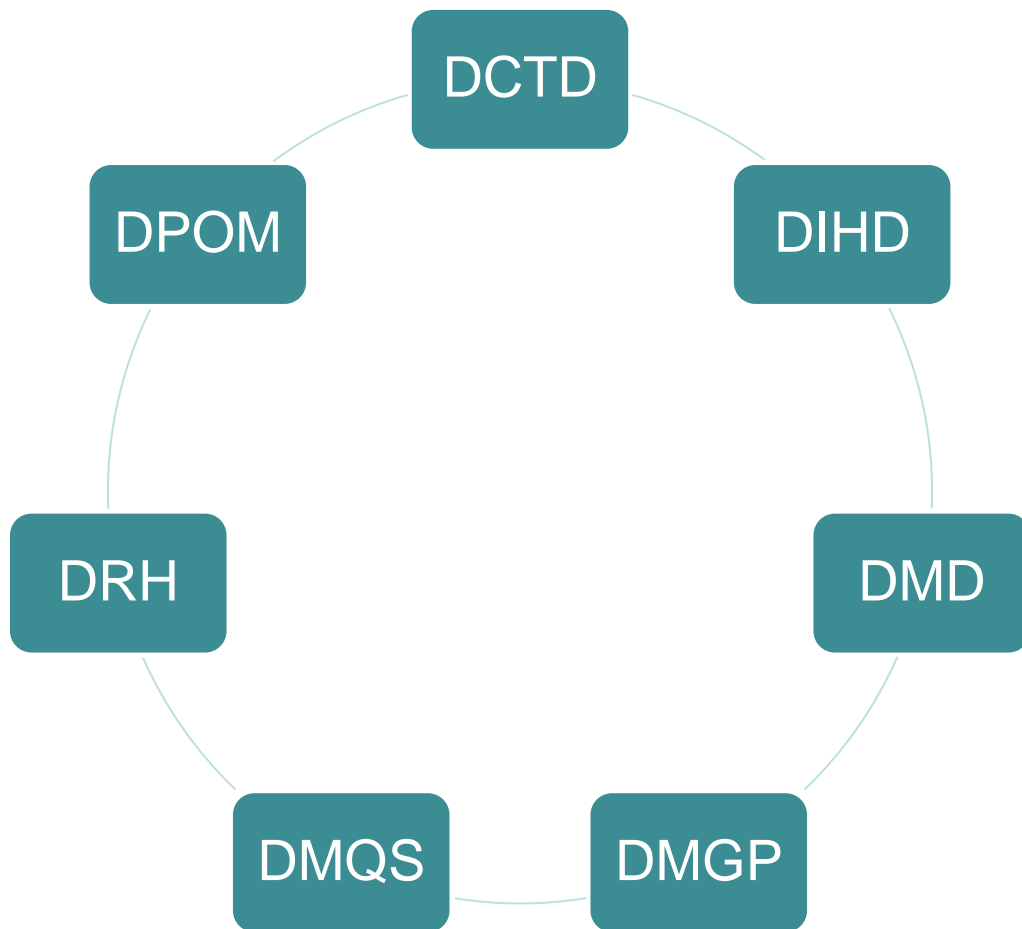
White Oak

Office of In Vitro Diagnostics and Radiological Health





Office of In Vitro Diagnostics and Radiological Health



Alberto Gutierrez, Ph.D.
Director

Donald St. Pierre
Deputy Director for New Product Evaluation

James L. Woods
Deputy Director for Patient Safety and Product Quality

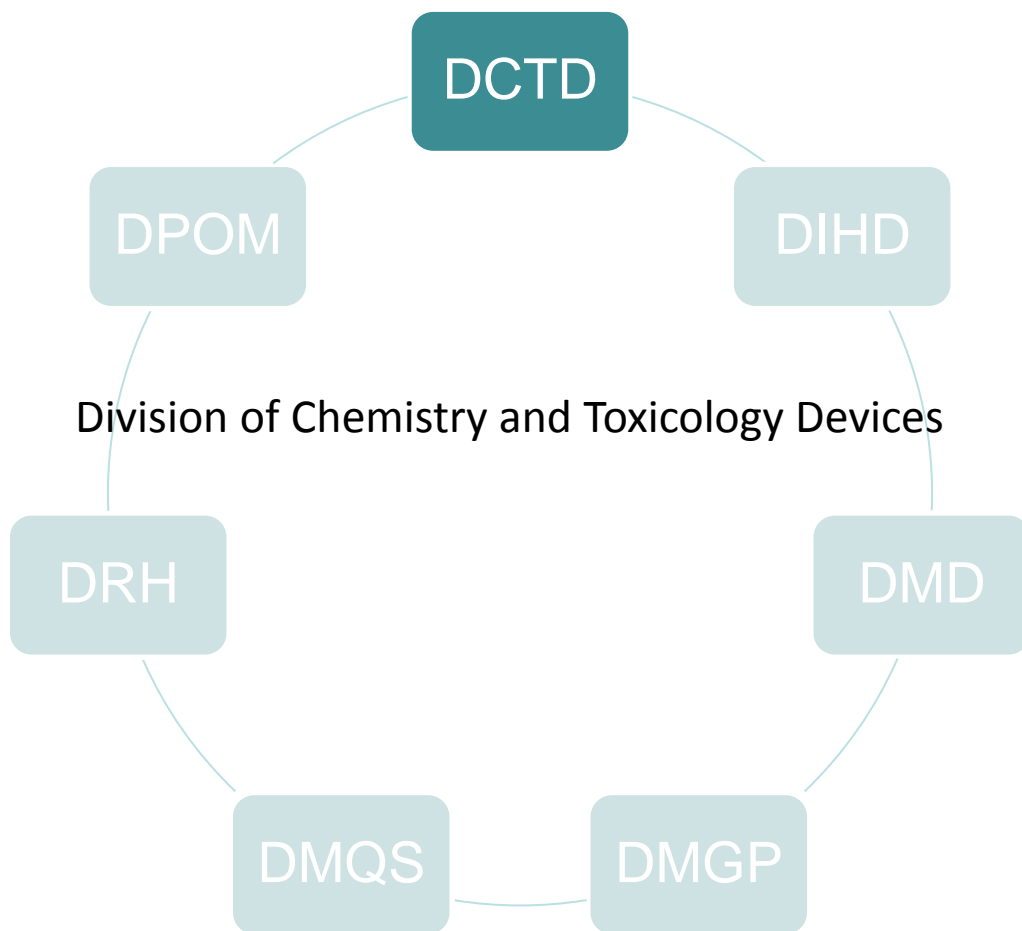
Mary S. Pastel, Sc.D.
Deputy Director for Radiological Health

