PMF Newsletter

A quarterly publication of the Pharmaceutical Microbiology Forum

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Formation of the Pharmaceutical Microbiology Forum

A meeting was held on April 26, 1993 to establish the Pharmaceutical Microbiology Forum (PMF), an association formed to promote the interests of pharmaceutical microbiologists. The mission of the PMF is to provide a forum for microbiologists to exchange information on microbiological issues in the pharmaceutical industry, and interact with the USP and regulatory agencies. Presently, the PMF consists of the Organizational Board, the FDA/USP Liaison Board, and the *PMF Newsletter* committee.

The Organizational Board consists of six elected members who are currently developing the organizational bylaws. Following completion of the bylaws later this year, new members will be accepted into the PMF. The *PMF Newsletter* will be published quarterly beginning this fall and will include microbiological topics related to QA/QC, method development and validation, interviews, regulatory issues and 483's, meeting reports, job offers, and other information of interest to members. The FDA/USP Liaison Board will interact with regulatory agencies and the USP to communicate the views of pharmaceutical microbiologists before changes are made to monographs or informational chapters.

For more information on how you can become involved in the Pharmaceutical Microbiology Forum, please contact L. Valdes, AAI, Inc., 1206 North 23rd Street, Wilmington, NC 28405 [Tel (919) 251-6786 or FAX (919) 251-6755].

Current Issues:

Irradiated vs. Nonirradiated RODAC® Plates

Contributed by a PMF Member

We use RODAC® plates with TSA medium supplemented with Tween and lecithin. It is not economically feasible to produce these specialized plates in our facility so we purchase them from vendors. There has been much discussion as to whether our company should switch to irradiated RODAC® plates that are certified sterile; or use plates that have been produced in a controlled cleanroom; or to continue to use plates that have been produced under standard manufacturing conditions.

A sterile plate is very attractive. There is a definite advantage in knowing you will not be taking contaminated plates into a clean zone. If this happens it can result in the rejection of one or more production lots, at a great loss in time, money, and creditability to both user and vendor. The investigation and clean up is a nightmare. I have been there!

RODAC® is a registered Trademark of Becton Dickinson and Co.

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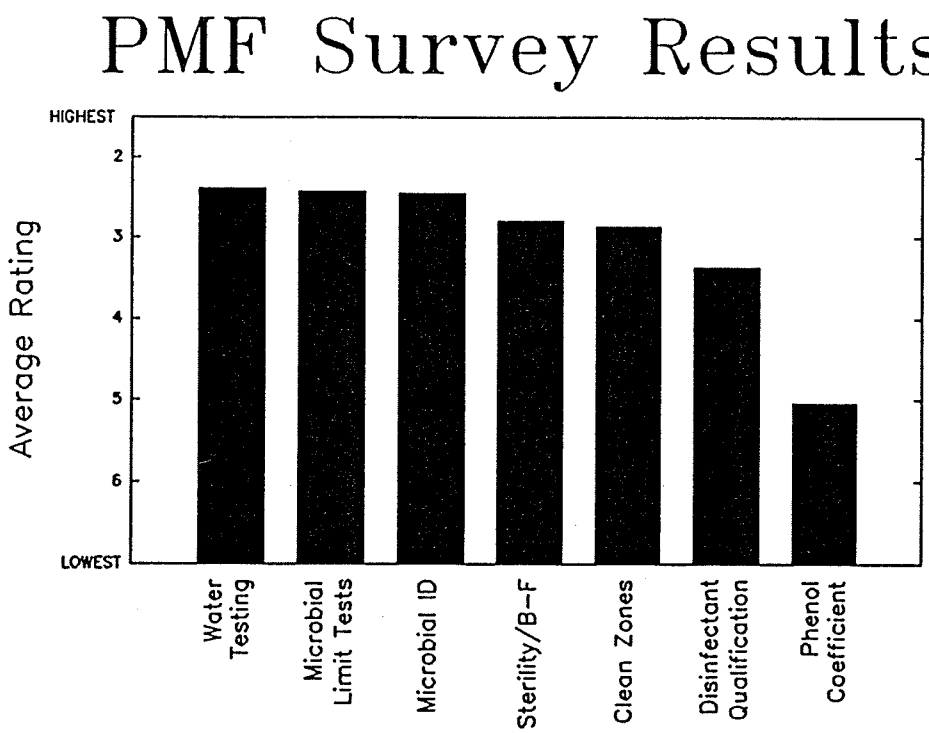
Survey Results

