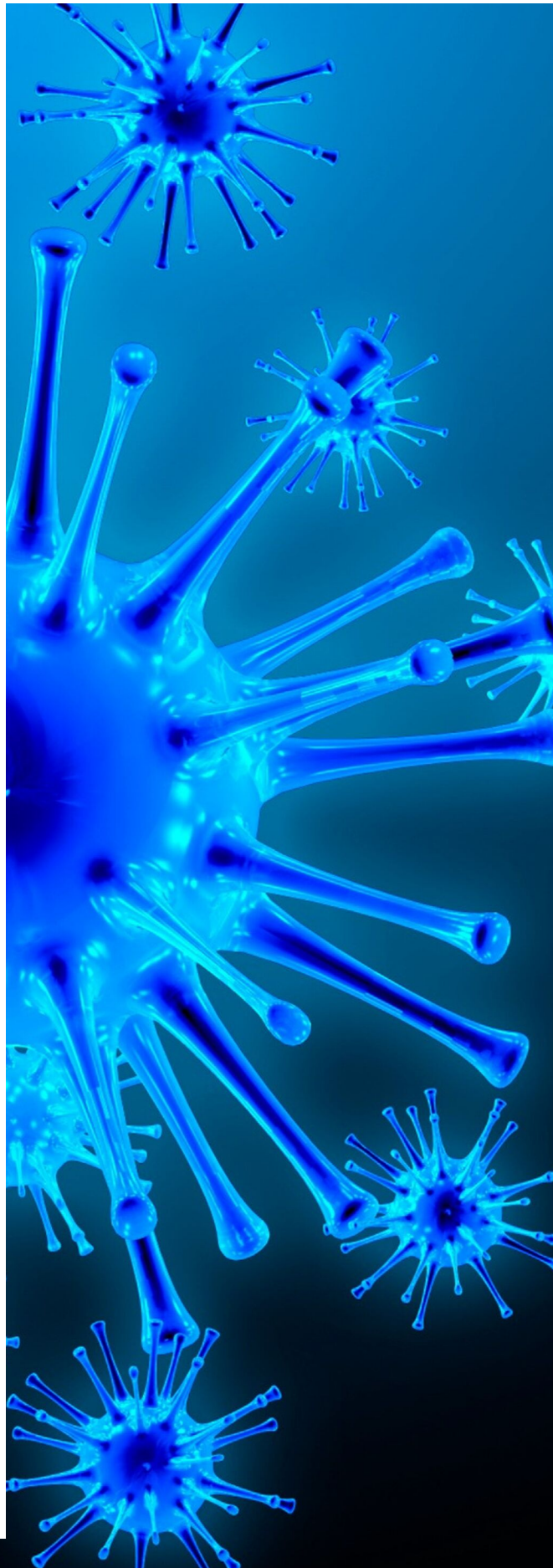
4TH ANNUAL BIOCIDES CONFERENCE 2019

eurofins | BioPharma Product Testing

BPR: FROM REGULATION TO IMPLEMENTATION. HOW TO DEAL WITH BIOCIDAL PRODUCTS

PLANNING A BIOCIDAL PRODUCT FAMILY AUTHORIZATION WORKSHOP: QUATERNARY AMMONIUM COMPOUND

SEPTEMBER 26 - 27, 2019
MELIÁ HOTEL, MILAN - ITALY



Inside

Regulatory framework

Product Authorisation: Practical aspects

Legal and regulatory challenges

Strategic planning of a biocidal product family

Selected speakers

Michele Cavalleri, Eurofins Biolab
Maristella Rubbiani, EU COM - DG Sante
Daniela Romano, Eurofins Biolab
Lucilla Cataldi, Istituto Superiore di Sanità
Stuart Green, Lonza Consumer Care
Giorgia Deplano, Unilever Italy Holdings
Darren Abrahams, Steptoe & Johnson LLP
Anna-Kristina Rudolph, knoell Germany

AGENDA

9:15 Welcome and introduction
Chairman, Michele Cavalleri, GLP Facility Manager - Eurofins Biolab Italy

Session 1: Regulatory aspects framework

9:30 Implementation of the evaluation criteria for Endocrine Disruptors in the light of BPR Regulation 528/2012:
·The EU COM strategy for Endocrine Disruptors
·Application of the guideline
·Impact on dossier evaluation
·Update on next steps and future perspective
Maristella Rubbiani, EU COM - DG Sante Pesticides and Biocides Unit

