PMF Newsletter

A quarterly publication of the Pharmaceutical Microbiology Forum

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Letter from the PMF President:

We have started a new year, and look forward to gaining more knowledge in our field. The PMF, as you can see, is active. However, we need your help. First, we would like to thank all of you who have paid your membership dues. We have found a company, AAI(formerly Applied Analytical Industries, Inc.) that has taken the role of printing and mailing our newsletter. Due to this, the Organizational Board of PMF has decided that dues will only be paid once for now. Should the organization need additional money in the future, we will let you know. If you have not paid you dues, please do so. This is officially your last copy of this newsletter.

Second, we are looking for someone to handle our very short tax forms. Can you do this for us? Third, we need someone who has filed papers to make an organization non-profit to assist us in accomplishing this for PMF. Do you know how to or someone who can help us?

Last, but not least, PMF has a great offer for you. Should you send us an article that we publish in this newsletter on any topic related to Pharmaceutical Microbiology, you will get a free membership automatically. Remember that articles will not have your name or company name unless you authorize us in writing to use them.

I am looking forward to your assistance during 1995 to grow our organization. Send letters to:

Laura Valdes-Mora-PMF
AAI, Inc., 1206 North 23rd Street, Suite 110
Wilmington, NC 28405

Considerations for a Microbiologist in a Cleaning Validation Team

Contributed by a PMF Member

The most popular and newest request these days is to be involved in a cleaning validation. As microbiologists, we are called to be part of cleaning validation teams. If your company is not considering microbiological cleanliness, you may like to raise the concern. A cleaning validation package is considered complete if it addresses chemical and microbiological cleanliness.

What is our role as microbiologists in a cleaning validation? First, we are called to develop a method for the determination of bioburden either from swabs or rinse samples. After the method is validated and the SOP is written on how samples will be processed, then we may be left with the task of sampling and testing.

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Inside This Issue

(Cleaning Validation cont.)

The following are points to consider when developing the methodology for bioburden testing in support of a cleaning validation:

1. What is the product? The type and form of the product will determine if the microbiological sampling will be minimal or quite involved. It will also indicate how to set acceptance criteria.

Example A-Tablets/Capsules-Simple approach from Microbiology

Example B-Liquid unpreserved product-Requires a higher degree of assessment than Example A

Example C-Biological Product-Requires the highest degree of microbiological assessment

2. What is the cleaning methodology? This should be analyzed and tested *in vitro* by the microbiologist. By doing this exercise, one will be able to determine if the method chosen may present a problem in the reduction or elimination of bioburden.

3. For how long will the product sit in the equipment before the equipment is cleaned? This should be mimicked during the in vitro test.

4. How does the product affect microbial growth? Is it bacteriostatic, fungistatic, bacteriocidal, fungicidal, or growth promoting?

5. Of what material is the equipment made? Which are the critical areas? These two questions will be answered by other members of the team. A set of samples from the material(s) also referred to as coupons are to be used during the method validation. You need to prove that the material does not interfere with the determination of bioburden.

This is just a brief introduction to the "new " world of cleaning validations. We will all hear a lot about this topic during 1995. Most pharmaceutical companies are re-evaluating their cleaning methods. others never had any validated and they are in the process of establishing a program. FDA has been quite busy issuing FDA 483's in our industry for lack of documentation of cleaning procedures or inadequacy of the same. Currently there is no one specific approach to the microbiological aspect of cleaning validation. If your approach is different than the one described here, we would like to hear from you. Send a summary of your approach, or feel free to write an article for the newsletter.

Send your questions on cleaning validation to PMF and they will be addressed in the next newsletter. Also, feel free to let us know if you agree with the points described in the article. What would you add or eliminate and why? Let us make this a real forum for exchange of information.

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.

April 10-13, 1995, *PDA New Brunswick Courses*, New Brunswick, New Jersey

April 26-28,1995, *Applied Analytical, Inc.(AAI), Validation in the Pharmaceutical Microbiology Laboratory, What's New in 1995?*, Wilmington, North Carolina

May 15-19, 1995, *PDA Kansas City Courses*, Kansas City, Missouri

May 21-25, *95th General Meeting, American Society for Microbiology*, Washington, DC

MICROTOONS

THE DAY BACTERIA GOT VOICE

"Huh . . . me worthless . . . I keep you in salary."

Purified Water System Survey Results

Is your Microbiology Department responsible for?

