Successfully Navigating the Pre-Sub Process

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Background

Guidance History

- Pre-IDE Program March 1999
- Draft Pre-Sub Guidance July 2012
- Final February 2014 entitled, “Requests for Feedback on Medical Device Submissions: the Pre-Submission Program and Meetings with Food and Drug Administration Staff”

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Requests for FDA Feedback ("Q" Subs)

- The Pre-Sub Program
- Informational Meetings
- Study Risk Determinations
- Formal Early Collaboration Meetings
- Submission Issue Meetings

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Meetings with CDRH & CBER Staff

- FDA Response to Meeting Requests
- Security Screening
- During the Meeting
- Activities after the Meeting
- Future Submissions

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Appendix 1

- Pre-Sub for an IDE Application
- Pre-Sub for a NSE, Exempt, or OUS Study
- Pre-Sub for a 510(k)
- Pre-Sub for a PMA
- Pre-Sub for an HDE
- Pre-Sub for an IVD

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Appendix 2

- Q-Sub Acceptance Checklist

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So, Pre-Subs…

- When?
- What?
- Who?
- Where?