

# Workshop Series



Global BioPharmaceutical Resources, Inc.

## Rapid Microbiological Methods Critical Aspects and Recommendations for a Successful Implementation

October 14, 2010 - San Francisco, CA

### Presenters

Jeanne Moldenhauer, PhD  
Pascal Yvon, PharmD, MBA

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### ABOUT THE PROGRAM

#### Description

The workshop will provide an overview of the critical aspects to consider when looking at implementing a RMM, will provide recommendations, and will be an interactive environment to exchange with speakers and all participants.

#### Overview

Rapid microbiological Methods (RMMs) can deliver many benefits. Despite these significant advantages, RMMs are still being implemented slowly by pharmaceutical and biotech companies. Moreover, few companies have successfully gained approval of rapid methods in different countries. While there are many advantages to the use of rapid methods, there are also challenges to address. Understanding the full benefits of RMMs and selecting the method that best fits the company needs, translating technical benefits into financial ratios, addressing the regulatory expectations allow you to build your case, generate better submission data and increase the likelihood of a successful regulatory submission and implementation of a RMM in your organization

#### Topics

- What to consider when looking at implementing a RMM
- Review of critical aspects and recommendations. Overview of available technologies
- Regulatory Issues With selecting a system
- Develop a Validation Strategy
- Comparability protocol
- ROI (return on investment) justification

#### Learning Objectives

At the completion of this seminar, the attendees will be able to:

- Identify the potential benefits of a RMM in relation with their company needs.
- Build their case to present to management.
- Identify some of the potential regulatory risks associated with submission of a rapid method.
- Discuss ways to mitigate or eliminate these regulatory risks.
- Design a regulatory and validation plan that will meet the requirements of various countries.

### ABOUT THE SPEAKERS

#### Jeanne Moldenhauer, PhD

##### Vice President, Excellent Pharma Consulting

Jeanne Moldenhauer has over 25 years experience in the pharmaceutical, biotechnology and medical device industries. She is a certified quality manager and certified quality engineer. She chairs the PDA's Environmental Monitoring and Microbiology Interest Group and serves on the Scientific Advisory Board. She has authored several books and numerous publications including topics on quality, biological indicators, sterilization, rapid microbiology, comparability protocols, and inspections.

#### Pascal Yvon, PharmD, MBA

##### President, BioSciences Expansion

Pascal Yvon is the Founder and President of BioSciences Expansion. BioSciences Expansion helps life sciences companies develop their activities by providing comprehensive services and solutions from strategic planning to operational execution. Pascal has over 20 years experience working with biotech, pharmaceutical, and diagnostics companies on a worldwide basis. An expert in implementation of new technologies, in particular Rapid Microbiology, Pascal speaks at leading industry events, conferences and webinars. Pascal authored several trade journals and chapters in industry reference books. Pascal is also the Founder of BioSciences Quality Testing Forum, which is an interactive communication platform on analytical tools and methods for the Biotech, Pharmaceutical, Cosmetics and Personal Care industries—[www.BioQTForum.com](http://www.BioQTForum.com). Pascal holds a Doctorate in Pharmacy from Paris University, and an Executive MBA from Rutgers University, NJ. Pascal is a member of BioNJ, the biotech association of NJ, where he co-chairs the Diagnostics Committee.

## AGENDA

7:00 to 8:00 am Continental breakfast & registration

### 8:00 to 8:45 am **What to consider when looking at implementing a RMM**

Pascal Yvon, President, BioSciences Expansion

Sets of information need to be considered when looking at RMMs. You need to answer questions, such as, what exactly do you want to do with the system/what tests do you need to run? What benefits will the RMM system deliver? What do you need to know to submit the capital expense request? What do you need to know about site infrastructure to install the system? What information do you need to have for the validation step? What do you need to know about the vendor for an optimal installation, training and routine use? A review of the points to consider will be presented in an interactive session with the attendees.

### 8:45 to 9:30 am **Review of critical aspects and recommendations. Overview of available technologies**

Pascal Yvon, President, BioSciences Expansion

Several technologies and instruments are available on the market and the selection of the system depends on the type(s) of testing you plan to perform. Systems have specific features that provide different benefits and present different limitations. With the applications you want in mind, it is important to understand each unit technology and performances (benefits/limitations). A review of the critical aspects and an overview of the main commercially available technologies will be presented and discussed with the attendees.

### 9:30 to 10:30 am **Regulatory Issues with selecting a system**

Jeanne Moldenhauer, VP, Excellent Pharma Consulting

While many regulators indicate that their agencies want to see the newer microbiological methods integrated into pharmaceutical manufacturing, the road to approval has been different across various agencies. This talk will discuss some of the issues associated with regulatory approvals in different companies and using different types of technologies.

10:30 to 11:00 am Refreshment Break

### 11:00 to 11:45 am **Taking Rapid Methods to the Next Level, the role of Automation**

David Jones, Director of Technical Services, Rapid Micro Biosystems

### 11:45 am to 12:30 pm **Practical Approaches to Rapid Microbial Identifications**

David Shelep, Senior Account Manager, Accugenix

With the implementation of rapid microbial methods, the time expended in generating the identification of unknown organisms becomes more and more critical. This presentation will review regulatory requirements for identifications, how an unknown organism "flows" through the identification process and where turnaround time and technology improvements can be made with use of rapid methods as opposed to conventional techniques.

12:30 to 1:30 pm Lunch

### 1:30 to 3:00 pm **Develop a Validation Strategy**

Jeanne Moldenhauer, VP, Excellence Pharma Consulting

This talk will provide information on developing an approach to validation of your new microbiology method in order to gain approval by regulatory agencies. Additionally, while some guidance exists, it can be difficult to determine how this applies to what your instrument is capable of performing. This talk focuses on the practical methods of application to use in validation.

3:00 to 3:30 pm Refreshment Break

### 3:30 to 4:15 pm **Developing and Using a Comparability Protocol**

Jeanne Moldenhauer, VP, Excellence Pharma Consulting

A comparability protocol can provide many benefits when validating and implementing a new method for regulatory submission. This talk will provide information on the nuts and bolts of doing this type of submission. It will also provide some useful tips on getting the most flexibility out of your submission.

### 4:15 to 5:00 pm **ROI (return on investment) justification.**

Pascal Yvon, President, BioSciences Expansion

A clear statement of the financial benefits is the most critical part of any proposal evaluating the possible implementation of RMMs. Calculating the scientific benefits of RMMs as ROI dollars is necessary to convince management, and will be different for each company. A review of the key elements and financial formulas to consider building your business case will be presented in an interactive session with the attendees

### 5:00 to 5:15 pm **5 Tips to implement a RMM successfully**

Jeanne Moldenhauer, VP, Excellence Pharma Consulting

Pascal Yvon, President, BioSciences Expansion

## REGISTRATION FORM

Register for the workshop using one of the following options:

Online: [www.gbprinc.com](http://www.gbprinc.com)

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Mail: P.O. Box 177, Clarksburg, MD 20871

## CONTACT INFORMATION

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City: \_\_\_\_\_ State/Province \_\_\_\_\_

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Check the event on October 14, 2010 in San Francisco, CA:

**Rapid Microbiological Methods: Critical Aspects and Recommendations for a Successful Implementation**

**Before September 20: \$695 USD**

**After September 20: \$995 USD**

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