eurofins | BioPharma Product Testing

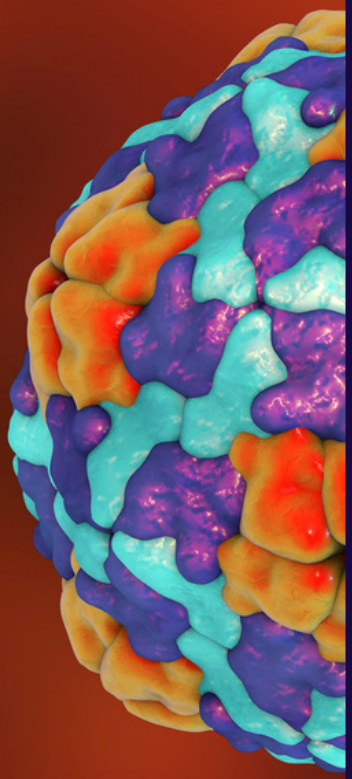
6TH CONFERENCE ON BIOCIDES

JUNE 21, 2023

HALF DAY WORKSHOP

JUNE 22, 2023

ENTERPRISE HOTEL, MILAN



Selected speakers:
Michele Cavalleri | Eurofins BPT Italy
Cindy van der Mer | CTGB
Jordane Wodli | Policy Officer, European Commission
Sofia Ribeiro | Christeyns
Darren Abrahams | Steptoe & Johnson LLP
Linda Musitelli | Eurofins Regulatory & Consultancy Services Italy
Siobhan Murphy | Contec Cleanroom Ltd, UK
Marcel Hulsman | ERM
Martijn van Velthoven | Troy Corporation

Organization and contacts:
Eurofins BioPharma Product Testing Italy
FormazioneFarma@eurofins.com

JUNE 21, 2023 | CONFERENCE AGENDA

Session 1: Regulatory Aspects

9:00 – 9:30
Member state overview
Cindy van der Mer | CTGB

9:30 – 10:00
BPR requirements from Competent Authority perspective
To be defined

10:00 – 10:30
Company experiences of biocidal product families:

- Before and after the Biocidal Product Families Concept
- Notes on Preparation, submission, approval, and post-approval

Sofia Ribeiro | Christeyns

10.30 - 11.00 Coffee Break

Session 2: Updates on Testing and Efficacy

11.00 - 11.30
Physical hazards testing/update of the physico-chemical TAB
Linda Musitelli | Eurofins Regulatory & Consultancy Testing Italy

11.30 - 12.00
Efficacy evaluation of disinfectants PT-1 to PT-5, PT-21 and treated articles PT-10 based on current development and ECHA efficacy guidance including biofilm-activity testing
Michele Cavalleri | Eurofins BioPharma Product Testing Italy

12.00 - 12.30
Disinfectant efficacy: Experience of preparing efficacy for a product family and how the guidance works in practice

- State of Play: Biocidal Product Family guidance
- State of Play: EU Efficacy Guidance
- Implementing the guidance in practice
- Complications and Uncertainties
- Outcomes
- Keeping up to date

Siobhan Murphy | Contec Cleanroom Ltd

12.30 - 14.00 Lunch Break

JUNE 21, 2023 | CONFERENCE AGENDA

Session 3: BPR and sustainability

14.00 – 14.30
EU Chemical Strategy for Sustainability (CSS)
Marcel Hulsman | ERM

14:30 – 15:00
Industry perspective sustainability & biocides
To be defined

Session 4: The assessment of Endocrine Disrupting chemicals under the BPR

15.00 - 15.30
Overview of discussions on EDC criteria at horizontal level
Jordane Wodli | Policy Officer, European Commission

15.30 - 16.00
ED assessments and legal issues
Darren Abrahams | Steptoe

16.00 - 16.30
Industry ED assessment experiences
Martijn van Velthoven | Troy Corporation

16.30 - 17.00 Q&A

NOTES:
The official Conference language will be English.

