

Rapid Microbiology Newsletter

A newsletter for the Rapid Micro User's Group™



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Letter from the Editor

"Times are a changing..."

It is with sadness that RMUG says good-bye to one of its members, speakers, colleagues, and friends. Dr. Michael Korczynski passed away in January of this year; we wish to remember his work, not only in this edition of the newsletter, but for years to come.

A different kind of sadness has hit the RMUG staff directly as well. Vicky Strong will be moving on to new opportunities and we wish her nothing but success and happiness. Her impact on RMUG was significant and we will miss her dearly.

A hearty, thank you is extended to Ann Steger at Advanced Analytical Technologies, Inc. for her contribution of the article on the RBD 3000. We hope you enjoy this informative article as much as we did!

Stay warm! Spring is coming!

Best Wishes,

Michele
Michele Conway

The Year in Review – 2005

Vivian Green Retires

For those of you who have been involved in generating or reviewing the microbiology portion of New Drug Applications to FDA, many have encountered a review of your submission by Ms. Vivian Greenman. Ms. Greenman has been working at FDA for many years, as a microbiology reviewer. Ms. Greenman recently retired from FDA. Her strong scientific knowledge base was evident in the questions she asked, and the opinions offered when questioned. She remembered every detail for years.

We will certainly miss her as a reviewer and wish her well in her retirement.

Ajaz Hussain Leaves FDA to Join Industry

Dr. Ajaz Hussain has served at FDA and has been a leader in the area of Process Analytical Technology. Under his leadership, FDA established a PAT Team and initiated guidance documents on the PAT process. Rapid microbiological methods were included in many of the meetings on PAT. As such, industry started to reduce their fears about the FDA acceptance of rapid microbiological methods. Today most of the pharmaceutical companies have

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established PAT teams looking at ways to implement rapid microbiological methods in their facilities.

Dr. Hussain recently left FDA to join industry. We want to offer a special thank you for promoting rapid microbiological methods.

Encyclopedia of Rapid Microbiological Methods

For many companies interested in rapid microbiological methods, a common problem was the lack of resources available to assist during the evaluation and selection of these systems.

A comprehensive set of books has been published on rapid microbiological methods. This set of books provides a wealth of information on the selection, implementation, validation and regulatory submission for these new methods. There are also chapters on various different technologies that are available. This encyclopedia was edited by Dr. Michael Miller.

Thanks to Dr. Miller for creating such a valuable resource for people interested in Rapid Microbiology.

Microbiologist of the Year Announced

This year IVT initiated a program for people to select the Microbiologist of the Year. Individuals are allowed to nominate candidates via an electronic form. The winner of the 2005 program is Dr. Tony Cundell. Congratulations to Dr. Cundell.

Rapid Sterility Test Method Approved

In December of 2005 the FDA's Office of New Drugs approved an alternate sterility test submission using ScanRDI technology. In January 2006, a similar submission was approved by OGD. Congratulations to the company responsible for these submissions.

Special thanks to the microbiology reviewers for their progressive thinking and support of rapid microbiological methods.

Advanced Analytical Technologies' RBD 3000 for Rapid Quantitative, Qualitative and Antibody-Specific Microbial Detection and Enumeration

Ann M. Steger, M.A., Director of Client Services, Advanced Analytical Technologies, Inc., Ames, IA

The Rapid Bacteria Detector (RBD) 3000 is an automated, laser-based technology that provides rapid quantitative and qualitative results, as well as antibody-specific microbial detection and enumeration, from one easy-to-use platform. The technology is based on the principles of flow cytometry and uses specialized fluidic, optic and electronic components for enumeration of microorganisms. The RBD 3000 can detect cells ranging in size from 0.1 to 15 microns and has an extensive enumeration range from 1 to 6 log₁₀ cfu/mL.

The RBD 3000 is fully automated and uses fluorescent dyes to label the microorganisms for detection and enumeration. Three-milliliter samples are dispensed into 5 mL sterile tubes and placed in a sample tray with a corresponding sterile 1 mL syringe. The sample tray is loaded into the RBD 3000 and the robotic system automatically adds all of the reagents, mixes the sample, and performs the sample injection for enumeration. The samples are injected into the flow cell where the labeled microorganisms pass single-file through a focused laser beam. The microorganisms emit both laser-induced fluorescence and scattered laser light, which is optically separated and collected on independent detectors. The RBD 3000 electronically counts and records each fluorescent and corresponding scatter event. The output generated is a real-time, dot density plot of fluorescence intensity versus side scatter intensity, as well as counts per volume analyzed.

Simply, the RBD 3000 replaces the traditional culture plate method with a rapid enumeration or presence/absence result in 10 to 20 minutes. The output generated by the RBD 3000 software is reported as the number of counts/mL, which correlate with the traditional plate count result in cfu/mL, or as a pass/fail result based on acceptance criteria established in the software. The RBD 3000 software is 21CFR Part 11 compliant and is supported by a complete validation package to assist with successful implementation.

Currently, the RBD 3000 is employed in major pharmaceutical, personal care, and cosmetic companies, the animal health and biotechnology industry, public research institutions and environmental water agencies. The RBD 3000's fully automated, user friendly, robust design affords its placement in the manufacturing facility, quality control laboratory, and research and development department. The RBD 3000's flexible configuration is used for numerous applications, such as monitoring purified and environmental water, fermentation cultures and downstream processes, as well as screening raw materials, in-process samples, and final products for microbial contamination.

The RBD 3000 is unmatched in providing real-time quantitative total viable organism results in only 18 minutes to customers using the instrument for monitoring purified and environmental water systems. Water samples are collected and dispensed into sample tubes and simply loaded onto the RBD 3000. The analysis occurs automatically, generating a result in number of total viable organisms per milliliter in 18 minutes. The RBD 3000's real-time results provide proactive monitoring of critical control points allowing for immediate corrective action, as opposed to reactive monitoring with the standard plate count method that requires 2-7 days to obtain results.

