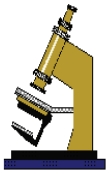
PMF
Pharmaceutical Microbiology Forum



PMF NEWSLETTER

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In This Issue:

Vectech
HPA High Peaks Associates, Inc.

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- Vectech Pharmaceutical Consultants, Inc, (http://www.vectech.com)
- High Peaks Associates, Inc. (http://www.highpeaks.us)

A Mixed Bag

This month's newsletter is a mix of topics. To start off, there is a review of the methodology for Microbial Limits Tests (Enumeration) comparing critical aspects of the current USP and Pharm. Eur. Tests with the published draft of the Harmonized document. This is very current, as the PDG approved a final harmonized document last November, one that is reported to be virtually identical to the draft version. This is the first of three articles on the harmonized documents that will appear in the next few months.

The "483 Alerts" column reappears this month. A very popular feature of the *PMF Newsletter*, Rich Almond provides a compilation of observations of concern to microbiologists. This is followed by a review of the recent PMF Bacterial Endotoxin Summit, an event that was very well attended and received.

Important Links:

Information on the PMFList at http://www.microbiol.org/pmflist.htm

Past Issues of the *PMF Newsletter* at http://www.microbiologyforum.org/news.htm

Ziva Abraham of Microrite provides the *PMF Newsletter* readership with a bonus this month. Along with this issue of the PMF Newsletter is a copy of the word list for BactiSpell ver. 2006 (it arrived as a separate attachment to your Email). The file is zipped—if you do not have a copy of WinZip you may get a free evaluation copy from http://www.winzip.com. The word lists provide custom dictionaries for MS Office programs that are specific for microbiology.

Finally, a bibliographic listing of relevant articles that appeared in 2005 is provided. This is not presented as an exhaustive list, and I apologize in advance to those I missed, but it may by useful to some. If you have an article that should have appeared, please send me a PDF copy of the article. I will put out an update later in the year if there are many missed.

The *PMF Newsletter* keeps on growing. This month's edition will be directly distributed to 5,000 subscribers in over 60 countries. Please recommend this publication to your colleagues.

Scott Sutton, Ph.D.
Editor, *PMF Newsletter*

The Harmonization of the Microbial Limits Test - Enumeration

Scott Sutton, Ph.D.
Vectech Pharmaceutical Consultants

The USP and the European Pharmacopoeia (EP, Pharm Eur) Microbial Limits Tests are in the final stages of harmonization. They were signed off to Stage 6A at the November, 2005 meeting of the Pharmacopeial Discussion Group (PDG) held in Chicago, IL USA (USP 2006a). However, the signed-off versions have yet to be published. This makes the description of the test a bit difficult, as the current tests will be disappearing, and the final, harmonized test is not yet public knowledge. However, we do know that the harmonized tests do not differ greatly from the drafts published in 2003 (USP 2003a, USP 2003b, USP 2003c), and so we will use those drafts as the description of the finalized test.

The Microbial Limits Tests are actually two chapters in the current USP:
Current USP <61> Microbial Limits Tests (USP 2006b) and <1111> Microbiological Attributes of Nonsterile Pharmaceutical Products (USP 2006c). This will be modified in the harmonized version to mirror the European format:

Stages of the PDG Process

1. Identification of the item to be harmonized
2. Investigation into existing texts
3. Proposal for Expert Committee Review
4. Official Inquiry
   This is the version published in the *Pharmacopeial Forum* or *PharmEuropa* for public comment
5. Consensus
   5A – Provisional
   This is the coordinating pharmacopeia's proposal for consensus. If all three agree, it goes on to 5B, otherwise work continues for consensus
   5B – Draft Sign-off
6. Regional Adoption and Implementation
   6A – Adoption
   6B – Implementation
7. Inter-Regional Implementation

Table 1: Harmonized Chapter Numbering Scheme

USP	EP
<61> Microbiological Examination Of Nonsterile Products: Microbial Enumeration Tests	2.6.12 Microbiological Examination Of Nonsterile Products: Microbial Enumeration Tests
<62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms	2.6.13 Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms
<1111> Microbiological Quality of Nonsterile Pharmaceutical Products	5.1.4 Microbiological Quality of Nonsterile Pharmaceutical Products

This review will only address the microbial enumeration portions of the harmonization effort – that which will become USP chapter <61> and Pharm. Eur. chapter 2.6.12.

