ECA Certified Microbiological Laboratory Manager Course*

With a visit of bioMérieux's media manufacturing site in Lyon

Photo: Courtesy bioMérieux

Microbiological Culture Media

26-27 October 2010, Lyon, France

SPEAKERS:

Robert Butler
bioMérieux, France

Dr Corinne de la Foata
bioMérieux, France

Barbara Gerten
Merck, Germany

Dr Bettina Lauer
Vetter-Pharma, Germany

Matthias Schaar
Novartis Pharma, Switzerland

Hartmut Schmidt
CSL Behring, Germany

LEARNING GOALS:

- Quality Control of Microbiological Media
- Regulatory Requirements and Harmonised Methods for Media
- Critical Validation Points on Media Fill test
- From Own Production to Ready-to-Use Media Purchase
- Qualification of Media Suppliers
- Case Study: Ready-to-Use Media for Media Fill

ECA
EUROPEAN COMPLIANCE ACADEMY

* This education course is recognised for the ECA GMP Certification Programme „Certified Microbiological Laboratory Manager". Please find details at www.gmp-certification.eu

Microbiological Culture Media

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Objectives

The formulations of many microbiological media are described in the Pharmacopoeias but with the international harmonisation activities a lot of changes took place.

During this Education Course, you will get familiar with all GMP-relevant aspects of culture media. Experts from pharmaceutical industry and media manufacturing will show you their approach in practise and share their experience from daily business.

Background

Culture media are of essential importance for the microbiological quality control. Or, put it in another way, without culture media there would be no microbiological QC.

The quality of the used media has a direct influence on the results of microbiological analysis. For that reason a strict quality control and assurance of the media is necessary, irrespective whether the media are produced in own laboratories or purchased from a supplier.

Culture media are used for
- Microbiological Monitoring
- Media Fills
- Enumeration Tests
- Test of Specified Microorganisms
- Sterility Test
- Microbial Identification

For all these tests, media are used with different requirements relative to composition and consistency. For instance, media used for environmental monitoring must guarantee the growth of a preferably broad spectrum of microorganisms. In contrast, the detection of specified microorganisms requires selective media which cultivate a special organism and inhibit the growth of other organisms.

Target Audience

- Associates and executives of microbiological laboratory
- Heads of quality control
- Associates of quality assurance and licensing
- Representatives of regulatory bodies involved in microbiological questions

Moderator

Axel H. Schroeder, Concept Heidelberg

Social Event

On Tuesday, October 26 you are cordially invited to a conference dinner. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere

Programme

Quality Control of Media
- Regulatory requirements
- Media manufacturing and storage
- Quality control of media
- Lab and laboratory equipment
- Training of staff
- Analysis of test results
- Deviations

Culture Media- from Own Production to Ready-to-Use Media Purchase
- Outsourcing – Why?
- Pros and cons of own production and outsourcing
- Costs
- Approach
- Examples

Critical Validation Points on Media Fill Test: a Manufacturer Perspective
- Growth promotion and reading
- Sterility and mycoplasma-free aspect
- Filterability

Qualification of Media Suppliers
- Regulatory requirements
- Classifications of suppliers
- Audit intervals
- Audit performance

Media and Media Fills
- Selection and pre-treatment of culture media
- Design of media fill
- Examination of a media fill
- Actions after deviation
- Qualification of personnel

Case Study: Ready-to-use Media for Media Fill
- Experience report: Implementation of ready-to-use media for media fills
- Flexibility: from stainless steel tank to bag system
- Capabilities of bag systems

Reproducibility of ready to use media
- Development of media
- QC strategy
- Performance versus shelf-life

Regulatory Requirements and Harmonised Methods for Media
- Harmonisation of microbiological pharmacopoeia methods
- Sterility test
- Enumeration test
- Test for specified microorganisms
- Non-harmonised methods

On the second day, we will visit bioMérieux's media manufacturing site in Lyon

A world leader in the field of in vitro diagnostics for 45 years, bioMérieux is present in more than 150 countries through 39 subsidiaries. Producing over 180 million culture media plates per year bioMérieux provides a wide range of solutions for microbiological control dedicated to the pharmaceutical, biotechnology and clinical laboratories. From the microbial monitoring of air and surfaces to automated identification, bioMérieux offers a full array of integrated solutions to provide efficient and reproducible microbiological results.

Each new product is validated following the stringent performance criteria expected by customers and set by regulatory bodies such as:

- the FDA,
- the US, European and Japanese Pharmacopoeias, and ISO Standards.

bioMérieux solutions are developed, validated and manufactured in ISO 9001 facilities following Corporate Design Control procedure. All facilities are compliant with the FDA Good Manufacturing Practices, cGMP 21 CFR Part 820. Development and Validation files are archived in Design History Files, which are fully accessible upon audit request.

