# 2019 OIR Submissions Workshop
# Meeting Agenda

## Monday / April 8, 2019
**9:00 a.m. – 5:00 p.m.**

| | | Room |
|---|---|---|
| **8:00 – 9:00 a.m.** | **Registration / Breakfast** | White Flint |
| **9:00 – 9:45** | **Welcome and OIR Update**<br>Don St. Pierre, Deputy Director, OIR<br>Ann Quinn, AMDM | |
| **9:45 – 10:00** | **Division of Industry and Consumer Education (DICE)**<br>Anike Freeman, OCE | |
| **10:00 – 10:30** | **Registration and Listing** / Lisa King, OC/DAPO | |
| **10:30 – 10:45** | **Break** | |
| **10:45 – 11:15** | **MDR** / Eveline Arnold, OIR/DCTD | |
| **11:15 – 11:45** | **510(k) Program** / Marjorie Shulman, ODE/POS/510(k) | |
| **11:45 – 12:15** | **Precision Medicine** / Kate Donigan, OIR | |
| **12:15 – 1:30** | **Networking Lunch with FDA** | Brookside A |
| **1:30 – 2:00** | **CLSI: Overview** / Marina Kondratovich, OIR | |
| **2:00 - 2:30** | **Third Party** / Greg Pishko, OIR/DPOM | |
| **2:30 - 2:45** | **Break** | |
| **2:45 - 3:00** | **DeNovo** / Josh Balsam, OIR/DCTD | |
| **3:00 – 3:15** | **Pre- and Post-Market Cybersecurity for Medical Devices**<br>Seth Carmody, OIR | |
| **3:15 – 3:45** | **Submissions for Molecular Devices** / Karen Bijwaard, OIR/DMGP | |
| **3:45 - 4:30** | **Companion Diagnostics** / Pam Gallagher, OIR/DMGP | |
| **4:30 – 5:00** | **Q&A** | |

# 2019 OIR Submissions Workshop
# Meeting Agenda

## Tuesday / April 9, 2019
**9:00 a.m. – 5:00 p.m.**

| | | Room |
|---|---|---|
| **8:00 –9:00 a.m.** | **Registration / Breakfast** | White Flint |
| **9:00 – 9:30** | **Pre-Submissions and Q-Subs**<br>Majda Haznadar, OIR/DIHD | |
| **9:30 – 10:00** | **Bioresearch Monitoring** / Tamika Allen, OC/DBM | |
| **10:00– 11:00** | **Quality System Regs and Compliance Interactions**<br>Rick Mallonee, OIR/DMD | |
| **11:00 – 11:15** | **Break** | |
| **11:15 – 11:45** | **IDE** / Kate Donigan, OIR | |
| **11:45 – 12:15** | **Health Hazard Evaluation** / Ian Pilcher, OIR/DCTD | |
| **12:15 – 1:30** | **Networking Lunch w/FDA** | Brookside A |
| **1:30 –2:00** | **CLIA Categorization and Waiver Processes** / Peter Tobin, OIR/DPOM | |
| **2:00 – 2:45** | **CLIA Waiver Study Design and Dual Submission**<br>Marina Kondratovich, OIR | |
| **2:45 – 3:15** | **Guidance Highlights**<br>Rob Sauer, Chief Premarket Policy & Operations, OIR/DPOM | |
| **3:15 – 3:30** | **Break** | |
| **3:30 – 4:45** | **Ask the FDA** / FDA Panel | |
| **4:45 – 5:00** | **Review & Wrap Up** / OIR Staff | |