Elizabeth A. Mansfield, Ph.D.
Deputy Director for Personalized Medicine and Molecular Genetics

Robert L. Becker, Jr, M.D.
Chief Medical Officer for In Vitro Diagnostics

Donald L. Miller, M.D.
Chief Medical Officer for Radiological Health

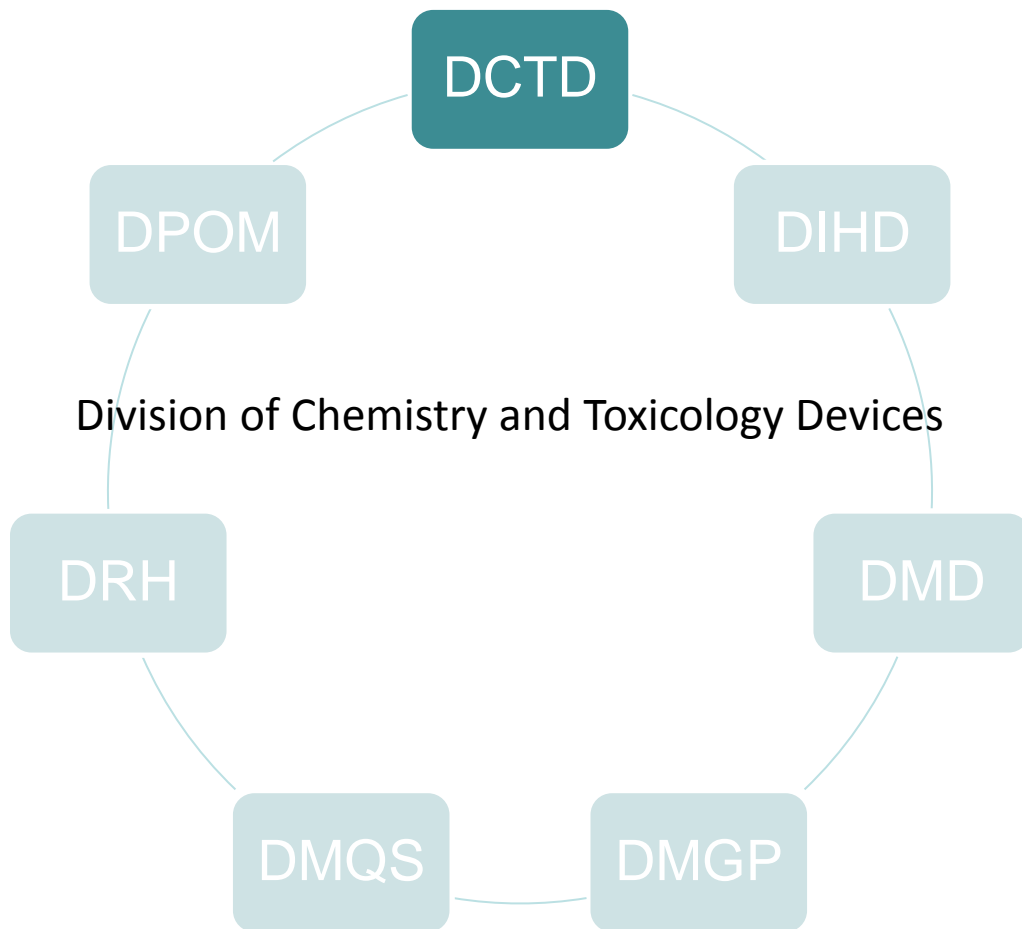
Office of In Vitro Diagnostics and Radiological Health



- General chemistry tests
- Specialized chemistry tests including neonatal biochemical screening tests, endocrine tests, and tests for women's health
- Drugs of abuse tests
- Therapeutic drug monitoring tests
- Minimally invasive and non-invasive tests