Please note: bioMérieux reserves the right that participants from direct competitors may not participate in the site visit. In this case we will inform you 14 days after your registration at the latest.

Speakers

Robert Butler, ***bioMérieux, France***
After graduating from a degree in Biochemistry and a Master's degree in Microbiology, Robert joined bioMérieux in the UK in 2004 as a member of their production team in the culture media manufacturing facility. Over the last 6 years, Robert went on to work in the microbiology QC lab and customer support department, specializing in pharmaceutical culture media applications. Robert now holds the position of global product manager for pharmaceutical culture media within the corporate headquarters of bioMérieux in Lyon. Media fill, ready to use plates and Bioball are some of the products Robert is covering for the pharmaceutical industry.

Dr Corinne de la Fota, ***bioMérieux, Lyon, France***
R&D Director for biopharmaceutical applications
Corinne DE LA FOATA holds a Ph D in Human Biology. Since 2010, she has been the director of all biopharmaceutical R&D: culture media, identification, rapid microbiological methods. She worked for several years in research for the development and validation of new culture media, especially for pharmaceutical products such as irradiated media, sterility media and media fill. She was the project leader and technical leader to develop the new media fill range with a colour indicator."

Barbara Gerten,
Merck KGaA, Darmstadt, Germany
After her studies in microbiology and biochemistry, Barbara Gerten was employed in different companies responsible for QC and R+D. Since 2008 she is head of the laboratory RTU Media/Validation at Merck KGaA. She is a member in several national and international bodies of microbiological topics in ISO and CEN.

Dr Bettina Lauer , ***Vetter Pharma Fertigung GmbH & Co. KG, Ravensburg, Germany***
Dr Bettina Lauer graduated in 1994 as a Biologist, specialising in Microbiology. In 1997 she received her Ph.D. in Biology with the focus on Microbiology at the University of Tuebingen, Germany. After 2 years of postdoctoral research she joined Vetter Pharma-Fertigung GmbH & Co. KG in Ravensburg, Germany. During her time at Vetter Pharma-Fertigung GmbH & Co. KG she worked as lab manager of different laboratories focusing on environmental monitoring, testing of utilities and product testing. At present, Dr Bettina Lauer is deputy head of Microbiology and works as a senior expert in Microbiology responsible for customer audits and authority's inspections. As Black Belt she is involved in process optimization projects using the tools of Six Sigma.

Matthias Schaar, ***Novartis Pharma AG, Basle, Switzerland***
Matthias Schaar is currently employed at Novartis Pharma AG in the QA/QC division and is there responsible specialist amongst others for media fill.

Hartmut Schmidt, ***CSL Behring, Marburg, Germany***
After his apprenticeship as Biology Laboratory Technician he has worked in research and process development at CSL Behring (former Behringwerke AG). Since 2003 he is responsible as Coordinator of Validation for Media Fills and other validation processes.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

If the bill-to-address deviates from the specifications on the right, please fill out here:

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Microbiological Culture Media, 26-27 October 2010, Lyon, France

☐ Mr. ☐ Ms.

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **PO Number if applicable**

Street/P.O. Box

City | Zip Code | Country

Phone/Fax

E-Mail (please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)!

Date

Tuesday, 26 October 2010, 09.30 h – 17.30 h
(Registration and coffee 09.00 h – 09.30 h)
Wednesday, 27 October 2010, 08.00 h – 15.30 h
(includes site visit and transfer)

Wednesday 27 October, Site Visit at bioMérieux
Bus transfer to bioMerieux from 8.00 h to 9.00 h
Bus transfer to hotel/airport from 14.30 h to approx. 15.30 h

Venue

NH Hotel Lyon Aéroport
Terminal 1, BP 202
69125 Aéroport Lyon Saint Exupéry , France
email: nhlyonaeroport@nh-hotels.com
Phone +33 4 72 23 05 50
Fax +33 4 72 23 06 60

Fees

ECA-Members: € 1,521.– per delegate + VAT
APIC Members: € 1,605,- per delegate + VAT (does not include ECA Membership)
Non-Members: € 1,690.– per delegate + VAT
EU GMP Inspectorates: € 845.– per delegate + VAT
Including: Conference documentation, lunch on both days, all refreshments, dinner on the first day. The registration fee is payable in advance after receipt of invoice. VAT is reclaimable.

Accommodation

CONCEPT has reserved a limited number of rooms in the conference hotel. Reservation should be made directly with the hotel not later than 27 September 2010. You will receive a room reservation form when you have registered for the course. Please use this form for your room reservation or be sure to mention "VA 6376 ECA Course" to receive the specially negotiated rate for the duration of your stay. Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted CONCEPT HEIDELBERG with the organisation of this event.

CONCEPT HEIDELBERG
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