PMF NEWSLETTER

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Watch This Space!

The PMF is undergoing some dramatic changes in the next few months. This is being pretty much forced on us by our success, and the need to adjust the way we are doing business.

First of all, let me issue an invitation on behalf of the editorial staff of the PMF Newsletter. If you have an interesting case study, or a well-reasoned "white paper" that you would like to see have a wider audience, please consider submitting it for publication in the newsletter. This is your publication and provides a vehicle for discussions beyond that allowable on the PMFList email format.

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

Secondly, the PMF Newsletter will shortly be joined by the LAL User's Group Newsletter. Karen McCullough will be serving as editor of this newsletter and the LAL User's Group will begin activities again under the umbrella of the PMF.

Finally, we have an aggressive conference schedule this fall. The two ever-popular conferences (Fall Forum and Bacterial Endotoxin Summit) are being joined by the Cosmetic Microbiology Conference in September. These conferences are well worth the time and effort.

While we are talking about conferences, feel free to propose a conference. We can help each other bring current issues out for discussion with a minimum of fuss and paperwork. Let's use the wonderful tool we have to serve as a force for change from the bench!

Scott Sutton scott.sutton@mcirobiol.org

Microbiological Aspects of Stability Programs

Scott Sutton, Ph.D.
Vectech

In reviewing Emails from the PMFList, it seems there may be some confusion over the role of microbiological assays in the stability program for pharmaceutical and medical device products. It can only be assumed that a similar uncertainty exists for the cosmetic industry, although not evident in PMFList traffic. This short article will attempt to lay out one view of the need and extent of microbiological testing for stability programs.

There are three separate types (at least) of stability programs to evaluate*. The first is the product development stability program, used to establish expiry dating of the product in preparation for regulatory submission. The second type of stability program is the post-market stability normally conducted as a regulatory commitment to demonstrate continued QC of the product, or as a means to extend the expiry dating of the product. Finally, microbiological evaluations play a role in raw material stability studies to demonstrate the adequacy of storage conditions for bulk excipient and API awaiting manufacture.

The chemical requirements for these stability programs are well-known. Less recognized, however, is the need to demonstrate the stability of the microbiologically-related product characteristics with time.

Basic Requirements

Temperatures

Stability studies are conducted under different conditions of temperature and humidity. Leaving aside humidity considerations, the incubation of product at different temperature is done for two reasons. The first is to establish stability under room temperature for different parts of the globe (1). Microbiological evaluation should be part of this examination as the formulation, particularly the more complex formulations, can behave in an unpredictable manner in terms of microbiological response. It must always be remembered that the reason microbiological analysis is being performed is that chemistry cannot predict the microbiological response. The bacteria are living organisms that respond to stimuli, sometimes very complex stimuli well beyond the question of whether a specific chemical is present at a specific level.

The second reason for incubating samples at different temperatures on a stability program is to predict the stability of the product on an "accelerated" schedule. The idea here is that incubation of the formulation at elevated temperatures will mimic the degradation of compounds seen at lower temperatures over longer periods. It has been my experience that this may work in many situations for microbiology, but when it fails to work it does so in a dramatic fashion. The wildly inaccurate results that are collected create a great deal of confusion as the "real-time" data catch up with the accelerated conditions, or falsely describe stability problems that do not materialize on the real-time studies. The microbiological tests on stability are critical in describing the product characteristics over time, but care must be exercised in the design of the program. At least for microbiology data it must always be remembered that the real-time studies are the only ones providing dependable information.

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* Before you stabilitarians get all cranky at me I do know that there are many more than three designs. I am intentionally leaving out freeze-thaw, light studies and all the others as microbiology rarely plays a role in these studies.

Biosafety in the QC Microbiology Laboratory

Scott Sutton, Ph.D.

The issue of lab safety is a matter of some debate. It begins with the somewhat overly cautious classification of common lab organisms as "Risk Factor 2" organisms. These are defined by NIH as "Agents that are associated with human disease which is rarely serious and for which preventative or therapeutic interventions are *often* possible." They are defined by the World Health Organization as "A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited."

