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OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

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**PREPARING A MEMORANDUM OF CONFERENCE (MOC)**

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**I. PURPOSE**

This document:

- Defines a Memorandum of Conference (MOC)
- Describes what information should be included in an MOC
- Explains the responsibilities of the preparer, assigned consulting reviewers, and other participants
- Includes timeframes for preparing, commenting on, and finalizing an MOC and acknowledgement letter
- Provides information on presubmission conference agreements
- Describes options for documenting concurrence on an MOC
- Describes how to respond to correspondence related to an 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 is the official record of the meeting, and we send a copy to the outside party accompanied by an acknowledgement letter.

An MOC should provide enough detail to allow individuals reading the MOC now and potentially years later to understand the nature and substance 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, including any agreements reached and action items identified. Any information that was not discussed at the meeting, but needs to be communicated to the sponsor following the meeting, should be included in the acknowledgement letter that accompanies the MOC, rather than in the MOC itself.

### **III. WHEN DO YOU PREPARE AN MOC?**

An MOC is generally required for all meeting requests when a meeting is held. Meeting requests are identified in our Submission Tracking and Reporting System (STARS) as "Z" submissions. In STARS there are two meeting types:

1. A presubmission conference (PS)<sup>1</sup>, and
2. Other meeting (OM) (e.g. meeting with a sponsor to discuss a "technical section incomplete" letter).

An MOC is always required for a presubmission conference. You are required to document the substance of any other meeting with an outside party when you determine that such information will be useful.<sup>2</sup> You may document an informal meeting or discussion (unrelated to a "Z" submission) with a memo to file ("Q" submission), or if the discussion is related to a pending submission, as part of the review documentation prepared for that pending submission. This type of documentation is not considered an MOC and does not fall under this P&P.

### **IV. CONTENT OF THE MOC AND ACCOMPANYING ACKNOWLEDGEMENT LETTER**

#### **A. Preparing the MOC**

Prepare the MOC using the office template and include the following information (see Appendix 1 for some instructions for using the MOC template):

1. Title ("Memorandum of Conference")
2. Meeting date
3. Submission identifier
4. Sponsor name
5. Drug or product name
6. Species (and class, where necessary) of animal

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<sup>1</sup> 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.

<sup>2</sup> See §10.65(e).

7. List of attendees (with affiliation). For CVM attendees, provide enough information to identify their affiliation within CVM at the time of the meeting and include managers' administrative titles (e.g., division director). You should not use mail codes ("HFV-") because they are subject to change and may not provide adequate identification for those unfamiliar with agency mail codes.
8. History or background pertinent to the request for the meeting
9. Summary of key points of discussion, using appropriate headings to form an outline and adding subheadings as needed (required for a presubmission conference)
10. Presubmission Conference Agreements section, if the meeting is a presubmission conference; Note if there were no agreements, state this under the "Presubmission Conference Agreements" heading in the MOC
11. Action items including the responsible party and date for completion, if applicable (required for a presubmission conference); if there were no action items, state this under the "Action Items" heading in the MOC

The preparer and the appropriate management chain must sign the final MOC.<sup>3</sup>

#### **B. Documenting concurrence**

The preparer must document MOC concurrence of assigned consulting reviewers and other CVM participants in a review, submission summary, or other review-related documentation. There are different ways to document concurrence (e.g., record individual email responses and attach those to the review prepared for the "Z" submission, provide a general statement in the review that says each CVM participant was contacted and concurred on the prepared MOC, etc.). The specific way concurrence is documented will vary depending on the level of discussion and editing that ensue following the meeting. Discuss with your supervisor what methodology would be best for your particular situation. It is suggested presubmission conference concurrence be documented using the Outlook process described below.

There are times when review documentation, such as a submission summary or review, might not be required. Those instances are rare and would be for situations where no internal discussions were required to prepare for the meeting. This is allowed because no documentation is needed for FDA's record other than what happened at the meeting with the sponsor. It is still necessary to document concurrence on the MOC. In those instances, document concurrence using Outlook in the following steps.

