

JANUARY 25–26, 2010

BALTIMORE, MARYLAND

THE PHARMACEUTICAL MICROBIOLOGY FORUM PRESENTS

PARTICIPATING IN CHANGE:

**OPEN CONFERENCE**  
**ON COMPENDIAL**  
**ADVANCES**

2010



**CEU CREDITS ARE AVAILABLE  
FOR THIS CONFERENCE**

**FACILITATOR**

Scott Sutton, Ph.D., Microbiology Network, Inc. PMF, USP MSA

**ORGANIZERS**

The Pharmaceutical Microbiology Forum  
High Peaks Associates (meeting coordinators)



## CONFERENCE SCHEDULE

The conference will be devoted to a discussion of the international regulatory climate with special emphasis on harmonized Compendial chapters, and recently implemented chapters of the USP.

We will begin with a keynote address by Susan de Mars, J.D., the USP's chief counsel, on "The Importance of Participation to Improvement of the USP."

Mornings will continue with presentations from regulatory experts. Afternoons will consist of smaller discussion groups on the following topics, moderated and led by Compendial experts:

- Clean Rooms and Process Control
- Microbial Identification (<1113>)
- Best Lab Practices (<1117>)
- Non-sterile Production
- Water Microbiology (USP <1231>)

### MONDAY, JANUARY 25

8:00 – 8:30 AM	Registration and Continental Breakfast
8:30 – 8:45 AM	Welcome SCOTT SUTTON
8:45 – 9:30 AM	Keynote Address SUSAN DE MARS
9:30 – 10:15 AM	Microbiology Best Lab Practices - New Draft DON SINGER
10:15 – 10:45 AM	Break
10:45 – 11:30 AM	Non-sterile Manufacturing - New Chapter LEN MESTRANDREA
11:30 AM – 12:30 PM	Water Testing - New Draft T.C. SOLI
12:30 – 1:30 PM	Lunch
1:30 – 3:00 PM	Discussion Session #1
3:00 – 3:30 PM	Break
3:30 – 5:00 PM	Discussion Session #2
5:00 – 7:00 PM	Reception (Casual Dress)

### TUESDAY, JANUARY 26

7:30 – 8:00 AM	Continental Breakfast
8:00 – 9:00 AM	Microbial Identification - New Draft SCOTT SUTTON
9:00 – 10:00 AM	Clean Rooms and Process Control - New Draft DAVID HUSSONG
10:00 – 10:30 AM	Break
10:30 – 11:15 AM	Harmonized Referee Tests (Microbial Limits, Sterility, Bacterial Endotoxin) RADHA TIMURALAI
11:15 – NOON	Reference Chapters DAVID PORTER
NOON – 1:00 PM	Lunch
1:00 – 2:30 PM	Discussion Session #3
2:30 – 3:00 PM	Break
3:00 – 4:30 PM	Discussion Session #4
4:30 PM	Conference ends

### HOTEL INFORMATION

Baltimore Marriott Inner Harbor at Camden Yards  
110 S. Eutaw Street, Baltimore, Maryland.  
800-228-9290

### SPONSORSHIP OPPORTUNITIES

Available sponsorship opportunities include Breakfast, Breaks, Lunch, Reception or company logo on signage and conference materials.

### EXHIBIT/DISPLAY OPPORTUNITIES

Table Exhibit includes a 6-foot skirted table and two chairs. Exhibitors should bring all required exhibit materials and signage.

To make sponsorship arrangements call 888-844-8561 or go to [www.microbiologyforum.org/2010/HPA1001/exhibitors.html](http://www.microbiologyforum.org/2010/HPA1001/exhibitors.html)

## REGISTRATION

Registration for Participating in Change: 2010 PMF Open Conference on Compendial Advances is \$1,795.

GROUP RATE: Three or more registrants from the same company, registering at the same time, may register for \$1,615 each.

*The fee (paid in U.S. dollars drawn on a U.S. bank, net of all bank charges) includes continental breakfast, luncheon, and refreshment breaks daily. The fee does not include transportation, hotel accommodations or dinners.*

## QUESTIONS

For questions regarding registration, special dietary needs, etc., please e-mail [mary.ellen@highpeaks.us](mailto:mary.ellen@highpeaks.us) or call toll free (888) 844-8561.

Attendee  Exhibitor  Sponsor

Mr. Ms. Dr.

*please circle*

First Name

M.I.

