"Speaking Out"

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Francis Lamm

Francis has worked extensively in the medical products industry and has a great working knowledge of the FDA's CGMP. He also specializes in the implementation and internal auditing of the various Quality Management System standards including, ISO 13485, AS9100, and ISO 9001.



MEETINGS

Meeting Guidelines

By Francis Lamm

Formal and informal meetings are a necessary part of the workday for organizations of all sizes and in all sectors of businesses providing a myriad of products and services. They are useful to discuss and resolve important issues and to convey information to all concerned parties at the same time, particularly when instant feedback is essential. While productive meetings have their place, from time to time, too many of us have been involved in long drawn-out meetings that stray off subject or accomplish little or nothing except waste time that could be better spent doing our primary job responsibilities. Other times, non-productive meetings occur when attendees are not sufficiently prepared, haven't done required research, made up handouts when required, or when some individuals tend to monopolize meetings with non-essential subjects.

For maximum effectiveness and productivity, the following are general guidelines for conducting formal meetings that meet the requirements for FDA/GMP, FAA, Military, Governmental Agency, ISO/TS/AS requirements and Good Business Practices.

GENERAL FORMAL MEETING GUIDELINES:

- Depending on the topic and preparation needed, initiators send out a meeting notice 3 to 10 working days in advance with a proposed agenda of discussion, action items, inputs, reports due, and required attendees.
- Start and end meetings on time.
- Assign someone to take and record meeting minutes/summaries.
- Take and record attendance.
- Everyone is to be prepared to discuss the agenda items, summary reports, handouts, new discussion items, etc.
- Avoid detailed reports. All status reports are to be brief summaries. If detailed reports are necessary, call a separate meeting of interested parties to discuss report details,
- Advise the receptionist and front office with names of attendees.

- Minimize meeting interruptions (sign-offs, phone calls, non-emergencies, etc.)
- Set a projected meeting time limit and end on time.
- Follow the meeting agenda and stick to it.
- Minimize or defer side discussions of limited group interest. Set time limits for presentations and discussions.
- Observe common business courtesies at all times.
- Record minutes of meeting in sufficient detail, including action item assignments and follow-up activities, deadlines, corrective actions, new items, etc.
- Set advance date(s) for next scheduled and side discussion meetings, as applicable.
- Distribute meeting minutes to participants and copy interested parties within five working days.
- Maintain record files of meetings for history files, as reminders of required activities and as documented evidence of what took place, when, why, where, who attended, and assigned follow-up action assignments.

Note: If formal and informal business & production meetings are not adequately documented in writing and distributed for historical purposes, there is no evidence the meetings ever took place for regulatory purposes. Individuals' hand-written notes that are not distributed do not suffice.

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