



PMF NEWSLETTER

A PUBLICATION OF THE PHARMACEUTICAL MICROBIOLOGY FORUM
Distributed Internationally to 9,997 Subscribers in over 100 Countries

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April 2012

Letter from the Editor



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Welcome to the April issue of the 2012 *PMF Newsletter*.

We're very pleased to present our "2011 Articles of Interest" issue. Dr. Sutton has compiled an extensive list of literature references on a wide variety of topics that were of much interest and discussion last year. His annual bibliographies have proven to be of great value to GMP microbiologists, and this year is no exception.



We are always interested in your input and concerns. Please let us know if there are articles or topics you would like to see addressed in this newsletter.

Bob Westney

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Articles of Interest – 2011

Scott Sutton, Ph.D.
The Microbiology Network, Inc.

The PMF Newsletter has published this bibliography of interesting articles from the previous year on an annual basis since 2006. It has turned into one of the more popular offerings. Hopefully you will find something of use in this listing again this year.

It is my belief that keeping up on the academic literature, as well as the trade publications, is critical for “science-based regulation” and I believe that it is our responsibility to continue to improve the level of regulatory science and compliance of our companies and our industries.

The continued merge of pharma, medical device,

personal care products and dietary supplements from the regulatory perspective has been reflected by a shift, or perhaps an expansion, of the participants on the PMFList. This year’s bibliographic review will hopefully offer something for all these areas of QC microbiological interest. However, this list is not comprehensive - that would be a herculean task and almost certainly doomed to failure. If your article was omitted please accept my apologies. Be sure to send me a copy of any article you publish in 2012 and I will get it in next year’s bibliographic review.

Topics Covered:

- Aseptic Manufacturing
- Contamination Control
- Environmental Monitoring
- GMP
- Identification
- Lab Operations
- Lab – Enumeration
- Lab – Handwashing
- Objectionable Organisms
- Personal Care Product Microbiology
- Rapid Microbiological Methods
- Finished Product Tests
- Water/Biofilm

Aseptic Manufacturing

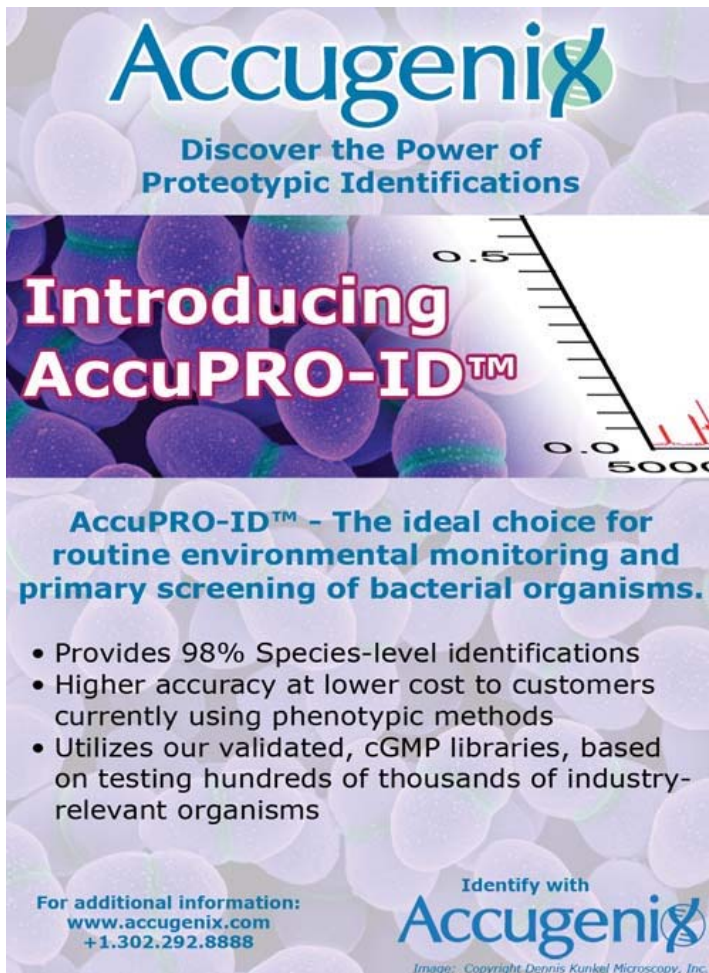
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Past Issues of the *PMF Newsletter* at <http://www.microbiologyforum.org/>

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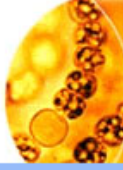

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Don't miss!

**Bacterial Endotoxin Summit –
“Interference in the BET”**

September 17 - 18, 2012

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Upcoming PMF Conferences

2012 PMF Bacterial Endotoxin Summit Interference in the BET

September 17-18, 2012 San Francisco, CA

http://microbiologyforum.org/2012/HPA1206_Interest.html

The standard gel, chromogenic and turbidimetric Bacterial Endotoxins Test test methods, as described in harmonized USP chapter <85> are validated, meaning that the methodology has been proven and accepted. However, the QC laboratory can't assume that these validated test methods are suitable for the products under test. It is incumbent on the laboratory to demonstrate suitability for each material under test through the execution of the compendial "Test for Interfering Factors", also known as Inhibition/Enhancement testing. While the compendial requirements for this activity are straightforward, the advent of unique formulations and presentations of modern pharmaceutical products may result in test interference that could complicate these otherwise simple tasks.

This conference will be moderated by Karen Z. McCullough, Principal at MMI Associates.

PMF Fall Forum – Leading the Modern QC Microbiology Lab

October 15-16, 2012 - Philadelphia, PA

http://microbiologyforum.org/2012/HPA1207_Interest.html

Effective leadership in the QC Microbiology lab is critical to its effectiveness in the corporation, and the accuracy of the data generating in the lab. Unfortunately, many of us concentrate heavily in the science, without specific training or thought to what goes in to leading the lab. There are the technical aspects that might be more comfortable to us, but there are also budget and planning issues, motivation of personnel, interaction with other departments as the subject matter expert, dealing with consultants and contract labs, and so on. We normally learn these skills by doing the activities. Alternately, there are those who are identified as potential management material and are assigned leadership of the QC microbiology lab as a training experience in management.

This conference will be moderated by Scott Sutton, Ph.D.

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About the Author:

Scott Sutton is the founder and principal consultant of Microbiology Network, Inc (<http://www.microbiol.org>). He is a recognized consultant and trainer with emphasis in GMP, investigations, Environmental Monitoring and contamination control as well as microbiology laboratory audits and operations. He can be reached at scott.sutton@microbiol.org or by phone at +1-585-594-8273.



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