
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

PREPARING A MEMORANDUM OF CONFERENCE (MOC)

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I. PURPOSE

This document:

- Describes what information should be included in the Memorandum of Conference (MOC) for a meeting,
- Includes timeframes for preparing, commenting on and finalizing the MOC and acknowledgement letter, and
- Describes how to respond to correspondence relating to the MOC.

II. WHAT IS AN MOC?

An MOC is a document prepared by Office of New Animal Drug Evaluation (ONADE) personnel that documents the nature and substance of a meeting with an outside party. The MOC we prepare is the official record of the meeting and we send a copy to the outside party.

The MOC should provide enough detail to allow individuals reading the MOC now and potentially years later to understand the substance and nature of the meeting. It should

not be a transcript of the meeting. The scope of an MOC should be limited to discussions and information exchanged during the meeting. Any information that was not discussed at the meeting but that needs to be communicated to the sponsor following the meeting should be included in an “Additional Comments” section in the acknowledgement letter that accompanies the MOC, not in the MOC.

III. WHEN DO YOU PREPARE AN MOC?

You are always required to prepare a memorandum for a presubmission conference.¹ You are required to document the substance of any other meeting with an outside party when you determine that such documentation will be useful.² Therefore, generally, you should prepare an MOC for other meeting requests (i.e., Z submissions) when you hold a meeting (for example, meetings with the sponsor to discuss an incomplete letter).

As a person responsible for handling a matter, you are also responsible for ensuring the completeness of the administrative file relating to that matter.³ Therefore, there will be instances when you will need to document internal meetings and impromptu discussions with outside parties (for example, an outside party calls to get clarification on an incomplete letter, it is handled without a meeting request, and you think documentation of this will be useful). As a way to make certain the information becomes part of the file on the matter, you may document these situations with a memo to file or if a relevant submission is pending, as part of that review.

IV. CONTENT OF THE MOC AND ACCOMPANYING ACKNOWLEDGEMENT LETTER

A. The MOC should include the following information:⁴

- Title (“Memorandum of Conference”),
- Meeting date,
- Submission identification,
- Sponsor name,

¹ See §514.5(f)(1). “Presubmission Conference” means one or more conferences between a potential applicant and FDA to reach a binding agreement establishing a submission or investigational requirement.

² See §10.65(e).

³ See §10.70.

⁴ There is an office template for the MOC. Some instructions for using the MOC template are in Appendix 1.

- Drug or product name,
- Species (and class, where necessary) of animal,
- List of attendees (with affiliation),⁵
- List of materials distributed to participants,
- History or background pertinent to the request for the meeting,
- Summary of key points of discussion using the agenda items as headers to form an outline and adding subheadings as appropriate,⁶
- Presubmission Conference Agreement section , if applicable, and
- Action items, assignments of responsibility for them, and dates set for their completion if applicable. If there are no action items, state this under the Action items heading in the MOC.

The last four items must be included in the MOC for a presubmission conference.⁷ The preparer must sign and date the final MOC.⁸ If your division or staff procedures require that you document concurrence on the MOC, you will do this by filling in the concurrence table at the end of the MOC template.

B. The acknowledgement letter should inform the outside party that:

- The MOC is enclosed with this letter,
- ONADE's MOC is the official record of the meeting,

⁵ For CVM attendees provide enough information to identify their affiliation within CVM and, for managers, include administrative titles, for example, division director. You should not use mail codes because they are subject to change and may not provide adequate identification for those unfamiliar with agency mail codes.

⁶ We should not discuss any issues that the outside party did not identify in the agenda and for which we did not receive advanced materials sufficient to allow for productive discussion.

⁷ See §514.5(f)(1).

⁸ See §10.70(c)(2).

- The deadline to request changes to, or clarifications of, the contents of the MOC is 30 days from the date of the letter,⁹
- They should not submit their meeting minutes as a way to request changes to, or clarifications of, ONADE's MOC, and
- If they submit a copy of their meeting minutes, we will place their minutes in the administrative file without review or reply. We will not consider a copy of their minutes as a request to change or clarify the MOC.

The acknowledgement letter may also include additional comments that ONADE needs to communicate to the outside party relating to the meeting.

V. RESPONSIBILITIES

This section outlines the responsibilities of CVM meeting participants in preparing and reviewing an MOC and acknowledgement letter.

