# TRAINING AND COMMUNICATIONS

## FORMAL MEETINGS BETWEEN CDER AND CDER'S EXTERNAL CONSTITUENTS

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**PURPOSE** This MaPP describes the Center's policies and procedures for scheduling and conducting formal meetings between CDER staff and those outside CDER requesting such formal meetings. Among other things, it describes a maximum time after a request by which a meeting will be scheduled, the need for prompt preparation and sharing of minutes, and the need for a summary of major points and agreements at the end of every meeting.

**BACKGROUND**

- Formal meetings serve a beneficial purpose for both the Center and its external constituents to provide clarity and resolve issues related to the drug development and review processes, compliance actions, and policy development.

- This MaPP provides a consistent and transparent approach to scheduling and conducting formal meetings (face-to-face, teleconference, and videoconference) between individuals from CDER and CDER's external constituents outside FDA.

## REFERENCES

- MaPP 4510.3 “Telecommunications”

## DEFINITIONS

- **Formal Meeting**. A planned meeting that occurs through a face-to-face interaction, scheduled teleconference, or scheduled videoconference with a person(s) from outside FDA. Unscheduled meetings, such as "drop-in visits" and unscheduled teleconferences, are not included in this definition and are beyond the scope of this policy. In addition, this document does not address "emergency meetings." Meetings dictated by emergency situations shall be handled on a case-by-case basis, although meeting minutes should be prepared a described below.
- **External Constituents**. Individual(s) outside the FDA organizational structure.
- **Pre-Meeting**. An internal meeting of FDA personnel to discuss a strategy and/or meeting approach in anticipation of a formal meeting with external constituents.
- **Week**. Seven calendar days.
- **Day**. One calendar day.

## POLICY

- The Center will respond to requests for scheduling a formal meeting from external constituents consistently and promptly and will agree to such meetings unless they are clearly unnecessary or premature.
- All formal meetings will be conducted in an appropriate business-like manner according to a pre-determined agenda appropriate to the purpose of the meeting, with specified objectives, and accurate summarization of key points and action items at the end of the meeting.
- Accurate minutes ("official minutes") will be prepared promptly by CDER for all formal meetings with external constituents. Official minutes shall be promptly distributed to all Center participants and to the external constituents (unless not appropriate, such as minutes from formal meetings held for Compliance investigatory purposes).
- The Center will work with its external constituents to identify and resolve any inconsistencies, discrepancies, or disagreements between participants with respect to understandings of the outcome of the meeting.
- Letters described in this MaPP may generally be sent or received by facsimile. Hardcopies of all letters must be placed in the product's (or otherwise appropriate) administrative file.

## RESPONSIBILITIES

**Division Directors, or the appropriate higher manager, shall be responsible for:**

- ensuring that external constituents' requests for meetings are answered in a manner consistent with this policy,
- instituting procedures to insure the policies established in this MAPP are implemented,
- ensuring that formal meetings are conducted in a facilitative, business-like manner and in accordance with this policy,
- ensuring that accurate minutes are prepared, circulated, and distributed in accordance with this policy,
- ensuring that disagreements with respect to understandings concerning the outcome of the meeting are resolved.
- ensuring that any policy or procedural issues that arise from a meeting that cannot be resolved within the division should be dealt with by involving supervisors, other divisions or offices as appropriate or the CDER Ombudsman, if necessary,
- ensuring the production of a monthly report on formal meetings with CDER's external constituents. [Data for these reports can be gathered and maintained in whatever method or format is most convenient for the reporting unit. However, the data reported monthly should be in the attached format. (Attachment A). These monthly reports shall be sent to: the appropriate Office Director, the Director of the Office of Training and Communications, and the Center Senior Project Manager.]

**Office Directors shall be responsible for:**

- ensuring that the divisions for which they are responsible have instituted meeting procedures and indeed are conducting their formal meetings with external constituents in accordance with this policy.
- reviewing their divisions' monthly reports and deciding whether further input from the office director is needed to assure conformity with this policy.

**The Director of the Office of Training and Communications and the Center Senior Project Manager shall be responsible for:**

- ensuring that the divisional monthly reports are assessed for evidence of further training needs in meeting management or minuting practices.

- compiling (OTCOM) all Center meeting statistics to have available for the Center and for external requests.

## PROCEDURES

**Meeting scheduling**:

- Requests for a formal meeting with a Center component shall be made in writing to the appropriate CDER component (organizational work unit - most commonly, division).

- The written request should provide the following elements: 1) a brief statement of the purpose of the meeting; 2) a listing of the specific objectives/outcomes the requester expects from the meeting; 3) a proposed agenda, including estimated times needed for each agenda item; 4) a listing of planned external attendees; 5) a listing of requested participants from CDER; and 6) the approximate time at which supporting documentation for the meeting will be sent to CDER (i.e., "x" weeks prior to the meeting, but should be received by CDER at least 2 weeks in advance of the scheduled meeting).