The microbial enumeration test is a basic, simple design to count the number of CFU in a nonsterile product or raw material. The preferred method is to put the material into solution and then plate aliquots to determine the CFU/gram (or mL) of initial material. If the product cannot be put into solution, there are provisions to use the Most Probable Number method (MPN – see FDA BAM website). The method of plating can be either pour plate, spread plate or the filtration of material and then placing the membrane filter on the surface of an agar plate. The membrane filtration method should only be used when there are few expected colony forming units in the material to be tested as it is a good method to test a large volume of liquid, but can only count up to approximately 100 CFU/membrane.

The harmonized method provides a great deal more detail than any of the current pharmacopeial methods in terms of demonstration of method suitability (validation of the method) and in terms of media growth promotion.

The demonstration of method suitability should be performed using the challenge organisms listed (see Table 2 below) in accordance with the recommendations found in USP chapter <1227> (USP 2006d). Growth promotion is an area of some ambiguity in the compendial text. Although media growth promotion is not described in the tests, demonstration of media suitability is required, and the draft USP Chapter <1117> (USP 2004) provides assistance in designing the studies using 10-100 CFU of the challenge organisms (also see

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Application Note on this topic).

A major concern of many QC workers is if the changes in the harmonized chapter will necessitate revalidation of existing assays to meet the requirements of the harmonized test. There are several considerations that might lead to revalidation – a required change in media, in volume of material required for testing, in general testing conditions. It is difficult to determine whether all product types would require revalidation, and so a summary table is provided (Table 2) describing the critical aspects of the current Microbial Limits Tests (Enumeration) and the draft harmonization text. The summaries provided in Table 2 are only meants as an aid, the decision as to whether or not revalidation is necessary rests with each individual facility for their particular products.

References:

EP. 2006. 5.1.3 Efficacy of Antimicrobial Preservation. *Pharm Eur*. 5.0:447-449

FDA BAM (Bacterial Analytical Manual *Online*) website - http://www.cfsan.fda.gov/~ebam/bam-toc.html. The second appendix to this document is an excellent tutorial on MPN methods. This can be found at http://www.cfsan.fda.gov/~ebam/bam-a2.html

USP. 2003a. <61> Microbiological Examination Of Nonsterile Products: Microbial Enumeration Tests. *Pharm Forum*. 29(5):1714-1722.

USP. 2003b. <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms *Pharm Forum*. 29(5):1722-1733

USP. 2003c. <1111> Microbiological Quality of Nonsterile Pharmaceutical Products *Pharm Forum*. 29(5):1733-1735

USP. 2004. <1117> Microbiological Best Laboratory Practices. *Pharm Forum*. Sept/Oct 2004. 30(5):1713-1721.

USP. 2006a. <1196> Pharmacopeial Harmonization. USP 29:3031-3035

USP. 2006b. <61> Microbial Limits Tests USP 29:2503-2508

USP. 2006c. <1111> Microbiological Attributes of Nonsterile Pharmaceutical Products USP 29:2969

USP. 2006d. <1227> Validation of Microbial Recovery from Pharmacopeial Articles. USP 29:3053-3055

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483 Alerts

Richard Almond, Synthon Corp.