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Courtney Lias
Director

Katherine Serrano
Deputy Director

Ileana Elder
Lead, Consumer Safety Officer

Branch Chiefs

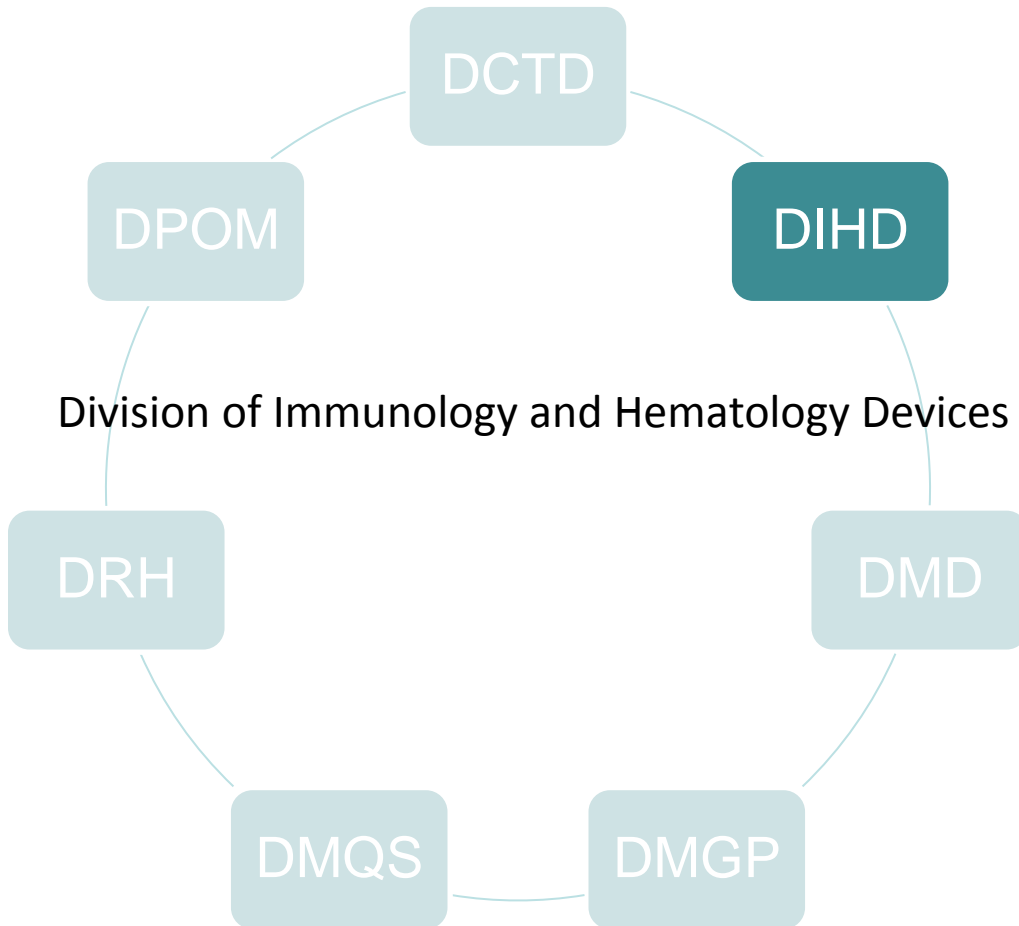
Yung W. Chan
Chemistry

Stayce Beck
Diabetes

James Mullally (*Acting*)
Toxicology

Kellie Kelm
Cardio-Renal Diagnostics

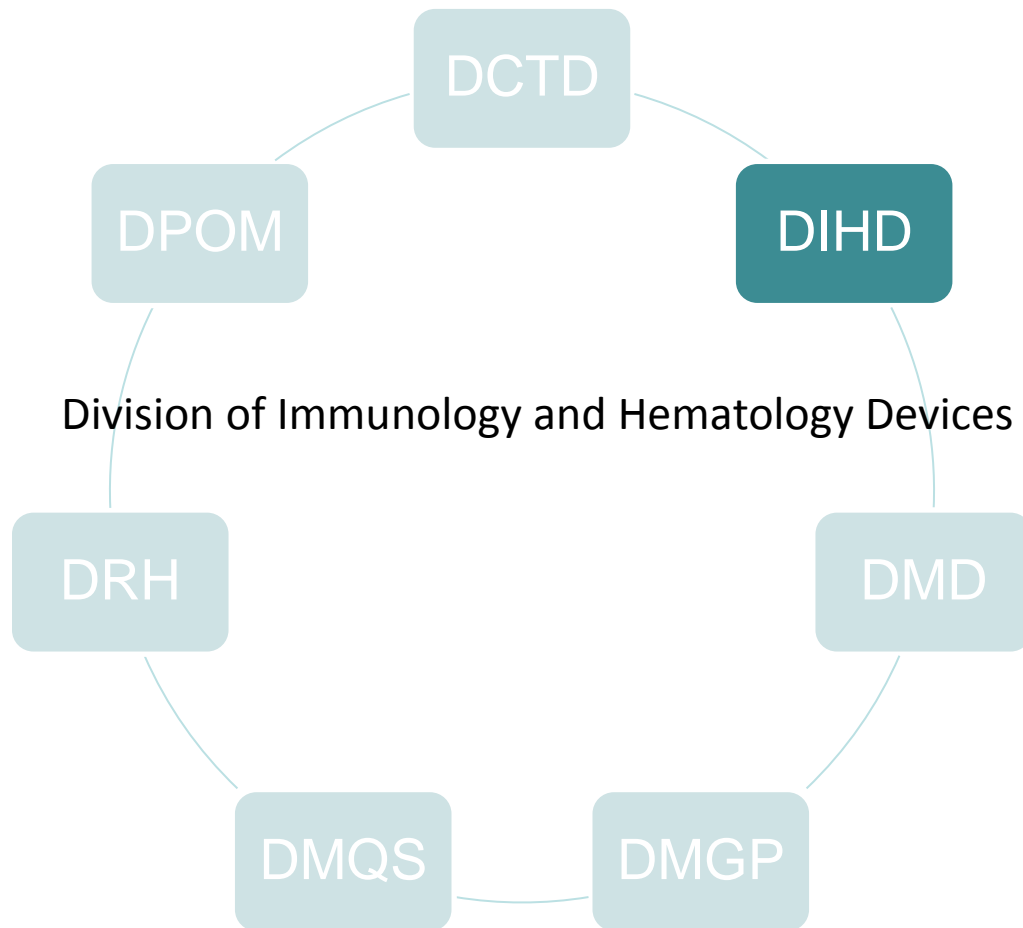
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- Hematology, pathology, flow cytometry, and coagulation tests
- Tests for immunological disease