JUNE 22, 2023 | HALF DAY WORKSHOP

OVERVIEW OF THE REGULATORY REQUIREMENTS AND EXPECTATIONS APPLIED TO EFFICACY UNDER THE EU BIOCIDAL PRODUCTS REGULATION

AGENDA (9.00H - 13.00H)

- General efficacy information requirements
  - o Review of test requirements for product types 1 to 5
  - o Relevant test organisms
  - o Discussion of available standard test methods

- Acceptable test methods and testing strategies
  - o Discussion of tiered testing
  - o What is meant by performance standards, pass/fail criteria
  - o What happens when data does not meet the requirements
  - o Quality expectations for individual reports and data sets

- Claim substantiation
  - o Identifying the potential label claims made for a product and how (using the Guidance) to use the available test data to support them

- Borderlines/scope issues

- Q&A

Speakers:

- Linda Musitelli | Eurofins Regulatory & Consultancy Testing Italy
- Michele Cavalleri | Eurofins BioPharma Product Testing Italy

NOTES:

- The official Workshop language will be English.
- Coffee break included, Lunch not included for the half-day Workshop.
- Delegates can select a joint registration to attend both the Conference and the Workshop with a discount rate, see submission form.
- For more details on speakers and further assistance please contact us at: FormazioneFarma@eurofins.com

TOP SPEAKERS

Michele Cavalleri | GLP Facility Manager of the Biocidal Products Division in Eurofins BioPharma Product Testing Italy.

Michele Cavalleri has a solid background as GLP and ISO 17025 Test Facility Manager within Eurofins BioPharma Product Testing Italy for over 14 years.

From a technical point of view, he has gained a strong and reliable expertise, first as a validation manager and afterwards as Subject Matter Expert within Eurofins BPT Italy, on efficacy validation of surfaces and equipment disinfection, as well as aseptic filtration procedures for the biopharmaceutical sites. He is also member of the European Committee CEN TC 216 that establishes standardized methods of test and requirements for the disinfectant and virucidal efficacy of chemical disinfectants and antiseptics.

Cindy van der Meer | Account Manager Biocides, CTGB, Netherlands

Cindy van der Meer is Account Manager Biocides at the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) in the Netherlands. Cindy has a PhD in Medical Biology and joined the biocides team of the Ctgb in 2010. She has been working as a project manager for 8 years. Since 2018 she is Account Manager of the Biocides team and in this role, she is the first point of contact for companies wishing to apply for a biocides registration at the Ctgb.

Sofia Ribeiro | Regulatory Affairs Project Manager at Christeyns Portugal

Sofia is a Biochemist, specialized in Clinical Biochemistry. With 7 years of experience in working with biocidal product regulation (BPR) and biocides, within the Corporate Regulatory Affairs Team at Christeyns, she is responsible for the development, preparation, and submission of BPR dossiers, as well as follow-up on on-going processes.

Siobhan Murphy | Regulatory Specialist, Contec Cleanroom Ltd, UK

Siobhan is a Regulatory Specialist with over 10 years experience in the field of chemical regulations, primarily biocidal product legislation. Having previously worked as a consultant, Siobhan joined Contec in April 2018 to manage the authorisation of their cleanroom disinfectants in the EU, GB and global markets.

Jordane Wodli | Policy Officer, European Commission

Jordane works at the European Commission at DG Environment, Unit Sustainable Chemicals, on policy developments on EDs, and on POP and PIC regulations. Before joining the European Commission this year, he worked for 5 years at the French Ministry of Environment at the Chemical Unit until 2017. Then after he worked as parliamentary assistant for a member of French National Parliament.

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.

Marcel Hulsman | Partner, ERM

Marcel has over 25 years of experience working in the specialty chemical industry, consultancy and governmental agencies. He joined the Ctgb (Board for the authorisation of plant protection products and biocides, NL) in 2013 as relationship / account manager and since 2018 he led Ctgb's biocide team.

Starting at ERM in 2021, he supports clients in providing regulatory awareness and strategic advice on biocidal product authorisation and active substance approval under the EU - Biocides Regulation (BPR) and national (transitional) biocides legislation. Marcel has a MSc in Chemical Engineering and a PhD in Analytical Chemistry from the University of Twente (NL).

Linda Musitelli | Senior Consultant Eurofins Regulatory & Consultancy Services Italy

M.Sc. Linda Musitelli's academic background is in biotechnology and chemical and toxicological risk assessment. She has joined Eurofins BPT in Italy in 2017, Consultancy division where she is responsible for activities related to the registration of biocidal products. Linda has a wealth of experience to enable clients to bring products to market and to develop cost-effective strategies. Through strategic advice she successfully drives clients to overcome the complex challenges of the regulatory scenario affecting biocidal products.

