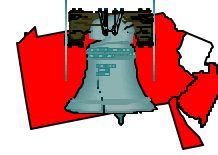


# The Delaware Valley Chapter of PDA

Serving Pennsylvania, Southern New Jersey and Delaware

**PDA**  
DELAWARE VALLEY CHAPTER  
Pennsylvania, Southern New Jersey, and Delaware



[www.pdadv.org](http://www.pdadv.org)



The Program Committee of the  
PDA Delaware Valley Chapter

**Cordially Invites You to Join**

**CSSIG – COMPUTER SYSTEMS  
SPECIAL INTEREST GROUP**

At a recent meeting, PDA's VP of Science and Technology, George Robertson, PhD. vigorously re-affirmed PDA's support and encouragement of chapter / local Special Interest Groups or SIG's. Dr. Robertson emphasized the value of the contributions of the PDA's individual members, through their chapters, in support of the scientific mission of PDA.

Encouraged by this, The PDA/DVC Program Committee has voted to promote several SIG's, including the Computer Systems Special Interest Group (CSSIG). The Committee cited the prior success of the CSSIG and it's peer-to-peer organization as key reasons for selecting it for promotion at their upcoming chapter meeting.

The CSSIG will have no formal committee structure per se, but The Hollis Group, Inc. has volunteered to administer the details of meeting space, meals, invitations, registrations, announcements, etc. If you are interested in attending, e-mail Thomas Quinn, President, Hollis, at: [tquinn@hollisgroup.com](mailto:tquinn@hollisgroup.com). If you include "DVC-CSSIG" in the subject line, you'll be automatically included in the invitation list.

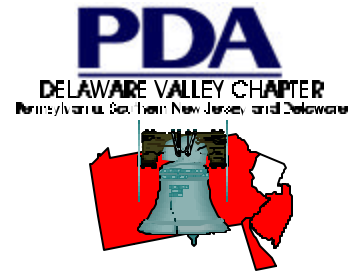
The CSSIG Charter and organizational details are presented below. Please let us know what you think about them. We're currently planning six meetings per year, with the first meeting in late July. Please let us know about any topics you would like to discuss or present. Our initial list includes these suggestions:

- Network / Infrastructure Qualification
- Asset Management Software
- e-Archiving and Restoration
- Distributed EDM Systems
- Clinical Remote Data Capture Systems
- Remote Workers – Bandwidth and Security Challenges

**CONTACT:** Thomas Quinn, The Hollis Group, Inc., 610 889 7350, [tquinn@hollisgroup.com](mailto:tquinn@hollisgroup.com)

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## PDA Delaware Valley Chapter Computers and Controls Special Interest Group CSSIG Organizing Notes / Meeting Moderator's Guide

### CSSIG Goals and Objectives:

The primary goal of the special interest group is to provide a forum where interested people can discuss the application of computer systems technology to pharmaceutical, biotech, and medical device research, manufacturing, and laboratory operations.

### Principles:

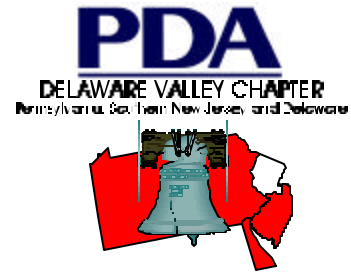
There are several principles that underlie the formation and continuance of the CSSIG, including:

- **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 half-duplex mode 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 CSSIG 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 “rough and tumble” examination.
- **Informality:** There is no formal “chain-of-command,” no minutes or notes are published, and it is expected that specifics of the style and form of the individual members’ contributions will remain within the group. The task of discussion moderator is passed on to the next volunteer at each meeting and, should no one volunteer, every participant is fair game to be drafted for the task.
- **Commercialism is OK:** The group actively solicits product and service vendors to pitch their wares at the meetings (signing up a vendor is one way for a moderator to meet their responsibility for presenting a topic). The goal here is to “ring out” the offering and ask the tough questions in a give-and-take forum. Generally, the CSSIG will use one-half of the scheduled meetings for vendor presentations.

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- **NOT computer validation:** The CSSIG is NOT the CSVSIG. The group will limit validations topics to (maybe) once a year.

## Organization:

In order to keep the group focused on the subjects at hand, the members of the SIG 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 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 at 11:45 with lunch in the conference room. Attendees may either bring their own, or buy lunch at the Wyeth cafeteria. The group spends about 30 minutes with lunch, networking, industry gossip, and selecting meeting dates, moderators, and subjects. The moderator then begins the program. The meeting adjourns at 2:00. The conference room / facility is usually available until 3:00, to accommodate in-depth and follow-up discussions.

## Administrative Details:

Steve Coates has very graciously arranged for conference space at Wyeth's Great Valley, PA facilities. While the official method for obtaining a seat at the SIG is merely to ask, we'd like to give Steve a heads-up as to how many folks to expect. The details for this are as follows.

Thomas Quinn will send notifications by e-mail about two weeks before the meetings. If you plan to attend, please return a confirming e-mail to [tquinn@hollisgroup.com](mailto:tquinn@hollisgroup.com). Most meetings will have a seating limit. Seats will be assigned on a first come, first serve basis. You will receive an e-mail confirmation.

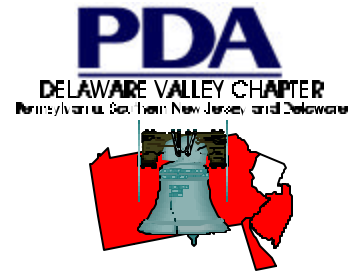
Seating for these meetings is limited and we need to do our best to make sure that everyone who wants to be there can get a seat. We hope that everyone respects that and if they RSVP that they will attend that they make every effort to do so. Unfortunately there have been some previous bad experiences with attendance. 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 will get the first shot at limited seating.

To be added to or deleted from the list, e-mail to [tquinn@hollisgroup.com](mailto:tquinn@hollisgroup.com). Include the phrase "DVC/CSSIG" 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 between 11:30 and 11.45, as Steve is required to escort us to and from the conference room. Also, remember to bring one 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, gently, when they do. 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 a collage of these.

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