- The responsible director for the CDER component, based on the information provided in the written meeting request, shall determine if such a meeting is clearly unnecessary or premature (not reasonably likely to be useful). If necessary the requester can be contacted for clarification of the purpose of the meeting.

- Information and/or supporting documentation necessary for a productive meeting does not need to be submitted before a meeting will be scheduled. This supporting documentation should be submitted and received by the applicable CDER component at least two (2) weeks prior to the agreed meeting date. If essential supporting documentation needed to conduct a productive meeting has not been received by the CDER component within this time frame, the meeting may be canceled and/or postponed, as determined by the Division Director. However, the meeting may take place if the component believes it would still be useful, even with a shorter time to review the package.

- If the meeting request is granted, details may be confirmed with the sponsor via the telephone. In addition, within 14 days of the meeting request, the division (usually the assigned Consumer Safety Officer (CSO)/Project Manager(PM)) shall notify the requestor, in writing (either by letter or fax), of the date, time, and place for the meeting to be held, as well as expected CDER participants. The meeting date shall reflect the next available date on which all applicable Center personnel are available to attend, consistent with the component's other business, but shall not exceed 75 days from the date of the external constituent's initial dated meeting request.

- If a commercial development program is stalled and cannot proceed until a meeting with FDA is held and agreement on issue(s) reached, the sponsor shall contact the

appropriate Office of Drug Evaluation director and request a "Special Considerations Meeting." If the Office Director agrees that the development program is stalled pending resolution of issue(s) with the FDA, the Office Director shall be responsible for insuring that a meeting with the appropriate FDA staff is scheduled and occurs within 30 days of the "Special Considerations Meeting" request. It is understood that scheduling of such meetings may require unusual times for the meeting.

- If scheduling conflicts make it impossible for certain requested CDER participants to attend a meeting scheduled within 75 days, the component shall consult with the requestor to decide whether the requestor prefers that the meeting be held without this person or delayed.

- The assigned CSO/Project Manager is responsible for ensuring that a meeting room appropriate for the projected number of participants is reserved. In addition, he/she should insure that all appropriate audiovisual equipment is reserved and available. This person shall also insure that all logistics are reconfirmed the day prior to the meeting.

- In the event that a request to schedule a meeting is denied (no meeting), the director responsible for the CDER component is responsible for assuring that the requestor is notified of the denial in writing (letter or fax) or by telephone with clear documentation of the telecon to the file within fourteen (14) days from receipt of the request. The notification shall include a clear explanation of the reasons for the denial. In addition, CDER's notification shall provide information detailing the appeal process.

**Meeting**:

- A"pre-meeting" of FDA personnel who will be attending the formal meeting should generally be held to brief FDA participants on the background and critical issues, to develop initial responses to questions specifically posed by the requestor (but recognizing that the discussion may modify these responses), and to consider the overall meeting strategy/plan. The objectives and agenda for the meeting should be discussed and understood by all. (See Attachment B) The agenda will generally be submitted by the external constituent. If any additional items for discussion are identified by FDA which might require preparation on the part of the constituent, the constituent should be notified prior to the meeting and any FDA materials should be provided to the constituent. Additionally, key persons should be identified (from those scheduled to attend the meeting) at the pre-meeting to: 1) chair/ facilitate the meeting for the FDA; 2) keep track of time; and 3) record minutes. The pre-meeting should preferably be held at least one day before the scheduled meeting with the external participant.

- The CDER chair/facilitator of the meeting shall provide initial structure to the meeting by welcoming the external constituents and clearly stating CDER's

understanding of the purpose and goals of the meeting. At the beginning of the meeting, the CDER chair/facilitator shall insure: that participants are introduced; that the person recording minutes for FDA is noted to the external constituent; that, if necessary, the timekeeper is noted to the external constituent; and that a decision is made between CDER and the external constituent as to who shall be the lead chair/facilitator (CDER or external constituent) for the discussion portion of the meeting. It is recognized that meetings are, and should be, highly interactive and that many meeting participants will participate in the discussions and respond to issues. The CDER chair/facilitator shall be responsible for assuring appropriate participation by FDA staff present.

- At the end of the meeting, the CDER chair/facilitator shall insure key points and/or decisions made are summarized and insure that all participants (FDA and external constituents) concur with the summarization and that any differences are resolved. The recorder shall note these summarized key points in the official FDA minutes of the meeting.

- The meeting timekeeper shall monitor the time dedicated to each agenda item. The timekeeper will notify the chair when discussions exceed the amount of time allocated on the agenda. A decision will then need to be made by the participants on how to utilize the remaining time allotted to the meeting.

- The senior management attendee is responsible for determining who should be the final signatory for the minutes and should inform the recorder. Generally it is expected that the senior management attendee will either be the final signatory or will indicate his/her concurrence with the minutes by initialing them.

- The recorder will accurately prepare minutes of the meeting, including the summarized key points as follows: 1) draft meeting minutes should be written and circulated (for review and comment) to all FDA personnel who attended the meeting within one week of the meeting date; 2) review and incorporate comments and finalize minutes within three (3) weeks after the meeting. (See suggested minute format at Attachment C.)

