

2017 Pre-Submissions Workshop Meeting Agenda

Wednesday

April 26, 2017

8:15 a.m. – 10:30 a.m.

7:30 – 8:15

Registration/Breakfast

Room:

White Flint

8:15 – 8:20

Welcome

Allen Hill, OIR / Cathy Craft, Cathy Craft, LLC

8:20 – 9:00

Pre-Submission Guidance Review with Q&A

Allen Hill, OIR, FDA

9:00 – 9:30

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

Cathy Craft, Cathy Craft, LLC

9:30 – 10:10

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

Marina Kondratovich, OIR, FDA

10:10 – 10:30

Panel Discussion/Q&A
