UNIVERSITÀ DI PAVIA
Department of Drug Sciences

UNIVERSITÀ DI PAVIA
Department of Electrical, Computer and Biomedical Engineering

Contamination Control Strategy (CCS)

28 March - 16 May

In collaboration with

FEDEGARI GROUP | TITAN DISRUPTIVE INNOVATION CENTER

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Contamination Control Strategy (CCS)

Aim:

The **Contamination Control Startegy** (CCS) course offers a concise overview of the latest regulations and technologies in contamination control for pharmaceutical environments. By focusing on sterilization methods and risk management, it enhances professional skills (upskilling) and operational efficiency. Its interdisciplinary scope deepens understanding of process-structure interactions while reducing costs. Emerging topics like automation and digital quality control provide a competitive edge in a rapidly evolving market. Overall, it is a strategic investment for staying current with industry demands and advancing one's career.

Syllabus

28 March **Introduction to microbiology (9:00 - 13:00, 4h)**
Gram+; Gram-; fungi; viability and methods of culture and growth

GMP Eudralex Vol 4 Part I (14:00 - 18:00, 4h)
Genetic structure of GMP and pharmaceutical regulations: quality system; personnel, equipment, production documentation, QC, outsourced activities, complaints and recalls, self-inspection
Annex 1
Manufacturing of sterile medicinal products (Utilities, Process and environmental monitoring)

04 April **ICHQ9 QRM (9:00 - 13:00, 4h)**
Risk Identification and Control

HVAC (14:00 - 18:00, 4h)
Cleanroom classification, maintenance and air quality monitoring

10 April **Barrier technologies 1 (14:00 - 18:00, 4h)**
Active and passive systems

11 April **Barrier technologies 2 (9:00 - 18:00, 8h)**
Open and closed RABS, isolators

17 April **Sterilising filtration (9:00 - 18:00, 8h)**
Filter and process validation; leables and extractables

08 May **Chemical sterilisation (9:00 - 18:00, 8h)**
VHP, NO2, ETO and residue control, ionising radiation (gamma and e beam)

09 May **Heat sterilization processes (9:00 - 18:00, 8h)**
General principles, wet dry, process and validation, case studies: porous loads, packaging components

17 april **Automation (9:00 - 18:00, 8h)**
Robotics and automated lines and on-line control of critical quality parameters, data integrity

Price: **2.000,00€**, for **60 hours** course