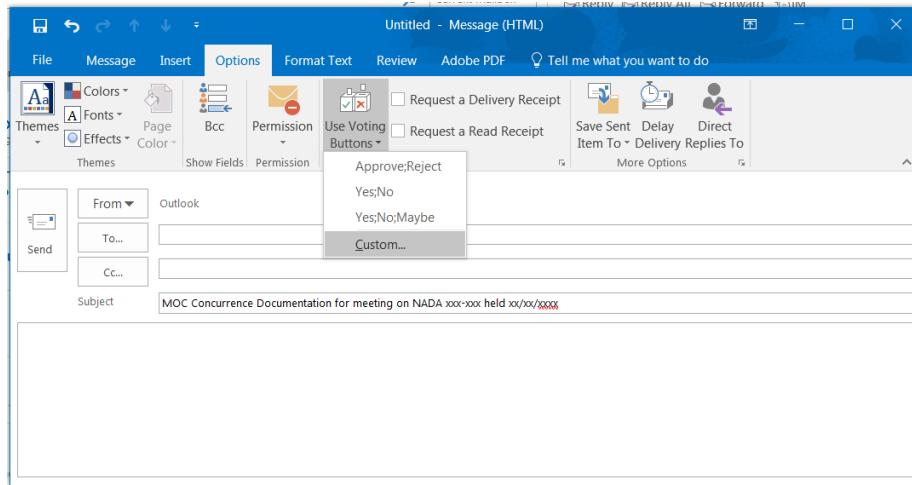
1. To generate Concurrence Documentation using Outlook, generate a new email message. In the "To" recipient field, enter the names of all the consulting reviewers and CVM participants. Add an appropriate title (such as "MOC Concurrence Documentation for meeting on NADA xxx-xxx held xx/xx/xxxx" or

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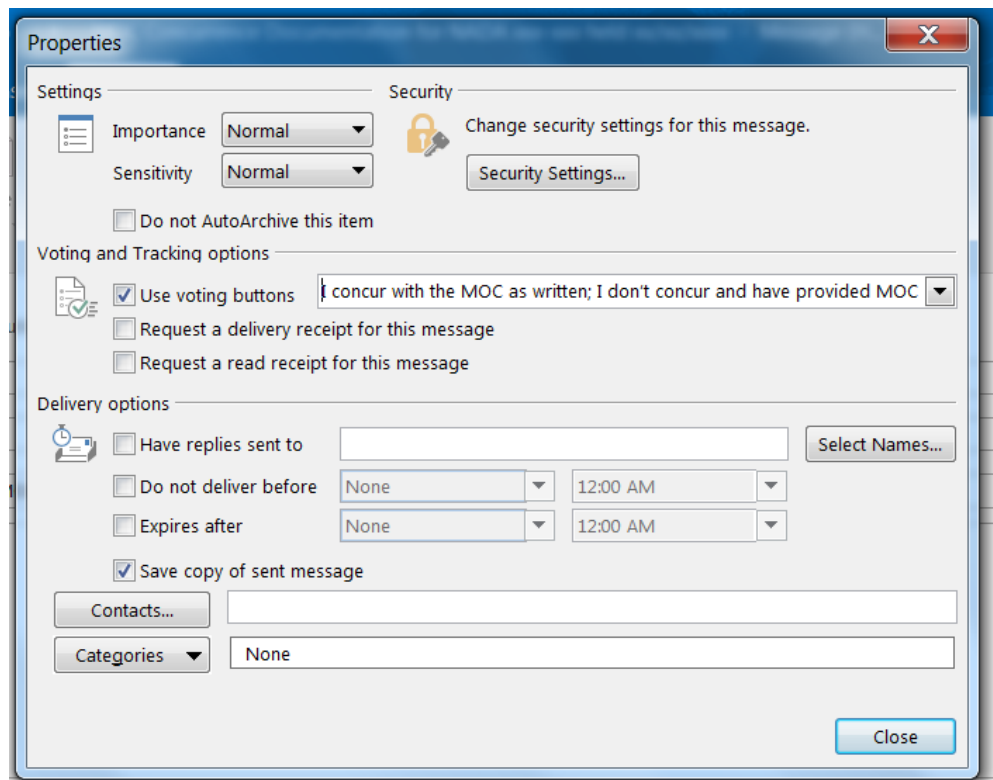
<sup>3</sup> See §10.70(c)(2).