These definitions fit organisms as diverse as *Bordetella pertussis* (Whooping cough), *Brucella, Clostridium tetani, Corynebacterium diphtheriae, Mycobacterium leprae* (leprosy), *Salmonella* (other than *typhi*), *Salmonella, E. coli, Staphylococcus aureus* and *Pseudomonas aeruginosa.* A complete description of the different levels and organisms may be found in the recently-released 5th edition of CDC's biosafety manual at http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm.

Reprinted below are specific suggestions for the QC microbiology lab from the recently published book Pharmaceutical Quality Control Microbiology: A Guidebook to the Basics* (details at https://store.pda.org/bookstore/ProductDetails.aspx?productabbreviation=17242.

From Chapter 3: Laboratory Design Considerations:

"SAFETY CONSIDERATIONS

Lastly, safety is critical when designing a new lab. As before, it is especially helpful to have some idea of the work flow in the lab prepared to assist in the placement of different activities and equipment.

Physical Safety Considerations

The physical safety concerns in a microbiology lab are similar to other laboratory environments. Particular attention should be paid to the electrical requirements of autoclaves, incubators, and other large equipment. A sufficient number of circuits should also be laid in to accommodate smaller appliances (vortex, battery chargers, plate counters, etc.) commonly used. The width of walkways is also important, although this will be an ongoing struggle as microbiologists seem to have an overwhelming urge to place carts and other equipment in these spaces.

The autoclaves should have their own area for a variety of reasons: stink, steam, accumulation of biohazardous material, but most important, for safety. They should be in an area with little traffic, where the potential for accidental burns is minimized.

Many labs also have gas supplied by tanks, rather than a house supply. These tanks should be segregated to a low traffic area, free from obstructions and well protected. Having one of these break its valve is a memorable experience, but one best avoided. If possible, a separate area should be designed for storage of hazardous material, including strong acids and bases, flammable materials, and carcinogenic material (if present).

A sink with soap in a suitable dispenser should be placed near each exit point from the lab. If needed, there should also be additional sinks throughout the lab to promote frequent hand washing. These sinks should be supplied with elbow faucets or foot switches to control the water so that the user does not have to use his hands to turn the water on and off.

Although it might not see much use, a chemical fume hood should be installed for use in the lab. Other considerations include a place to store material safety data sheets, a safety shower, an eye wash station, fire extinguishers, and smoke alarms.

Finally, noisy pieces of equipment should be segregated from lab workers. Microbiology testing is demanding enough without requiring technicians to deal with constant distractions and annoyances.

Biosafety Considerations

As already mentioned, many of the commonly-used control organisms are classified as risk level 2 by national authorities. This designation implies certain responsibilities on the laboratory design.

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The PMF Fall Conference Schedule

http://www.microbiologyforum.org

The PMF is offering three exciting conferences this Fall. If you would like to participate in the planning of an event or the presentation of material, please contact the editor with your ideas and suggestions.

Upcoming conferences include:

PMF Cosmetic Microbiology Conference

September 17-18, 2007
Newark, NJ

The purpose of this meeting is to provide a forum for the sharing of questions, answers and information on current topics affecting the cosmetic microbiologist for the Microbiology Laboratory. One of major concerns in the microbiology function is the identification of relevant guidance for the unique product category.

The program will endeavor to shed some light on issues found in the microbiology lab. Practical solutions to these issues will be discussed though lecture and small group discussions.

The program will range from presentations on technical and compliance-related problems to interactive case studies to round-table discussions. Participants will have the opportunity to interact with representatives from FDA, USP and CTFA.

