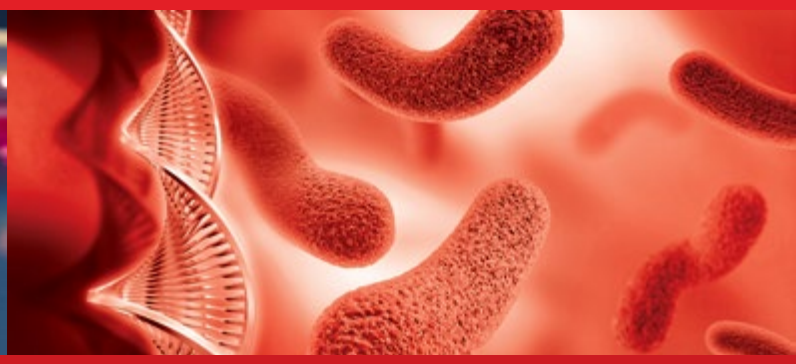
pharmig
EXCELLENCE IN MICROBIOLOGY

Formerly known as The Pharmaceutical Microbiology Interest Group

Presents: **Best Practices in Pharmaceutical Microbiology**



ONE CONFERENCE - TWO LOCATIONS

Tuesday 28th July 2015 **– Biocon – Bangalore**

Thursday 30th July 2015 **– Orchid Hotel – Mumbai**

Leading experts include:

Scott Sutton

Rachel Blount

Julie Roberts

Ken Muhvich

Who will cover:

- Regulatory Hot Topics and Warning Letters
- Data Integrity
- QC Microbiology and the Compendia
- Validating Disinfectant Efficacy & Test Methods
- Objectionable Organisms Within & Beyond Regulations for Steriles & Non Steriles
- Implementing a Disinfectant Programme: A Practical Approach
- Developing a Meaningful Environmental Monitoring Programme
- Microbiology Laboratory Investigations - Errors, Preparation and Success

Attend and receive automatic overseas membership to Pharmig until 31st December 2015 (see inside for more details)

Book early to avoid disappointment

Pharmig

T5 The Maltings, Roydon Road, Stanstead Abbotts, Hertfordshire, SG12 8HG, United Kingdom.

Tel: +44 (0) 1920 871 999 **Fax:** +44 (0) 1920 871 156

Email: info@pharmig.org.uk **Web:** www.pharmig.org.uk

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EXCELLENCE IN MICROBIOLOGY

Programme for Tuesday 28th July and Thursday 30th July

Kiran Mazumdar-Shaw, Chairperson & Managing Director of Biocon will kindly be opening the meeting on the 28th July 2015

09.30 – 10.00 **Registration with Tea/Coffee**

10.00 – 10.10 **Chairs Introduction**

10.10 – 10.50 **Regulatory Hot Topics and Warning Letters – How Can You Become Compliant?**
- Current regulatory findings
- Example warning letters and trends
- Compliance intelligence
- Hints to maintain compliance

Ken Muhvich – Principle Consultant, Micro-Reliance LLC (USA)

10.50 – 11.30 **Data Integrity and New Expectations**
- What is data integrity?
- Requirements for good data integrity - 'ALCOA'
- Understanding the expectations from Regulators
- Managing data integrity in your laboratory and at your production facility
- MHRA guidance on data integrity

Julie Roberts – Independent Consultant, J Roberts Associates Ltd & Pharmig Committee Member

11.30 – 11.50 **Morning break with Tea/Coffee and meet the Exhibitors**

11.50 – 12.30 **QC Microbiology and the Compendia**
- Harmonized finished product tests
- Informational and non-mandatory chapters of interest
- Critical guidance documents

Scott Sutton – Principle, The Microbiology Network Inc (USA)

12.30 – 13.00 **Validating Disinfectant Efficacy and Test Methods**
- Regulatory guidance and expectations
- Test methods available
- Interpretation of results
- Revalidation

Rachel Blount – Global Validation Manager, ECOLAB & Pharmig Committee Member

13.00 – 14.00 **Lunch and meet the Exhibitors**

14.00 – 14.40 **What are Objectionable Organisms?**
- Compendial Guidance on "Specified Organisms" vs 21 CFR 211 "Objectionable Organisms"
- Chapter <1111> and the rationale for "other organisms"
- How to streamline the research/ justification
- Process considerations
- Conclusions