The PMF conducted a survey of its members to determine the topics of most interest. Seven categories of pharmaceutical microbiology were rated from 1 (most important) to 7 (least important). Fifty percent of the 85 questionnaires were returned and the average response for each area of interest was calculated.



Focus Groups Forming

Based on the survey results, two Focus Groups are being formed by the Organizational Board to identify issues and review current regulatory activities associated with **Water Testing** and **Microbial Limits Testing**. The Focus Groups will present a summary and any recommendations to the Organizational Board for approval. After approval, the recommendations will be given to the USP/FDA Liaison Board who will interact with the appropriate organizations to voice our opinion. The work of the Focus Groups will also be presented at the PMF Annual Meeting in April. If you are interested in participating in a Focus Group, please contact L. Valdes, c/o AAI, Inc., 1206 North 23rd Street, Wilmington, NC 28405, [Tel (919) 251-6786 or FAX (919) 251-6755.

Future Topics

Contributions to *PMF Newsletter* are welcome and may be in the form of short articles, letters to the Editor, comments, or suggestions. Please direct your correspondence to *PMF Newsletter*, c/o L. Valdes, 1206 North 23rd Street, Wilmington, NC 28405 [Tel (919) 251-6786 or FAX (919) 251-6755. Submit any articles with your name and phone number in case we need to contact you. Your name and company will not appear without prior written authorization. Articles on the following topics would be greatly appreciated:

USP Update, Microbiology QA/QC, Method Development and Validation, Career Development, 483 Observations, Book Reviews

RODAC® Plates *(con't from Page 1)*

I investigated two vendors that sell irradiated plates, and one that produces plates under cleanroom conditions. The main question is what sensitivity, if any, is lost in the ability to grow organisms? How would I know if there were false negatives? I am not as concerned about the ability to grow the USP group of challenge organisms, as they are rather hardy; but rather some of the environmental organisms that may be more sensitive.

I asked each company how they determined that they had not compromised the nutritional integrity of the medium by irradiating the plates. One vendor recognized that there was some loss of nutrients at the level of radiation that they proposed to use. They increased the amounts of these nutrients to compensate. Does enhancement change any of the other characteristics of the medium?

Another vendor recognized the loss of nutrients, but chose to lower the level of radiation. They made the plates under very clean conditions which resulted in low bioburden. They validated the irradiation process to decrease the bioburden by 10^3 instead of 10^6. This lower level of radiation resulted in a minimal loss of nutrients. With this validation, they are still able to call their RODAC® plates sterile and will assume the liability that they are free of contamination before the bags are opened.

The third company recognized that irradiation could change the medium in undefined ways and chose not to irradiate their plates. They produce them under cleanroom conditions. They do not claim they are sterile and do not take the liability if they are contaminated. They will replace any plates that are found to be contaminated. The figures they quoted to me is less than 0.01% contaminated plates.

All vendors have plates available double wrapped and in some cases tripled wrapped in bags of ten. Additionally, two vendors put two bags to a box (20 plates/box). The difference is that the box from one vendor has been irradiated, while the other one was not. Cardboard boxes have the potential of being contaminated with fungi, mostly *Penicillium* and *Aspergillus* species. There is no control over how the box makers store their boxes, or how they are stored at the media manufacturers while waiting to be used. While this is not much concern in the clinical laboratory, it can be a major concern in the cleanroom.

