







UNIVERSITÀ DEGLI STUDI DI MILANO

PHARMACEUTICAL BIOTECHNOLOGIES AND ADVANCED THERAPIES: TRENDS AND SOLUTION FOR OVERCOMING THE PRODUCTION CHALLENGES

THURSDAY, MAY 9TH, 2024

MILAN UNIVERSITY, ROOM C03

VIA LUIGI MANGIAGALLI 25 (FLOOR – 1) 20133 MILANO

EDUCATIONAL COORDINATOR

Francesca Selmin - UNIMI - AFI - PDA Italy Chapter

MODERATOR - SPEAKERS

Marco Alberio - PharmaProcess - ISPE Claudio Bechini - Pharma-integration - ISPE Cristiana Campa - GSK Vaccines Siena - PDA Italy Chapter Lucia Ceresa - AFI - PDA Italy Chapter Francesco Contegno - Aware Lab - ASCCA Tommaso Dallavalle - Rise Italia - ASCCA Monica Gunetti - Ospedale Pediatrico Bambino Gesù - AFI Angela Molaschi - Pharmatex Italia - PDA Italy Chapter Maria Luisa Nolli - AFI Andrea Raso - GSK Vaccines Siena – PDA Italy Chapter Francesca Selmin - UNIMI - AFI - PDA Italy Chapter Andrea Tanzini - STAUBLI - ISPE Koji Ushioda - SKAN - ASCCA AIFA invited (to be confirmed)

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AIM OF THE CONGRESS

The event will focus on the evolution of vaccines and advanced therapies production. New technologies and dedicated solutions are available today for the most suitable contamination control strategies and continuous improvement. The challenge aspects of such different therapies will be considered as well as the criticality of products & productions that characterize the <u>different manufacturings</u> design.







AGENDA

8:30-9:00	Registration
9:00-9:30	Welcome and introduction: AFI, ASCCA, ISPE, PDA Italy Chapter, UNIMI
9:30-10:00	The most challenges aspect for ATMPs production: from autologous to the future allogenic therapies Maria Luisa Nolli - AFI
10:00-10:30	Development and improvement in the GMP production of ATMPs: what challenges for an academic hospital pharmaceutical workshop Monica Gunetti - Ospedale Pediatrico Bambino Gesù - AFI
10:30-11:00	Coffee break & welcome from the sponsors
11:00-11:30	Evolution within the vaccines production Cristiana Campa - GSK Vaccines Siena - PDA Italy Chapter
11:30-12:00	How to approach the CCS: a case study Andrea Raso - GSK Vaccines Siena – PDA Italy Chapter
12:00-12:45	Round table with the experts and AIFA Inspector
12:45-13:30	Lunch break with the sponsors
13:30-14:00	Design overview & technical solutions for modern Biotech and ATMPs manufacturing facilities Marco Alberio - PharmaProcess - ISPE
14:00-14:30	Risk-based and process-driven design of ATMP laboratories in hospital environment Francesco Contegno - Aware Lab - ASCCA Tommaso Dallavalle - Rise Italia - ASCCA
14:30-15:00	Novel Concept for Isolators to Manufacture Advanced Therapy Medicinal Products Koji Ushioda - SKAN - ASCCA
15:00-15:30	Coffee break with the sponsors
15:30-16:00	Robotics: Pharmaceutical Manufacturing best practices and compliance Andrea Tanzini - Staubli - ISPE
16:00-16:30	Biotech product filling: improve contamination control using robotics and human-less approach Claudio Bechini - Pharma-integration - ISPE
16:30-17:00	Round table 2: meeting with the experts and END of the congress

USEFUL INFORMATION

Congress venue

Milan University Via Luigi Mangiagalli, 25 20133 Milan Meeting room: **C03 (floor - 1)** Metro station: **M2 - Piola**

Participation

The **participation is free** of charge upon registration by **3rd May** through the following link:

Official language: Italian, with course material in English

Seats are limited. In case of interest, register as soon as possible.

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