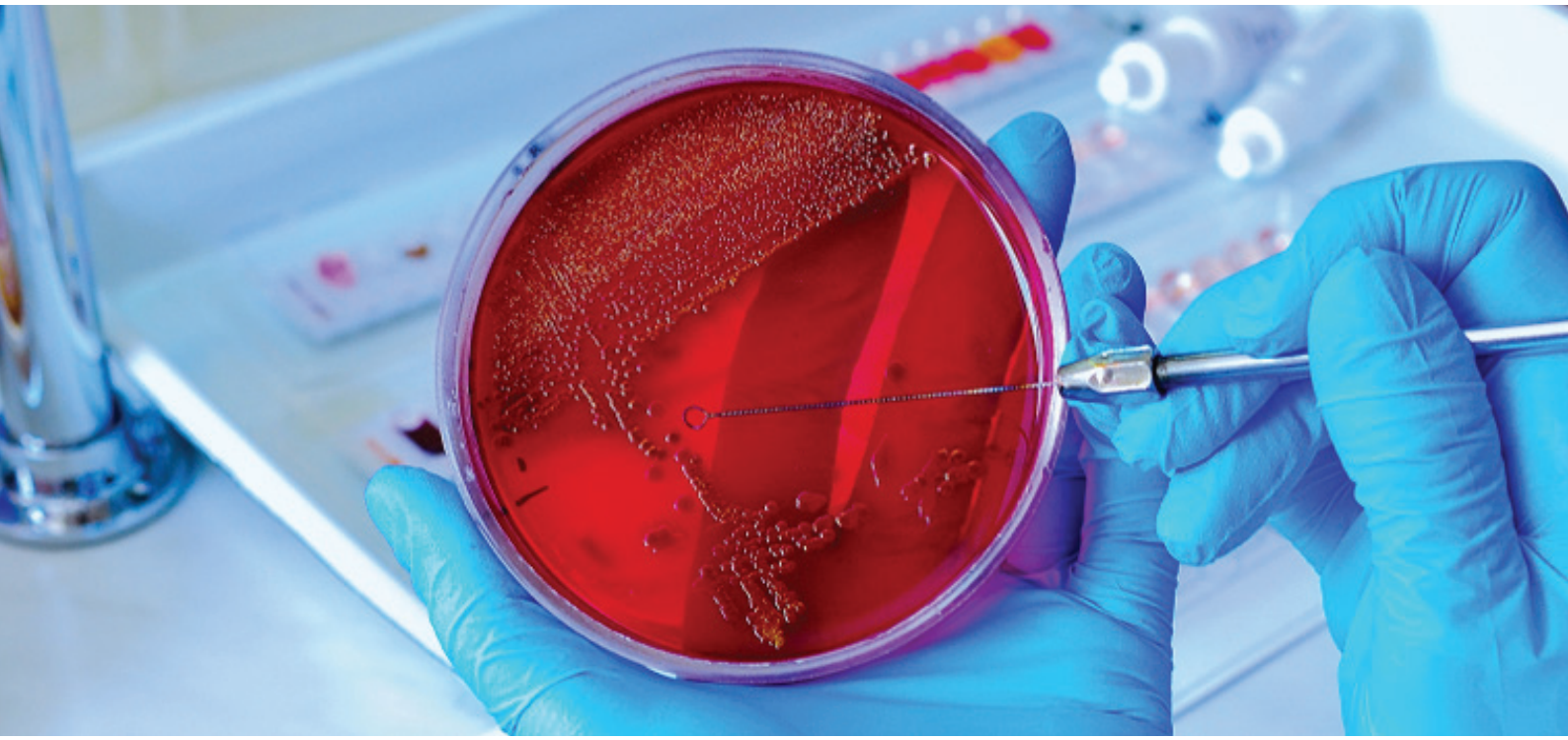
pharmig
EXCELLENCE IN MICROBIOLOGY



Best Practices in Microbiological Environmental Monitoring

INDIA 2019

15th October
Radisson, Hyderabad

16th October
Hilton, Mumbai

Attend and receive automatic overseas pharming membership to the end of December 2019

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TECHNOLOGY NETWORKS

ABOUT THE CONFERENCE

Microbiological Environmental Monitoring Conference will be covering challenges and best practice. Microbiological environmental monitoring is a key part of the assessment of pharmaceutical manufacturing facilities. Environmental monitoring data indicates if cleanrooms are operating correctly. Cleanrooms are the fabric within which pharmaceutical manufacturing takes place. This conference addresses key aspects of environmental monitoring presented by leading experts in Industry. The aim is for you to leave with the knowledge and key skills to go back to your facility and work towards best practices in microbiological environmental monitoring.

