

Rapid Microbiological Methods: Accepted. Validated. Approved. Implemented.

With the leading industry & world-wide expert – Dr. Michael J Miller

Tuesday 17th September, Birmingham (near the international airport)

&

Thursday 19th September, Dublin

Venues TBC

**Attend and receive Pharmig's PDF publication (in conjunction with the CTPA) on:
Rapid & Alternative Microbiological Methods**



Now more than ever, the use of rapid and alternative microbiological methods (RMM) is playing a significant role in demonstrating microbial control in manufacturing processes, in-process samples and finished product. With the development of novel medicinal preparations, such as ATMPs and other short-lived products, the need to quickly and accurately detect contamination is of utmost importance.

Although more and more companies around the globe have embraced rapid technologies and have validated and gained approval for their routine use, regulatory policies, compendial guidance and industry best practices for validation continue to evolve.

Pharmig has developed this comprehensive learning opportunity to help explain the current state of rapid methods within the pharmaceutical and biopharmaceutical industries. Taught by one of the global experts on rapid microbiology validation and implementation, attendees will be immersed in practical and informative discussions on how to pave the way for a successful RMM implementation program. Hands-on interaction with RMM technology innovators and suppliers will make this one of the most inclusive and rewarding gatherings in the ever-changing world of rapid methods.

PROGRAMME OUTLINE

08.45 – 09.15 Registration and Tea/Coffee

09.15 – 09.30 Chairs opening address

09.30 – 10.00 **Challenges and perceptions, industry needs and opportunities, applications for in-process and finished product testing**

10.00 – 10.50 **Regulatory policies and expectations, compendial enablers, new guidance for testing ATMPs**

10.50 – 11.10 **Morning break with our RMM Exhibitors**

11.10 – 12.30 **Overview of RMM technologies, scientific principles and workflows**

12.30 - 13.30 **LUNCH with our RMM Exhibitors**

13.30 – 14.50 **A roadmap for validation; practical guidance on validation plans, statistical analysis and case studies on industry success stories**

14.50 – 15.10 **Afternoon break with our RMM Exhibitors**

15.10 – 15.50 **Case study on developing a financial model for justifying return on investment (ROI)**

15.50 – 16.00 **Final comments and close of meeting**

About your presenter



Dr. Michael J. Miller is an internationally recognized microbiologist and subject matter expert in pharmaceutical, biotech and medical device microbiology and the design, validation and implementation of rapid microbiological methods (RMM). He is currently the President of Microbiology Consultants, LLC (<http://microbiologyconsultants.com>) and owner of <http://rapidmicromethods.com>, a website dedicated to the advancement of rapid methods.

For almost 30 years, he has held numerous R&D, manufacturing, quality, business development and executive leadership roles at multinational firms such as Johnson & Johnson, Eli Lilly and Company and Bausch & Lomb. In his current role, Dr. Miller consults with multinational companies in providing technical, quality, regulatory and training solutions in support of RMMs, sterile and non-sterile pharmaceutical manufacturing, contamination control, isolator technology, environmental monitoring, sterilization, antimicrobial effectiveness and pharmacy compounding. He has also served as a pivotal microbiology expert witness on numerous patent infringement and product liability cases.

Dr. Miller has authored more than 100 technical publications and presentations. He currently serves on the editorial and scientific review boards for American Pharmaceutical Review, European Pharmaceutical Review and the PDA Journal of Science and Technology. He is also an advisor to the SUP Microbiology Expert Committee. Dr. Miller holds a Ph.D. in Microbiology and Biochemistry from Georgia State University and a B.A. in Anthropology and Sociology from Hobart College.

Fees:

Pharmig Member £595/ €706*

NHS Member £300

Pharmig Non Member £795 / €950*

NHS Non Member £500

NOTE: *Euro fee is higher to cover conversion rates

Advance Delegate Booking Form

Please tick which date you wish to attend

- Tuesday 17th September, Birmingham
- Thursday 19th September, Dublin

Company Name & Address: _____

Contact Name (different from those attending) _____

Contact Email: _____ Tel: _____

Delegate 1

First Name: _____ Surname: _____

Job Title: _____ * Email: _____

Dietary requirements: _____

Delegate 2

First Name: _____ Surname: _____

Job Title: _____ * Email: _____

Dietary requirements: _____

***Please include your email address if you wish to continue to be contacted by Pharmig about these and future meetings**

Email or fax your completed booking form for a confirmed place:

Email: info@pharmig.org.uk Fax: to +44 (0) 1920 871 156

Cheque for £ sterling / _ euro to cover delegate fee(s) enclosed

Please supply invoice F.A.O.: _____

Cheque for £ sterling / _ euro to follow

Total of £ sterling / _ euro transferred electronically

Please quote purchase order number:

I wish to pay by credit card (*Pharmig will contact you for details*)

Note: Fees for both meetings include lunch, refreshments and links to download presentations in advance of the meetings if presentations are available.

Note: Fees do not include accommodation, which must be booked and paid for directly with the hotel once venues have been confirmed.

Hotel Information

For both meetings, this will be confirmed in due course

CANCELLATION POLICY:

Written cancellation will be accepted up to 30 days prior to the event, and all cancellations will incur a fee. No refunds are available 15 working days before the start date and full course fees will be due for delegates who fail to attend.

Substitutions may be made at any time, preferably in writing to Maxine Moorey. Please send to:

Maxine Moorey, Pharmig, T5 The Maltings, Roydon Road, Stanstead Abbots, Hertfordshire, SG12 8HG or by email:
maxine@pharmig.org.uk

Please note Pharmig reserves the right to alter the programme in the event of unforeseen circumstances.

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