"MOC Concurrence Documentation for Z-xxxx held xx/xx/xxxx), and then select "Options" on your email toolbar.

2. Click "Use voting buttons" and then select "Custom".



3. The properties window will open. Check the "Use Voting Buttons" box and insert the following (including semicolons) to be the voting options: I concur with the MOC as written; I don't concur and have provided MOC edits. Then, click the "Close" button.



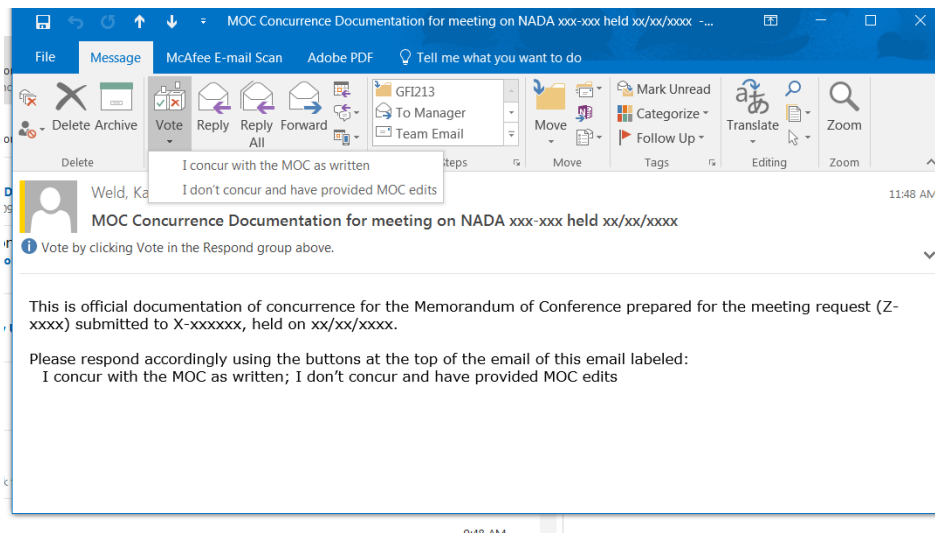
- In the body of the email, type-in or copy the following language:

This is official documentation of concurrence for the Memorandum of Conference prepared for the meeting request (Z-xxxx) submitted to X-xxxxxx, held on xx/xx/xxxx.

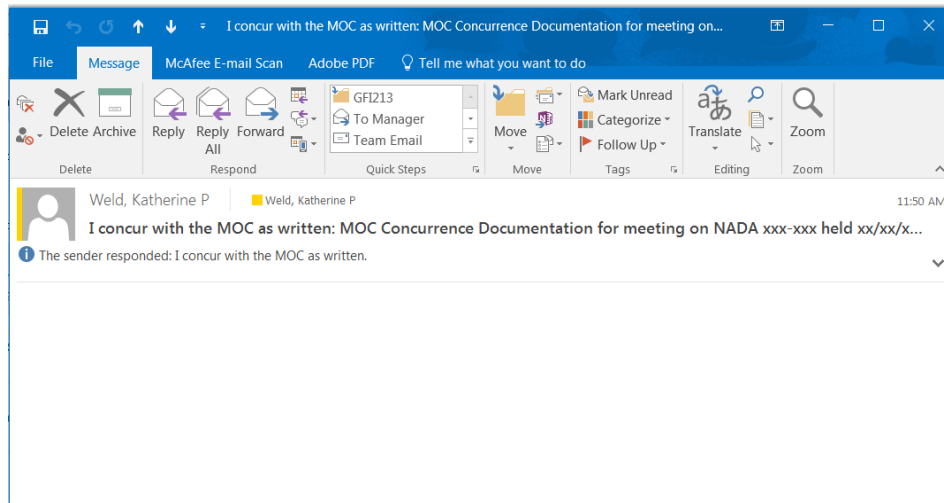
Please respond accordingly using the buttons at the top of the email labeled:

I concur with the MOC as written; I don't concur and have provided MOC edits

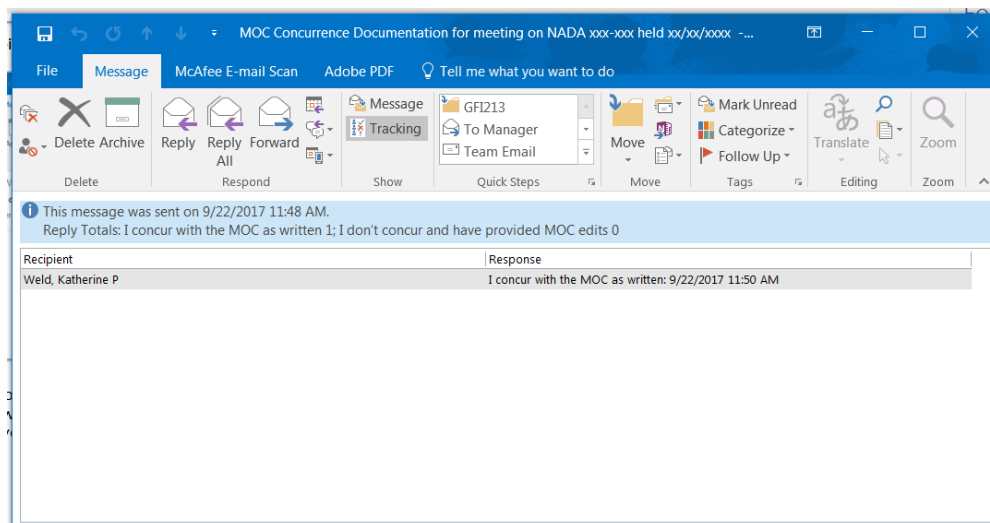
- When someone receives your email and they select the Vote option at the top of the email, they will see the following:



6. When someone replies, you'll receive an email that looks like the picture below. Click on the notification with the "i" symbol that says "The sender responded:" and an option to allow you to "View Voting Responses" will appear. If a person does not concur with the MOC, they need to provide edits that would result in their concurring on the MOC.

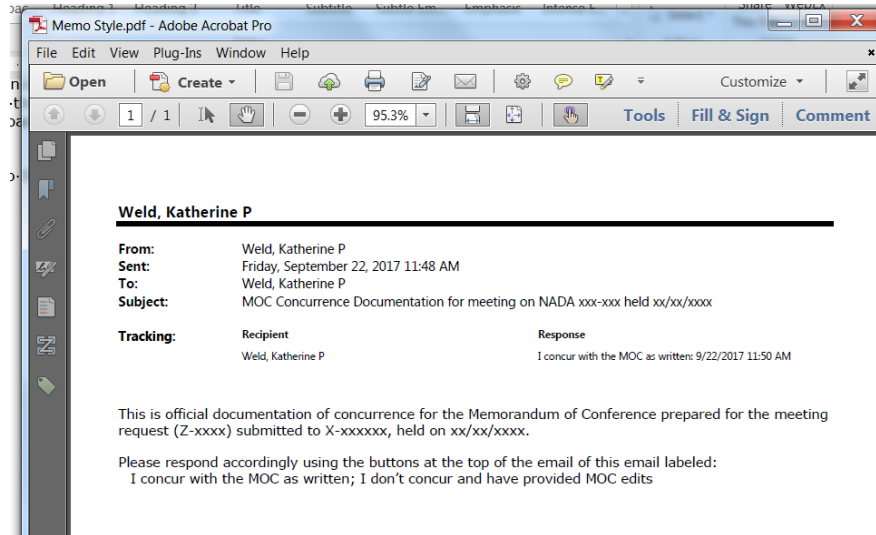


7. Select the "View Voting Responses" and you will see a list of all the recipients of your email requesting concurrence and the responses. In this window shown below, chose Print under the File menu. Select the print style as "Memo Style", which will include the original emailed instructions and a list of results at that point in time. Select "Adobe PDF" from the printer drop-down list and click the OK button.



8. When you are creating the PDF in the "Save PDF File As" window that appears, choose a descriptive file name (e.g., Documentation of MOC Concurrence for Z-

xxxx, dated xx/xx/xxxx) and click the save button. This PDF file will be the concurrence record for the MOC. Upload an electronic copy of this PDF file into Appian as "Other Review Related Files" when you are closing out the meeting request. An example of the PDF documentation in the "Memo Style" format is shown below.