A. The preparer

The preparer is the reviewer responsible for the "Z" submission or any other individual designated by office, division, or team procedures as responsible for writing the MOC and acknowledgement letter. The preparer should:

1. Discuss with each assigned consulting reviewer(s)¹⁰ who will write their specific portion(s) of the MOC¹¹ and how documents will be circulated for comment,¹²
2. Record the key discussion points, agreements, and action items during the meeting,¹³

⁹ See §514.5(f)(1)(iii).

¹⁰ Assigned consulting reviewer is defined under Section V.B.

¹¹ Generally, the assigned consulting reviewer should prepare the portion of the MOC relating to their specialty because their expertise is critical to the preparation of an accurate summary of those meeting discussions.

¹² The preparer should discuss with the assigned consulting reviewers what process they will use to collect and reconcile comments for the MOC and acknowledgement letter (i.e., providing email comments or sharing documents on a shared network drive).

¹³ The preparer should record the key discussion points, agreements, and action items associated with the assigned consulting reviewers' portion of the MOC even if the assigned consulting reviewer agreed to prepare

3. Draft the MOC and acknowledgement letter (incorporating the sections written by consulting reviewers when applicable),
4. Ensure that all consulting reviews have been logged as returned in the Submission Tracking and Recording System (STARS),
5. Get comments from the primary reviewer's team leader on the MOC prior to distributing a draft to the consulting reviewers for comment,
6. Provide all consulting reviewers the opportunity to review and comment on the draft MOC,
7. Include all documentation relating to comments received from the assigned consulting reviewers in the final action package,
8. Write the final version of the MOC and acknowledgement letter, incorporating comments from CVM participants (sent through the assigned consulting reviewers), as appropriate. If the comments received from the assigned consulting reviewers are in conflict, the preparer should resolve them with the appropriate assigned consulting reviewers and document the resolution, as appropriate, to ensure the completeness of the administrative file,
9. Circulate the final MOC to consulting reviewers by email. Provide recipients with two options in the email. They can either concur with the MOC as written or they can let you know what changes they would request be made so that they can concur. Revisions at this stage should be editorial in nature and there should be no need for substantive changes,
10. If the preparer is not the reviewer assigned the submission, include preparer information in the "other administrative information" box on the office template for the MOC. (Note: When preparing the final version of the MOC for the administrative file, prepare only two copies of the MOC. Print one white copy without administrative information for enclosing with the letter and a pink copy containing the administrative information (e.g., preparer information and concurrences, etc.). The pink copy is for the administrative file.),

their portion of the MOC. This is, because the assigned consulting reviewer may not be able to record complete notes while they are involved in the discussion of their area of specialty.

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11. Prepare the acknowledgement letter for signature,¹⁴
12. Submit a final action package to the Document Control Unit (DCU), and
13. Remind staff assigned the responsibility for action items to follow up on their action items within agreed upon timeframes.

B. Assigned consulting reviewer(s)

An assigned consulting reviewer is an individual assigned a consulting review through STARS. Each assigned consulting reviewer should:

1. Provide to the preparer, if they are writing their portion of the MOC, the key discussion points, agreements, and action items relating to their area of specialty, and any additional comments they want communicated to the outside party in the acknowledgement letter. The information forwarded to the preparer should incorporate comments received from other team/division participants, as appropriate.¹⁵
2. If the assigned consulting reviewer writes a review (see Section VI for when you should prepare a review) and has agreed to prepare their section of the MOC, the review should include:
 - a. Their portion of the MOC, and
 - b. Any additional comments they want transmitted to the outside party in the acknowledgement letter. These comments should be included in the review under the “Transmit to Sponsor” section and identified as “Additional comments to be communicated to the outside party in the acknowledgement letter.” Additional comments may be necessary if, for example, a correction to information discussed at the meeting is required, or we are responding to questions or action items that arose during the meeting.

¹⁴ Use the office template for the letter that will accompany the MOC. See P&P 1243.3010 for information on format and style conventions for letters.

¹⁵ An assigned consulting reviewer should discuss with other meeting participants from their team/division how, if requested, they will provide the information to be included in the MOC and any additional comments to be included in the acknowledgement letter and how they will resolve conflicting comments. For example, providing email comments or commenting on a document on a shared network drive.

3. Follow their division's procedures for returning the consulting review STARS package to the preparer through DCU (for example, some divisions may require that the team leader, division director, or both review and sign off on the consult),¹⁶
4. Review the draft MOC,
5. Provide to the preparer the team's/division's comments on, and any revisions to, the draft MOC.

