eurofins | BioPharma Product Testing

7TH CONFERENCE AND WORKSHOP ON BIOCIDES

CONFERENCE: 05 MARCH 2025
HALF-DAY WORKSHOP: 06 MARCH 2025

ENTERPRISE HOTEL MILAN, ITALY

Leading Authorities and Industry Experts:

Chiara Pecorini, European Chemicals Agency (ECHA)
Raffaella Perrone, Italian Ministry of Health
Lucilla Cataldi, Italian National Institute of Health (ISS)
Fabien Rouessay, Redebel Regulatory Affairs
Daniela Romano, Diversey
Darren Abrahams, Steptoe & Johnson LLP
Michele Cavalleri, Eurofins BioPharma Product Testing Italy
Linda Musitelli, Eurofins Regulatory & Consultancy Services
Simone Bertolini, Eurofins Regulatory & Consultancy Services

ORGANISATION: EUROFINS BIOPHARMA PRODUCT TESTING ITALY
CONTACTS: TRAINING-ITALY@BPT.EUROFINSEU.COM

05 MARCH 2025 | CONFERENCE | HR 9.00 - 17.00

Session 1: Updates from the authority

Recent updates and future outlook - Overview from ECHA:

- Update on ECHA processes
- Guidance updates
- Future perspective

Chiara Pecorini | European Chemicals Agency (ECHA)

Biocidal Products Regulation - State of the art:
Overview from the Italian Ministry of Health

Raffaella Perrone | Italian Ministry of Health

Session 2: Regulatory aspects

Regulatory insights on main challenges for active substance applications and renewals under the BPR:

- Different types of active substance applications under the BPR and associated challenges
- Data generation, data sharing, and legal aspects
- Evaluation of potential endocrine disrupting properties
- Lessons from (pre-Submission) and discussions with evaluating competent authorities (eCAs)

Linda Musitelli, Simone Bertolini | Eurofins Regulatory & Consultancy Services Italy

Discordances between Member States under BPR:

- Introduction and efinitions
- PT-2 swimming pool case
- PT-5 drinking water case
- Other cases encountered
- Consequences - How to manage?

Fabien Rouessay | Redebel Regulatory Affairs

9.00 - 9.30 REGISTRATION AND WELCOME COFFEE | 10.30 - 11.00 COFFEE BREAK

Lack of harmonisation and frequent guidance changes: Impact on the industry. Case studies on:

- PT-19 products
- PT-2 products
- Carrier based products

Daniela Romano | Diversey

Session 3: Technical insights

Annual evaluation of biocidal products technical dossiers assigned to the Italian National Institute of Health the (ISS):

- Main Challenges to compliance under ISS perspective
- Recommendations to develop targeted action plans
- Latest updates on biocides

Lucilla Cataldi | Italian National Institute of Health (ISS)

Antimicrobial resistance development for biocides. New resistance guidance:

- Status update from CEN TC 216
- Echa Guidance Document point of view
- Potential approaches: Literature review, methods, market surveillance

Michele Cavalleri | Eurofins BioPharma Product Testing Italy

PFAS and biocides. Emerging concerns and regulatory perspectives:

- Current rules
- Future regulatory impacts
- Lessons from beyond the EU

Darren Abrahams | Steptoe & Johnson LLP

NOTES:

- The official Conference language will be English.
- Delegates can select a joint registration to attend both the Conference and the Workshop with a discount rate, see event details and general conditions.
- Agenda might be subject to change.

12.45 - 14.00 LUNCH BREAK | 15.15 - 15. 45 COFFE BREAK | 17.00 FINAL CLOSURE

06 MARCH 2025 | WORKSHOP | HR 9.00 - 13.00

Operational Insights and Challenges under the BPR Regulation

Evolving challenges of the BPR Regulation: Past and present

- Transitional period in Europe: Operations and differences between Member States
- Dossier preparation: Risk sssessment challenges

Linda Musitelli, Simone Bertolini | Eurofins Regulatory & Consultancy Services Italy

Navigating labeling challenges under the BPR Regulation

- BPR rules and restrictions on labeling: Text amount and readability
- Claims and biocides: Compliance and Best Practices
- Impact of the CLP revision on labeling

Linda Musitelli, Simone Bertolini | Eurofins Regulatory & Consultancy Services Italy

Biocidal Product Families (BPFs): Selecting a representative test product for efficacy evaluation

- Determining a representative test product for efficacy evaluation of a BPF
- Designing appropriate bridging studies
- General approach for efficacy assessment

Michele Cavalleri | Eurofins BioPharma Product Testing Italy
Linda Musitelli, Simone Bertolini | Eurofins Regulatory & Consultancy Services Italy

NOTES:

- The official Workshop language will be English.
- 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 event details and general conditions.
- For more details and further assistance please contact us at: TRAINING-ITALY@BPT.EUROFINSEU.COM

9.00 - 9.30 WELCOME COFFE | 11.00 - 11.30 COFFEE BREAK | 13.00 FINAL CLOSURE

LEADING AUTHORITIES AND INDUSTRY EXPERTS

Chiara Pecorini | ECHA

Chiara joined the European Chemicals Agency (ECHA) in 2013 and is currently leading the Biocidal Products team in the Biocidal Products Unit.
Before joining ECHA, she worked in the Chemical Assessment and Testing Unit at the European Commission - Joint Research Centre in Ispra. Prior she held a post-doctoral fellowship at the Veterinary Medicine Faculty of the University of Milano. She also collaborated with the French National Institute for Agricultural Research and was a visiting research associate at the Department of Physiology and Biophysics, University of Colorado Denver.
Chiara Pecorini holds a master's degree in veterinary biotechnology and a PhD in biotechnology applied to veterinary and zootechnical sciences.

