



DALLAS DISTRICT FDA / MEDICAL DEVICE INDUSTRY COALITION

STANDARD OPERATING PROCEDURES: MEETINGS AND MEMBERSHIP

MEETING PROTOCOL

General

Meetings will be conducted using Robert's Rules of Order. Meetings will be scheduled for one day each quarter (or more often as necessary) at an agreed-upon location, in accordance with the coalition charter. Each meeting will follow an agenda that has been disseminated to all members prior to the meeting.

Responsibilities

The coalition co-chairpersons will alternate responsibility for preparing the agenda and chairing the meetings, and will assign a gatekeeper and recorder for each meeting.

The gatekeeper is responsible for facilitating a productive and efficient meeting in accordance with the established agenda.

The recorder is responsible for taking the meeting minutes, submitting draft minutes for review, making final edits/corrections, and distributing approved minutes.

Each committee chairperson is responsible for ensuring that committee reports are presented at each meeting.

Coalition members are responsible for their own compliance with the requirements of this procedure, and for completing all assigned actions in a timely manner. Coalition members are expected to actively participate in meetings and other coalition activities.

Quorum

In order to conduct official coalition business during a meeting, a quorum must be present. A quorum is defined as a simple majority from both industry/academia and regulatory groups.

Meeting Attendance

All members commit to attend and participate in scheduled meetings and agree to give meeting attendance high priority. Members who are unable to attend a scheduled meeting are responsible for minimizing disruption of coalition work due to their absence through the following:

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1) Timely notification. In order to ensure that a quorum will be present at the coalition meeting, and to provide for rescheduling if it is determined that a quorum cannot be present, any member who cannot attend a scheduled meeting is responsible for notifying their chairperson in a timely manner. Members agree to give notice at least one (1) week prior to the meeting whenever the absence can be so foreseen.

2) Alternate attendee assignment or remote attendance. Coalition members shall identify an alternate person who is authorized by their association to act on their behalf in the event of an absence. Coalition members are responsible for arranging the alternate person's attendance in the event of a foreseeable absence.

If circumstances permit, members who are unable to attend a meeting may participate via remote attendance (e.g., conference call). When reporting an absence, the member will notify their chairperson whether they will be available for remote attendance, and/or whether they will be sending an alternate attendee. Arrangements for any remote attendance will be made at that time, with the hosting site responsible for any conference call logistics.

3) Alternate information/assignment reporting. Any Coalition member who cannot attend the meeting is still accountable for any assigned tasks and/or committee activity reports, and is responsible for forwarding related information to the coalition.

Meeting Agenda/Minutes

Agenda topics may be proposed by Coalition members, and must be submitted to the Recorder at least two (2) weeks prior to the next scheduled meeting in order to be considered for the prepared agenda. Proposed topics submitted after the two (2) weeks date may be considered as "Add-On Topics" if time permits. Each submitted topic should include an approximate time needed to present the topic or report. A final agenda will be issued to all members no later than 2 days prior to the next meeting.

The agenda will contain the following standard agenda items:

- Call to Order
- Approval of the Agenda (including target time constraints for topics)
- Committee Reports – Each of the committees (Outreach, Publicity, and Finance) shall present a report outlining the activities of that committee.
- Old Business – Address action items from previous meeting(s).
- New Business – Discuss new topics submitted to the Agenda/Minutes Committee
- Add On Topics – Topics proposed after the agenda was finalized, subject to time constraints and coalition approval.
- Adjournment

The recorder will take meeting notes and prepare the official minutes. The initial draft of the minutes will be due to co-chairs by the end of the next week. Any comments from the co-chairs are due to the recorder one week or five business days from receipt. The

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recorder will incorporate any comments and forward the final minutes to the co-chairs for approval. Approved final minutes will be due to all members prior to the next scheduled meeting.

MEMBERSHIP

Adding Members

The coalition consists of representatives from industry associations, regulatory organizations, and academia. All primary nominees and alternates for membership into the coalition are to be submitted to the co-chairs on his or her association, organization or institution letterhead. The co-chairs will review the information and provide their recommendations during the next scheduled meeting. Final approval or disapproval will be decided by a coalition vote.

Members will reaffirm their membership every two years by a letter from their association, organization or institution supporting their role as primary or alternate. Reaffirmation will occur in tandem with the election of new co-chairs. The co-chairs, in cooperation with the Outreach Committee, are responsible for requesting letters of reaffirmation from the membership. If a member or alternate is approved within 12 months of election of the new co-chairs, no reaffirmation is required.

Removing Members

A member who is no longer able to participate in the coalition may simply resign by giving written notice. Resigning members are asked to assist in the recommendation of a successor, or to provide an association contact from which a successor may be recommended.

Members may ultimately be removed from the coalition for failing to comply with established standard operating procedures. Efforts to correct noncompliant situations shall begin with discussions between the corresponding chairperson and the member. If necessary, corrective efforts will be escalated to the member's association and finally to a membership review and recommendation by the co-chairpersons. The membership status of a representative is determined by a coalition vote.

Members who violate the ethics requirements established in the coalition charter shall be subject to immediate escalation to removal action, upon co-chairperson recommendation and coalition vote.

Members removed by vote shall be notified of their status in writing by the co-chairpersons.

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Version	Description of Change	Regulatory Co-Chair	Industry/Academia Co-Chair	Quality Committee Chair
9 Oct 09	Reformatted in entirety; added change control section The expression “sub-committee” was changed to committee throughout. Simple majority is redefined to include academia as part of the voting group industry/academia. Timing was changed for notification requirements and submission of agendas and meetings to provide more manageable objectives. The table of the timeline was removed. Text was added to clarify the timing of membership reaffirmation.			