The assigned consulting reviewer should evaluate the comments they receive from their team or division to determine which comments they will provide to the preparer.¹⁷ These comments should primarily address their area of specialty and be documented in a manner that ensures completeness of the administrative file.¹⁸ If the assigned consulting reviewer and others in their team or division who attended the meeting:

- a. Concur with the draft MOC as written, the assigned consulting reviewer should notify the preparer of their concurrence in an email.
 - b. Do not concur with the draft MOC as written, the assigned consulting reviewer should provide consolidated comments and revisions from the team/division to the preparer in an email. The consolidated comments and revisions should include documentation of the resolution of any conflicting comments within their team or division and describe the substantive comments that were not forwarded and the basis for not forwarding them to the preparer.
6. When you receive the final MOC for review, send the preparer an email with a subject line either "Concur" or "Concur after revisions." "Concur after revisions" means the assigned consulting reviewer concurs with the MOC if editorial changes are made. There should be no need for substantive

¹⁶ These procedures will be consistent with P&P 1243.3029.

¹⁷ Typically, the preparer will not be sending copies of the draft to the other participants. The assigned consulting reviewer will distribute copies of the draft MOC to other participants in their area. An assigned consulting reviewer should discuss with other meeting participants from their team/division to determine if they need to provide comment on the draft MOC and how, if requested, they will provide their comments on the draft MOC to the assigned consulting reviewer and how the assigned consulting reviewer will resolve conflicting comments.

¹⁸ See P&P 1243.2010 for responsibilities for creating and maintaining records.

changes at this stage. Editorial changes requested should be included in or attached to the email.

C. Other CVM participants

If requested by the preparer or an assigned consulting reviewer, CVM participants who attended the meeting but did not receive a STARS request for a consulting review should:

1. Review the draft MOC, and
2. Provide written comments and revisions, or a written statement that they have no comments in their area of specialty, to the assigned consulting reviewer for their team or division following the procedures specified by the assigned consulting reviewer (i.e., providing comments by email or commenting on a document on a shared network drive).

D. Team leaders and division directors

Team leaders and division directors are responsible for ensuring that the content of the MOC, in its entirety, is consistent with division, office and center policies, the regulations, and the Federal Food Drug and Cosmetic Act, and is easily understandable by the outside party. This is particularly important for MOCs for presubmission conferences in which we reach a presubmission conference agreement or agreements because these agreements are binding on the outside party and us. A thorough review of the MOC will also minimize the need for outside parties to request changes to, or clarifications of, the MOC and reduce the work for ONADE.

VI. WHEN TO PREPARE A REVIEW

A primary reviewer and the assigned consulting reviewer(s) should prepare a review relating to the meeting request, MOC and acknowledgement letter if it ensures the completeness of the administrative file. For example, if examination of background materials and decisions relating to the meeting need to be documented or if information related to the request for the meeting or the conference that cannot, or will not, be transmitted to the outside party in the MOC needs to be captured, it will be included in the review. See CVM Program Policy and Procedure Manual 1243.3009 for information on format and style conventions for a scientific review. The review may include, among other items:

- A review or summary of background materials examined,
- Background information that cannot be provided in the MOC for proprietary reasons, for example, recommendations about a specific issue based on previous submissions or related applications belonging to other sponsors,
- Chronology of relevant events or actions following the meeting, for example, need for correction of information provided to the outside party at the meeting, or completion of action items,
- Status of technical sections,
- References to other related meetings, for example, pre-meetings,
- A summary or record of further internal discussions that bear on the substance of the MOC or acknowledgement letter or lead to additional comments or recommendations in the acknowledgement letter,
- A “Transmit to Sponsor” section that may include additional comments that are to be included in the acknowledgement letter or
- The basis for any decision(s) not previously documented.

Each review should include a summary consistent with current procedures.¹⁹

VII. TIMEFRAMES FOR CLEARING THE MOC AND ACKNOWLEDGEMENT LETTER

We have **45 days** from the date of the meeting to issue the acknowledgement letter and a copy of the final MOC to the outside party.²⁰ Because the times allotted for preparing, circulating, and commenting on the MOC and acknowledgement letter and to close out the “Z” submission are relatively brief, it requires a collaborative effort. Individuals are expected to provide their review and comment within the timeframes described below.

¹⁹ See P&P 1243.3009.

²⁰ See §514.5(f)(1)(ii).

A. Preparing the draft MOC and acknowledgement letter

Step 1. Each **assigned consulting reviewer** should write their portion of the MOC²¹, any additional comments to be included in the acknowledgement letter (separately or as part of their review if one is written), and provide them to the preparer no later than **14 days** from the date of the meeting.