Topic List

- Preservative Efficacy Testing
- The Microbial Limits Tests
- Variability in Microbiological Data & Its Effects
- Laboratory Audits - Practical Considerations to Minimize Testing Errors
- Alternate Microbiological Methods

2007 PMF Fall Forum

October 11-12, 2007
Rochester, NY

The purpose of this annual meeting is to provide the microbiology community presentations of recent work in the areas of validation and qualification of microbiological methods and analyses in support of manufacturing. Special emphasis this year will be on current research into questions of environmental monitoring.

This conference is your opportunity to interact with thought leaders in a small, personalized format while learning from the academic and industry leaders. The PMF Fall Forum has earned its reputation as the premier conference for in-depth presentation of microbiological research and discussion. This year will focus on environmental monitoring, with academic leaders presenting their research and industry science and regulatory experts their perspectives. The strength of the meeting is in analysis and discussion - bring your questions for this *intentionally intimate* meeting! However, as the meeting is kept small by design, places fill quickly.

- Overview of Environmental Monitoring for Aseptic Processing; Scott Sutton, Ph.D., PMF
- Media Fills: Special Considerations for Clinical Manufacturing; Sarah Doshna, *Bristol Myers Squibb*
- Challenge Studies of the Blow-Fill-Seal Aseptic Packaging Process – The Effect of Heat Lethality on Product Contamination; Patrick Poisson *Cardinal Health, Inc*
- Microbiological Compliance and Risk in Aseptic Manufacturing; John Grazal, *AstraZeneca* A Risk-Based Approach for Investigating Environmental Monitoring Excursions; Robert Westney *QC Manager, MedImmune Vaccines, Inc*
- Weak Rolling Adhesion Enhances Bacterial Surface Colonization; Albert Ding, Ph.D. *Dept. Bioeng, Univ. Washington, Seattle*
- Investigations into Sterility Failures; Frank Setterini
- Investigation of Cut-Off Sizes and Collection Efficiencies of Portable Microbial Samplers; Greg Mainelis, Ph.D. *Dept Environ Sci - Rutgers University*
- USP Perspectives; Radha Tirumalai, Ph.D. *USP*

2007 PMF Bacterial Endotoxin Summit

November 8-9, 2007
Philadelphia, PA

The purpose of this meeting is to provide a forum for the sharing of questions, answers and information on the Bacterial Endotoxins Test. The program will range from presentations on technical and compliance-related problems to interactive case studies to round-table discussions. In addition, we'll have a mini exhibition, where vendors of BET testing reagents and

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First, there should be at least one Class II biosafety cabinet in the lab. This cabinet is not for routine use and is only really needed with risk level 2 organisms if aerosols are going to be generated by sonication or other violent activity. Virtually all activities in the QC microbiology laboratory (vortexing, pipetting, plating, etc.) can be conducted under aseptic techniques on the lab bench. This encourages frequent cleanup of the lab, and proper techniques. Over-reliance on an excess of biosafety cabinets encourages sloppy technique, and may result in a much more hazardous situation than would be the case if proper techniques were used on the open bench. In addition, biosafety cabinets are an extremely expensive form of lab bench space, and should only be used when needed as an act of stewardship of the company's money. Other biosafety considerations have already been mentioned, but should be repeated. The laboratory should be designed for easy decontamination. All corners should be curved, all materials non-porous. Bench tops should be made from a sturdy material suitable for frequent decontamination and should not be allowed to become chipped or cracked. Access to the laboratory should be controlled and restricted to trained personnel, especially when experiments are under way."

From Chapter 12; Training:

"BIOSAFETY TRAINING

It is common practice to consider QC microbiology laboratories as biosafety level 2 facilities. Reasonable people may disagree over whether working with a lab strain of *Pseudomonas aeruginosa* is of the same concern as working with live pathogens in a fermentation process for vaccine production. However, the prevailing sentiment in the industry is that we are better served by being conservative in our interpretation. As this is the case, there are some requirements for management and workers in a biosafety level 2 facility as detailed by the US Centers for Disease Control (CDC)...:

- ... laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures."
- The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur."
- A laboratory-specific biosafety manual must be prepared and adopted as policy. The biosafety manual must be available and accessible."
- The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-2 agents."

