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Biotech
Academy
In Rome

Specialized Update Course in
**CONTAMINATION CONTROL STRATEGY
IN A LIGHT OF ANNEX 1 IMPLEMENTATION**

November 20th and 21st, 2023

Scientific Direction



Prof. Giorgio Minotti
Full Professor
of Pharmacology
Università
Campus Bio-Medico
di Roma



Dott. Valerio Branchi
President
Biotech Academy
in Rome



Igor Gorsky

Igor Gorsky has been a pharmaceutical industry professional for over 35 years. He held multiple positions with increasing responsibility at Alpharma Wyeth and Shire and has worked in Production, Quality Assurance, Technical Services and Validation, including as an Associate Director of Global Pharmaceutical Technology at shire. He is currently holding a position as a Principal Consultant at Valsource. He is leading the PDA Water Interest Group. He is also leading the PDA Task Force for a revision of PDA TR 29: Points to Consider for Cleaning Validation. In addition, he is a member of ASTM E55 and one of the authors of ASTM E3106 and E3207. He is the author of several books, namely Principles of Parenteral Solution Validation (2019) and one of the authors of Pharmaceutical Process Scale-Up (1995, 2000, 2005).

PURPOSE

The Specialist Course in Contamination Control Strategy in the Light of Annex 1 Implementation aims to provide knowledge and insight into the new version of Annex 1 "Manufacture of Sterile Medicinal Products" which came into force in August 2023. The new version of Annex 1 is significantly modified from the previous version, with a focus on critical analysis of manufacturing processes, facilities and personnel training. In addition, for the first time, there is a section dedicated to the use of "single-use" materials, which are revolutionizing manufacturing processes, particularly for large molecule and advanced therapy products.



OBJECTIVES

The Specialist Course in Contamination Control Strategy in the Light of Annex 1 Implementation aims to provide new elements to a professional capable of understanding the regulatory requirements aimed at designing the quality and safety of sterile medicinal products with a risk assessment approach involving all aspects of production.

KEY FACTS



Participants

The course is primarily intended for professionals, managers, directors, and specialists working in the pharmaceutical and biotechnology fields, such as quality, process engineering, validation, regulatory.

Duration and organization

The training course is divided into **2 days** of frontal lessons, on the **20th** and the **21st** of **November**. It will be delivered in phygital mode, i.e. with the possibility of participation in person and/or remotely, through the e-learning platform of the Campus Bio-Medico University of Rome (<https://ecm.unicampus.it>).



During breaks participants will be able to do the VR experience offered by Pharma Integration. Users will be allowed to immerse themselves in a virtual environment that replicates the exact interface of the real machine, enabling a detailed view of the system down to the smallest construction details. The software powering the simulated machine is identical to that found on the actual machine, thus enabling an innovative, efficient, and secure approach.

This activity will be held outside the conference hall and is not ECM accredited.

Registration fee

The **registration fee** is **€1.875,00**.

The payment must be made to the following bank account:

Campus Bio-Medico University of Rome - Unicredit Spa

IBAN: IT04A0200805181000300478588

Reason: Name and surname of the participant, Contamination Control Strategy Course
Discounted rates are available for PDA members, PhD and for participants from sponsoring companies.

No refund is provided under any circumstances.



KEY FACTS



Application process:

To register please send an email to ucbmacademy@unicampus.it

Maximum number of participants: 50



Released Title:

At the end of the course, a certificate of participation from the Campus Bio-Medico University of Rome will be issued.

For those who participate in person, there is also the possibility to take 13 CME credits.



Location

Università Campus Bio-Medico di Roma - Aula Magna Trapezio
Via Álvaro del Portillo, 21 - 00128 Roma



Language:

The official language of all activities and materials is English



Save the dates

Application deadline: **17th november 2023**



SCHEDULE - NOVEMBER 20TH

08.30 Opening and introduction

G. Minotti, V. Branchi

09.30 Subject 1: Introduction of PDA Italy

O. Cultrera

10.30 Subject 2: ELEMENTS OF A CONTAMINATION CONTROL STRATEGY

I. Gorsky

11.30 Coffee Break/VR Experience

12.30 Subject 3: PROCESS DESIGN, MICROBIAL CONTROL, AND MONITORING

I. Gorsky

13.30 Lunch

14.30 Subject 4: FACILITIES AND UTILITIES

I. Gorsky

15.30 Subject 5: RAW MATERIALS

I. Gorsky

16.30 Coffee Break/VR Experience

17.00 Closure of the first day

L. Sibilio

17.30 Sponsor Speech: PROCESS RISK BASED APPROACH TO CCS

G. Ponzo (Pat Way)



SCHEDULE - NOVEMBER 21ST

08.30 Subject 1: ENVIRONMENTAL CONTROL, VALIDATION, AND MONITORING

I. Gorsky

10.00 Subject 2: PERSONNEL TRAINING AND QUALIFICATION

I. Gorsky

11.00 Coffee Break/VR Experience

11.30 Subject 3: EQUIPMENT DESIGN, VALIDATION AND ONGOING CONTROL

I. Gorsky

13.00 Lunch

14.00 Subject 4: PRODUCT CONTAINERS AND CLOSURES

I. Gorsky

15.00 Subject 5: QUALITY SYSTEMS

I. Gorsky

16.00 Coffee Break/VR Experience

16.30 Conclusions

L. Sibilio

17.00 Sponsor Speech: Design of Aseptic Isolator handling toxic powder/liquid

S. Butti (FPS)

17.30 Sponsor Speech: Annex 1 & Robotic Fill Finishing

C. Bechini (Pharma Integration)

18.00 Cocktail and final greetings

UCBM Academy

The UCBM Academy promotes post-graduate training at the Campus Bio-Medico University of Rome through courses in line with the most current scenarios and the most relevant needs of the labor market, within developed programs also in partnership with companies, incubators and business accelerators.

UCBM Academy is a physical and virtual place, where the continuous sharing of knowledge contributes to produce value and employability in the healthcare and in the technological and nutritional world, responding to the urgent challenges of innovation and sustainability.

Biotech Academy in Rome

Biotech Academy in Rome is a dynamic, forward-thinking institution that equips students and professionals with the skills, knowledge, and ethical principles to shape the future of biotechnology and positively impact the world.

Through innovation, collaboration, and responsible research, we aim at nurturing biotechnologists and prepare them to tackle the opportunities of tomorrow. We aim at inspiring and motivating a new generation of biotechnologists to deal with the challenges of a field in constant and quick evolution.

With the patronage of:



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