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Leonthena Carrington

Director

Kelly Oliner

Deputy Director

Nisar Pampori

Lead, Consumer Safety Officer

Branch Chiefs

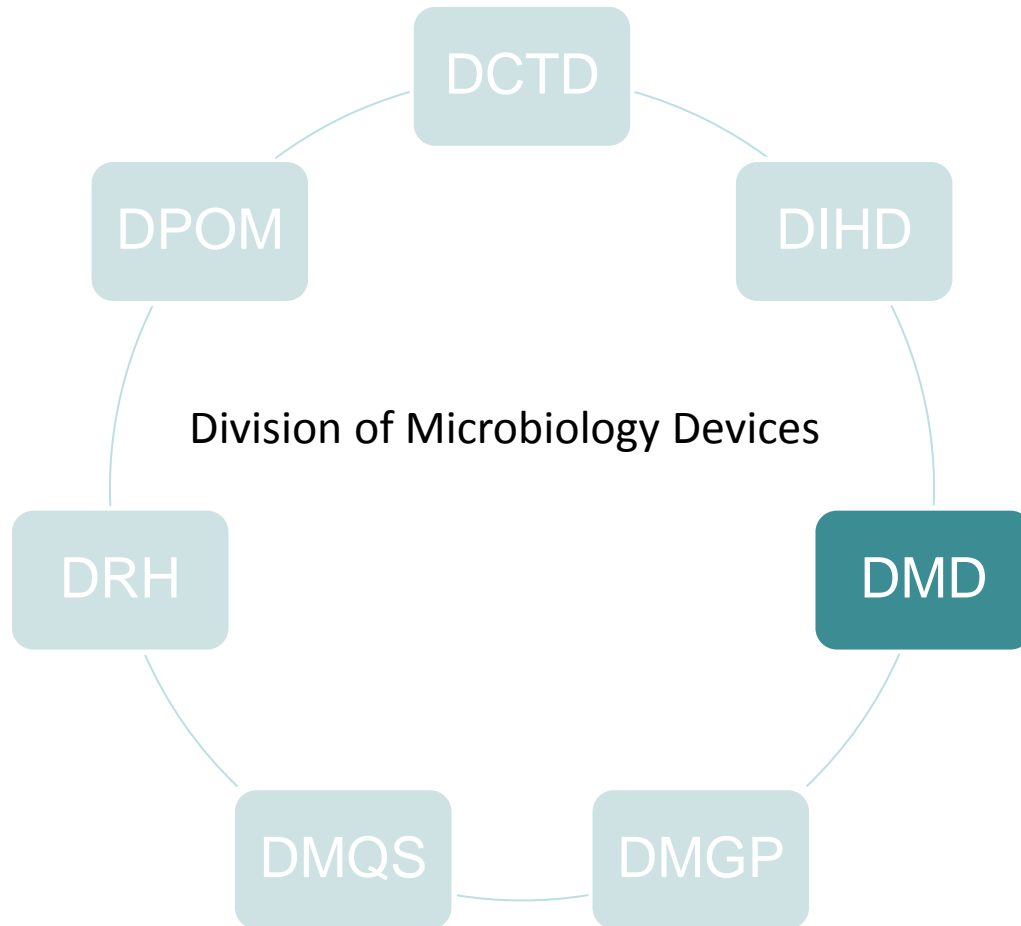
Cheng Zhang

Hematology

Julia Lathrop *(Acting)*

Immunology and Flow Cytometry

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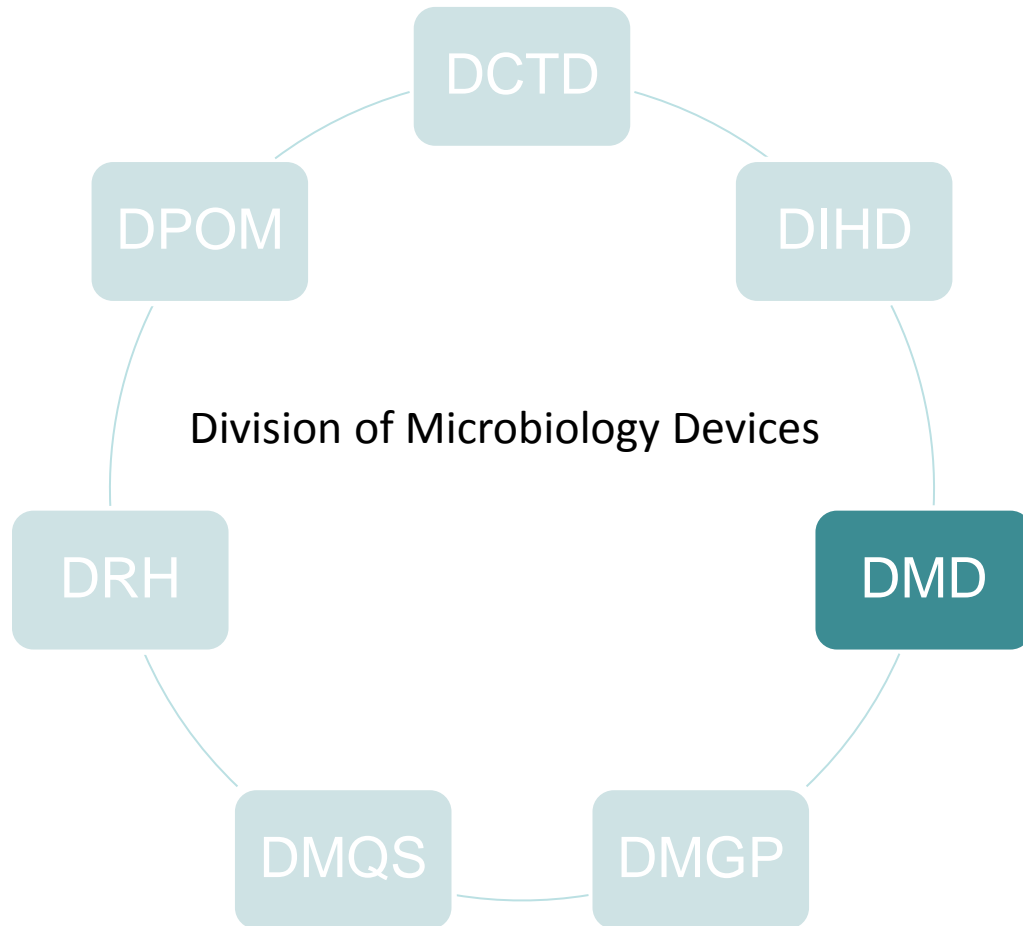


- Detection of microorganisms (bacteria, fungi, mycobacteria, viruses) by chemical, immunological, and nucleic acid amplification methods

- Bio-threat agents

- New and emerging infectious diseases

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Uwe Scherf
Director

Steven Gitterman
Deputy Director

William Shackelford
Lead, Consumer Safety Officer

Branch Chiefs

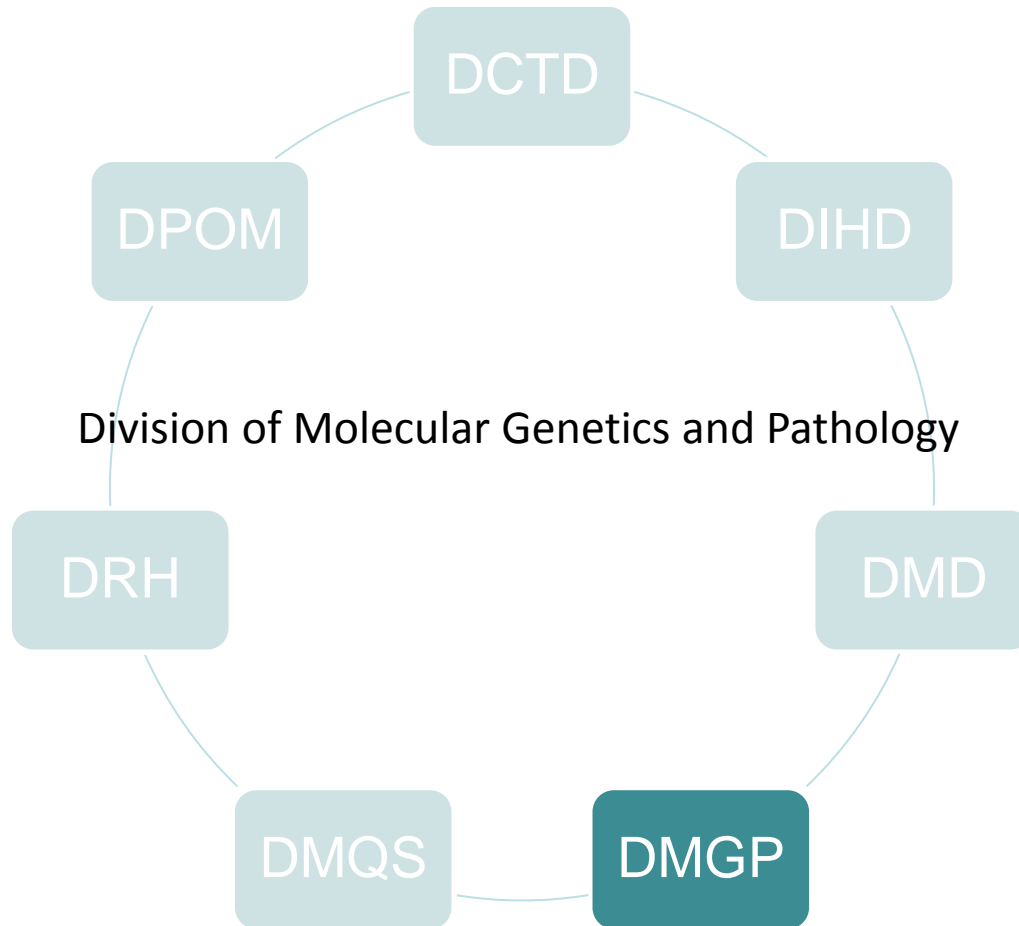
Tamara Feldblyum
Viral Respiratory and HPV