10:10 Outcome BPF working party

10:40 Question & Answers

10:50 - 11:20 Coffee break

Session 2: Product Authorisation Practical aspects

11:20 Best practice for a product family authorisation:
·The concept of chemical similarity of BPF
·Backbone' composition of the family products
·Grouping of co-formulants
Lucilla Cataldi, Istituto Superiore di Sanità, Italy

12:00 The practical CRO and Consultant point of view in BPF authorisation: Do's and Don'ts
Daniela Romano, Eurofins Biolab Italy

12:40 - 14:00 Lunch break

14:00 Company experience in a BPF authorization
Stuart Green, Lonza Consumer Care

14:30 Company experience in a BPF authorization
Giorgia Deplano, Unilever Italy Holdings

15:10 Question & Answers

15:30 - 16:00 Coffee break

Session 3: Legal/regulatory issues

16:00 Post Brexit scenario
·Implications for compliance strategies and supply chains
·Data sharing issues
·The UK biocides regime
Darren Abrahams, Partner, Steptoe & Johnson LLP, Belgium

16:40 BPR – what next from a regulatory point of view?
·Implications of legislative and guidance changes
·Progress and challenges of the review programme
·Initiatives for industry
·The future of the biocides market
Anna-Kristina Rudolph, knoell Germany

17:20 - 17:30 Questions and answers

The official Conference language will be English.

We will organize in the relaxing area of Melià at the end of the Conference, on 26th, a refreshment for speakers and delegates. Please confirm your presence while submitting.

SEPTEMBER 27, 2019

POST CONFERENCE WORKSHOP

PLANNING A BIOCIDAL PRODUCT FAMILY AUTHORIZATION: QUATERNARY AMMONIUM COMPOUND

Daniela Romano, Regulatory Affair Manager
for Biocidal Products, Eurofins Biolab, Italy

Introduction

A biocidal product family consists of multiple products with different concentrations of the same active substance. All products within a biocidal product family are covered by one authorisation under the Biocidal Products Regulation.

The basic product requirements for a product family are:
Similar uses
Identical active substance(s)
Similar compositions with defined limits
Similar hazard profile
Similar effectiveness

For all applications data must be generated as specified in Annex III BPR for the product or the products from the family.

This Workshop aims to provide a fully understanding of all the aspects related to the strategic planning of a biocidal product family.

Agenda (9.30h - 12.30h)

09:30 General Introduction:
Biocidal Product Family concept

09:45 Strategic and technical aspects to be evaluated when planning of a biocidal product family

10:30 Case Study: Introduction of a number of products to be allegedly inserted in the family

10:45 Coffee break

11:00 Case Study: Data gap analysis and structuring of the biocidal product family. How to outline the testing plan by identifying the most appropriate product to use for different tests

12:15 - 12:30 Questions and answers

The official Workshop language will be English.

Delegates can select a joint registration to attend both the Conference and the Workshop with a discount rate.

For more details on speakers and further assistance please us at:
FormazioneFarma@eurofins.com

Full Conference and Workshop details:
https://www.eurofins.it/formazione/conferenze-e-workshop/

TOP SPEAKERS

Michele Cavalleri, Chairman
Eurofins Biolab, Italy

GLP Facility Manager of the Biocidal Products Division in Eurofins Biolab (Italy). He has gained a solid expertise on efficay assessment of disinfectants. He is also member of the European Committee CEN TC 216 that establishes standardized methods of test and requirements for the antimicrobial efficacy of chemical disinfectants and antiseptics.

Lucilla Cataldi
Istituto Superiore di Sanità (ISS), Italy

With a degree in chemistry joined Istituto Superiore di Sanità (ISS, Rome) in 2003 as a scientist. Since 2005, has worked in the evaluation of technical dossiers and drafting of Competent Authority Reports (CARs) for the inclusion/approval of active substances assigned to Italy under the Review Programme for Biocides. Evaluation of technical dossiers and drafting of Product Assessment Reports (Pars) for the authorization of biocidal products at national level since 2009. BPC-APCP-Working Group flexible member at ECHA since 2013.

Maristella Rubbiani
National Seconded Expert at EU COM - DG Sante - Pesticides and Biocides Unit

Maristella is a member of the CA, BPC Committee and the national Committee for authorization of biocides and PPPs. She is responsible of the national database for poison centres according to Art 45 CLP and has more than 30 years of experience in regulatory toxicology and C&L for risk assessment of substances and preparations. She has a degree in Biology and a PhD in Industrial and Environmental Hygiene.