Failure to assure each drug product is free of objectionable microorganisms throughout their expiration dating period. [21 CFR 211.166 (a)]

Anti-microbial preservative effectiveness testing conducted on finished drug products are inadequate as it does not assure that the anti-microbial preservatives formulated into your prescription, oral-liquid drug products, are effective in inhibiting the growth of objectionable microorganisms throughout the expiration-dating period of your drug products. In order to demonstrate the effectiveness of the preservatives added to your multi-dose prescription liquid products, appropriate challenge of your preservatives must be conducted.

Our investigator found that in addition to the lack of adequate preservative effectiveness testing, no microbiological testing of stability samples was conducted as required in your firm's stability protocols. The investigator was informed that your firm is considering removing the microbiological specifications from the protocols. We wish to point out that you are required to conform to the stability testing protocol approved by your quality unit and any deviation from the protocol should be approved by your quality unit and documented with an appropriate scientific rationale. We regard the failure to conduct appropriate preservative or microbiological testing to be a serious CGMP deviation because of the potential hazard microbiologically contaminated drug products can pose to patients.

Failure to establish written procedures for the cleaning and maintenance of manufacturing equipment, including utensils, used in the processing, packing or holding of a drug product. [21 CFR 211.67 (b)]

Your firm has still not performed cleaning validation for several pieces of manufacturing equipment used to manufacture a variety of different prescription drug products. For example, cleaning validation studies for the semi-automatic filling machine, 35 liter stainless steel mixing pot and hand mixing utensils have not been performed. Therefore, there is a lack of assurance that cross contamination does not occur between drug products manufactured sequentially with the same equipment. Additionally, a microbiological assessment of the effectiveness of your cleaning agent was not

Failure to have control systems necessary to prevent contamination during the course of aseptic processing operations, including an air supply filtered through high-efficiency particulate air [redacted] filters under positive pressure [21 CFR 211.42(c)(10)(iii)]. The manufacture of your ophthalmic drug products is not conducted in a controlled room environment or under appropriate [redacted] filtered air supply necessary to prevent contamination.

Failure to collect, maintain, and identify reserve samples of each lot of active ingredient and each lot of finished drug product manufactured for one year after the expiration date of the drug product [21 CFR 211.170(a) & (b)].

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed in accordance with 21 CFR 211.113(b).

Specifically,

Not all personnel who enter the sterile core are monitored each day. Maintenance and cleaning personnel are only monitored during the annual gowning re-certification and/or semi-annual media fills. Additionally, not all operators who gown and enter the sterile core to assemble equipment or unload the autoclave are monitored.

The 2006 PMF Bacterial Endotoxin Summit

What a great conference! The 2006 PMF Bacterial Endotoxin Summit (BES) was held February 15th and 16th in Philadelphia, PA and addressed the issues of the BET ranging from the basic to the advanced and future technologies.

Karen McCullough of Roche Molecular Systems moderated the conference, providing commentary and perspective from her years of experience both from a corporate setting and as a consultant. She did a fantastic job of putting together an outstanding faculty for this event.

Michael Dawson of Associates of Cape Cod gave an industry perspective on compliance documents, on problems peculiar to the test in terms of inhibition/enhancement and on setting specifications for finished products and raw materials.

Ronald Berzofsky, Ph.D. represented Cambrex Bio Science (now with GeneChoice) provided context to the discussion with a strong overview of the science underlying the BET. He also presented on photometric methods, depyrogenation considerations, and process validations. Foster Jordan of Charles River Endosafe provided a background on the gel clot method, described methods for setting endotoxin limits and performing cleaning validation. Robert Mello, Ph.D. of FDA provided a perspective on regulatory and compliance directions under consideration at the Agency.

All speakers provided commentary throughout the conference (frequently on each other's topics!) and were accessible at breaks and during the reception for further conversation. The meeting ended with each speaker providing an glimpse of what was new in the industry from their perspective.

The reception was a big hit. We had a special visitor, "Benjamin Franklin" who dropped by to celebrate his 300th birthday with the conference attendees. Ben was introduced to the reception by Karen, and spent over an hour mingling with the attendees, discussing history, philosophy, and politics.