Stephen Lovell
General Viral and Hepatitis

Ribhi Shawar
General Bacterial and Antimicrobial Susceptibility

Kristian Roth
*Bacterial Respiratory and Medical
Countermeasures*

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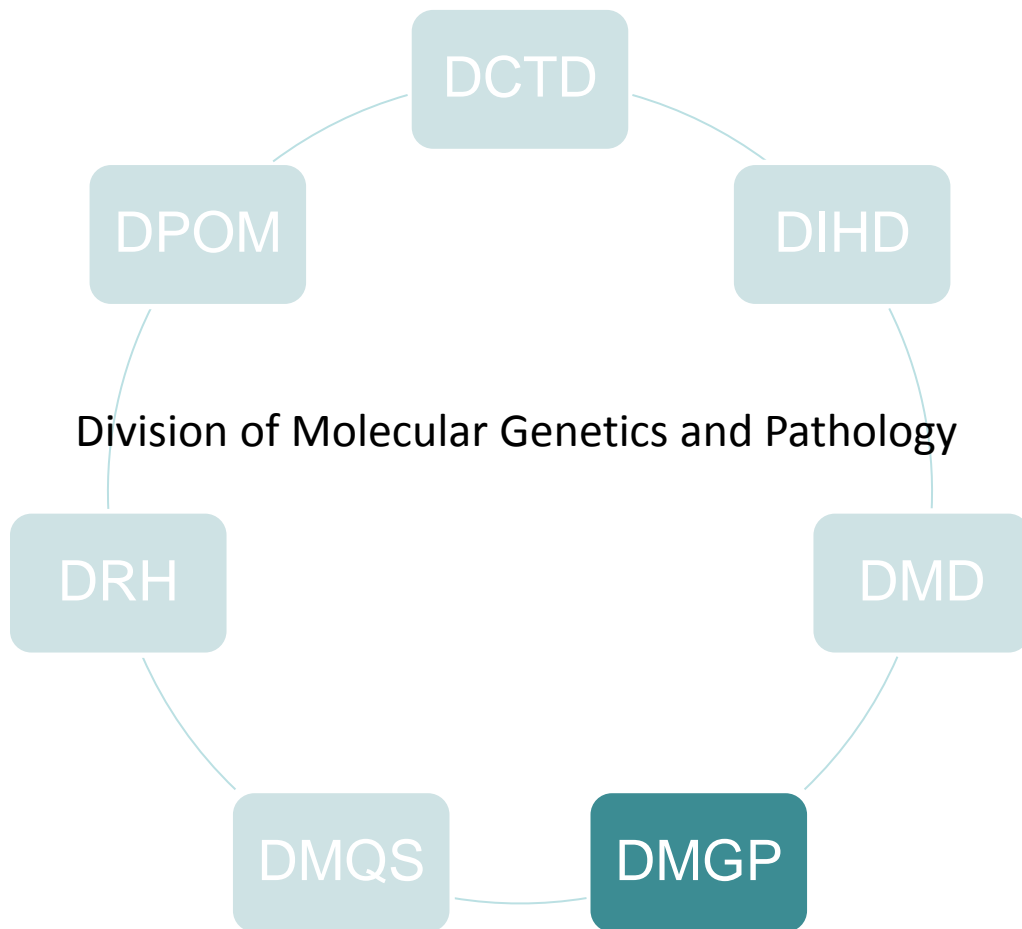


Provides oversight of a variety of product areas including:

- Genetic disorder molecular tests
- Pathology and cytology
- Oncology molecular tests
- Companion diagnostic tests



