

JOINT WEBINAR



Associazione per lo Studio
ed il Controllo della
Contaminazione Ambientale



ISPE® | Italy
Affiliate



Biotech and **Advanced Therapies** at a **Glance**

When: **24-25-26 November 2020** | Time: **2.00 pm - 5.30 pm** CEST | Where: **ZOOM platform**

How: **On line free registration - www.ascca.net** | Official language: **ENGLISH**

Main
Sponsors



charles river



Pohling
TECHNICAL SOLUTIONS



wood.



24 November
2020

Advanced Therapies: new technological and regulatory challenges

Chair: **Marco Fadda** (Comecer)

The advanced therapies represent now the future of the pharmaceutical and biological research. Through the experience of the involved companies and actors we will review the technological solutions implemented by who is working actively on this field

2.00 pm - 2.30 pm CEST

Welcome and introduction from ASSCA, ISPE and PDA

2.30 pm - 2.40 pm CEST

Introduction of the webinar

M. Fadda (Comecer)

2.40 pm - 3.20 pm CEST

Industrial manufacturing of cell based drugs according to GMP: challenges and solution

S. Guidi (Rigenerand)

3.20 pm - 4.00 pm CEST

Cell manufacturing facility at Lausanne University Hospital, GMP rules into a public institution: we do it.

J.F. Brunet (Lausanne University Hospital)

4.00 pm - 4.40 pm CEST

A private laboratory for the production of Advanced Therapies coordinated with Cord Blood Bank: challenges and opportunities

L. Mariotta (Swiss Stem Cell Biotech)

4.40 pm - 5.30 pm CEST

Final discussions, Q&A



25 November
2020

The automation and digital era of Biotech Manufacturing

Chair: **Matteo Valle** (Air Liquide)

High capacity levels, high safety standards and production flexibility have a crucial role in the production of Biotech medicines. Technology can support in meeting these requirements through the use of Single Use Technology and the possibility of a customized manufacturing. The case studies presented in this session will give us practical examples

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M. Valle (Air Liquide)

2.40 pm - 3.20 pm CEST

Single Use Technology vs stainless steel within biotech facilities and relevant study through a process simulation tool

M. Magni - F. Stoppa (Jacobs Italia)

3.20 pm - 4.00 pm CEST

Dedicated vs. multi-product biotech facility: GMP and operational issues from an User standpoint

B. Kiss (Gedeon Richter Plc.)

4.00 pm - 4.40 pm CEST

Opportunities for modern robotics in biopharma manufacturing

M. Mangiarotti (Takeda)

G. Orlandi (Wood Lifesciences)

4.40 pm - 5.30 pm CEST

Final discussions, Q&A



26 November
2020

Quality challenges in Biotech Manufacturing

Chair: **Cristiana Campa** (GSK Vaccines)

The vaccines and conjugated medicines manufacturing are currently one of the hottest topics in pharmaceutical world. Quality aspects have a crucial role in the production of effective and safe drugs and high-level standards are mandatory in the production of this type of medicines.

The case studies presented in this session will give us practical examples of quality requirements in Biotech manufacturing

2.00 pm - 2.30 pm CEST

Welcome and introduction from ASSCA, ISPE and PDA

2.30 pm - 2.40 pm CEST

Introduction of the webinar

C. Campa (GSK Vaccines)

2.40 pm - 3.20 pm CEST

Vaccine platforms: the GMMA case study

F. Micoli (GSK Vaccines Institute)

3.20 pm - 4.00 pm CEST

Comparability in development and lifecycle of biological products

S. Cianetti (GSK Vaccines)

4.00 pm - 4.40 pm CEST

Development and optimization of a conjugation process: manufacturing and quality

C. Paolella (BSP Pharmaceuticals)

4.40 pm - 5.30 pm CEST

Final discussions, Q&A