

# The Delaware Valley Chapter of PDA

Serving Pennsylvania, Southern New Jersey and Delaware  
[www.PDADV.org](http://www.PDADV.org)

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



## Environmental Monitoring Cleaning and Disinfection Media Fill Special Interest Group



### Purpose:

The Environmental Monitoring – Cleaning and Disinfection – Media Fill Special Interest Group has been created to facilitate the following:

- An exchange of valuable industry related information between cGMP organizations
- To provide a vehicle for people with common interests to interact within PDA
- To provide information exchange and networking opportunities and an
- An avenue for member involvement
- Source of special interest members that provide can feedback on future program ideas and presentations.

### Premise:

To establish common dialog in how cGMP operations control contamination, monitor for contamination and react to peaks in environmental monitoring data from a particulate and microbial standpoint.

### Scope:

The scope of the group is to discuss subject matter in the areas of:

Environmental Monitoring  
Control of the Environment  
Cleaning and Disinfection  
Media Fills  
Aseptic Processing  
Microbiology  
FDA and Guideline Interpretation

### Organization:

The group is organized with a total membership of 25 individuals. The group is a self sufficient but integral part of the Delaware Valley Chapter of PDA. The group is intended to work as a team that will not only meet and discuss subject matter but will also organize events, share expenses and share responsibilities. The following are the particulars of the organization.

**CONTACT:** Art Vellutato, Jr., Veltek Associates, Inc. 610 983-4949 x 110, [Artjr@sterile.com](mailto:Artjr@sterile.com)

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## **Location:**

The location of each future meeting will be decided at the previous discussion group meeting.

## **Time:**

The time of each future meeting will be decided by the group at the previous group meeting.

## **Frequency:**

The frequency for future meetings will be decided by the discussion group. An anticipated basis is to meet at least 4 times a year. This schedule will be further organized at the first meeting

## **Membership requirements:**

1. Present dialog on the subject matter scheduled in the meeting agenda notes<sup>1</sup>
2. Moderate the discussion group on a rotating basis
3. Host the discussion group meeting at their facility (if possible)
4. Rotate as the Secretary for the creation of meeting notes

## **Costs:**

All costs will be shared equally among the members of the group.

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## **PDA Delaware Valley Chapter** **Environmental Monitoring - Disinfection - Media Fill** **Special Interest Group** **(Termed the EMDM)**

### **Organizing Notes / Meeting Moderator's Guide**

#### **EMDM Goals and Objectives:**

The primary goal of the special interest group is to provide a forum where interested people can discuss the application of environmental monitoring, cleaning and disinfection and media fill technology to pharmaceutical, biotech, and medical device research, manufacturing, and laboratory operations.

#### **Principles:**

There are several principles that must be established for the formation and continuance of the EMDM, which include the following:

- 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 discussion” not “sit and listen.”
- Collegiate information exchange: All of the EMDM 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, will remain within the group and will be considered confidential. The task of discussion moderator is passed

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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.
- The group's subject matter is very broad. An agenda for the meeting topic will be announced in advance. As the group's topics can be vast, the group may decide to branch off in separate interest groups. This must be done with the permission of the Delaware Valley Chapter of PDA's President and Planning Committee.

## Organization:

In order to keep the group focused on the subjects at hand; the members of the EMDM have deliberately instituted a loose or free 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 times and dates will be announced prior to the meeting and such start times will be critical. Tardiness is not acceptable.

The group will spend approximately 30 minutes discussing networking, industry gossip, and selecting meeting dates, moderators, and subjects. The moderator then begins the program. All meetings will adjourn at 2:00 PM. The conference room / facility is usually available until 3:00 PM to accommodate follow-up discussions.

## Administrative Details:

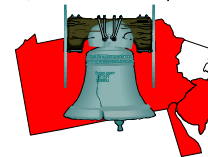
The first meeting of the EMDM group will be held at Glaxo SmithKline in Conshohocken, PA. The second meeting will be held at Veltek Associates, Inc. in Phoenoexville, PA. The third meeting will be held at Merck & Company in West Point, PA. Lists of contacts for these meetings are provided below. Subsequent meeting places will be determined based on the groups travel.

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Interest Group	Organizer(s)	Contact
Environmental Monitoring/ Disinfection/Media Fills	Art Vellutato, Jr Veltek Associates, Inc.	Artjr@sterile.com 610 983-4949 x 110
	Steve Trombetta GlaxoSmithKline	stephen.s.trombetta@gsk.com 610 270-7132
	Mike Dolan Merck & Company	michael_dolan@merck.com 215 652-8087

Steve, Art and Mike have very graciously arranged for conference space at their facilities. The official method for obtaining a seat at the EMDM is merely to ask, we would like to give ALL a heads-up as to how many people to expect and to ensure gate clearance. The details for this are as follows: Art Vellutato, Jr. will send notifications by e-mail about two weeks before the meetings. If you plan to attend, please return a confirming e-mail to [artjr@sterile.com](mailto:artjr@sterile.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 will get the first shot at limited seating.

To be added to or deleted from the list, e-mail [artjr@sterile.com](mailto:artjr@sterile.com). Include the phrase “EMDM” in the title to be automatically added to the invitation. Include your name, affiliation, and phone numbers in the message, for our database.

When you come to the meeting, you should arrive 15-30 MINUTES EARLY. 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, verify applicability, and decide whether the group wishes to discuss the topic. 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 moderate) the discussion. Moderators who are experts on topics will need to focus on keeping the session as a discussion versus a tutorial.

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## **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 at the start of 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.