Benjamin Franklin (center) with the BES speakers: (L-R) Robert Mello, Michael Dawson, Ronald Berzofsky, Karen McCullough, Foster Jordan

The conference was well received by the attendees. Everyone took away valuable information from the speakers, and in addition the conference materials included a complete copy of the presentations as well as a copy of the book "Endotoxins: Pyrogens, LAL Testing, and Depyrogenation (Drugs and Pharmaceutical Science, Vol. 111)" by Kevin L. Williams (ed) Marcel Dekker Publishers. (2001) for future review.

Comments received on the event:

"Please do this AGAIN! I was very pleased with the scope of the discussions. It was nice to address technical items but with more focus on Quality and regulatory issues. I have plateaued on all the training offered recently and I feel this time I actually learned something new and came away with a new perspective and a new direction in which to move our lab and additional tools for consulting our sponsors."

"The conference was very beneficial for discussing endotoxin issues, etc. in the industry. All of the speakers were very approachable, presentation materials were excellent. I liked that it was a very informal setup."

"Very interesting in so many areas. So informative. … The reception was a great opportunity to network."

"Thought the conference was very well organized, great information, very useful. I was glad that there was a focus on the details (calculating MVD, etc) rather than a high-level overview. I will be able to use this information in my laboratory. Overall a great conference – looking forward to the next one!"

"Very good, easy to follow overview topics; Good hands-on practice with current/important industry topics. Venue choice excellent."

"I am new to the LAL Assay – however involved with microbiology for some time. I found this meeting and sessions very useful and informative. Plenty of opportunity to participate and I felt I was hearing form the best in the industry."

"Good mix of presentations! It would have been nice to have this in a more central location, or an east & west coast summit."

"Excellent conference! If it's possible to add to future summits I would like to see more of the math used with BET and Pyrogen testing!"

As we're always looking to improve on a good thing, the organizers have taken participant suggestions seriously, and are considering adding break out sessions for problem solving, more opportunities for round table discussion, a new and exciting location and more math (!)"

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Clearly this conference was a strong addition to the year, and one that PMF was glad to be able to bring this event to the industry. We would like to thank the organizers – High Peaks Associates (http://www.highpeaks.us) for the fantastic job they did "behind the scenes" both in the preparation and execution of the conference leaving the scientists able to concentrate on the content, rather than the machinery of the conference.

The Bacterial Endotoxin Summit will be presented again through the Pharmaceutical Microbiology Forum, and we look forward to seeing you at the next one.

USP Corner

Revalidation of Microbial Limits Tests?

The Microbial Limits chapters were finalized by the PDG (Pharmacopeial Discussion Group, made up of representatives of the JP, EP, and USP) in November of 2005. This month is the first of three installments on the Microbial Limits Tests. These installments will cover:

- Microbial Enumeration Tests
- "Absence of Specified Microorganisms" Tests
- What is the Difference Between "Specified" and "Objectionable" Microorganisms?

The first two installments will focus on **the need to revalidate product tests**. The final installment in this series will look at FDA concerns as they relate to non-sterile finished products, and the compendial perspective.

Any questions concerning USP documents should be sent to Radhakrishna (Radha) Tirumalai, Ph.D. You can reach Dr. Tirumalai at: (301) 816-8339, via mail at United States Pharmacopeia, 12601 Twinbrook Parkway, Rockville, MD 20852-1790 or via e-mail at **RST@USP.org**. You can write representing your company, or as an individual scientist.