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Reena Philip
Director

Yun-Fu Hu
Deputy Director

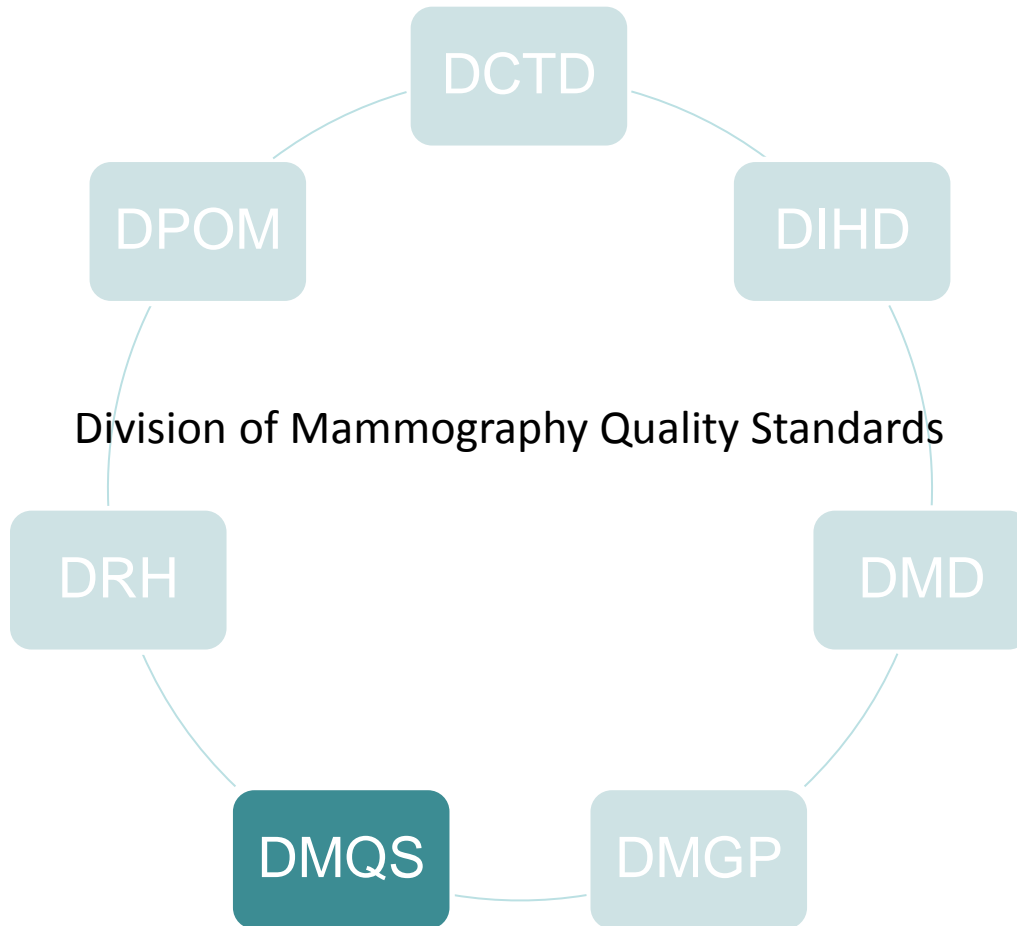
Joshua Levin
Lead, Consumer Safety Officer

Branch Chiefs

Eunice Lee
Molecular Pathology and Cytology

Donna Roscoe
Genetic Disorders

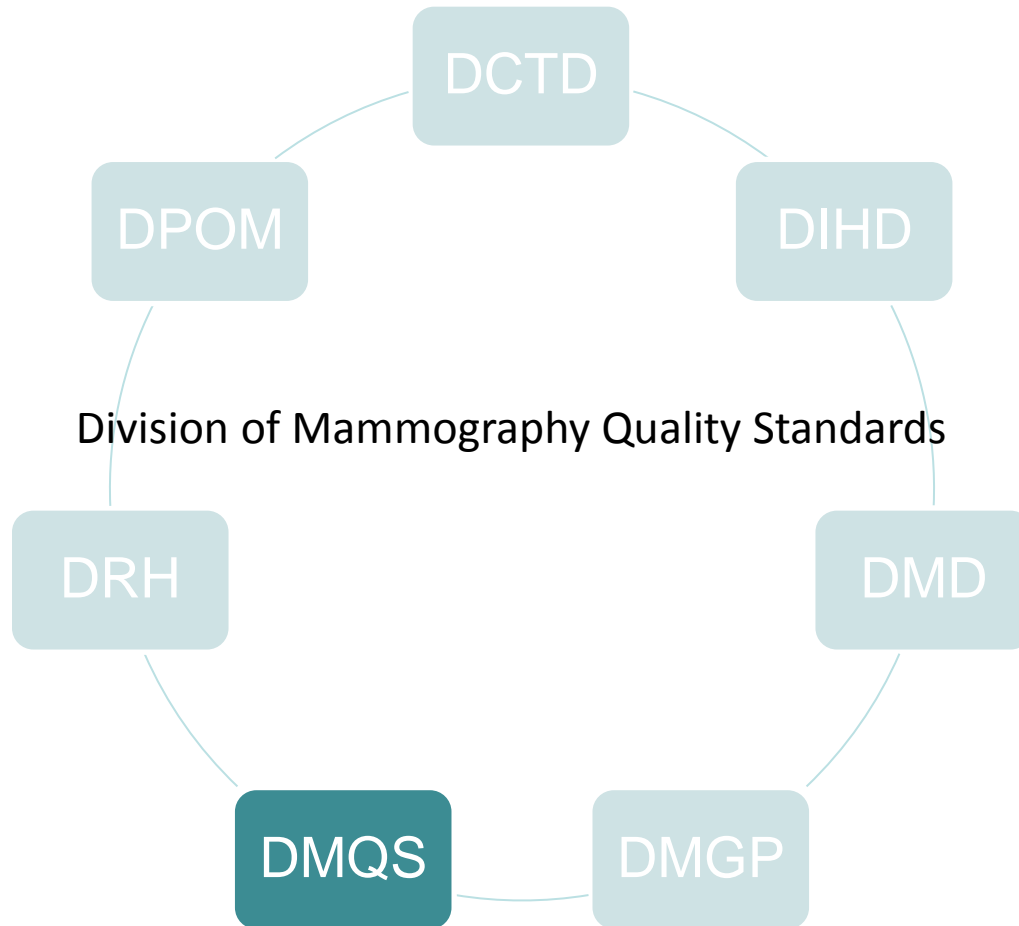
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- Implements the Mammography Quality Program authorized by the Federal Mammography Quality Standards Act of 1992