Scott Sutton – Principle, The Microbiology Network Inc (USA)

14.40 – 15.20 **Implementing a Disinfectant Programme: A Practical Approach**
- Selection of suitable biocides for the grade of area
- Rotational programme
- Application techniques
- Records and documentation

Rachel Blount – Global Validation Manager, ECOLAB & Pharmig Committee Member

15.20 – 15.40 **Afternoon break with Tea/Coffee**

15.40 – 16.20 **Developing a Meaningful Environmental Monitoring Programme**
- Methods of monitoring, specifications and alert levels
- Risk analysis and selection of sampling locations
- Data management; trending and review of data
- Annual review of the environmental monitoring programme

Julie Roberts – Independent Consultant, J Roberts Associates Ltd & Pharmig Committee Member

CONTINUED OVERLEAF

Programme for Tuesday 28th July and Thursday 30th July - Continued

16.20 – 17.00 **Viable Microbial Contamination Investigations**

- Practical investigation approach
- Goals for the investigation
- Check lists
- Commonly observed errors
- Root cause identification
- Investigative environmental monitoring
- Drawing appropriate conclusions

Speaker: Ken Muhvich – Principle Consultant, Micro-Reliance LLC (USA)

17.00 – 17.30 **Put Your Questions to the Microbiology Experts**

A chance to pick the speakers brains with all your burning questions
Rachel Blount, Ken Muhvich, Julie Roberts, Scott Sutton

17.30 – 17.40 **Closing Remarks**

ONE CONFERENCE - TWO LOCATIONS

About Your Presenters

Scott Sutton

Scott Sutton is the Principal of Microbiology Network, Inc (http://microbiologynetwork.com/) a company he started in 1996 as a means to encourage training and communications within the microbiological community.

The Microbiology Network operates two Email discussion groups – the PMFList (for pharmaceutical microbiology) and the PSGDList (for stability issues). With over 90 publications and hundreds of presentations, Scott is a recognized consultant and trainer with emphasis in CGMP, investigations, Environmental Monitoring and contamination as well as microbiology laboratory audits and Quality operations. Scott has helped companies in pharma, compounding pharmacies, personal care products with questions and product development issues in both sterile and non-sterile production.

Dr. Sutton is an adjunct faculty member of the Wegman's School of Pharmacy at St. John Fisher University (Rochester, NY) and is a long-time USP volunteer, having served as an elected member of the USP Microbiology Committee of Experts since 1995.

Rachel Blount

Rachel Blount has over 25 years of experience in Contamination Control. She started her career in Microbiology for The Bodyshop International. She went went on to work at Diversey for 23 years where she was responsible for the European Contamination team. She was responsible for the implementation of the new 3rd party manufacturer for all sterile disinfectants and the standards and processes required. She has been involved in numerous projects with Customers and routinely carried out Audits, Training and coordinated the Disinfectant studies for Pharmaceutical sites.

Rachel joined Ecolab Contamination Control in January 2014 as Global Validation Manager. In her current role Rachel provides technical support to Ecolab customers, advising on cleaning and disinfection performs site surveys, presents at seminars and also project manages the third party laboratories that perform disinfectant efficacy studies. She is an accredited IRCA auditor and is a current Pharmig committee member.

About Your Presenters

Julie Roberts

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.

Ken Muhvich

Ken Muhvich is the Principal Consultant for Micro-Reliance LLC, which specializes in Microbiology and Sterility Assurance Consulting. He has more than 30 years experience as a microbiologist. He founded Micro-Reliance LLC in January 2002. He has conducted numerous Mock Pre-Approval Inspections for sterile product manufacturing facilities, including their microbiology laboratories. He frequently guides companies in sterile process design and validation. He provides consultancy on sterility assurance investigations such as sterility test failures and growth-positive media fills. He also provides advice on risk-based contamination control programs for viable microbes, including filamentous molds. From 1992 to 1997 Ken was a Review Microbiologist at the U.S. Food & Drug Administration's Office of Generic Drugs. While at the FDA, he performed more than six hundred sterility assurance reviews. He is a recognized expert in aseptic processing of sterile drug products.

