



Workshop:
Microbial Identification:
Bacteria, Burkholderia cepacia/Complex and Fungi
May 22nd, 2019 - Milan

Speakers:

Arnaud Carlotti

PhD, HDR, CEO Eurofins IDmyk

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Introduction

The identification of microorganisms plays a fundamental role to define causes of sterility testing failures or to determine sources of ongoing microbial investigations. The presence or absence of specified microorganisms in a product is relevant to determine whether a substance or preparation complies with an established specification for microbiological quality. The importance of achieving the microorganisms identity is esplicated in the most relevant Guidances, Regulations and Testing standards applied to pharmaceutical, medical device, biocides and cosmetic industry.

One of the most ubiquitous bacterial species in nature associated with numerous health issues is *Burkholderia cepacia* and its BCC Complex. Pharmaceutical products contaminated with *B. cepacia* and/or it's complex may pose serious consequences to vulnerable patients. Given the robust nature of the organism preventing *B. cepacia* contamination in drugs by addressing the potential sources of this complex in drug manufacturing is a public health goal.

Pharmacopeial Forum designed a new draft General Chapter USP<60> "Microbiological Examination of Nonsterile Products—Tests for *Burkholderia cepacia* Complex" designed as an extension of USP <61>/<62> that focuses on the probability of detection of the BCC over the methods described in USP<62>. The newer technology emphasizes the use of *recA* to identify the microorganisms.

The focus of this Workshop is to explore the «state of the art» to identify microorganisms including the BCC "cluster" in order to avoid out of trends, sterility test failures or other product failures and provide useful knowledge to determine which method can be more appropriate for use in your site.

Practical case studies and examples from our extensive daily analytical activities, developed within our center of excellence in Microbial Identification, will be presented to illustrate main topics and real lab-life aspects.

The Workshop led by our higly skilled experts in Eurofins IDMYK and Eurofins Biolab will also give the opportunity to bring your specific questions and case studies along to the course for discussion and to help to determine a resolution in order to enhance the learning experience.



Who should attend

This workshop will be rewarding for QC managers, QC technicians, AQ managers from pharmaceutical, medical device, biocides and cosmetic industry.

Workshop language

The official workshop language will be English.

Agenda

Introduction and general overview

Part 1

Identification of bacteria:

- Bacterial species definition, Taxonomy and Phylogeny

State of the art in bacterial identification:

- Polyphasic approach

Chemotaxonomic methods:

- Cell wall composition

Phenotypic methods:

- Biochemical, proteomical (MALDI-TOF)

Genotypic methods

- Comparative sequencing unilocus, multilocus
- Specific qPCR testing
- Whole genome sequencing

Typing of strains

Part 2

Isolation and identification of B. cepacia/Complex

- Burkholderia cepacia complex definition
- Virulence, pathogenicity, biofilm formation
- Propagation of this microorganism and its Complex
- New general chapter USP <60>
- Genomic data and usefulness
- Typing of BCC isolates

Part 3

Identification of fungi (yeasts and molds):

- Fungal species definition, taxonomy and phylogeny
- State of the art in fungal identification

Phenotypic mycology:

- Macro-microscopique observations
- Proteomical (MALDI-TOF)

Molecular mycology:

- Comparative sequencing unilocus, multilocus o 25S rDNA, ITS1 and ITS2, other markers
- Specific qPCR testing

Typing of strains

Q&A Session

Speakers

Arnaud Carlotti, PhD, HDR

Arnaud Carlotti completed his PhD at the University of Lyon, France, with a speciality in Microbiology. In 2000, he founded the IDmyk service company that successfully become a leading competence center for detection, identification and molecular typing of microorganisms (bacteria, yeasts and molds) of industrial importance (technological microorganisms and/or contaminants) for the pharma industry. With more than 30 years of experience in industrial microbiology is now President of Eurofins IDmyk. He has published over 30 scientific articles and book chapters including 2018 PDA/DHI publishing "Contamination Control" volume 5 chapter 14.

Dr. Simone Bertolacci

Simone Bertolacci studied at the University of Milan and University College of Dublin. He joined Eurofins Biolab in 2007 as Molecular Biology senior analyst. Highly skilled, has gained over 15 years of expertise and is now Head of Molecular Biology Laboratory in Eurofins Biolab.

Reservation Form (please complete in full):

Title, first name, surname _____

Company _____

Department _____

Address _____

Phone _____ Fax _____

e-mail _____

Important: Please indicate your company's VAT ID Number

If the bill-to-address is different please fill out here:

Registration fee:

150€ + 22% VAT (if applicable)

Discount rate for second participant: 120€ + 22% VAT

Including: Workshop documentation, lunch and refreshment.

The registration fee is payable in advance.

A certificate of attendance for professional development will be given to each participant who completes the workshop.

General terms and conditions:

If you cannot attend the workshop 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:

- until 1 week prior to the workshop 50% of the registration fee will be charged;
- less than 1 week prior to the workshop full registration fee will be charged.

Eurofins BioPharma Product Testing Italy reserves the right to cancel/alter the programme, the speakers, the date or venue. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. Eurofins BioPharma Product Testing Italy is not responsible for airfare, hotel or other costs incurred by registered delegates.

Terms of payment:

The registration fee is payable in advance.

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.

Only after we have received your payment, you are entitled to attend the workshop.

Date _____ Signature _____

Date:

May 22nd 2019, 09.30h - 17.00h
(Registration 09.00h-09.30h).

Venue

Eurofins Biolab srl

Via Bruno Buozzi 2, 20090 Vimodrone (MI)

<https://www.eurofins.it/pharma/contatti/come-raggiungere-eurofins-biolab-sede-di-vimodrone/>

Registration:

Via the attached reservation form, by e-mail at FormazioneFarma@eurofins.com

Bank details:

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We very much look to welcoming you at our upcoming Workshop on May 22nd.