TOPICS COVERED

- The environmental monitoring programme - what needs to be included
- Incubation strategies for environmental monitoring
- Data strategies and environmental monitoring
- Risk assessment and environmental monitoring
- Environmental Monitoring Identification (ID) Strategy
- Microbial data deviations

EXPERT SPEAKERS

Dr. TimSandle
Head of Microbiology,
UK Bioproducts Laboratory

David Keen
Senior Global, Microbiology
Consultant Ecolab

Julie Roberts
Pharmaceutical Professional
J Roberts Associates

Manish Bhatkar
Pharma Professional
Redlotus Pharmtech

WHO SHOULD ATTEND?

Departments:

Microbiology / Quality Control

Quality Assurance / Technical Operations

Manufacturing / Research & Development

Compliance / Regulatory affairs

Designation:

MD's/CEO's / SVP's Presidents, VP's

Head of Departments / Directors

General Managers, Senior Managers, Manangers

CLIENT TESTIMONIALS

Overall I think the conference was structured well covering various topics

Aurobindo Pharma

He is such a wonderful speaker and always delivers some new points and evokes new thoughtprocess which will be very useful. This is the second time to attend his presentation and I would always like to watch many in future.

David Keen

Both presentations on Data Integrity and Preparing the lab for audit, addressed many routine issues encountered in day to day life in Microbiology laboratory.Even the trainer tried to present the scenarios in Indian pharmaceutical Microbiology laboratories.

Julie Roberts

AGENDA : 15TH OCTOBER AND 16TH OCTOBER

08.30 am Registration

09.00 am – Chair's welcome

David Keen

Senior Global, Microbiology Consultant, Ecolab & Pharmig Chairman

9:15 am The environmental monitoring programme

- What makes for a good environmental monitoring programme?
- What to the regulations require?
- What needs to be assessed and included e.g. time of monitoring, locations for monitoring, frequencies for monitoring
- How should the programme be structured?
- How often should the programme be reviewed?

Julie Roberts

Quality Director, J. Roberts Associates Ltd & Pharmig Committee Member

10.00 am - Incubation strategies for environmental monitoring

- What is environmental monitoring trying to do?
- Which agar should you select?
- Should one or two agars be used?
- Which is the optimal temperature?
- For how long should you incubate for?
- What types of microorganisms can you expect to detect?

David Keen

Senior Global, Microbiology Consultant, Ecolab & Pharmig Chairman

10.45 am – Morning break with tea/coffee and meet the exhibitors

11.15 am – Data strategies and environmental monitoring

- How to collect data, including electronic systems
- How to evaluate data
- Trend analysis tools and tips
- Setting alert and action levels
- Data integrity issues

Manish Bhatkar

Founder & CEO, RedLotus Pharmtech & Pharmig Overseas Ambassador

*12.00 pm – Risk assessment and environmental monitoring – **VIA VIDEO LINK***

- Review of risk assessment tools
- Using risk assessment to determine frequencies of monitoring
- Using risk assessment to set monitoring locations
- Using risk assessment to investigate action level excursions or out-of-trends

Dr. Tim Sandle

Head of Microbiology, BPL

13.00 am - Lunch with the exhibitors

12.45 pm – Introducing Pharmig's interactive on-line training module: Cleaning & Disinfection of Cleanrooms and current publications

Pharmig Committee Member

*14.00 pm – Practical group workshop: **How to set environmental monitoring locations***

Led by: David Keen

Senior Global, Microbiology Consultant, Ecolab & Pharmig Chairman

4.45 pm – Afternoon break with tea/coffee with the exhibitors

15.00 pm – Environmental Monitoring Identification (ID) Strategy

- What to identify?
- How often to identify?
- I dentification technologies
- How far to go: morphologically, photographic library, biochemical analysis?
- What do the regulations require?
- Differences for steriles and non-steriles
- How to review and interpret the data?