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PMF Fall Conference Schedule (cont).

equipment will all have their products on hand for viewing by participants. This conference has been offered several times in the past, and this time will include the re-launch of the LAL-User's Group. Don't miss this excellent offering!

Planned Topic List

- Back to Basics
  - Endotoxin Limits – calculation and significance *Interactive*
  - MVD/MVC – uses in validation and routine testing *Interactive*
  - Gel Clot Test Method – advantages and limitations
  - Photometric methods – advantages and limitations
  - Regulatory/Compliance Issues
    - USP/EP/JP
    - Part 11
    - Aseptic Processing Guideline
    - Whatever happened to the LAL Guideline?
- Test Method Validation
  - Applications
    - Depyrogenation
    - Cleaning Validation
  - Process Validation
    - Before We Start – FMEA *Interactive*
    - HACCP Analysis for determination of critical control points *Interactive*
    - Endotoxin Limits for Non-compendial Materials *Interactive*
    - Raw Material Specifications/Vendor audits
  - Conducting Unbiased, Scientific and Timely Failure Investigations
    - Fishbones and Fault Trees *Interactive*
    - CAPA Interactive
  - Emerging Technologies – Show and Tell

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Testing Frequencies

The second consideration in the design of stability programs is the testing frequency. It is not uncommon for initial intervals in the chemistry analysis to be on a monthly basis. This is wildly impractical for microbiological assays which might take 6 weeks from beginning to finalized report. In general, microbiological assays should be performed no more frequently than at the initial, 6, 12 and 24 month time points. This provides sufficient assurance of the microbiological quality of the product, and allows trending of the data (as appropriate). Demonstration of the microbiological quality is *strongly* suggested at the initial and terminal points of stability, but intermediate demonstration is prudent. What are you left with after 24 months if you fail a specification and the only other data point is the initial test?

Sterile Products

Sterile products must meet the requirements for the compendial Sterility Tests. Ideally, they would be demonstrated sterile, but this is impractical given the currently available technology (2, 3). It is prudent to conduct sterility testing on stability at least on an annual basis.

FDA is also interested in the container closure integrity of packaging systems on stability (4). Several years ago a draft guidance document was even issued on the use of container closure testing rather than sterility testing as a stability assay (5). This guidance document was never finalized for a variety of excellent reasons. The topic of container/closure testing of packaging is a complex one, and will be discussed in a future newsletter.

Non-sterile Products

Stability of non-sterile products is based on several considerations, and so is much more complex from a microbiological perspective than stability studies of sterile products. The first (and easiest) consideration is bioburden. There are regulatory differences in the various regions as to what specifications mean in this situation. For example, an observed value of 154 CFU/g would fail a specification of "100 CFU/g" in the USA, while passing it easily in the EU. A scientific issue also exists with bioburden numbers. It is assumed that the distribution of microbial contamination in a sample is homogeneous throughout the product. This allows sampling of 10 g from a 100 Kg batch as "representative." However in practice it is well-established that microbial contamination is anything but homogeneous. Therefore, trending of bioburden data becomes somewhat imprecise as it is never clear whether an elevate count is due to growth of the contaminant or that the sampling event occurred in a "hot spot" of the larger batch.

A more difficult issue is the one of "absence of objectionable organisms." This is a GMP issue not addressed by the compendia. The Microbial Limits Tests evaluate "absence of specified" organisms, rather than objectionable. This

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disagreement has been reviewed in previous issues of the PMF Newsletter listed below and will not be discussed further.