He holds a Bachelors degree in Health Sciences from the University of Delaware. He holds a Masters degree in Medical Microbiology from West Virginia University. He supervised the Clinical Microbiology Laboratory at Sinai Hospital in Baltimore, Maryland for a decade. He holds a Doctor of Philosophy degree in Experimental Pathology from the University of Maryland. He is currently Co-leader of the Parenteral Drug Association's Task Force that is writing the Technical Report on Blow/Fill/Seal Technology.

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 & NHS Industries. 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 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

Attend and you will receive automatic Pharmig overseas membership to the end of December 2015

Overseas membership includes:

- A quarterly technical newsletter (PDF version only) - January / April editions will be sent to you
- Member rates to join Pharmig webinars
- Member rates to purchase any of Pharmig publications at the member listed prices. Visit the Pharmig website for more information www.pharmig.org.uk.

SEE LAST PAGE FOR ALL PHARMIG PUBLICATIONS

Exhibitor Opportunities

- There are limited exhibition places at the meeting on the 28th July – Biocon (maximum of 5 stands)
- More exhibition places are available at the meeting on the 30th July – Orchid Hotel, Mumbai

Fees:

- 47,700 INR + local taxes @ 14% = Total to pay 54,378 INR (£500 Sterling) to exhibit at one meeting
- Exhibiting at both meetings (28th in Bangalore and 30th in Mumbai) – a discount of 9600 INR will apply. 85,800INR + local taxes @ 14% = Total to pay 97,812 INR (£900 Sterling)

The booking form is located below. Bookings will be accepted on a first come-first serve basis and payment is due by Friday 17th July at the latest to confirm attendance.

Booking Forms / Payment / Venues / Accomodation Info

DELEGATE FEES:

6,000 INR + local taxes @ 14% = 6,840 INR Total to pay per person (Cheques made payable to Easy Solutions at the address below) / £60.00 GBP

DELEGATE BOOKING FORM

Please tick which meeting you would like to attend

☐ **28th July 2015, Biocon – Bangalore**

☐ **30th July 2015, Orchid Hotel – Mumbai**

1st Delegate

First Name: _____

Surname: _____

Job Title: _____

Company Name: _____

Address: _____

_____

_____

Email: _____

Dietary Requirements: _____

_____

2nd Delegate

First Name: _____

Surname: _____

Job Title: _____

Company Name: _____

Address: _____

_____

_____

Email: _____

Dietary Requirements: _____

_____

If you want to send more than 2 people - please add additional names to the booking form

Note: Individual fee includes refreshments, lunch and folder containing presentations and delegate list (name and company) for each meeting

Note: It excludes accommodation which needs to be booked directly with the hotel(s)

Note: Payments MUST be made in advance by Friday 17th July to guarantee a place at either meeting

Booking Forms / Payment / Venues / Accomodation Info

EXHIBITOR FEES

Attending 1 meeting 47,700 INR + local taxes @ 14% = Total to pay 54,378 INR (£500 Sterling) to exhibit at one meeting
Attending both meetings (subject to availability) 85,800INR + local taxes @ 14% = Total to pay 97,812 INR (Discount of 9,600 INR (£900 Sterling)

EXHIBTITOR BOOKING FORM - Please tick which meeting you would like to exhibit at

☐ 28th July 2015, Biocon – Bangalore

☐ 30th July 2015, Orchid Hotel – Mumbai

☐ Exhibit at both meetings (28th & 30th July)

EXHIBITOR INFORMATION

Company Name: _____

Company Address: _____

1st Representative Name: _____

Job Title: _____

Email: _____

Dietary Requirements: _____

1st Representative Name: _____

Job Title: _____

Email: _____

Dietary Requirements: _____

Note: Fees include 1 stand (3m x 2m), up to 2 representatives, refreshments and lunch, folder containing presentations and delegate list (name and company)

Note: It excludes accommodation which needs to be booked directly with the hotel(s)

Note: Payments MUST be made in advance by Friday 17th July to guarantee a place at either meeting

VENUES

Tuesday 28th July
Address: Prof. Tyler Jacks Auditorium - Biocon Park – Biocon Special Economic Zone, Plot No.2&3, Phase IV- B.I.A, Bommasandra-Jigani Link Road, Bangalore - 560099, India

Thursday 30th July
Address: Orchid Hotel - Nehru Road, Vile Parle East, Mumbai

PAYMENT

- Email / Fax booking forms to info@pharmig.org.uk / +44 (0) 1920 871 156 for a provisional place
- Individual provisional bookings can also be made via the Pharmig website www.pharmig.org.uk and click on meetings
- Payments can be made by DD (Demand Draft) or Cheque (at par) using the following details.