The double and triple bagged plates have an increased expiration date, up to four months, from the standard plates. This increased date is based on stability studies that measure moisture loss and the ability to maintain growth of the challenge organisms.

One other factor to consider is the amount of moisture in the bags and on the plates. It is not acceptable if the plates are wet. The vendor must take precautions to ensure the plates are dry before they are bagged and are stored so as not to produce moisture. Also, they must not be too dry, or they will not be usable to their expiration date.

Needless to say, the cost is doubled and in some cases tripled over the "standard" plates. This increase is for the assurance that the plates are not contaminated, the extra packaging, the Certificate of Quality, and the extra paperwork the vendor must put in place.

The position of the USP and the FDA is that each facility must validate the use of their medium to ensure it does what it proposes to do. The burden of proof is on the users.

What experiences have you had in the use of these plates, either good or bad? How did you validate the plates for use? Please write the *PMF Newsletter* and let us share some of your experiences with our readers. Your name and the name of your company will not be used without your permission, but we will need to confirm what you wrote, so please include your name and a phone number where you can be reached.

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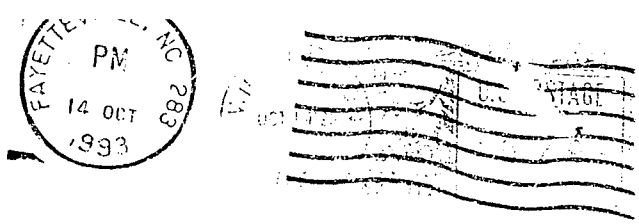

Address Correction requested

Calendar of Events

The Calendar of Events is provided as a service to PMF Newsletter readers. Submission of complete and accurate information will be published on a space-available basis.

1993

October 3, *International Society of Quality Assurance (ISQA), 4th Annual North American Mini-Symposium: Biotechnology and Medical Devices*, San Francisco, CA (703) 658-8926

October 4-7, *Society of Quality Assurance (SQA), 9th Annual Meeting: Bridging Science and Compliance*, San Francisco, CA (703) 914-0835

October 10-13, *American Biological Safety Association Annual Meeting*, Albuquerque, NM (708) 949-1517

October 12-15, *Fermentation Methods and Scale-up Strategies*, University Park, PA (800) 833-5533

October 17-20, *Interscience Conference on Antimicrobial Agents & Chemotherapy (33rd)*, New Orleans, LA (202) 737-3600

November 1-3, *Pharmaceutical Executive Conference*, Orlando, FL (503) 343-1200

November 30 - December 3, *International Conference on Advanced Pharmaceutical Substance Screening (1st)*, Vienna, Austria (ASACC, c/o Winfried Scheirer, SFI, P.O. Box 80, A 1235 Vienna, Austria)

1994

April 25-26, *Third Annual Microbiology Seminar Series*, Wilmington, NC (919) 392-4694

May 22-26, *American Society for Microbiology General Meeting (94th), Las Vegas, NV (202) 737-3600*

June 13-15, *BioPharm Conference, San Francisco, CA (503) 343-1200*

***July 9-13,** American Society for Virology Scientific Meeting (13th), Madison, WI (608) 262-9880*

***October 4-7,** Interscience Conference on Antimicrobial Agents & Chemotherapy (34th), Orlando, FL (202) 737-3600*

PMF Newsletter is published quarterly by the Pharmaceutical Microbiology Forum.

PURPOSE: To provide a forum for discussion of microbiology issues in the pharmaceutical industry.

The information contained in this newsletter are the professional opinions of our members and do not represent the policies or operations of any corporation or government agency to which members may be associated. *PMF Newsletter* is intended to serve as an open forum and confidentiality will be maintained. The information in *PMF Newsletter* is solely for information purposes and is developed from sources believed to be reliable. Statements expressed constitute current opinions derived through analysis of available information and professional networking. The *PMF Newsletter* cannot make any representations as to the accuracy or completeness of the information presented and the publisher cannot be held liable for errors.