For the moment, then, let's assume that we are going to agree that "absence of objectionable" microorganism studies will require the lab to identify every unique colony type from the bioburden study and determine its identity. What value is this information in a stability study? The obvious answer is none whatsoever. A strong case can be made for determining the bioburden of the sample over time, demonstrating that it does not support the growth of microorganisms (ignoring sampling issues of a heterogeneous mixture for the moment). However, the identity of the organisms is of less value. Of course, it is possible to conceive of a situation where a pathogenic organism is present in low numbers and the product provides a selective pressure in favor of the pathogen's growth in preference to all other organisms yielding a horribly contaminated product after a period of time. However, following the bioburden provides a measure of control over this situation, and little additional protection is likely to be offered by the dramatic increase in expense involved in identifying every organism on stability.

The final consideration for non-sterile stability studies is that of the product's water activity. This characteristic is well-known in the food industry for its effect on stability (6), it is becoming more established in the pharmaceutical arena (7, 8). In fact, a new chapter in USP was released (second supplement to USP 29, 2006) on the topic under the title "<1112> Application of Water Activity Determination to Nonsterile Pharmaceutical Products." The water activity of a product is not, in and of itself, a microbiological parameter, but it is a strong indicator of the ability of that formulation to support the proliferation of microorganisms and should be considered in designing stability test schedules (9). It is important to remember in this analysis that low water activity does not necessarily result in cell death, but can be effective in the prevention of growth.

Multi-use Products

Multiple use products must be protected from proliferation of adventitious contamination. That is, they must be preserved. The standard method to demonstrate preservation of a formulation is the antimicrobial efficacy test (AET). This test is a suspension test, where challenge organisms are suspended in the product to be tested and their survival determined with time. A standard format for this test is to individually suspend 4 or 5 challenge organisms to a final concentration of approximately 10^6 CFU/mL and check for survivors at 6 hours, 24 hours, 48 hours, 7 days, 14 days and 28 days. The multiple time points allow for determination of kill rate against the organism, and the organisms are selected to provide a range of responses to the preservative system. The use of these intervals may allow the data to be used in all regulatory regions.

The antimicrobial effectiveness test is one that can provide a great deal of information on a stability program. While each organism's response might not be illuminating, it is likely that at least one of the organisms will provide useful information. Unlike the chemical assay for identity and for

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concentration of the preservative, the AET evaluates the biological activity of the entire formulation. It is clearly a superior test for preservative activity to those available by HPLC. Unfortunately there seems to be a perception that chemical stability of the preservative moiety is directly related to the microbial performance. While this is generally true, the exceptions can lead to spectacular situations for the head of the microbiology group.

Excipient and API Stability

While it seems obvious, the storage conditions and expiry dating assigned to raw materials must be supported. Raw materials for product formulation are normally in an non-sterile condition, and the concern is always present that the microbial population could cause spoilage of the material. Depending on the material, it might be prudent to check the Total Aerobic Count and Total Yeast and Mold Count on an annual basis as part of the raw material stability program.

Of course, not all raw materials need to be tested. Some are inhospitable to life due to extremely low water activity - some by extremes of pH. These types of materials may confidently be assayed by purely chemical analysis as long as the rationale is documented and is scientifically justifiable.

References

1. ICH. 2004. Guidance for Industry - Q1F Stability Data Package for Registration Applications in Climatic Zones III and IV
2. Moldenhauer, J and SVW Sutton. 2004. Towards an Improved Sterility Test. *PDA J Pharm Sci Tech*. 58(6):284-286.
3. Cundell, AM. 2004. Microbial Testing In Support of Aseptic Processing. *Pharm Technol*. 28(6):58-66.
4. FDA. 1999. Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics.
5. FDA. 1998. Guidance for Industry - Container and Closure Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products. DRAFT GUIDANCE.
6. Beuchat, L. 1981. Microbial Stability As Affected by Water Activity. *Cereal Foods World*. 26 (7):345-349.
7. Friedel, RR and AM Cundell. 1998. The Application of Water Activity Measurement to the Microbiological Attributes Testing of Nonsterile Over the Counter Drug Products. *Pharm Forum* 24 (2):6087-6090.
8. Friedel, RR. 1999. The Application of Water Activity Measurement to Microbiological Attributes Testing of Raw Materials Used In the Manufacture of Nonsterile Pharmaceutical Products. *Pharm Forum.* 25(5):8974-8981.
9. Fontana, A. 2006. Understanding Water Activity *PMF Newsletter* Volume 12, Number 10.

