



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

Photo: Courtesy bioMérieux

Microbiological Culture Media

26-27 October 2010, Lyon, France

SPEAKERS:

Barbara Gerten
Merck, Germany

Dr Bettina Lauer
Vetter-Pharma, Germany

Arnaud Paris
bioMérieux, France

Prof Christine Rozand
bioMérieux, France

Hartmut Schmidt
CSL Behring, Germany

Matthias Schaar
Novartis Pharma, Switzerland

Marthe Ludwig
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



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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.

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.

Marthe Ludwig,

CSL Behring, Marburg, Germany

Marthe Ludwig is responsible at CSL Behring for validation of Media Fills and Microbiology.

Arnaud Paris,

Biopharma global product manager, bioMérieux, France

Mr Paris is global product manager at bioMérieux for the pharmaceutical industry. He holds an engineering degree in Biochemistry and worked for several years as consultant in Biotechnology and Pharmaceutical industry. After an experience in medical devices for injectables he joined bioMérieux and drove numerous developments of culture media, especially with the 3P™ range of products. From the harmonisation of the microbiological examination techniques for non sterile products, to the recent innovative media fill range.

Prof Christine Rozand,

bioMérieux, Lyon, France

Christine Rozand has done a doctors degree in veterinary medicine and held a PhD in Human biology. Since 2003 she is a Professor in Food Safety and Veterinary Public Health. After professional activities as head of Food Research Unit at Veterinary School of Lyon, Professor in the chair "Food Hygiene" of the Veterinary School of Lyon and Head of the National Reference Laboratory on *E. coli* in France, she joined BioMérieux in June 2009 as Global R&D director.

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.

Speakers

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.

Easy Registration



Reservation Form:
CONCEPT HEIDELBERG
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69007 Heidelberg
Germany



Reservation Form:
+ 49 6221 84 44 34



e-mail:
info@concept-heidelberg.de



Internet:
www.gmp-compliance.org



+ 49 6221 84 44 34

Reservation Form (Please complete in full)

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)

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

CONCEPT HEIDELBERG
P.O. Box 101764
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D-69007 Heidelberg
GERMANY

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 week 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 bioMérieux from 8.00 h to 9.00 h
Bus transfer to hotel and airport from 14.30 h to approx.
15.30 h

Venue

NH Hotel Lyon Aéroport
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

Non-Members: € 1,690.- per delegate + VAT
ECA-Members: € 1,521.- per delegate + VAT
EU GMP Inspectorates: € 845.- per delegate + VAT
APIC Members: € 1,605,- per delegate + VAT (does not include ECA Membership)
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 28 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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For questions regarding content:

Mr Axel Schroeder (Operations Director) at
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or per e-mail at schroeder@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Ms Nicole Bach (Organisation Manager) at
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