Last Name

Title

Company

Business Address

Street/PO Box

City

State/Province

Zip Code

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E-mail Address

## METHOD OF PAYMENT

Check Enclosed (Please remit payment to: High Peaks Associates)

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Account Number

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Name as it appears on credit card

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REGISTER:

- Online: [www.microbiologyforum.org/2010/HPA1001/registration.html](http://www.microbiologyforum.org/2010/HPA1001/registration.html)
- Phone: (888) 844-8561 or (585) 594-3336
- Complete and return this form with payment to:  
High Peaks Associates  
150 Parkway Drive  
North Chili, NY 14514
- Fax this form to (585) 594-3338

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### Discussion Session Preferences

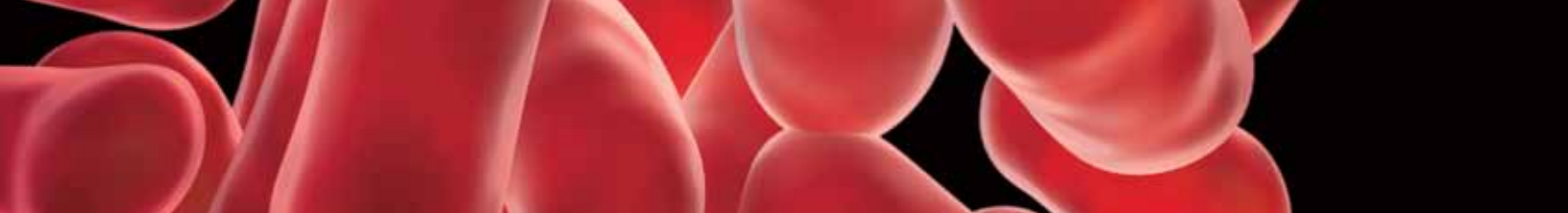
We will make every effort to place you in your top four choices.

*Please rank 1<sup>st</sup> to 5<sup>th</sup> choice for each*

- Clean Rooms and Process Control  
 Microbial Identification (<1113>)  
 Best Lab Practices (<1117>)  
 Non-sterile Production  
 Water Microbiology (USP <1231>)

## CANCELLATION POLICY

PMF and High Peaks Associates reserve the right to modify or cancel any event. In the event of a cancellation, registrants will be notified as soon as possible and all registration fees will be reimbursed. PMF and HPA are not responsible for lost airfare due to cancellations. Refund requests received at least 14 days prior to the date of the event will receive a full refund, less a \$200 processing fee. After that, no refunds will be issued. You may enroll a substitute at any time before the conference begins.



High Peaks Associates  
150 Parkway Drive  
North Chili, New York 14514

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## CONFERENCE DESCRIPTION

The relationship between the microbiology community and The Compendia is complementary. The Compendia play a large role in the activities of the QC laboratory. At the same time, our input into their discussion is crucial to both their deliberations and the quality of the documents that result.

This conference provides you with a unique opportunity to meet in small groups with representatives from regulatory agencies to discuss issues relating to laboratory operations, GMP and the microbiological quality of finished products.

It includes instruction and an opportunity for discussion of:

- the continuum of microbial control and test in the manufacture of sterile pharmaceutical products.
- the determination of the inconsistencies in Compendial, regulatory and industrial practices in microbial control, and the identification of how they could be made more consistent.
- the establishment of consensus positions whenever possible.

Come and pose your questions to those involved in writing the Compendial chapters! This is an unparalleled opportunity to benchmark your practices not only against current regulatory expectations, but also against other companies in the industry.

## WHO SHOULD ATTEND

This conference will be of particular interest to pharmaceutical microbiologists and microbiology laboratory managers, contract laboratory microbiologists and managers, pharmaceutical manufacturers, and individuals concerned with the regulatory aspects of microbial control.

## FEATURED PRESENTERS

- **SUSAN DE MARS, JD** Chief Counsel, USP
- **DAVID HUSSONG, PH.D.** Associate Director, FDA/CDER
- **LEN MESTRANDREA, PH.D.** USP MSA, Consultant
- **DAVID PORTER, PH.D.** Vectech Pharmaceutical Consultants, Past Director, USP
- **DONALD SINGER,** GlaxoSmithKline, USP MSA
- **TC SOLI, PH.D.** Solipharma Solutions; USP Purified Water
- **SCOTT SUTTON, PH.D.** Microbiology Network, Inc., USP MSA
- **RADHAKRISHNA TIMURALAI, PH.D.** USP Staff Liaison to USP MSA



High Peaks Associates is accredited by the International Association for Continuing Education and Training as a provider of continuing education. "Participating in Change: 2010 PMF Open Conference on Compendial Advances" (IACET #HPA1001) has been assigned 14.0 contact hours (1.4 CEUs).