Recent Hand Washing Articles of Interest

There have been a few articles of interest in hand washing that are worthy of note. One of the more recent looked at the efficacy of antibacterial soaps (1). In a word, they are not particularly impressive. The abstract for the paper is reproduced below:

"***Background.*** Much has been written recently about the potential hazards versus benefits of antibacterial (biocide)–containing soaps. The purpose of this systematic literature review was to assess the studies that have examined the efficacy of products containing triclosan, compared with that of plain soap, in the community setting, as well as to evaluate findings that address potential hazards of this use—namely, the emergence of antibioticresistant bacteria.
Methods. The PubMed database was searched for English-language articles, using relevant keyword combinations for articles published between 1980 and 2006. Twenty-seven studies were eventually identified as being relevant to the review.
Results. Soaps containing triclosan within the range of concentrations commonly used in the community setting (0.1%–0.45% wt/vol) were no more effective than plain soap at preventing infectious illness symptoms and reducing bacterial levels on the hands. Several laboratory studies demonstrated evidence of triclosan-adapted cross-resistance to antibiotics among different species of bacteria.
Conclusions. The lack of an additional health benefit associated with the use of triclosan-containing consumer soaps over regular soap, coupled with laboratory data demonstrating a potential risk of selecting for drug resistance, warrants further evaluation by governmental regulators regarding antibacterial product claims and advertising. Further studies of this issue are encouraged."

Apparently it is important to scrub after all. A second article of interest dealt with compliance of health care workers in a laboratory setting. The study evaluated new regulations in the facility dealing with removing all jewelry and washing procedures. The article is summarized in the abstract below (2):

"We performed a study to measure the compliance of laboratory personnel with different components of hand hygiene. The level of compliance at the end of duty was 100%; however, 36.7% of subjects wore a ring, 46.9% wore a watch, and 6.1% wore a bracelet. Pathogenic microorganisms were exclusively found on hands of laboratory personnel who wore jewelry. After interventions, the level of compliance with the no-jewelry policy among laboratory personnel showed sustained improvement. Efforts to improve hand hygiene should be directed not only at healthcare workers but also at laboratory personnel."

OK - remove the jewelry. Finally, it wouldn't be microbiology if we didn't argue about methods. The final article I will mention compared two methods for demonstrating efficacy of hand washes (3):

The antimicrobial efficacies of preparations for surgical hand antisepsis can be determined according to a European standard (prEN 12791 [EN]) and a U.S. standard (tentative final monograph for health care antiseptic drug products [TFM]). The U.S. method differs in the product application mode (hands and lower forearms, versus hands only in EN), the number of applications (11 over 5 days, versus a single application in EN), the sampling times (0, 3, and 6 h after application, versus 0 and 3 h in EN), the sampling methods (glove juice versus fingertip sampling in EN), and the outcome requirements (absolute bacterial reduction factor [RF], versus noninferiority to reference treatment in EN). We have studied the efficacies of two hand rubs according to both methods. One hand rub was based on 80% ethanol and applied for 2 min, and the other one was based on 45% propan-2-ol, 30% propan-1-ol, and 0.2% mecetronium etilsulfate and applied for 1.5 min. The ethanol-based hand rub was equally effective as the 3-min reference disinfection of prEN 12791 in both the immediate (RFs, 2.97 ± 0.89 versus 2.92 ± 1.03, respectively) and sustained (RFs, 2.20 ± 1.07 versus 2.47 ±1.25, respectively) effects. According to TFM, the immediate effects were 2.99 $\log_{10}$ (day 1), 3.00 log10 (day 2), and 3.43 log10 (day 5), and bacterial counts were still below baseline after 6 h. The propanol-based hand rub was even more effective than the reference disinfection of prEN 12791 in both the immediate (RFs, 2.35 ±0.99 versus 1.86 ± 0.87, respectively) and sustained (RFs, 2.17 ± 1.00 versus 1.50 ± 1.26, respectively) effects. According to TFM, the immediate effects were 2.82 log10 (day 1), 3.29 $\log_{10}$ (day 2), and 3.25 $\log_{10}$ (day 5), and bacterial counts were still below baseline after 6 h. Some formulations have been reported to meet the efficacy requirements of one of the methods but not those of the other. That is why we conclude that, despite our results, meeting the efficacy requirements of one test method does not allow the claim that the requirements of the other test method are also met."

