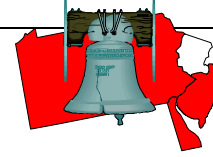


The Delaware Valley Chapter of PDA

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PDA Delaware Valley Chapter

Quality Assurance/Inspection Trends Special Interest Group (QITSIG)

Organizing Notes / Meeting Moderator's Guide

Goals and Objectives:

The primary goal of the Quality Assurance /Inspection Trends Special Interest Group (QITSIG) is to provide a forum where interested people can discuss trends and experiences in Quality Assurance and regulatory authority Inspections in pharmaceutical, biotech, and medical device research, manufacturing, and laboratory operations.

Principles:

There are several principles that underlie the formation and continuance of the QITSIG, including:

- **Expense reduction:** The group has been formed to permit information sharing without requiring the expense of overnight travel or conference fees. There are no charges for the sessions. Individual participants are only responsible for their own expenses (lunch, travel, etc.).
- **Discussion:** The group conducts discussions of the topic at hand, led by a moderator who has volunteered for the task. This format has been agreed upon specifically to avoid the format of a formal lecture followed by questions. One of the key goals of this group is “back and forth” not “sit and listen.”
- **Collegiate information exchange:** All of the QITSIG participants will treat each other as equals and expect the same in return. Scholarly discussion and lively debate on the subject at hand is expected and encouraged. The group expects to be open and specific about projects, products, and services, giving every subject a thorough, scientific, well debated examination.
- **Informality:** There is no formal "chain-of-command," or a requirement for minutes or notes to be published. It is expected that individual contributions to the discussion including product names, industry experiences, specific testing methods, individual regulatory observations, etc. will remain within the group and will be considered confidential. The task of discussion moderator is passed on to the next volunteer at each meeting and in the event no one volunteers, every participant will be fair game to be drafted for the task.
- **Commercialism:** In general, commercialism for products or services is not permitted. The group will determine whether or not it is in the best interest of the group to engage in a commercialized presentation during a scheduled meeting.
- **Topics:** The group's subject matter is very broad. The moderator will announce an agenda for the meeting topic in advance. As the group's topics may be vast, the group may decide to branch off

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into separate interest groups. This must be done with the permission of the Delaware Valley Chapter of the PDA's President and Planning Committee.

Organization:

In order to keep the group focused on the subjects at hand, the members of the QITSIG have deliberately instituted a loose organizational structure. There is no formal chairperson, and the moderator responsibility for each meeting is rotated among the group members.

Each meeting is an informal discussion of a technical subject among a group of quality professionals, scientists, researchers, and engineers. The format employs the minimum amount of structure required to initiate the discussion and to keep it focused on the session's topic. This structure usually takes the form of the discussion moderator presenting 5 - 10 overhead slides about the subject at hand, and the group "jumping in" to the discussion.

Meetings start times and dates will be announced prior to the meeting and start times are critical. Tardiness is not acceptable.

The group spends about 30 minutes greeting, discussing, networking, industry gossip, and selecting meeting dates, moderators, and subjects. The moderator then begins the program. The meeting will be adjourned after a total of two hours. The conference room / facility should be scheduled for an additional one hour to accommodate in-depth and follow-up discussions.

Administrative Details:

The official method for obtaining a seat at the QITSIG is merely to ask, we would like to give ALL a heads-up as to how many people to expect and to ensure clearance into the host facility. The details for this are as follows: Michael VanDerWerf will send notifications by e-mail about two weeks before the meetings. If you plan to attend, please return a confirming e-mail to michael.vanderwerf@aventis.com.

Most meetings will have a seating limit. The group can accommodate a maximum of 25 people. Seats will be assigned on a first come, first serve basis. You will receive an e-mail confirmation. Seating for these meetings is limited and we need to do our best to make sure that everyone who wants to be there can get a seat. We hope that everyone respects the RSVP policy and will make every effort to attend.

Our plan is to offer seating first to those participants that maintain a good track record of attendance. If a participant RSVPs that they will attend and then "no shows" twice in a year, they will receive their meeting notification a week later than everyone else. This assures that the people who make a good effort and are committed to the topic will get the first shot at limited seating.

To be added to or deleted from the list, e-mail michael.vanderwerf@aventis.com. Include the phrase "QITSIG" in the title to be automatically added to the invitation. Include your name, affiliation, and phone numbers in the message, for our database.

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When you come to the meeting, you should arrive 15-30 MINUTES EARLY. Also, remember to bring a handful of your business cards.

Moderator Responsibilities:

Subject: The moderator's first job is to state the subject of the discussion to all participants, to verify that it is of interest, and that the group is able to discuss it. The moderator should be conversant with the subject under discussion, preferably being someone who deals with the subject routinely. It is not necessary that the moderator be an authority on the subject, just knowledgeable enough to understand (and regulate) the discussion. Moderators who are experts on topics will need to focus on keeping the session a discussion as opposed to a tutorial.

Initiation: It is the moderator's responsibility to initiate the discussion, and to re-start it if it lags. One suggestion is for the moderator to prepare a short (5 -10 pages or overhead slides) information package concerning the subject and to distribute this to start the discussion. This package may include a recent industry journal article, a case study from the moderator's experience, vendor materials, etc. After making a few remarks (30 minutes or less, please!), and if the conversation has not begun, the moderator should then direct an open-ended question or two to the group.

Discussion: The most important role of the moderator is to keep the discussion focused on the subject at hand. People will naturally tend to wander and the moderator should remind them, kindly, to remain focused on the issue. The moderator should also volunteer to intercede in situations where confidential or proprietary information is involved, reminding participants that the discussion is, indeed, an open forum.

Close: The moderator's final job is to watch the clock, and remind everyone when the meeting's close is approaching. Offering to collect and coordinate an attendee list can serve as a good device to bring about a firm closure. The favorite method for this has been to collect one business card from each attendee and to photocopy and distribute to the group.