### C. Preparing the acknowledgement letter

Use the office template to prepare the acknowledgement letter. The acknowledgement letter may 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 primary reviewer assigned to the "Z" submission or any other individual designated by office, division, or team procedures as responsible for preparing the MOC and acknowledgement letter. The preparer should:

1. Determine, with the consulting reviewers, who will be responsible for writing which portions of the MOC and how comments will be shared. Generally, consulting reviewers should prepare the portion of the MOC related to their specialty because their expertise is critical to accurately documenting the discussion. Consulting reviewers can send MOC text to the preparer through email or their returned consulting review.
2. Record the key discussion points, agreements, and action items during the meeting. Generally, the preparer should record these even if consulting reviewers agreed to prepare their portion of the MOC.

3. Draft the MOC and acknowledgement letter (incorporating the sections written by consulting reviewers when applicable).
4. Ensure that all consulting reviews are returned in STARS.
5. If applicable per division procedure, get comments from the primary reviewer's team leader on the MOC prior to distributing it to consulting reviewers for concurrence or comment.
6. Provide all consulting reviewers the opportunity to review and concur with or comment on the MOC. The MOC and acknowledgment letter may be circulated for comment through email or posted in a shared location for changes or comments to be entered directly. Consulting reviewers should either concur with the MOC as written or provide necessary revisions before they can concur.
7. Prepare the final version of the MOC and acknowledgement letter, incorporating comments from CVM participants (sent through the consulting reviewers) as appropriate. If the comments received from consulting reviewers are in conflict, the preparer should resolve them with the appropriate consulting reviewers and document the resolution, as appropriate, to ensure the completeness of the administrative file.
8. Close out the final action package.
9. Remind staff assigned the responsibility for any action items to follow up on their action items within agreed-upon timeframes.

#### **B. Consulting reviewer(s)**

A consulting reviewer is an individual assigned a consulting review through STARS. It is important to note that sometimes other individuals in the consulting reviewer's team or division may participate in the meeting and will not have formal consults in STARS.

Note: If other individuals in the consulting reviewer's team or division will be participating in the meeting, before the consulting reviewer sends or shares their written contribution with the preparer of the MOC, the consulting reviewer should determine with those other participants from their team or division:

1. how they will consolidate and provide information to be included in the MOC and acknowledgement letter (through email or posted in a shared location);
2. how they will resolve conflicting comments within their team or division;
3. who will review the MOC, how they will provide comments to the consulting reviewer, and how the consulting reviewer will resolve any conflicting comments; and .
4. who will concur on the MOC.

Each consulting reviewer will:



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 or division participants, as appropriate, and should be cleared through the appropriate management chain.
2. If the consulting reviewer writes a review (see Section VI for when to prepare a review) and has agreed to prepare their section of the MOC, the consulting review should include:
  - a. Their portion of the MOC.
  - 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. See section C. Other participants regarding conveying statements or information from participants who do not attend the meeting.
3. Return the consulting review package to the preparer following consulting reviewer's team and division clearance procedures.<sup>4</sup>
4. Review the MOC and tell the preparer they:
  - a. concur with the MOC as written, or
  - b. do not concur with the MOC and provide comments and revisions to the preparer, indicating in an email that they will concur with the MOC if the revisions are made to the MOC.

Note: Typically, the preparer sends the MOC only to consulting reviewers, who may distribute it to other participants in their team or division. If the consulting reviewer has determined that others from their team or division will comment on the MOC, the consulting reviewer will follow the agreed upon process established before the meeting to evaluate the comments received from those team or division participants to determine which comments they will provide to the preparer. These comments should primarily address their area of specialty and be documented in a manner that ensures completeness of the administrative file.<sup>5</sup>

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<sup>4</sup> These procedures will be consistent with P&P 1243.3029, "Closing Out a Consulting Review for STARS Submissions."

<sup>5</sup> See P&P 1243.2010, "Responsibilities for Creating and Keeping Records."