Each **assigned consulting reviewer** should return your final version of your review to the preparer through STARS no later than **21 days** from the date of the meeting.²²

Step 2. The **preparer**, using notes taken during the meeting should begin drafting the MOC as soon as possible after the meeting. You should incorporate the information provided by assigned consulting reviewers verbatim as soon as you receive it. You should provide the draft MOC and letter to the appropriate team leader for review before circulating the draft MOC to the consulting reviewers for comment. Team leaders will comment on the draft MOC and letter **before** you send the consulting reviewers the draft. You should finish the writing of the draft MOC and acknowledgement letter, including any edits from the team leader, no later than **21 days** from the date of the meeting.

B. Circulating the draft MOC to consulting reviewers for comment

Step 1. The **preparer** should circulate the draft MOC to all consulting reviewers (those with STARS consults) no later than **21 days** from the date of the meeting.

Step 2. Each **assigned consulting reviewer** should provide their team/division's comments on the draft MOC no later than **28 days** from the date of the meeting.

²¹ The "Transmit to sponsor" information can be written separately or as part of a review. In any instance, assigned consulting reviews are to be returned through STARS within 21 days from the date of the meeting.

²² The wording in the consulting review may not necessarily be identical to the wording in the final MOC. Any changes resulting from the circulation of the draft MOC will be documented in the review written by the reviewer responsible for the Z submission.

C. Preparing the Final MOC and acknowledgement letter

Step 1. The **preparer** should consider all comments received from the assigned consulting reviewers, write the final versions of the MOC and acknowledgement letter no later than **35 days** from the date of the meeting.

D. Circulating the final version of the MOC to consulting reviewers for concurrence

Step 1. The **preparer** should circulate the final version of the MOC to the assigned consulting reviewers no later than **35 days** from the date of the meeting.

Step 2. Assigned consulting reviewers should send an email response to the preparer with the subject line “Concur”, or “Concur after revisions”,²³ with the final MOC. The assigned consulting reviewer should send the email within **38 days** from the date of the meeting.

E. Preparing the final action package

Step 1. The **preparer** should make any necessary editorial changes to the MOC and acknowledgement letter. The preparer should complete the final action package so that the “Z” submission can be finalized and the MOC and acknowledgement letter can be sent to the outside party no later than **45 days** from the date of the meeting.

VIII. COMPLETING THE FINAL ACTION PACKAGE

The final action package should include:

- The original sign-in sheet for meetings held in person (for teleconferences or video conferences simply record the persons participating in the MOC),
- A copy of the agenda and meeting materials,

²³ Reminder: “Concur after revisions” means the assigned consulting reviewer concurs with the MOC if the suggested editorial changes are made. There should be no need for substantive changes at this stage. Editorial changes requested should be included in or attached to the email.

- A submission summary for the meeting request, as a stand-alone document or as part of a written review, written by the primary reviewer assigned the “Z” submission,
- Consulting reviews and related emails (for example, for documenting resolution to internal discussions),
- Concurrence given from the assigned consulting reviewers by email,
- White copies of the acknowledgement letter and MOC (with the administrative information removed from the bottom), and a properly addressed envelope,
- Pink copies of the acknowledgement letter and the MOC each containing the administrative information and signatures, cc blocks etc, which are for the administrative file²⁴ and
- Any other documentation necessary to ensure the completeness of the administrative file.

Be certain you identify that this submission was a Presubmission Conference on the STARS Final Action Form. In all other respects, preparer should follow established procedures when completing the final action package.²⁵

IX. HANDLING CORRESPONDENCE SUBMITTED BY THE OUTSIDE PARTY

The DCU codes correspondence from the outside party directly relating to the meeting minutes as a “Y” submission in STARS.²⁶ To determine what final action you, the person assigned the “Y” submission, may need to take you should read the cover letter to determine the purpose of the submission.

²⁴ Note that the MOC is not on yellow paper and is not included as part of a review. It is included only in the form of an enclosure for the letter (and printed on white paper) and as a file copy on pink paper.

²⁵ See P&P 1243.3030.

²⁶ If the outside party addresses action items that result from the meeting, these submissions are not directly related to the meeting minutes and should be handled (and coded) in a manner appropriate to the nature of the submission.

A. Outside party meeting minutes

If the outside party submits only their version of the meeting minutes, the preparer should final out the submission in STARS using the “Submission filed with no review documentation; no letter sent” final action.

