

2016 Pre-Submissions Workshop

Meeting Agenda

Wednesday

April 20, 2016

8:15 a.m. – 10:30 a.m.

7:30 – 8:15 a.m.

Registration / Breakfast

Room:
White Flint

8:15 – 8:20

Welcome

Allen Webb, OIR / Judi Smith, Precision for Medicine

8:20 – 9:00

Pre-Submission Guidance Review with Q&A

Elaine Blyskun, OIR, FDA

9:00– 9:20

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

Cathy Craft, Illumina

9:20– 9:40

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

Judi Smith, Precision for Medicine

9:40– 10:10

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

Marina Kondratovich, OIR, FDA

10:10 – 10:30

Panel Discussion / Q&A