### C. Other participants

If requested by the preparer or a consulting reviewer, other CVM participants should:

1. Review the draft MOC.
2. Provide written comments and revisions, or a written statement that they have no comments in their area of specialty, to the requestor following the procedure specified (through email or posted in a shared location).
3. If the participant(s) are not attending the meeting, but have prepared statements to provide the sponsor, the statements should be in the ACK letter according to the procedures in P&P 1243.3050 Identifying and Documenting Technical Section Requirements for Approval.

### D. Team leaders and division directors

Team leaders and division directors are collectively responsible for ensuring that the final MOC is complete, easily understandable by the outside party, and accurately represents the discussion in the meeting. This is particularly important for MOCs for presubmission conferences because presubmission conference agreements are binding on the outside party and CVM. A thorough review of the MOC should also minimize the need for outside parties to request changes to, or clarifications of, the MOC.

## VI. WHEN TO PREPARE A REVIEW

A submission summary is typically required, either as a stand-alone document or as part of a review document prepared by the primary reviewer.<sup>6</sup> The primary reviewer should prepare a review relating to the meeting request, MOC, and acknowledgement letter. Each consulting reviewer should prepare a review if it is needed to ensure 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 meeting that cannot or will not be transmitted to the outside party in the MOC needs to be captured, it will be included in a review. See P&P 1243.3009 "Format and Style Conventions for Reviews and Submission Summaries" 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, e.g., recommendations about a specific issue based on previous submissions or related applications belonging to other sponsors

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<sup>6</sup> There are times when a submission summary and review might not be required. Those instances are rare, and this would be for situations where no internal discussions were required in order to prepare for the meeting and therefore, there is no need to document anything for FDA's record other than what happened at the meeting with the sponsor.

- Chronology of relevant events or actions following the meeting, e.g., 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, such as 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
- The basis for any decision(s) not previously documented

## VII. TIMEFRAMES FOR COMPLETING 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.<sup>7</sup> Because the times allotted for preparing, circulating, and concurring or commenting on the MOC and acknowledgement letter, and closing out the "Z" submission, are relatively brief, it requires a collaborative effort. Individuals are expected to provide their review and concurrence or comment within the timeframes described in the summary provided at the end of this section.

### A. Preparing the MOC and acknowledgement letter

1. Each **consulting reviewer** should write their portion of the MOC and 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 **21 days** from the date of the meeting.

Each **consulting reviewer** should also return the final version of their review to the preparer through Appian no later than **21 days** from the date of the meeting. The wording in the consulting review may not necessarily be identical to the wording in the final MOC.

NOTE: In some cases, multiple consulting reviewers will contribute to a single portion of the MOC. For example, a presubmission conference "Effectiveness" portion may include text from the target animal division (TAD), biostatistics, and pharmacokinetics. In such a case, the reviewers may agree to designate a "lead" consultant (in this example, it would be a TAD reviewer) and other consultants should provide their text to the designated lead consultant no later than **10 days** from the date of the meeting. The lead consultant will work with the other consultants, following team and division clearance procedures, to confirm the final text to be provided to the preparer by the day 21 deadline.

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<sup>7</sup> See §514.5(f)(1)(ii).

2. The preparer, using notes taken during the meeting, should begin drafting the MOC as soon as possible after the meeting. The preparer should incorporate the information provided by consulting reviewers verbatim. The preparer may make minor editorial changes, such as ensuring consistency of the sponsor's name throughout the MOC and defining acronyms. ; any substantive changes should be discussed with the appropriate consulting reviewer(s) first. The preparer should provide the draft MOC and letter to their team leader for review, if applicable per division procedure, before circulating the MOC to the consulting reviewers for concurrence.

#### **B. Circulating the MOC to consulting reviewers for concurrence**

1. The **preparer** should circulate the MOC to the consulting reviewers no later than **28 days** from the date of the meeting.
2. Consulting reviewers should send an email response to the preparer specifying whether they "Concur" or "Concur after revisions" with the MOC. Consulting reviewers should refrain from making edits to any text other than that which they initially prepared, but may recommend revisions to other sections for the respective consulting reviewer's consideration. The consulting reviewer should make any agreed-upon revisions to their own section themselves. The consulting reviewer should send the email concurring or concurring after revisions no later than **35 days** from the date of the meeting.