Michele Cavalleri | Eurofins BioPharma Product Testing Italy

Senior Scientific Director of Eurofins BioPharma Product Testing Europe for the validation of efficacy processes, including aseptic filter validation and virus retention processes.
He is also Eurofins Business Unit Cluster Manager the Biocide & Virus testing units of Eurofins BioPharma Product Testing Italy as well as GLP/ISO 17025 test facility manager at the Eurofins site of Milan.
Michele has a sound background in microbiology (MSc in microbial genetics) and virology and worked in Eurofins as an analyst and GLP study director in the microbiology department for many years. He strongly contributed to setup the filter validation testing lab in the site of Milan to meet the requirements of the biopharmaceutical and medical device industries.
He is also an expert of CEN/TC 216 that establishes standardised methods of test and requirements for the antimicrobial efficacy of chemical disinfectants and antiseptics.

Lucilla Cataldi | Italian National Institute of Health (ISS)

Lucilla is currently a Senior Scientist at the Istituto Superiore di Sanità (ISS) in Rome. She has extensive experience in evaluating technical dossiers and drafting Competent Authority Reports (CARs) for the approval of active substances assigned to Italy under the Review Programme for Biocides, a role she has held since 2005. Since 2009, she has been responsible for evaluating technical dossiers and drafting Product Assessment Reports (PARs) for the authorisation of biocidal products at the national level. She has been a flexible member of the BPC-APCP Working Group at the European Chemicals Agency (ECHA) since 2013. In 2020, she became the Coordinator of the ISS Working Group for Biocidal Products.

Raffaella Perrone | Italian Ministry of Health

Italian Ministry of Health expert within the General Directorate for Medical Devices, Pharmaceutical Services and Safety in Healthcare.

Fabien Rouessay | Redebel Regulatory Affairs

Fabien Rouessay spent some 15 years in the chemical industry and more specifically in the biocidal regulation area before joining Redebel Regulatory Affairs seven years ago as project and consortium manager. In addition to providing expertise during the dossier preparation phase, he assists applicants in defending their dossiers throughout the challenging evaluation period and beyond, also by representing them at meetings with competent authorities.

LEADING AUTHORITIES AND INDUSTRY EXPERTS

Daniela Romano | Diversey

After her Ph.D. in Biophysics and a Post Doc position in medical research, Daniela has been working on Biocides, since 2003.
She has been a GLP study director for chemical physical studies and then the manager of a GLP Chemistry laboratory.
Since 2013 she manages projects aimed to Biocidal Products authorisation, offering support from the data gap analysis to the product authorisation.
Due to her previous laboratory experience, her expertise on Biocidal products covers both the testing and the regulatory aspects of the projects.
From 2021 to 2024, she worked with knoell as senior regulatory consultant for biocidal products. In 2025 she started a new adventure, in the biocides word, joining Diversey as senior regulatory affairs specialist.

Linda Musitelli | 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.

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.

Simone Bertolini | Eurofins Regulatory & Consultancy Services Italy

Specialising in biocides, Simone offers strategic support to clients, expertly navigating complex chemical regulations to deliver high-quality, customised solutions. With a commitment to promoting safe and compliant practices within the chemicals sector, Simone focuses on ensuring your biocidal products meet all regulatory standards

EVENT DETAILS AND GENERAL CONDITIONS

REGISTRATION LINK | HTTPS://FORM.JOTFORM.COM/242610699925466

REGISTRATION FEES:

EARLY BIRD PRICE - VALID UNTIL 24 JANUARY 2025

- CONFERENCE AND HALF-DAY WORKSHOP: 400€ + VAT *
- CONFERENCE ATTENDANCE ONLY (5 MARCH 2025): 360€ + VAT *
- HALF-DAY WORKSHOP ATTENDANCE ONLY (6 MARCH 2025): 160€ + VAT *

* VAT APPLICABLE TO ITALIAN COMPANIES ONLY

FULL PRICE - VALID AFTER 24 JANUARY 2025

- CONFERENCE AND WORKSHOP: 490€ + VAT *
- CONFERENCE ATTENDANCE ONLY (5 MARCH, 2025): 440€ + VAT *
- HALF-DAY WORKSHOP ATTENDANCE ONLY (6 MARCH, 2025): 230€ + VAT *

* VAT APPLICABLE TO ITALIAN COMPANIES ONLY

PAYMENT OPTION VALID: BANK TRANSFER

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: TRAINING-ITALY@BPT.EUROFINSEU.COM
WWW.EUROFINS.IT/BIOPHARMA

VENUE

ENTERPRISE HOTEL MILAN
CORSO SEMPIONE 91 - 20149 MILAN
HTTPS://WWW.ENTERPRISEHOTEL.COM/EN/

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.

eurofins | BioPharma Product Testing

EVENT HIGHLIGHTS

6 PAST EDITIONS OF EXCELLENCE BRINGING TOGETHER

300+ ATTENDEES

100+ COMPANIES

KEY SPEAKERS

JOIN US!

ORGANISATION: EUROFINS BIOPHARMA PRODUCT TESTING ITALY
CONTACTS: TRAINING-ITALY@BPT.EUROFINSEU.COM