Martijn van Velthoven | Global Director Regulatory at Arxada

Business leader and EUROTOX Registered Toxicologist with over 15 years of product safety experience in cosmetic, detergent, biocides, foods, FMCG, fragrance, chemical industry.

Thorough global regulatory toxicology and regulatory compliance expertise regarding food, environmental and chemicals legislation, with a specificatie focus on Europe. Specialties: regulatory & toxicological leadership, regulatory (eco)toxicology (FMCG (cosmetics, detergents, foods), fragrance, industrial chemicals, biocides), regulatory compliance, product safety, advocacy/issue management and innovation support.

SUBMISSION FORM

TITLE, FIRST NAME, SURNAME _____

COMPANY _____

DEPARTMENT _____

ADDRESS _____

PHONE _____ MOBILE_____

E-MAIL _____

IMPORTANT: PLEASE INDICATE YOUR COMPANY'S VAT ID NUMBER

_____

IF THE BILL-TO-ADDRESS IS DIFFERENT PLEASE FILL OUT HERE:

_____

_____

EARLY BIRD FEE - VALID UNTIL MAY 10, 2023

- ☐ CONFERENCE & HALF DAY WORKSHOP
  350€ + VAT (VAT APPLICABLE TO ITALIAN COMPANIES ONLY)
- ☐ CONFERENCE ONLY (JUNE 21, 2023)
  295€ + VAT (VAT APPLICABLE TO ITALIAN COMPANIES ONLY)
- ☐ WORKSHOP ONLY (JUNE 22, 2023)
  110€ + VAT (VAT APPLICABLE TO ITALIAN COMPANIES ONLY)

FULL FEE - VALID AFTER MAY 10, 2023

- ☐ CONFERENCE & HALF DAY WORKSHOP
  395€ + VAT (VAT APPLICABLE TO ITALIAN COMPANIES ONLY)
- ☐ CONFERENCE ONLY (JUNE 21, 2023)
  345€ + VAT (VAT APPLICABLE TO ITALIAN COMPANIES ONLY)
- ☐ WORKSHOP ONLY (JUNE 22, 2023)
  130€ + VAT (VAT APPLICABLE TO ITALIAN COMPANIES ONLY)

NOTES:

- THE REGISTRATION FEE IS PAYABLE IN ADVANCE
- DAY 1: LUNCH INCLUDED; DAY 2: LUNCH NOT INCLUDED
- 15% DISCOUNT OF HOTEL RATES TO BE APPLIED DEPENDING ON HOTEL ROOMS AVAILABILITY

FEE INCLUDES: DOCUMENTATION, LUNCH AND REFRESHMENT.
A CERTIFICATE OF ATTENDANCE WILL BE GIVEN TO EACH PARTICIPANT WHO ATTENDS THE CONFERENCE.

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 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 RESERVES THE RIGHT TO CANCEL OR 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 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 CONFERENCE.

DATES:
CONFERENCE
WEDNESDAY JUNE 21, 2023
09:00H - 17.00H
(REGISTRATION 08:45H-09:00H)

WORKSHOP
THURSDAY JUNE 22, 2022
09:00H - 13.00H
(REGISTRATION 08:45H-09:00H)

VENUE:
ENTERPRISE HOTEL
CORSO SEMPIONE 91, 20149 MILANO
HTTPS://WWW.ENTERPRISEHOTEL.COM/EN/LOCATION.HTML

REGISTRATION:
VIA THE ATTACHED RESERVATION FORM, ONLINE FORM OR BY E-MAIL AT:
FORMAZIONEFARMA@EUROFINS.COM

BANK DETAILS:
UNICREDIT SPA
ABI: 2008 CAB: 20600 CIN: N
C/C: 000004846325
IBAN: IT04 N020 0820 6000 0000 4846 325
BIC/SWIFT: UNCRITM1257

VAT NUMBER: 00762140960

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WE VERY MUCH LOOK TO WELCOMING YOU ON IN MILAN.

DATE _____

SIGNATURE _____