#### **C. Preparing the final action package**

The preparer should make any necessary final changes to the MOC and acknowledgement letter. The preparer should only accept edits in sections that were made by the consulting reviewer assigned to that section. If edits were made by other consulting reviewers, the preparer should notify the consulting reviewer assigned to that section and obtain their concurrence or comments on the additional edits before moving forward. The preparer may opt to have an additional round of concurrence with the appropriate consulting reviewers if needed. The preparer should complete the final action package so that the "Z" submission is finalized out and the MOC and acknowledgement letter are sent to the outside party no later than 45 days from the date of the meeting.

#### **D. Summary of timeframes**

1. Day 10 Provide draft text to designated "lead" consultant (when applicable)
2. Day 21 Provide MOC section, comments for letter to preparer
3. Day 21 Close consult through Appian
4. Day 28 Circulate MOC to consulting reviewers
5. Day 35 Provide MOC concurrence or concurrence after revisions
6. Day 45 Close out final action package

## VIII. COMPLETING THE FINAL ACTION PACKAGE

The primary reviewer will load the following documents into Appian (consulting reviews returned through Appian will automatically be included as part of the final action package):

1. 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 to the "Z" submission.<sup>8</sup> The submission summary should include supporting documentation as needed to ensure the completeness of the administrative file (for example, emails documenting resolution to internal discussions) and concurrence given from the consulting reviewers by email.
2. The acknowledgement letter
3. The MOC (note that the MOC should be signed in Appian by the appropriate management chain; the signatures will not be transmitted to the sponsor)

## IX. HANDLING CORRESPONDENCE SUBMITTED BY THE OUTSIDE PARTY

Correspondence from the outside party directly related to the MOC is coded as a "Y" submission in STARS. If the outside party addresses action items that result from the meeting, the submission is not directly related to the MOC and should be coded and handled in a manner appropriate to the nature of the submission. The preparer should determine the appropriate final action by reading the cover letter to assess the purpose of the submission.

### A. Outside party meeting minutes

If the outside party submits only their version of the meeting minutes, the preparer should finalize the submission in Appian 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 consulting reviewers. We have **45 days** from the receipt of the request to respond to the outside party.<sup>9</sup> 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

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<sup>8</sup> There are times when a submission summary and review might not be required. Those instances are rare, and this would be for situations where no internal discussions were required in order to prepare for the meeting and therefore, there is no need to document anything for FDA's record other than what happened at the meeting with the sponsor.

<sup>9</sup> See §514.5(f)(1)(iii).

the MOC are necessary, the preparer will write an amended MOC following the format in this policy and procedure document. The preparer will title the MOC "Amended Memorandum of Conference."

## **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

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.

May 11, 2012 – revised to reflect current practice, including changes to the administrative process due to the implementation of Appian and eSubmitter

September 4, 2012 – revised to incorporate minor edits

September 10, 2014 – revised to update the internal timeframes associated with completing an MOC to reflect a single round of review, with more time allotted earlier in the process for consolidating text among different assigned consulting reviewers and clearing text through the appropriate management chain; minor edits made in other portions of the text

November 4, 2014 – removed text added September 10, 2014, which indicated that attendees' degrees should not be listed

July 8, 2016 – minor revisions to formatting and content.

September 21, 2017 – revisions to provided information on how to document concurrence using Outlook email, appendix added to provide detailed information on presubmission conference agreements, and other updates. Internal information redacted from internet version. Appendix 2 redacted.

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## XII. 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 and the general topics of discussion. Subsequent paragraphs should briefly describe any background information pertinent to the request for a 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 information (such as other sponsors' proprietary 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 include managers' administrative titles (example, division director). Document an attendee's affiliation as it was at the time of the meeting. Do not use acronyms. Do not use mail codes because they are subject to change. Delete any unused rows, or add rows if necessary.

**Discussion:** Briefly summarize the main points discussed at the meeting for each item, using appropriate headers to form the outline and adding subheadings, as needed (examples of headers include technical sections or the outside party's agenda items).

**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 timeframes and other conditions associated with the agreements. Carefully consider what should be 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.

There are different headings built into the template in the Presubmission Conference Agreements section. Delete any that do not apply and add a Chemistry, Manufacturing, and Controls heading when needed. Note Human user safety and abuse potential are captured under Target Animal Safety.

**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.