1. Sampling the Water System

   YES 16(89%) NO 2(11%)

2. Water Bioburdens

   YES 18(100%) NO 0

3. Water Chemistries

   YES 6(33%) NO 12(67%)

4. Is your incoming water from:

City System	17(89%)
Well Water	2(11%)

5. What components are in you purified water system?

Resin Beds	14(82%)
RO	9(53%)
Still	7(41%)
Other(Sand)	1(6%)

6. Are there any 0.1µm filters on your system?

   YES 3(18%) NO 14(82%)

7. Do you test for endotoxins?

   YES 8(45%) NO 10(55%)

8. What method do you use for endotoxin testing?

Gel Clot	5(62%)
Turbidimetric	1(13%)
Chromogenic	2(25%)

9. What method do you use for Bioburden Testing?

Membrane Filter	15(68%)
Pour Plate	7(32%)

10. What Medium do you use?

Plate Count	3(17%)
R2A Medium	7(38%)
TSA	3(17%)
BAP	1(6%)
TGEA	3(17%)
Millipore	1(6%)

11. What temperature do you incubate the plates?

20-25C	1(6%)	30-35C	15(82%)
20-25C/30-35C	1(6%)		
Other(33-37C)	1(6%)		

12. How long do you incubate the plates?

2 Days	8(44%)	3 Days	2(11%)
5 Days	5(28%)	7 Days	3(17%)

13. Testing Interval

Daily	6(32%)
Weekly	8(42%)
Monthly	3(16%)
Other(2x/week)	2(10%)

14. Is your water system validated?

   YES 15(83%) NO 3(17%)

15. Do you sanitize your system:

Weekly	1(6%)
Monthly	4(23%)
2x/year	4(23%)
None	1(6%)
Yearly	2(12%)
As Needed	3(18%)
Daily	2(12%)

16. What do you use to sanitize your system?

H_2O_2	5(31%)
Hot Water	4(25%)
Chlorine	3(19%)
Ozone	1(6%)
None	1(6%)
Metabisulfite	1(6%)
Steam	1(6%)

17. What are your specifications for bioburden?

50/ml	9(50%)	100/ml	7(38%)
0.2/ml	1(6%)	25/ml	1(6%)

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(Purified Water cont.)

18. Do you test for coliforms?

    YES 16(89%) NO 2(11%)

19. Have you ever isolated a coliform from your water?

    YES 6(38%) NO 10(62%)

20. In how many years of testing?

    1-5 years 2 5-10 years 2

21. Were you able to identify the source of the E. coli?

    YES 4 NO 2
    Well Water 1 Municipal 3

22. Do you test for Total Organic Carbon?

    YES 7(39%) NO 11(61%)

23. If so, how long have you been testing for TOC?

    2-7 years 3

24. What method or equipment do you use to test for TOC?

    Send Out (2) In-Line (1)
    Anatel (2)

25. What does your company produce?

Pharmaceutical Products	16
Cosmetics	1
Diagnostics	1
Medical Devices	1

Congratulations to Laura Valdes-Mora on the birth of Joana Liliana Mora. The future microbiologist arrived 02/15/95 at 2:51pm, weighing 7lbs 12oz.

Future Topics

The purpose of the Newsletter is a sharing of information among Microbiologists. Your contributions to *PMF Newsletter* are needed in the form of short articles, letters to the Editor, comments, or suggestions. Please direct your correspondence to *PMF Newsletter*, c/o L. Valdes-Mora, 1206 North 23rd Street, Wilmington, NC 28405 [Tel (910) 251-6786 or FAX (910) 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.

EMPLOYMENT ANNOUNCEMENT

Microbiologist (Assistant Lab Director)
Independent testing lab seeks experienced, responsible individual to perform all USP microbiology testing of pharmaceutical and medical devices. Supervisor experience required. ASM certification and a M. S. Degree preferred. Excellent benefit package. Submit resume to:

President
MicroTest Laboratories, Inc.
P. O. Box 848
Agawam, MA 01001

The Pharmaceutical Microbiology Forum would like to express its appreciation and thanks to AAI (Applied Analytical Industries, Inc.) for their continued support.

PMF Newsletter is published quarterly by the Pharmaceutical Microbiology Forum.

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

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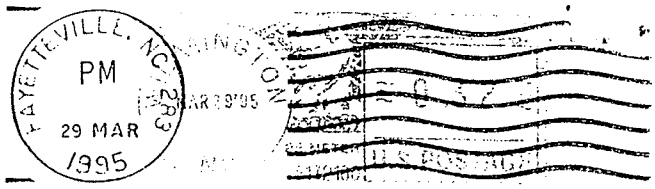

Address Correction Requested