- Meeting participants will review draft minutes and return to recorder within one week of receiving the draft minutes.

**Post-Meeting (follow up)**:

- Minutes of formal CDER meetings with external constituents shall include the appropriate "CC" (IND, NDA, ANDA, or other file as appropriate) and distribution list to ensure meeting minutes are incorporated into the appropriate administrative file.

- All agency personnel attending the meeting shall receive a copy of the final meeting minutes within four (4) weeks of the meeting.

- The CDER component shall send the external constituents a copy of the final meeting minutes within four (4) weeks of the meeting. The external constituents are responsible for notifying CDER of any significant differences in their understanding of the meeting outcomes (as reflected in the minutes). The CDER component shall notify the external constituent of this responsibility in the CDER letter accompanying the minutes.

- The division director (in consultation with meeting chair, if different from division director) shall be responsible for resolving differences identified by the external constituent between the FDA minutes and their understanding of the meeting outcomes. This negotiation may be accomplished by the project manager, but the division director has ultimate first-line responsibility for a successful resolution. If policy issues or requirements related to a particular application that emerge during or after a formal meeting cannot be resolved at the level of the component holding the meeting, the usual appeals mechanisms can be invoked by the external constituent, including requesting the mediation services of the CDER Ombudsman.

- All correspondence regarding meeting minutes, from FDA or external constituents, shall be submitted to the appropriate product administrative file.

- Monthly reports on formal meetings should include the information contained in the sample format outlined in Attachment A for each meeting (meeting date, company name, meeting chair, IND/NDA/ANDA#, drug name, date minutes issued to sponsor, recorder), and shall be submitted to the following, as defined under "Responsibilities:" appropriate Office Director; Director, Office of Training and Communications; and the Center Senior Project Manager. Copies of minutes of meetings at which policy decisions are made that affect more than one division or component shall be sent to the Associate Director for Policy, CDER.

**Appeals**

The appeals process shall be in accordance with CDER's appeals policies and procedures (CDER Appeals Procedures MAPP)**.**

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**FORMAT**

- Monthly Meetings Report (see Attachment A)

- Meeting Agenda (see Attachment B)

- Meeting Minutes (see Attachment C)

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**EFFECTIVE DATE**

This MaPP is effective upon date of publication.

**Attachment A**

**Division Monthly Meetings Report**
**(Formal Face-to-Face, Teleconference, and Videoconference)**

Division:

Month of _____

Report preparer:

| | Mtg Date | Cmpy Name | Frmt | Type | IND/NDA ANDA/ # | Drug Name | Chair | Recorder | Date Minutes Issued |
|---|---|---|---|---|---|---|---|---|---|
| 1. | | | | | | | | | |
| 2. | | | | | | | | | |
| 3. | | | | | | | | | |
| 4. | | | | | | | | | |
| 5. | | | | | | | | | |
| 6. | | | | | | | | | |

Format: F=face-to-face; V=videoconference; T=teleconference
Type: R=RTF; PI = Pre-IND; EP2 = end of P2; PN=Pre-NDA; C=compliance, A=Advertising/promotion; S= major safety concern; O= other
Attach copies of meeting agendas for above meetings.
Also attach copies of meeting minutes finalized that month.

Copies to:

Appropriate Office Director(s)
Director, Office of Training and Communications
Center Senior Project Manager

**Attachment B**

**Suggested Format for Meeting Agenda (if prepared by FDA)**

Meeting Date: Location: Time:

External participant:

IND/NDA # and name of product, if appropriate:

Meeting Chair (FDA) Sponsor lead:

Introductions:

Meeting Objective(s):

Meeting Discussion Items:

| | Name of Presenter | Discussion Item | Time Allocated |
|---|---|---|---|
| 1. | | | |
| 2. | | | |

Summarize Agreed-upon Points/Unresolved issues

Discuss any necessary follow-up

Close meeting

Attachments/Handouts

Attachment C

**Suggested Format for Meeting Minutes**

Meeting Date: Time: Location:

IND/NDA/ANDA # (If Applicable) and Drug Name:

External participant (External meeting requestor - sponsor):

Type of meeting (45 day, RTF, pre-IND, End of P2, Pre-NDA, compliance, promotion, etc.)

Meeting Chair: External participant lead:

Meeting Recorder (CSO/Project Manager):

FDA Attendees, titles and offices:

External constituent and titles:

Meeting Objectives:

1.

2.

3.

Discussion Points (bullet format):

1.

2.

3.

Decisions (agreements) reached:

1.

2.

3.

Unresolved issues or issues requiring further discussion:

1.

2.

3.

Action Items:

| Item | Responsible person | Due Date |
|---|---|---|
| 1. | | |
| 2. | | |
| 3. | | |

Signature, minutes preparer: _____
Concurrence Chair (or designated signatory): _____

Attachment/Handouts