B. Request for changes or clarifications

If the outside party requests changes to, or clarification of, our MOC, then the preparer should route the submission to the necessary assigned consulting reviewers through the DCU. We have **45 days** from the receipt of the request to respond to the outside party.²⁷ Therefore, the preparation and review of an acknowledgement letter responding to the outside party’s request and an amended MOC, if necessary, should follow the procedures and timeframes (using the date of receipt of the request) described for the original MOC.

The acknowledgement letter responding to this submission should either inform the sponsor that we have not made any changes to the original MOC or should summarize the changes that were made in response to the request. If changes to the MOC are necessary, the preparer should write an amended MOC following the format in this guide. The preparer will title the MOC “Amended Memorandum of Conference.”

The preparer should complete the final action package for this submission consistent with established procedures²⁸ and should include sufficient documentation to ensure the completeness of the administrative file.²⁹

X. REFERENCES

Code of Federal Regulations

Part 10 – Administrative Practices and Procedures

§10.65, Meetings and correspondence

§10.70, Documentation of significant decisions in administrative file

²⁷ See §514.5(f)(1)(iii).

²⁸ See P&P 1243.3030.

²⁹ See P&P 1243.2010.

Part 514 – New Animal Drug Applications

§514.3, Definitions

§514.5, Presubmission conferences

CVM Program Policy and Procedures Manual

1243.2010 – Responsibilities for creating and maintaining records

1243.3009 – Format and style conventions for reviews and submission summaries

1243.3010 – Format and style conventions for letters

1243.3029 – Closing out a consulting review for STARS submissions

1243.3030 – Completing final action packages for STARS submissions

XI. VERSION HISTORY

November 10, 2004 – original version

August 10, 2006 – revised to update and change consulting review timeframe to 21 days, add a Summary of Procedure section, remove the sample letter because the office now uses a template, and make other clarifications agreed upon by ONADE Management.

December 4, 2008 – revised to clarify that there are only two copies of the MOC prepared. One copy on white paper, which serves an enclosure and accompanies the letter, and the other on pink paper. The pink copy contains administrative information and is for the administrative record. Section II. Summary was removed as this is no longer our standard format.

APPENDIX 1: INSTRUCTIONS FOR FILLING IN SOME OF THE MOC INFORMATION IN THE TEMPLATE

Submission Descriptor Information: This information should appear in the top right hand corner of page 1. Fill in the fields with the appropriate information. If a drug does not yet have a proprietary name or an established name, list the active ingredient, drug class or other identifier. Example: AZ-01234 (a macrolide).

Background: The first paragraph of this section should state who requested the meeting (the outside party or ONADE), date of the request, and the general topics of discussion. Subsequent paragraphs should briefly describe any background information pertinent to the request for meeting and any other information that is necessary to ensure the completeness of the administrative file. For example, it may be appropriate to include information about other submissions received before the request for meeting that relate to the meeting agenda, drug information, or proposed indications. Do not include proprietary information or other information that we cannot share with the outside party in this section.

Attendees: Add the names of the meeting attendees, with affiliations, to the table. For attendees with the outside party, affiliations help to identify them as consultants, U.S. agents, and representatives. For CVM attendees, provide enough information to identify their affiliation within CVM (and for managers include administrative titles, for example, division director). Do not use acronyms. Do not use mail codes because they are subject to change. Delete any unused rows, or add rows if necessary. Include the original sign-in sheet in the final action package to ensure its inclusion in the administrative file.

Discussion: Using the outside party's agenda items as headers to form the outline and adding subheadings as appropriate, briefly summarize the main points discussed at the meeting for each item. Do not attempt to capture every detail of the meeting. You should provide enough detail to allow those persons reading the MOC now and years later to understand the substance and nature of the meeting. We should not discuss any issues that the outside party did not identify in the agenda and for which we did not receive advanced materials sufficient to allow for productive discussion.

Presubmission Conference Agreements: Presubmission conferences are the only meetings in which agreements may result. If the meeting is not a presubmission conference, you should **not** include this section in the MOC. If an agreement on any investigational or submission requirement is reached during the meeting, this section should include enough detail to ensure the terms of the agreements are clear, for

example, it should include time frames and other conditions associated with the agreements.

Carefully consider what is included in this section: These should be specific agreements on submission or investigational points that will allow us to make a determination about safety and effectiveness. When we write these agreements, they need to be very clear.

Action Items: List each item that requires further action or clarification. For each item on the list, include the person(s) responsible for the action(s) and the “due date” if applicable. If there are no action items, state this under the heading.