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Helen Barr
Director

Tim Haran
Deputy Director

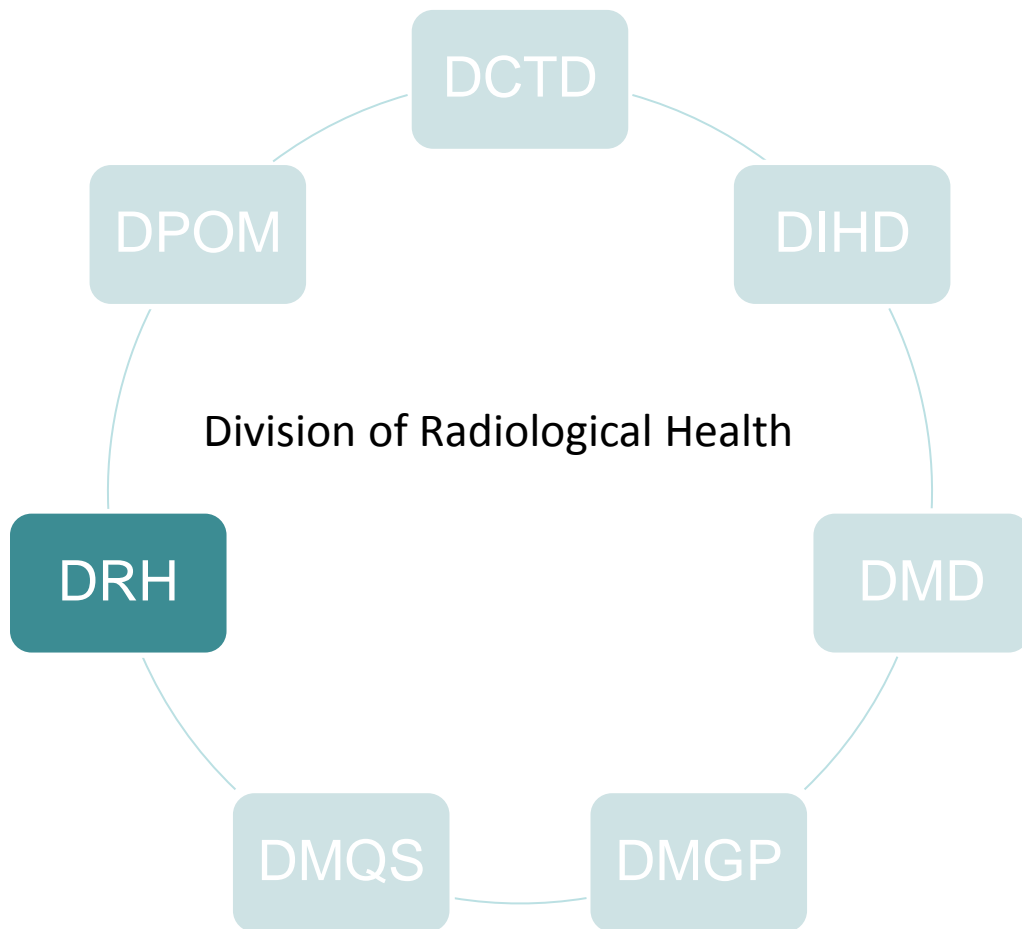
Kathleen Sheridan
Associate Director

Branch Chiefs

Preetham Sudhaker
Program Management

Dan Trammell
Information Management

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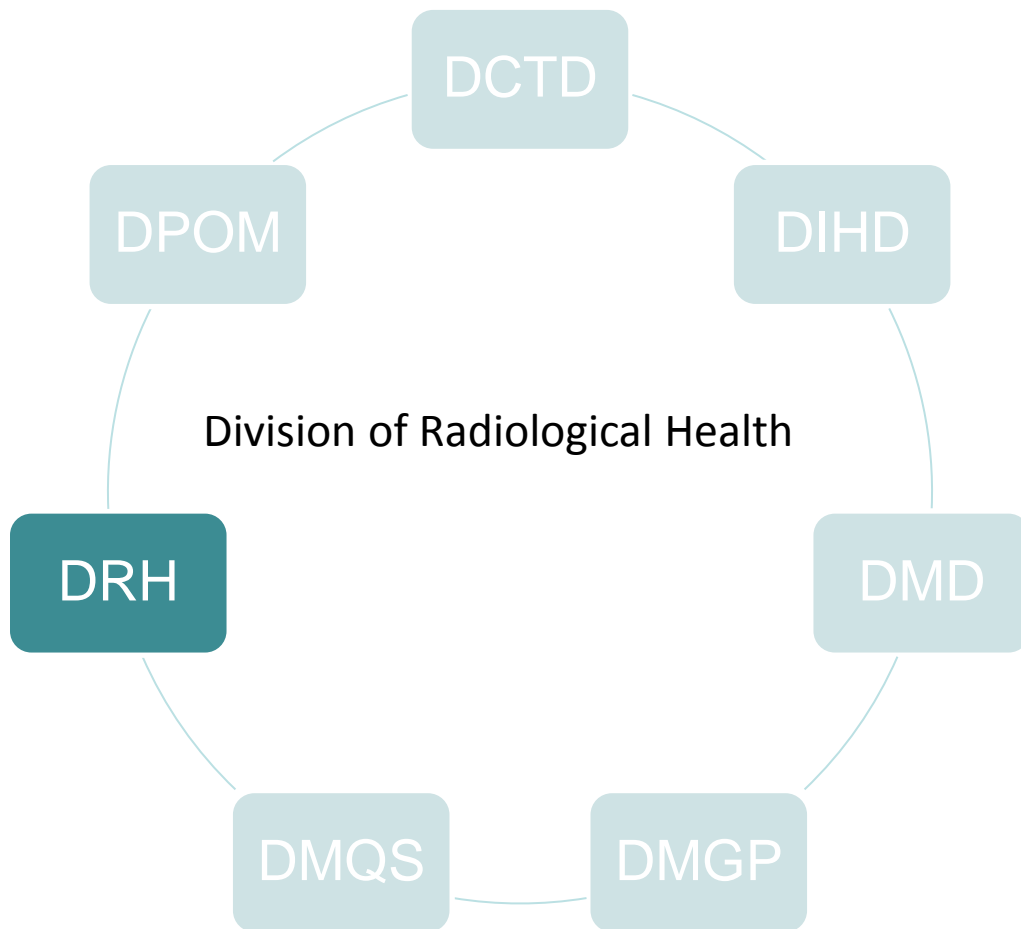
- Diagnostic radiology devices (e.g. X-ray devices, magnetic resonance imaging systems, computed tomography systems, ultrasound systems, nuclear medicine devices, picture archiving and communications systems)

- Radiation therapy devices (e.g. linear accelerators, brachytherapy systems)

- Medical and non-medical electronic product radiation control (e.g. ultrasound products and devices, laser products and devices, and microwave products and devices)



Office of In Vitro Diagnostics and Radiological Health



Division of Radiological Health

Robert Ochs
Director

Michael O'Hara
Deputy Director

Patrick Weixel
Lead, Consumer Safety Officer

Charles Myers
Lead, Consumer Safety Officer

Branch Chiefs

Patrick Hintz
Magnetic Resonance and Electronic Products

Scott Gonzales (Acting)
Diagnostic X-Ray Systems

William Jung
Nuclear Medicine and Radiation Therapy

Jeffrey Ballyns
Mammography, Ultrasound, and Imaging Software

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- Provides scientific support, incorporating project management activities as well as shared oversight of all the necessary quality assurance and quality control mechanisms to ensure smooth running of premarket and postmarket operations

- Provides administrative support, including oversight over program management functions (human resources, budget, travel, training, etc.) that enable management and staff to operate efficiently



