



U.S. Food and Drug Administration
Protecting and Promoting Public Health



Pre-Submission Program and Meetings with FDA Staff

AMDMD IVD Submissions Workshop
April 2016

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Pre-Submission Program and Other Meetings with FDA

Mechanism for applicants to obtain FDA input on:

- Various types of upcoming applicant submissions (PMA's, 510(k)s, IDE's)
- Various types of applicant questions
- Questions at different stages of product development

Mechanism for FDA to become familiar with upcoming submissions



"Which 'win' is ours? Because the one on the left looks bigger."

FDA Guidance Document:

- *Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with FDA Staff*
 - Draft guidance issued July 13, 2012
 - Final guidance issued February 18, 2014

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf>

FDA Guidance Document: *Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with FDA Staff*

- Explanations of the various submission types for requesting FDA feedback
 - tracked as “Q-Submissions” and include pre-submissions and other meeting types.
- Recommendations for when to submit Q-submissions.
- Recommended information to include in Q-submissions.
- Timelines.
- Scheduling and other meeting logistics.



What are the different Q-Submission types?

Q-Submission Type	Features
Pre-Submission	Opportunity for applicant to obtain FDA feedback prior to an intended submission (account for the large majority of Q-sub)
Submission Issue Meeting	To discuss deficiencies identified during premarket review
Study Risk Determination	To help the sponsor, investigator, or IRB in making the risk determination for IDE's
Informational Meeting	To share information with FDA (without expectation of feedback).
PMA Day 100 Meeting	To discuss the review status of a PMA
Formal Early Collaboration Meetings	FDAMA provides for agreement meetings and determination meetings http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073604.htm

Questions?

