

# 2018 Pre-Submissions Workshop Meeting Agenda

**Wednesday / April 18, 2018**

**8:15 a.m. – 10:30 a.m.**

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**7:30 – 8:15**

**Registration/Breakfast**

Room:  
White Flint

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**8:15 – 8:20**

**Welcome**

Liz Lison, AMDM President

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**8:20 – 9:00**

**Pre-Submission Guidance Review with Q&A**

Allen Hill, OIR, FDA

*John.Hill@fda.hhs.gov*

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**9:00 – 9:30**

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

Carol Ryerson, Sr. Principal Advisor, Regulatory Affairs, RCRI

*cryerson@rcri-inc.com*

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**9:30 – 10:10**

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

Marina Kondratovich, OIR, FDA

*Marina.Kondratovich@fda.hhs.gov*

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**10:10 – 10:30**

**Panel Discussion/Q&A**

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