Microrite's BactiSpell 2006

In the year 2000, after 25 years of being a microbiologist in clinical and industry settings, I realized that I could not spell bacterial names correctly. At first I thought it was just me, but reflecting on the spelling errors in various reports, laboratory data and results I had reviewed, I plunged into the project of creating a spellchecker that will help me and many others like me. It was a long drawn process of collecting names of bacteria from known resources as well as references and then verifying them against Bergey's Manual. I was surprised to find that many names were spelled differently in different references. Of course, I chose Bergey's as the Gold Standard. This collection of words was then compiled into a software package. The software was called Bactispell. Long hours of programming and Beta testing were spent to ensure that the software matched the Genera with their correct species names. There were many cases when the Genera and the species were spelled the same way. The software was programmed to recognize these special instances. Essentially the software recognized the Genera and capitalized the first letter, if it was not capitalized and recognized the species names and un-capitalized them. The program followed this procedure as it went through the document, and concurrently it italicized all the bacterial names.

This software was sold on Microrite's website for Office 95 and then upgraded to work with Office 98. It was when Office 2000 was released that Bactispell was discontinued due to inability to keep up with the error messages while installing, and the trouble shooting efforts that it demanded for different operating systems. The advanced security systems installed on personal computers increased software support beyond what we could support.

I offered the text version to the microbiology community for free use in the PMF newsletter in 2002.

Dr. Scott Sutton recently decided to add more technical terms to the word list before we offered it for free download on PMF and Microrite websites. The three word lists Bactispell 1; Bactispell 2 and Bactispell 3 are extensive, and can help you spell check bacterial names and technical terms.

Please take advantage of this tremendously helpful tool and save time by not checking references for correct spellings.

Ziva Abraham
Microrite, Inc.
http://www.microrite.com

Come Visit Our Website at
http://www.microbiologyforum.org

Archives of the *PMF Newsletter* at
http://www.microbiology forum.org/news.htm

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Table 2 – Aspects of the Current and Harmonized Microbial Limits Tests (Enumeration)

Issue	USP <61>	EP Chapter 2.6.12	Harmonized
Media Growth Promotion – Organisms for Trypticase Soy	*Staphylococcus aureus* *Escherichia coli* *Pseudomonas aeruginosa* *Salmonella*	*Staphylococcus aureus* ATCC 6538 (NCIMB 9518, CIP 4.83) *Escherichia coli* ATCC 8739 (NCIMB 8545, CIP 53.126) *Bacillus subtilis* ATCC 6633 (NCIMB 8054, CIP 5262)	*Staphylococcus aureus* ATCC 6538 (NCIMB 9518, CIP 4.83, NBRC 13276) *Pseudomonas aeruginosa* ATCC 9027 (NCIMB 8626, CIP 82.118, NBRC 13275) *Bacillus subtilis* ATCC 6633 (NCIMB 8054, CIP 5262, NBRC 3134) **Note** – detail provided on method of preparation and culture
Media Growth Promotion – Organisms for Sabouraud Dextrose	Not mentioned	*Candida albicans* ATCC 10231 (NCPF 3179, IP 48.72) *Aspergillus niger* ATCC 16404 (IMI 149007, IP 1431.83)	*Candida albicans* ATCC 10231 (NCPF 3179, IP 48.72, NBRC 1594) *Aspergillus niger* ATCC 16404 (IMI 149007, IP 1431.83, NBRC 9455) **Note** – detail provided on method of preparation and culture
Media Growth Promotion – Methodology	Not detailed	Use less than 100 CFU per media Counts must be within five-fold of control (95% confidence interval for MPN)	Use less than 100 CFU per media Counts must be within 50% of control (95% confidence interval for MPN)
Media Sterility Check	Not detailed	Combined with Negative Product Control	Recommended
Suitability of the Counting Method	Inoculate diluted specimens of the product to be tested with challenge organisms May stop validation effort after sufficient effort has shown a particular organism cannot be recovered.	Must show recovery in presence of product	Preparation of Test Strains detailed Use less than 100 CFU of challenge organism Instruction provided on the neutralization of antimicrobial activity Recovery must be within 50% of control May stop validation effort after sufficient effort has shown a particular organism cannot be recovered.