References

1. Aiello, AE *et al.* 2007. Consumer Antibacterial Soaps: Effective or Just Risky? *CID* . 45:S137-S147.
2. Alp, E *et al.* 2006. Hand Hygiene Among Laboratory Workers. *Infect Control Hosp Epidemiol* 27:978-980.
3. Kampf, G. 2006. Evaluation of Two Methods of Determining the Efficacies of Two Alcohol-Based Hand Rubs for Surgical Hand Antisepsis. *Appl Environ Microbiol*. 72(6):3856-3861.

Upcoming Events

2007 PMF Cosmetic Microbiology Conference
Sept. 17 & 18, 2007
Newark, NJ

2007 PMF Fall Forum
October 11-12, 2007
Rochester, NY

Implementation of Harmonized Compendial Tests
October 18-19, 2007
San Francisco, CA

2007 PMF Bacterial Endotoxin Summit
November 8-9, 2007
Philadelphia, PA

Offering In-House Courses on Microbiology/Aseptic Processing:

- The Microbiology Network/High Peaks Associates
- http://www.highpeaks.us/in-house.htm
  Experienced in custom-designed courses for the lab or the manufacturing facility, including:
  - GMP for the Microbiology Lab
  - Microbiology for Manufacturing
  - Microbiology for Management
  - Auditing the Microbiology Function
  - Investigating Microbiological Data Deviations
- USP
  Contact Steven Paul (stp@usp.org) for information on the course "Fundamentals of Microbiological Testing"

USP Corner

Any questions concerning USP documents should be sent to Radhakrishna (Radha) Tirumalai, Ph.D. You can reach Dr. Tirumalai at: (706) 353-4514, via mail at United States Pharmacopeia, 126 Twinbrook Parkway, Rockville, MD 20852 or via e-mail at RST@USP.org. You can write representing your company, or as an individual scientist.

Discussion List Update

PMFList:
Number of Subscribers: 2,521
Number of Countries: 64
Number of Messages Last Month: 279

PSDGList (Pharma Stability Discussion Group):
Number of Subscribers: 1004
Number of Countries: 26

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

You can ask, answer, or read questions and comments from your colleagues. Archives of the lists are available at:

- http://lists.microbiol.org/archives/PMFLIST.html
- http://lists.microbiol.org/archives/PSDGLIST.html

Recent News

A Changing Regulatory Environment for Healthcare Products in Sub ...

Due to the high burden of disease in sub-Saharan Africa (SSA) and growing pressure from international organisations, governments are multiplying efforts to control the quality of pharmaceutical products and medical devices available in the market.http://www.newswiretoday.com/news/22079/

Medical science aims to microchip you

Imagine a microchip the size of a grain of rice, implanted under your skin, that doctors can scan in order to retrieve your medical information. The American Medical Association has endorsed the use of implantable microchips to help reduce medical errors and adverse drug reactions.
http://www.thestar.com/living/Health/article/246045

FDA rules to benefit medical device firms

The United States Congress is close to approving new rules that will ease access to the US market for small Irish firms in the medical device sector. Companies with annual turnover of less than $100 million will be able to save up to $210,000 on applications to the Food and Drug Administration (FDA) to bring innovative new products to the US market. The full $281,400 pre-market approval application fee will be exempted in the case of companies with annual sales of less than $30 million, making their first such application to the US regulator.
http://www.biotechinfo.ie/pooled/articles/BF_NEWSART/view.asp?Q=BF_NEWSART_292755