  Bank Name: DBS Bank Ltd,
  Branch name: Anna Salai Branch
  Branch Address: 806, Anna Salai, Chennai 600 002
  Account Holder Name: EASY SOLUTIONS
  Bank Account No: 826210090632
  IFSC Code: DBSS0IN0811
  MICR No: 600641002

- **Payments can be made via Cheque (payable to Easy solutions) and sent to:** Easy Solutions NEW41, OLD # 42, PETER'S ROAD ROYAPETTAH CHENNAI 600 014,INDIA. Ph:- 044-40182200

Note: Payments MUST be made in advance by Friday 17th July to guarantee a place at either meeting

Note: Sterling payments **only** can be made via the Pharmig website www.pharmig.org.uk

ACCOMODATION

Meeting at Biocon - Tuesday 28th July

- Limited accommodation has been reserved at the Crowne Plaza Bengaluru (Bangalore)
- 6750 INR + taxes inclusive of buffet breakfast and wifi
- Rooms need to be booked directly with the hotel (**please quote Pharmig** to ensure you receive the reduced rate)
- Contact number: + 1-80-30030303 / Email: reservations@cpbengaluru.com

Meeting at the Orchid Hotel - Thursday 30th July

- Limited accommodation has been reserved at The Orchid Hotel
- 6000 INR + taxes inclusive of buffet breakfast and wifi
- Rooms need to be booked directly with the hotel (**please quote Pharmig** to ensure you receive the reduced rate)
- Contact number: +91-22-26164000 / Email: res@orchidhotel.com

Additional information

QUESTIONS

If you have any questions or require further information please email Pharmig at info@pharmig.org.uk

THANK YOU

Pharmig would like to thank Biocon, Easy Solutions and Novatek for their help and support in organising these inaugural meetings.

Biocon is India's largest fully-integrated, innovation-led biopharmaceutical company that is driven by a passion to develop research-driven, cutting-edge therapies. It is committed to reduce therapy costs of chronic diseases like diabetes, cancer and autoimmune diseases by leveraging India's cost advantage to deliver affordable healthcare solutions to patients, partners and healthcare systems across the globe.

Biocon has successfully taken a range of novel biologics, biosimilars, differentiated small molecules and affordable recombinant human insulin and insulin analogs from 'Lab to Market'. As an emerging global enterprise, Biocon is addressing the needs of patients through differentiated products in over 85 countries.
Biocon's tryst with innovation has enabled it to cross new milestones in the area of drug affordability. In doing so, the Company has earned the trust of partners, doctors, patients, care givers and healthcare ecosystems around the world. A combination of tryst and trust has powered Biocon to reinforce its vision of emerging as a relevant global enterprise, delivering cutting-edge innovation that is affordable, available and accessible.

Easy Solutions was founded in 2001 with the aim of providing a full spectrum of contamination control services and supplies to the Pharmaceutical, Medical device or Biotech sectors - **http://cleanroommart.com/**

Novatek International provides a new breed of all-encompassing, process-driven LIMS and other software solutions that target the pharmaceutical, biotech and other health-care industries. Our unique portfolio of out-of-the-box, easy to use software solutions features specialized modules that help you manage all aspects of your quality environment with less effort and time. Novatek delivers solutions that go beyond LIMS for total enterprise wide automation - **http://www.ntint.com/**

Additional Information for those delegates attending the meeting on the 28th July at Biocon

ADDITIONAL ACCOMMODATION FACILITIES AROUND BIOCON

a) **Crowne Plaza** I 5★	Contact: Vrushali Kummar	E: vrushali@cpbengaluru.com	T: + 91 9620800506
b) **Lemon Tree** I 4★	Contact: Ankit Upreti	E: sales1.ec@lemontreehotels.com	T: + 91 9986045090
c) **The Sahar Pavilion** I 3★	Contact: Kapil Raina	E: kapil.raina@thesahar.com	T: +91 7022 888565
d) **IBIS I 3★**	Contact: Pritam Choudary	E: pritam.choudhary@accor.com	T: + 91 7760 976303
e) **Keys** I 3★	Contact: Shibo Varghese	E: hibo.varghese@keyshotels.com	T: + 91 9900031686

DOMESTIC FLIGHT TRAVEL AGENTS

Contact: Sachin E: sachin@uniglobeatb.com T: + 91 9886655396

TAXI SERVICES TO AND FROM THE AIRPORT AND HOTEL(S) IN BANGALORE

Contact: Shravan Kumar E: bookings@esanchaara.com T: +91 9591290555

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EXCELLENCE IN MICROBIOLOGY

Pharmig publications have been written by industry leaders and some endorsed by the MHRA. They contain key information relating to GMP standards and regulations.