In the personal care industry, the RBD 3000 is used for qualitative results when screening products or raw materials for the presence/absence of microbial contamination. Product is added to neutralizing enrichment media and incubated for a minimum of 18 hours. The enriched product is diluted in buffer and placed on the RBD 3000 for analysis. Enriched samples are considered positive for microbial growth if the counts are >5-times the negative control counts. Acceptance criteria are established in the software and generate an objective pass/fail result.

Advanced Analytical Technologies has developed a Strategic Partnership Program to promote collaborations with a range of companies for the advancement of rapid microbial detection. Recently, Strategic Partnerships have been established with Alberto-Culver Company, Procter & Gamble, and Mohawk Valley Water Authority.


Further information on the RBD 3000, and its various applications, can be found at the Advanced Analytical Technologies website, www.aati-us.com. Additionally, there will be three chapters dedicated to the RBD 3000 in Volume II of the Encyclopedia of Rapid Microbiological Methods (Miller). One chapter will provide a detailed description of the RBD 3000 technology and two chapters will present two different RBD 3000 users' perspectives.

Reference:

Miller, MJ, editor. Encyclopedia of Rapid Microbiological Methods, Volumes I, II & III. (Volume I released in January 2006, Volume II released in February 2006, Volume III to be released in March 2006). River Grove (IL): DHI/PDA.

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Call out for Articles!

As you know, RMUG® is your users group and without your feedback it would not be in existence. We want to hear from you!

Got a question? Are you a vendor who would like to advertise/discuss your technology? Are you an end-user who would like to share some of your positive/negative experiences? If so, drop us a line at mconway@vectech.com. We take articles of any length throughout the year.

An Unfortunate Loss

The microbiology industry lost a pioneer in the area of sterilization microbiology in January of this year when Dr. Michael Korczynski passed away. Dr. Korczynski worked at Abbott for many years. During this time period, he published numerous research articles in the areas of sterilization science and microbiology. This research provided significant information for the understanding of sterilization processes.

Dr. Korczynski was actively involved in PDA for many years. He advanced to the Board of Directors and President. His contributions to the organization were significant. Additionally, Dr. Korczynski worked at PDA to initiate the PDA Training and Research Institute. Many a student benefited from the programs initiated during his tenure there.

Another area where Dr. Korczynski was involved was at USP. He served on the microbiology committee for many years, and authored many of the chapters we routinely use.

Dr. Korczynski also was very involved in ISO and generation of documents, e.g., Aseptic Processing Guidance.

In recent years Dr. Korczynski served on the Office of Pharmaceutical Sciences Advisory Committee for CDER. He was a strong supporter for Rapid Microbiology and Process Analytical Technologies. One of his most recent endeavors was to encourage industry to use PAT and Parametric Release to move to concurrent validation in our processes.

Our condolences are extended to Mike's friends and family. His legacy will continue in all of us who were mentored by him.

In and Around the Rapid Micro Community

Watch this space for upcoming information on Rapid Micro events including The 5th Annual RMUG® conference.

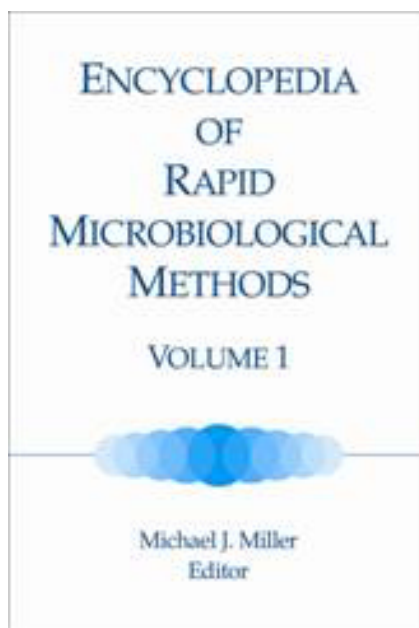
If you know about, or would like to include information on conferences or events of interest, please provide the appropriate information to rmug@vectech.com.

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Your Global Resource for Pharmaceutical and Biopharmaceutical
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Encyclopedia of Rapid Microbiological Methods, Volume I, II, & III

Editor: Michael J. Miller



Microbiologists and management alike are working together to remove the perceived barriers to implementing RMM within many companies. This three volume encyclopedia focuses on regulatory and compendial initiatives currently in place that should help pharmaceutical microbiologists begin the journey of implementing RMM in their facilities and describes the many rapid methods currently available.

2005/2006. Hardcover.

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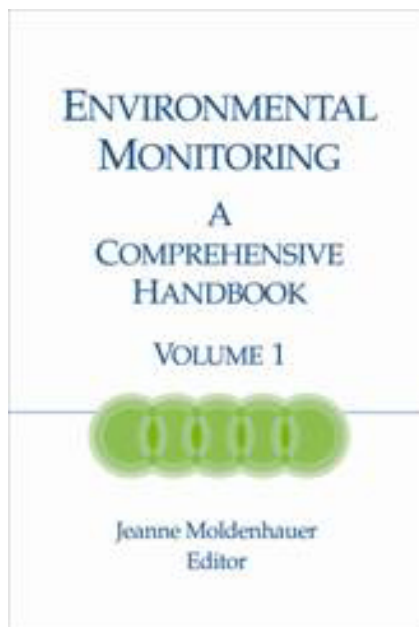
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Environmental Monitoring: A Comprehensive Handbook

Editor: Jeanne Moldenhauer



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Volume I, Volume II and Protocol CD

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Did you find this newsletter helpful?

Informative

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