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Table 2 – Aspects of the Current and Harmonized Microbial Limits Tests (Enumeration) (cont)

Issue	USP <61>	EP Chapter 2.6.12	Harmonized
Sampling Plan	Not detailed	Must follow well-defined sampling plan Batch size Health hazard Product Characteristics Expected Level of Contamination	Sampling plan not detailed Discussion of modifications to sample volume: Active agents in low concentrations Bulk materials Small batches
Sample Volume	10 grams	10 grams	10 grams
Categories	Water soluble Water-immiscible fluids, ointments, creams, waxes Fluid in aerosol form	Water-soluble products Non-fatty Products insoluble in water Fatty Products Transdermal Patches	Water-soluble products Non-fatty Products insoluble in water Fatty Products Fluids or solids in aerosol form Transdermal Patches
Methodology – Membrane Filtration	Not listed	Transfer 1 gram to each of two filters (0.45 um nominal pore size), filter Three 100 mL washes One filter on TSA, one on SDA Incubate TSA Plate at 30-35^{o}C for 5 days Incubate SDA Plate at 20-25^{o}C for NMT 5 days Count plates with NMT 100 CFU	Transfer validated amount to two filters Wash each filter by validated method Total Aerobic Microbial Count (TAMC) filter is placed on TSB, incubated at 30-35^{o}C for 3 to 5 days Total Yeast and Mold Count (TYMC) filter is placed on SDA, incubated at 20-25^{o}C for 5 to 7 days
Methodology – Plate Count: Pour Plate	Add 1 mL of sample at appropriate dilution to 9 cm diameter petri dish. Add 15-20 mL liquified agar (TSA and SDA) Plate in duplicate Incubate TSA at 30-35^{o}C for 18 to 72 hours for Total Aerobic Microbial Count; Incubate SDA at 20-25^{o}C for 5-days for Total Combined Yeast and Mold Count	Add 1 mL of sample at appropriate dilution to 9 cm diameter petri dish. Add 15-20 mL liquified agar (TSA and SDA) Plate in duplicate Incubate as above Count plates with not more than 300 CFU	Prepare sample by a method shown to be suitable. Plate 1 mL in at least duplicate on TSA and SDA Incubate TSA plates at 30-35^{o}C for 3 to 5 days Incubate SDA plates at 20-25^{o}C for 5 to 7 days Count from plates with less than 250 for TAMC, less than 50 CFU for TYMC

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Table 2 – Aspects of the Current and Harmonized Microbial Limits Tests (Enumeration) (cont)

Issue	USP <61>	EP Chapter 2.6.12	Harmonized
Methodology – Plate Count: Spread Plate	Not listed	Add 0.1 mL of sample at appropriate dilution to 9 cm diameter petri dish containing agar (TSA and SDA) Plate in duplicate Incubate as above Count plates with not more than 300 CFU	Prepare sample by a method shown to be suitable. Plate 0.1 mL in at least duplicate on TSA and SDA by spreading on surface of prepared plates Incubate as above Count from plates with less than 250 for TAMC, less than 50 CFU for TYMC
Methodology – Most Probable Number (MPN)	Assemble 14 tubes of TSB (9 mL each Do a 10-fold dilution series of the sample (in triplicate) into twelve of the tubes Incubate all 14 tubes Negative controls must remain clear Read results from table	Use only for bacteria Prepare at least three ten-fold dilutions in series Inoculate three aliquots of each dilution 1g or 1mL samples into each of three tubes of 9-10 mL TSB Incubate 30-35^{o}C for 5 days Read results from table provided	Prepare sample by a method shown to be suitable. Incubate tubes 30-35^{o}C for 3 to 5 days Read results from table provided
Additional Controls	None	Use sterile sodium chloride-peptone solution pH 7.0 as test preparation to test: Sterility of Medium Sterility of Diluent Aseptic Performance of the test	Use Sterile Diluent as the test preparation for each batch of diluent to verify testing conditions.
Interpretation of Results	Must meet specs Retest allowed using 25 gram sample	Must be within five-fold of specification for product	Must be within two-fold of specification for product