Pharmig Publications

Fees listed are in Sterling only

Guide to Disinfectants & their use in the Pharmaceutical Industry

The objective of this Guide is to review current standards to aid in the selection and validation of disinfectants. Key topics include:

- Types & selection of disinfectants
- Validation of disinfectants detailing the BSEN current test methods
- Practical use of disinfectants

Member **£60** Non Member **£85**

Guide to Microbiology Laboratories in the Pharmaceutical Industry

This Guide details what Pharmig considers to be best practice for establishing and operating microbiology laboratories in pharma and associated industries. The Guide describes considerations to be applied to the design, set up and running of the microbiology unit. Topics range from:

- Test methods • Environmental monitoring
- Documentation • Method verification and validation

Member **£60** Non Member **£85**

Microbiological Control for Non-Sterile Pharmaceuticals

This publication is relevant to pharmaceuticals/ cosmetics & toiletry industries and aims to provide guidance around GMP. Topics include:

- Facility, design and requirements • Micro control
- Cleaning & disinfection
- Risk assessment & management
- Microbiological monitoring

Member **£60** Non Member **£85**

Current perspectives on Environmental Monitoring - Review # 1

This review surveys some of the current practices, trends and approaches to environmental monitoring. Technical articles include:

- Constructing an environmental monitoring programme
- Particle monitoring & control
- Environmental monitoring & risk assessment
- Microbiological risk assessment case study

Member **£60** Non Member **£85**

Best practices for the Bacterial Endotoxin Test: A Guide to the LAL Assay

This guide to the Bacterial Endotoxin Test (BET) provides the reader with an overview of the history, regulation and practical use of the different BET assays. Information on method development, validation and routine testing are discussed as well as more advanced subjects such as depyrogenation, medical devices, trouble shooting and problem samples. The guide should provide a useful reference document for LAL users and laboratory management.

Member **£50** Non Member **£75**

LAL Fact Sheets

A series of Limulus Amoebocyte Lysate (LAL) laminated Fact Sheets on pyrogen/ endotoxin testing have been produced by the LAL Action Group. The series of 6 LAL fact sheets (as a package) currently available are:

- What is LAL/BET?
- Calculation of Endotoxon Limits
- Medical Devices
- Gel Clot Methods
- Photometric Methods
- Product Validations Quantitative Methods

Member **£20**
Non Member **£35**

Purchase in conjunction with Best practices for the Bacterial Endotoxin Test: A Guide to the LAL Assay and receive the **LAL Fact sheets free of charge**

A series of 8 Microorganisms Fact Sheets

The microbial enumeration test and test for specified microorganisms can represent a challenging area for pharmaceutical microbiology. To act as a training aid for new staff, and an aide memoire for more experienced staff, Pharmig have produced eight fact sheets. Seven of the fact sheets profile each one of the key microorganisms (or microbial groups), using colour photographs illustrating growth on agar and by Gram-stain. These are supported by facts relating to the organism's profile and methods for identification. The eighth sheet offers some useful guidance about the interpretation of the test.

Member **£30**
Non Member **£50**

A series of 8 Major Objectionable Microorganisms Fact Sheets

One of the expectations of GMP regulators is that microbiology laboratories are knowledgeable about the main objectionable microorganisms that could be found in pharmaceutical products or in the manufacturing environment. The identification, characterisation and interpretation of these microorganisms can be challenging. To act as a training aid and information resource, Pharmig have produced eight new fact sheets (Fact Sheet Pack 2). Seven of the fact sheets profile some of the most important objectionable microorganisms (together with Geobacillus stearothermophilus, used for biological indicators). An eighth fact sheet provides useful information about risk assessing objectionable microbes.

Member **£30**
Non Member **£50**