Office of In Vitro Diagnostics and Radiological Health



David Warren
Director

Brendan O'Leary
Deputy Director

Cathy Oliveri
Associate Director for Digital Health

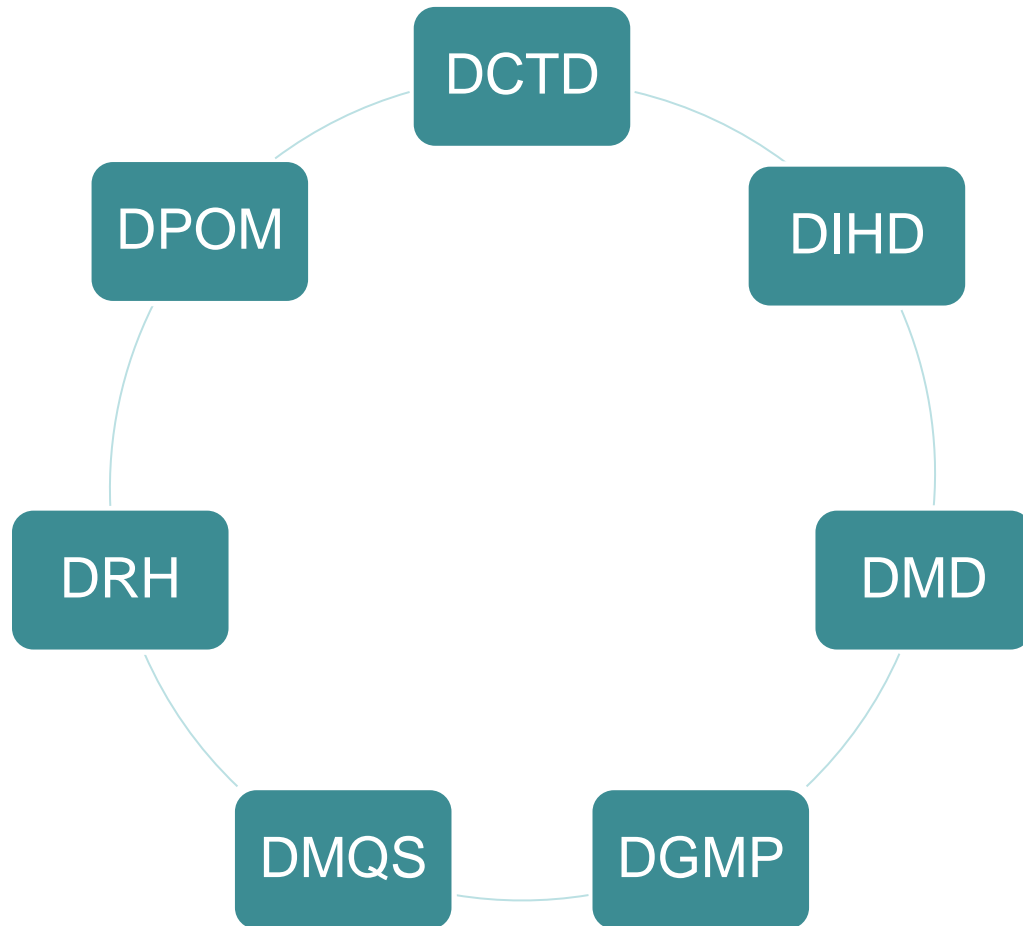
Brendan O'Leary (Acting)
Program Management Officer

Team Leads

Debra Cooper
Program Management



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OIR Losses					
	Reassignment Outside Center (within FDA)	Reassignment within Center	Resignation, Termination, or Transfer to Another Agency (outside FDA)	Retirement	TOTALS
FY-14	5	3	7	10	25
FY-15	7	1	9	11	28
FY-16*	8	5	5	2	20
*(as of 5/25/16) FY-16 figures do not include two pending retirements.					



2016 Strategic Priorities

Establish a National Evaluation System **for Medical Devices**

- Increase access to real-world evidence to support regulatory decision making
- Increase the use of real-world evidence to support regulatory decision making



2016 Strategic Priorities

Partner with Patients

- Promote a culture of meaningful patient engagement by facilitating CDRH interaction with patients
- Increase use and transparency of patient input as evidence in our decision making



2016 Strategic Priorities

Promote a Culture of Quality and Organizational Excellence

- Strengthen FDA's culture of quality within the center for devices and radiological health
- Strengthen product and manufacturing quality within the medical device ecosystem



Recent CLIA Waivers by Application

- Wondfo's Rapid Strep A Test
- Cepheid Gene Xpert Xpress System, Xpert Flu+RSV Xpress Assay



Key Issues and Guidances

- Left over De-Identified Specimens
- Patient Preference Information
- Emerging Postmarket Medical Device Signals
- Emergency Use Authorization of Medical Products and Related Authorities

PMA Approvals

Medtronic Minimed Paradigm REAL-Time Revel System

- **Paradigm REAL-Time Revel insulin pump** for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.
- **Enlite Sensor** for use with the Paradigm REAL-Time Revel insulin pump systems to continuously monitor glucose levels in persons with diabetes.



PMA Approvals IVDs

Ventana PD-L1(SP142) CDX Assay (5/18/16)

- complementary diagnostic for Tecentriq (atezolizumab), the first product in its class approved to treat urothelial carcinoma.

Epigenomics Epi proColon (4/12/16)

- a qualitative in vitro diagnostic test for the detection of methylated Septin 9 DNA in EDTA plasma derived from patient whole blood specimens.



PMA Approvals IVDs

Abbott VYSIS CLL FISH Probe Kit (4/11/16)

- to detect deletion of the LSI TP53 probe target via fluorescence in situ hybridization (FISH) in peripheral blood specimens from patients with B-cell chronic lymphocytic leukemia (CLL)

Dako PD-L1 IHC 28-8 pharmDx (1/23/16)

- previously approved as a complementary diagnostic for testing tumor specimens from patients with non-small cell lung cancer. This approval expands the indication to tumor specimens from patients with melanoma.



Draft Guidances

- Infectious Disease Next Generation Sequencing Based Diagnostic Devices: Microbial Identification and Detection of Antimicrobial Resistance and Virulence Markers
- Display Devices for Diagnostic Radiology
- Class II Special Controls Guideline: *In Vitro* Diagnostic Devices for *Bacillus* spp. Detection



Final Guidances

- Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices
- Radiation Biodosimetry Medical Countermeasure Devices
- Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays
- Class II Special Controls Guideline: Gastrointestinal Microorganism Multiplex Nucleic Acid-Based Assays for Detection and Identification of Microorganisms and Toxin Genes from Human Stool Specimens



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Questions?