

# 2019 Pre-Submissions Workshop Meeting Agenda

**Wednesday / April 10, 2019**

**8:15 a.m. – 10:30 a.m.**

---

**7:30 – 8:15**

**Registration/Breakfast**

Room:  
White Flint

---

**8:15 – 8:20**

**Welcome**

Ann Quinn, AMDM Board Member

---

**8:20 – 9:00**

**Pre-Submissions and Q-Subs**

Majda Haznadar, FDA/OIR, Senior Staff  
*Majda.Haznadar@fda.hhs.gov*

---

**9:00 – 9:30**

**Effective Use of the Pre-Submission Process:  
An Industry View**

Diana Dickson, Senior Director, Clinical & Regulatory Science  
Fujirebio Diagnostics, Inc.  
*dicksond@fdi.com*

---

**9:30 – 10:10**

**Analytical and Clinical Studies Design  
Considerations for IVD Devices**

Marina Kondratovich, FDA/OIR, Associate Director  
*Marina.Kondratovich@fda.hhs.gov*

---

**10:10 – 10:30**

**Panel Discussion/Q&A**

---