

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

Liz Lison, AMDM President

8:20 – 9:00

Pre-Submission Guidance Review with Q&A

FDA Speaker Invited

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**

FDA Speaker Invited

10:10 – 10:30

Panel Discussion/Q&A