Giorgia Deplano
Unilever Italy Holdings

After a degree in Pharmaceutical Chemistry, she joined Unilever R&D organization in 2002, gaining solid experience in technical projects management for different product types. Since 2015 she has been working on BPR compliance for Household care category where she manages technical aspects for Biocidal product authorisation in collaboration with internal and external counterparts.

Stuart Green
Regulatory Manager, Lonza Consumer Care

Stuart Green is Regulatory Manager in the Consumer Care Business Unit at Lonza. He is based in Manchester in the UK and his main focus is on Biocidal Products and Biocidal Product Families.

Daniela Romano
Eurofins Biolab, Italy

After her PhD in Biophysics and a Post Doc position in medical research, Daniela has been working with Eurofins, mainly on Biocides, since 2003. She was first in charge of stability studies and then the management of the Chemistry laboratory. She managed projects aiming towards Biocidal Products authorisation for several years and is now also involved in the risk assessment procedures. She has sound experience with a large variety of biocidal products.

Darren Abrahams
Partner, Steptoe & Johnson LLP, Belgium

Darren enables clients throughout the chemicals and life sciences supply chain to get and keep their products on the European Union market. He focuses on defense of products through strategic advice, advocacy before institutions and agencies, and litigation before EU and national courts and tribunals. He has a wealth of experience with the EU regulation of biocidal products, plant protection products (agrochemicals), REACH, classification, labelling and packaging, GM food and feed, cosmetics, and endocrine disruptors.

Anna-Kristina Rudolph
knoell Germany GmbH

Kristina joined knoell's Efficacy Task Force in 2017. Since then she has been working as an efficacy expert and regulatory manager for biocides, thereby supporting clients in projects ranging from active substance approvals to authorisations of complex biocidal product families. One of her main areas of expertise is the development of customized efficacy testing strategies for biocides.

EVENT DETAILS

EARLY BIRD PRICE - VALID UNTIL JULY 26, 2019

☐ Conference and Workshop:
280€ + VAT (if applicable)

☐ Conference attendance only (September 26, 2019):
*210€ + VAT (if applicable)

☐ Workshop attendance only (September 27, 2019):
**90€ + VAT (if applicable)

FULL PRICE - VALID AFTER JULY 26, 2019

☐ Conference and Workshop:
370€+ VAT (if applicable) - First delegate
☐ 330€ + VAT (if applicable) - Second delegate

☐ Conference attendance only (September 26, 2019):
*300€ + VAT (if applicable) - First delegate
☐ *260€ + VAT (if applicable) - Second delegate

☐ Workshop attendance only (September 27, 2019):
**110€ + VAT (if applicable) - First delegate
☐ **100€ + VAT (if applicable) - Second delegate

*Day 1: Lunch included;**Day 2: Lunch not included

PAYMENT OPTION VALID: BANK TRANSFER

REGISTRATION FORM

Title, first name, second name:

_____

Company:

_____

Department:

_____

Company address:

_____

Bill-to-address (if different):

_____

Phone/Mobile number:

_____

E-mail:

_____

Important: Indicate your company's VAT ID Number:

_____

I will attend the post-conference refreshment on September 26, 2019:

YES ☐ NO ☐

Date _____ Signature_____

VENUE AND TIMING

Meliá Milano, *****Hotel
Via Masaccio, 19, 20149 - Milan, Italy
https://www.melia.com/en/hotels/italy/milan/melia-milano/index.htm

Conference: September 26, 2019
09.15h - 17.30h
Registration of delegates: 08:45h-09:15h

Workshop: September 27, 2019
09.30h - 12.30h
Registration of delegates: 09:00h-09:30h

BANK DETAILS

UNICREDIT SPA
ABI: 2008 CAB: 20600 CIN: N
C/C: 000004846325
IBAN: IT04 N020 0820 6000 0000 4846 325
VAT ID: 00762140960

ORGANIZATION AND CONTACTS

Eurofins BioPharma Product Testing Italy
Via Bruno Buozzi, 2
20090 - Vimodrone (MI)
Tel. + 39 0225071535
e-mail: FormazioneFarma@eurofins.com
https://www.eurofins.it/formazione/conferenze-e-workshop/

General terms and conditions

The registration fee is payable in advance through bank transfer. Only after we have received your payment, you are entitled to attend the Conference and/or Workshop.

If you cannot attend the Conference/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 conference 50% of the registration fee will be charged;
- less than 1 week prior to the conference 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. Your data will be processed in accordance with EU regulation no. 679 of 27 April 2016 and Legislative Decree 30 June 2003, n. 196.