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## >> Meetings with the FDA: Advanced

### □ Session Objectives

- Attendees will learn
  - How to assemble the Meeting Package in support of the meeting
  - Become familiarized with the operational activities associated with the meeting
    - ✓ Preliminary responses
    - ✓ Meeting preparation/rehearsal
    - ✓ Attending the meeting
    - ✓ Post-meeting activities

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## Meetings with the FDA: Advanced

- ❑ **Meeting Granted Letter**
  - Will receive a “Meeting Granted” letter from the FDA ~2 after submitting the Meeting Request Letter
  - Will include date, time, location of meeting
  - Number of desk copies to be submitted (and when)
  
- ❑ **Note Well: Overlap between the Meeting Request Letter and Meeting Package is indicated by red font below**



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## Contents of Meeting Package

- ❑ **Contents of Meeting Package:**
  - **Cover Letter**
    - Reference to Meeting Granted Letter
  - **Application Number**
    - Will be included in Meeting Granted Letter
    - PIND 123456 (Preliminary IND #)
  - **Product Name**
    - Company code name (AB-123) or generic name
  - **Chemical name, established name (if available) and structure**
  - **Proposed regulatory pathway**
    - 505(b)(1) or 505(b)(2)



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## » Contents of Meeting Package

### □ Contents of Meeting Package (cont'd):

- **Proposed Indication**
- **Dosage Form, Route of Administration, and Dosing Regimen**
  - For example: AB-123 will be supplied as 100 mg capsules for oral administration. The anticipated dosing regimen is once daily.
- **Pediatric Study Plan**
- **Human Factors Engineering Plan**
- **Combination Product Information**
- **Updated List of Sponsor's Attendees**
  - The list of attendees can be updated/changed from what was in the Meeting Request Letter



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## » Contents of Meeting Package

### □ Contents of Meeting Package (cont'd):

- **Background Information**
  - **Brief** history of the development program and relevant communications with the FDA before the meeting
    - ✓ One to two-page summary of the development program and a summary of previous interactions with FDA
      - Generally not applicable for a Pre-IND Meeting but can be substantial for a Pre-NDA Meeting
  - Substantive changes in product development plans
    - ✓ Again, generally not applicable to Pre-IND Meetings
  - Current status of product development
    - ✓ Include any non-US activities



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## » Contents of Meeting Package

### □ Contents of Meeting Package (cont'd):

- **Purpose of the Meeting**
- **Proposed Agenda**
- **Final Questions for Discussion**
  - You can add/delete questions that were in the Meeting Request Letter; however, you can not add new disciplines
- **Data to Support Discussion**
  - Provide sufficient detail so that the FDA can answer the questions
  - Summaries of completed studies
  - Protocols/protocol outlines of planned studies



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## » Operational Activities

### □ Operational Activities Associated with the Meeting

- No later than 2 weeks prior to the meeting, submit to the FDA a “Foreign Visitor Data Request Form”
  - Name, country, date of birth, passport number, etc.
  - Will not be able to attend meeting without it
- Preliminary Responses
  - Approximately 2-3 days prior to the meeting, the FDA will issue their “preliminary responses” to the questions
    - ✓ If all questions have been answered satisfactorily, the Sponsor can cancel the meeting without prejudice
    - ✓ If the meeting is to continue, it is advisable to identify those questions for which issues are still outstanding
      - Only those questions will be discussed at the meeting
      - Indicate to the FDA why the Sponsor would like to discuss the issue

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## » Operational Activities

### □ Operational Activities Associated with the Meeting (cont'd)

- **Meeting preparation/rehearsal**
  - **Every Sponsor takes a different approach**
    - ✓ **No rehearsal > 2-3 days of rehearsal**
    - ✓ **Generally held in hotel near the FDA**
    - ✓ **Who will be moderator of the meeting?**
    - ✓ **Who will take notes?**
  - **Go over outstanding issues**
    - ✓ **Who from the Sponsor will address the issues?**
    - ✓ **Decide what will be important to get out of the discussion?**
    - ✓ **Slides/presentations are generally not advised; however, if the issue is complicated and slides would be beneficial, they need to be submitted to the FDA prior to the meeting**

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## » Operational Activities

### □ Operational Activities Associated with the Meeting (cont'd)

- **Attending the Meeting**
  - **Arrive at FDA early (one hour before the meeting)**
  - **Will check in at front desk and be given a badge**
    - ✓ **You MUST have picture ID/passport**
  - **You will go through a metal detector much like the airport**
  - **Approximately 5 minutes prior to the scheduled start of the meeting, you will be escorted to the meeting room**
  - **Generally, FDA attendees sit on one side of the table and Sponsor attendees the other**
  - **Introductions will be brief: Name, title, affiliation**

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## » Operational Activities

### ❑ Operational Activities Associated with the Meeting (cont'd)

#### ▪ Attending the Meeting (cont'd)

- After introductions, moderator generally introduces the first issue to be discussed
- Some Divisions at FDA generate the Meeting Minutes in “real time” during the meeting
- Once all issues have been discussed, moderator will summarize the key agreements reached during the meeting
- Meeting is adjourned and Sponsor is escorted to the lobby



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## » Operational Activities

### ❑ Operational Activities Associated with the Meeting (cont'd)

#### ▪ Post Meeting Activities

- Have an immediate “debrief” to make sure all critical aspects/agreements at the meeting have been captured and understood
- Although the FDA will issue the official Meeting Minutes, plan to submit the Sponsor’s “Draft” Meeting Minutes to the FDA within 2 weeks (ideally shorter) of the meeting
- FDA will issue the official Meeting Minutes ~30 days after the meeting
  - ✓ Sponsor can ask FDA to reconsider if there is a difference of opinion regarding a particular issue



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## >> Meetings with the FDA: Advanced

### ☐ Next Session: The Investigational New Drug (IND) Process: *Advanced I*

- Clinical holds
- Protocol amendments
- Information amendments
- Annual Reports
- IND safety reporting

### ☐ Questions?



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