



NUI Galway
OÉ Gaillimh



Selection, Validation and Implementation of Rapid Microbiological Methods for ATMPs

Galway Bay Hotel, Salthill, Galway; 12th and 13th June

The Centre for Cell Manufacturing Ireland is delighted to present an intensive training course which will provide a comprehensive review of rapid microbiological methods (RMM) and how they can be used to support the manufacture and release of advanced therapeutic medicinal products (ATMPs). Taught by the industry's global leader in rapid methods and pharmaceutical microbiology, the attendee will be immersed in scientific and regulatory discussions that will provide a robust and understandable roadmap for how to evaluate RMMs and employ them in their own laboratory and manufacturing areas.

A review of conventional microbiological methods and applications will be provided followed by discussions on novel opportunities for improving time to result, sensitivity, throughput and automation. Current technologies, their scientific principles and workflows will be examined.

Next, a thorough analysis of US and EU regulatory policies and pharmacopeia chapter revisions relevant to rapid microbiological testing of ATMPs and other applicable sample matrices will be considered in great detail. Rapid sterility testing of finished product and alternative material, as well as sample size considerations, will be highlighted during these discussions. As such, the proposed USP chapter <1071>, Rapid Sterility Testing of Short-Life Products: A Risk-Based Approach, Ph. Eur. Chapter 2.6.27, Microbiological Examination of Cell Based Preparations, the EU Guidelines for Good Manufacturing Practices for ATMPs and revisions to Annex 1 will be examined.

This will be followed by an all-inclusive dialogue of validation strategies for rapid qualitative, quantitative and identification technologies, including the use of statistical models for demonstrating an alternative microbiology method is equivalent or non-inferior to an existing conventional method. Interpreting the validation requirements set forth in PDA Technical Report #33, USP <1223> and Ph. Eur. Chapter 5.1.6 will also be reviewed during these discussions.

The Centre for Cell Manufacturing Ireland (CCMI) is accredited under EU GMP and was granted a manufacturing authorisation by the Health Products Regulatory Authority (HPRA) in 2013 for the manufacture of human mesenchymal stem cells (hMSCs), enabling the manufacture of clinical grade Advanced Therapy Medicinal Products (ATMPs) for clinical trials. Currently there are 4 active clinical trials ongoing through CCMI.

For further information contact: aoife.duffy@nuigalway.ie





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AGENDA: DAY 1

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| 08.30 | Registration tea/coffee |
| 09.00 | Introduction, applications and implementation opportunities. Overview of global regulatory expectations. |
| 10.45 | Coffee |
| 11.00 | Regulatory and compendial policies for rapid sterility testing of ATMPs. Review of RMM technologies Part 1 |
| 13.00 | Lunch |
| 14.00 | Review of RMM technologies Part 2 |
| 15.30 | Coffee |
| 16.00 | Review of RMM technologies Part 3 |
| 17.30 | Wine reception at exhibitors |
| 19.00 | End of Day 1 |

AGENDA: DAY 2

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| 09.00 | Validation and statistical analysis of rapid methods Part 1 |
| 10.45 | Coffee |
| 11.00 | Validation and statistical analysis of rapid methods Part 2. How to perform a return on investment assessment. |
| 13.15 | Lunch |
| 14.00 | CCMI case study |
| 14.30 | Kevin Williams: ENDOZYME II GO, well, to go... faster, further |
| 15.00 | Case Study: A rapid mycoplasma method accepted by regulatory agencies for lot-release testing. Speaker TBC. |
| 15.30 | Case study: Validation of an RMM for an ATMP. Speaker TBC. |
| 16.00 | End of Day 2 |

About the Expert

Michael J. Miller,
PhD, President, Microbiology Consultants, President

Dr. Michael J. Miller is an internationally recognized microbiologist and subject matter expert in pharmaceutical microbiology, contamination control, aseptic processing, sterilization, laboratory design and the 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 within healthcare related industries.

Dr. Miller has authored more than 100 technical publications and presentations and is the editor of PDA's Encyclopedia of Rapid Microbiological Methods. 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. Dr. Miller also was the chairperson during the revision of PDA Technical Report #33, Evaluation, Validation and Implementation of New Microbiological Testing Methods. He currently serves as an advisor to the USP Microbiology Expert Committee in the area of rapid sterility testing. Dr. Miller holds a Ph.D. in Microbiology and Biochemistry from Georgia State University (GSU) and a B.A. in Anthropology and Sociology from Hobart College.

Please register at <https://clr.ie/127992>

Early Bird before April 15th: €1,250 per attendee

Early Bird before April 15th: 2 or more from one company
€1,000 per attendee

After April 15th: €1,500 per attendee

After April 15th: 2 or more from one company €1,250 per attendee