Julie Roberts

Quality Director, J. Roberts Associates Ltd & Pharmig Committee Member

15.45 pm – Microbial data deviations

- How to investigate out of limits results
- How often to identify?
- Case studies for out of trend situations
- How many repeat samples to take?
- How to set CAPA?

Manish Bhatkar

Founder & CEO, RedLotus Pharmtech & Pharmig Overseas Ambassador

16.30 pm – Open discussion and Q&A session with the presenters

16:40 pm
Chair's closing remarks

ABOUT THE SPEAKERS

David Keen

Senior Global, Microbiology Consultant, Ecolab & Pharmig Chairman

David is a microbiologist working for Ecolab as a Senor Global Microbiology Consultant for their Lifesciences division. David got his first taste of Pharmig quite a depressing number of years ago. In 2007 he became a committee member of Pharmig. In November 2013 he had the honour of being elected as Pharmig Chair. David started life at GSK Barnard Castle.

Here he performed environmental monitoring and clean room qualification before moving on to sterile finished product testing. David then moved to a small start-up company called SCM Pharma. Here he set up a new microbiology lab and developed a new microbiology team. He helped design and qualify the new clean rooms. He then moved from microbiology to project management and became the technical manager. David then moved to Reckitt Benckiser at their Hull site where he discovered the magic and pain of working in an FMCG environment. His role was to improve microbiological awareness on the site and a large amount of time was spent investigating significant microbial contamination events with suppliers and products. He was lucky enough to be sent across the world investigating microbiological issues on behalf of the company.

If you get caught by him at the bar, he can bore you to death on the wonders of seaweed. In 2012 David moved back to GSK at the Ulverston site in the Lake District. This is a large scale primary API manufacturing site makes bulk sterile antibiotics. It uses isolator technology in a primary environment, which was a bit of a steep learning curve. David started a new role as a microbiological consultant for Ecolab in March 2018. In this role David utilizes his experience to help Ecolab's clients with microbiological and manufacturing issues, across the globe. David is experienced in most drug dose forms from sterile needless injection systems, explosive aseptic ampoules to inhalation devices, oral doses of microbial sensitive products and sticky capsules. Plus a great deal of primary manufacturing to boot. He is now dipping his toe into the world of disinfectants and contamination control – a microbiologist's best friend.

Julie Roberts

Quality Director, J. Roberts Associates Ltd & Pharmig Committee Member

Julie has 25 years in the Pharmaceutical industry working for multi-national companies such as AstraZeneca, GSK and Eli Lilly. In recent years she has worked in an international corporate role assessing sites for due diligence and inspection readiness across all dosage forms. As an experienced microbiologist, Julie has also designed, set up, managed and audited microbiology laboratories and provided remedial support where required. With a strong technical competency in API operations and parenteral manufacture, Julie has practical experience in water system design and qualification, clean room classification, EM programmes.

Julie became eligible to work as a Qualified Person in Europe in 2001, is a power user of TrackWise and has lean Six Sigma experience as a Green Belt. Since becoming an independent Consultant Julie has worked extensively in Asia, Europe and the US conducting on-site gap analyses against EU and US regulations, coaching, training and educating staff to remediate gaps and prepare them for FDA inspections and EMA/MHRA audits. Julie conducts work under her own company name 'J Roberts Associates' and also as a consultant for the US-based consultancy group 'Jeff Yuen & Associates Inc.', and the Irish-based consultancy group 'McGee Pharma International' and is a current Pharmig committee member.

Dr. Tim Sandle

Head of Microbiology, BPL
(presenting via video link)

Tim is the Head of Microbiology at the UK Bio Products Laboratory. His role involves overseeing a range of microbiological tests, batch review, microbiological investigation and policy development. In addition, Tim is an honorary consultant with the School of Pharmacy and Pharmaceutical Sciences, University of Manchester and is a tutor for the university's pharmaceutical microbiology MSc course. Tim is a chartered biologist and holds a first class honours degree in Applied Biology; a Master degree in education; and a PhD in microbiology. Tim serves on several national and international committees relating to pharmaceutical microbiology and cleanroom control (including the ISO cleanroom standards), and he has acted as spokesperson for several microbiological societies. He is a committee member of the microbiology society Pharmig. Tim has written over one hundred-and-fifty book chapters, peer reviewed papers and technical articles relating to microbiology.