Pharmaceutical groups turn to home delivery

Drugs companies are turning increasingly to home delivery of medicines as a way to boost profits by cutting out wholesalers and pharmacists. The total size of the UK market for pharmaceuticals delivered directly to patient's doors is already worth an estimated £250 million and is growing at 10 to 15 per cent per year.
http://business.timesonline.co.uk/tol/business/industry_sectors/health/article2337383.ece

Flu vaccine should be put on Pharmaceutical Benefits Scheme: AMA

The Australian Medical Association is calling for flu vaccine to be freely available to all Australians from the age of six months. http://www.abc.net.au/am/content/2007/s2010519.htm

Famous Trial of Pharmaceutical Company Exposes Counterfeit Medicine Production

The well-known pharmaceutical manufacturer Qiqihar No.2 Pharmaceutical Co., Ltd. held a national GMP (Good Manufacturing Practice; drug production quality control standard) certification. Its pharmaceuticals were sold all over the country.
http://en.epochtimes.com/news/7-8-20/58854.html

JOBS

QC Microbiology Associates (Job #CL1094)
Supporting **QC Microbiology** activities, routine studies and processing of clinical specimens. Running ELISA's, GMP / GLP experience a plus.
http://providence.craigslist.org/sci/398422766.html

Aerotek Job Posting
A mid-sized pharmaceutical company in Chelsea has an immediate need for a Manager of Quality Control Microbiology. Will provide leadership and direction to the microbiology group including the hiring and evaluation of staff, validation of methods and development of procedures and protocols, approval of product specifications, and product or facility investigations. Must keep abreast of current industry practices, regulatory standards and trends, and new technologies to establish policies direction of internal and partnered programs.
http://www.careerbuilder.com/JobSeeker/Jobs/JobDetails.aspx?job_did=J3I5406FKXWC3GGF7M7

Manager QC (Wyeth Pearl River)
Provides day-to day supervision to the Compliance Group in the Quality Control Microbiological and Environmental Services Department. In general the Compliance Group is responsible for the performance of Laboratory Investigations (LIR, MIR), Training, Change Control Initiation and Management, Internal Housekeeping and Compliance Audits, Commitment Tracking, CAPA, and the coordination of Facility/Equipment maintenance & validation/re-qualification scheduling.
http://www.gadball.com/Jobs/Details.aspx?jID=8330909

MANAGER, QC MICRO/ENV. SERVICES
This position is critical to the operation and management of the QC Micro/EM services group. Represent Micro/EM systems to Regulatory Agencies as well as project negotiations with internal and external customers. Manage the personnel and activities of the QC testing laboratory in the microbiology area.
Diosynth Biotech
http://jobsearch.monster.com/getjob.asp?JobID=60731360&AVSDM=2007-08-02%2003:19:00&WT.mc_n=RSS2005_JSR

QC Microbiology Supervisor
Our CAPS (Central Admixture Pharmacy Services) division is currently seeking a QC Microbiology Supervisor who is responsible for supervising laboratory personnel and all activities associated with the functional area to ensure that the laboratory operates efficiently and effectively while performing routine tasks.
B. Braun
http://jobsearch.monster.com/getjob.asp?JobID=60617201&AVSDM=2007-07-30%2015:50:00&WT.mc_n=RSS2005_JSR

US-CA-Irvine-QC Microbiology Manager
We are currently looking for a QC Microbiology Manager to work for an innovative Science company. Organize and supervise the Environmental Monitoring Program, including the review of EM records, the investigation of Alert and Action levels / OOLs, facilitate and oversee implementation of CAPAs due to EM excursions, and the trending of EM results. Train personnel to perform EM procedures and Microbiological test methods.
BioPhase Solutions, Inc.
http://jobview.monster.com/getjob.asp?jobid=60207016