Upcoming Events

March

- 13th -14th **Species and speciation in micro-organisms**
  Location: The Royal Society, 6-9 Carlton House Terrace, London SW1Y 5AG.
  Phone: 020 7451 2500
  Email: events@royalsoc.ac.uk
  Web Site: www.royalsoc.ac.uk/events

- 13th – 15th **Microbiology Course Series**
  - Validation of Microbiological Methods
  - Auditing QC Microbiology Laboratories
  - Water System Microbiology
  - Microbial Identification Methods

  Location: San Francisco Bay Area
  Phone: 888-844-8561 (toll-free, North America)
  or +1 585-594-3336
  Email: register@highpeaks.us
  Web Site: http://www.highpeaks.us/upcoming.htm

- 19th – 22nd **Annual Conference of the Association for General and Applied Microbiology**
  Location: Friedrich-Schiller-University Jena, Germany
  Phone: +49(0)3641 35 33 15
  Email: vaam@conventus.de
  Web Site: http://www.vaam.de; http://www.conventus.de/vaam

- 23rd – 24th **Investigating Microbial Contaminations** Course
  Location: Caribe Hilton (San Juan, Puerto Rico) Phone: +1 408-445-0507
  Web Site: http://www.microrite.com/Investigating_Microbial_Contaminations_Puerto_Rico_March_2006.pdf

- 27th - 28th **2006 International Conference on Biocontainment Facilities**
  Location: St. Petersburg, FL
  Phone: 925-254-1744
  Email: bill@tradelineinc.com
  Web Site: http://www.tradelineinc.com/bio

- 27th - March 1 **Managing Risk in Aseptic Filling and Processing for Pharmaceutical and Biopharmaceutical Products**
  Location: London
  Website: http://www.iir-events.com/IIR-Conf/page.aspx?id=246

- 29th - 31st **The Environmental Monitoring and The Stability Technical Seminar and Workshop**
  Location: Hilton New York, NY
  Phone: 514-788-6023
  Web Site: http://www.novaseminars.com

April

- 19th – 21st **Microbiology Course Series**
  - Validation of Microbiological Methods
  - Auditing QC Microbiology Laboratories
  - Water System Microbiology
  - Microbial Identification Methods

  Location: San Juan, Puerto Rico
  Phone: 888-844-8561 (toll-free, North America)
  or +1 585-594-3336
  Email: register@highpeaks.us
  Web Site: http://www.highpeaks.us/upcoming.htm

- 24th –29th **PDA Annual Meeting**
  Location: Anaheim Marriott, Anaheim, CA.
  Web Site: http://www.pda.org/annual2006

Offering In-House Courses on Microbiology/ Aseptic Processing:

- The Microbiology Network/High Peaks Associates http://www.highpeaks.us/in-house.htm

- USP
  Contact Steven Paul (stp@usp.org) for information on the course "Fundamentals of Microbiological Testing"

Discussion List Update

PMFList:
Number of Subscribers: 1,464
Number of Countries: 52
Number of Messages Last Month: 271
PSDGList:
Number of Subscribers: 777
Number of Countries: 20

Are you aware of our on-line discussion group?

Membership is FREE. To **join the PMFList**, visit http://www.microbiol.org/pmflist.htm and register.

A sister Email is devoted to topics in the **stability testing** of pharmaceuticals, medical devices and personal products. To **join the PSDGList**, visit http://www.microbiol.org/psdglist.htm and register.

You can ask, answer, or read questions and comments from your colleagues.

2005 Bibliography

A listing of articles that may be of interest to the readership.

Aseptic Processing

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http://www.bact.wisc.edu/Microtextbook/	News, useful training information.
If you have found an Internet site that contains information of relevance to pharmaceutical microbiology, please let us know.	

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