ABOUT THE SPEAKERS

Manish Bhatkar

Founder & CEO, RedLotus Pharmtech & Pharmig Overseas Ambassador

Manish Bhatkar is an experienced pharma professional, diligent in his core functional area (pharmaceutical technical operations) and committed to the profession. Before founding RedLotus Pharmtech Private Limited (A Technical Services Company) in 2016, in his 25 years of service, he has discharged executive as well as leadership responsibilities in the areas of design & development, manufacturing, qualification & validation, operations management, quality assurance, quality management, audits & compliance, regulatory affairs, technology transfer, project management, and technical consulting.

He has worked in R&D, API's, formulations and technical consulting environments and has demonstrated equivalent capabilities in managing manufacturing, technical as well as quality operations with ease. He was instrumental in establishing and growing the validations & GMP compliance services business vertical for a German pharmaceutical engineering house Pharmaplan GmbH (Now, NNE Pharmaplan) in India. As head of the Dabur Oncology Plc. Operations, in his 5 years' tenure in UK, he single handedly led the efforts in resolving complex technological, regulatory and GMP compliance issues (including USFDA warning letter) that resulted in making commercial manufacturing and product supplies possible from the site.

As head of Lupin Limited' Technical Services, he lead the mission to transform the quality mindset and culture at their Goa manufacturing facility for meeting the exceptional and extreme Japanese quality requirements/ expectations. International experience of working in different geographies and work cultures helped him further strengthen his technical as well as leadership skills and capabilities. His main area of expertise is aseptic processing & areas of interests are sterility assurance, manufacturing technology, process validation, failure investigations, trouble-shooting, continuous improvement and resolution of complex technical/ regulatory/ GMP issues. Additionally, he has lead team of experts in preparing the inspectional observations of various regulatory agencies, such as WHO, ISO, USFDA, UK-MHRA, ANVISA, ENVIMA, Russia, Romania, Hungary, Germany etc. Manish has worked with medium to large, well respected pharmaceutical products manufacturing and services organizations like Dr. Reddy's Laboratories Ltd., Lupin Limited, Dabur Oncology Plc. UK, Pharmaplan (India) Ltd., and Zydus Cadila. He has been involved in many projects from concept design to successful delivery of commercial product to the continuous improvement phases and also led organization(s) efforts and teams in managing and resolving regulatory challenges like regulatory review/ inspectional observations, warning letters and consent decree.

Manish has joined the Pharmig Committee as an overseas ambassadoralso.

ABOUT PHARMIG

Pharmig is a non-profit making professional organisation, established in 1991, that represents the interests of individuals who work in, have responsibility for, or work alongside microbiology within pharmaceutical, healthcare, cosmetics Industries as well as the NHS and other not-for-profit related organisations.

It provides a focus for continuing professional development and serves as a unique network for the exchange of microbiological information through training courses, conferences, publications and its website forum.

The Group has grown significantly since 1991 expanding the portfolio of products it now offers to the Membership whilst remaining true to the initial needs of microbiologists which include:

- Organising meetings, training courses, conferences, on-line training modules and producing publications that provide topical information and views on microbiologically related topics
- Advancing the science of microbiology and its practical application
- Influencing the development of regulations and guidelines surrounding microbiology
- Acting as a confidential forum for the dissemination of information concerning all aspects of microbiology

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Package	Early Bird	Standard	Late Onsite	Early Bird	Standard
Conference	India:INR 15000 Foreign: $ 250	India:INR 20000 Foreign: $ 350	India:INR 35000 Foreign: $ 650	India:INR 20000 Foreign: $ 350	India:INR 35000 Foreign: $ 450

Note : Fee includes conference attendance refreshments, lunch, and links to download presentations after the event

Group discounts - 3 + 1 - register 3 delegates and receive 1 free place

(On standard price)(*applicable for full conference on standard price)

15th October, Hyderabad | 16th October, Mumbai

PERSONAL DETAILS

Title (Mr./Ms./Mrs./Dr.)	Name	Department & Designation	Email ID

Organization:

Attending Location:

Address:

Post Code/Pin Code **Country:** **Telephone & Fax:**

Authorizing Manager name

Email ID: **Mobile:**

Date: **Signature & Stamp:** **GST Number:**

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