

Razionale

This International Meeting is dedicated to one of the most important regulatory transformations currently shaping the future of transfusion medicine, therapeutic apheresis, cell processing and advanced therapies in Europe.

We are discussing a profound change in the way Europe will govern, protect and promote the use of Substances of Human Origin throughout the entire therapeutic pathway.

The new SoHO Regulation represents far more than a legislative update.

It introduces a common European framework designed to strengthen quality, safety, traceability and resilience, while supporting scientific innovation and ensuring equitable access to life-saving therapies across all Member States.

For professionals working in therapeutic apheresis centers and cell manipulation laboratories, this transition represents both a challenge and an extraordinary opportunity.

Advanced Therapy Medicinal Products, immune cell therapies, stem cell transplantation and regenerative medicine are rapidly expanding, placing apheresis centers and cell processing laboratories at the very heart of modern medicine.

In this rapidly evolving landscape, regulatory compliance can no longer be viewed as a purely administrative requirement.

Instead, it should be regarded as an essential driver of quality, patient safety, innovation and clinical excellence.

Over the course of two days, internationally renowned experts from across Europe will share their perspectives on how the new SoHO regulatory framework will impact our daily clinical practice.

We will discuss quality management, risk assessment, technological innovation, digitization, regulatory preparedness, and the future organization of apheresis centers and cell processing laboratories.

Above all, we will explore how to transform regulatory requirements into opportunities for harmonization, collaboration, and continuous improvement.

The effective implementation of the SoHO Regulation will require close collaboration among physicians, transfusion specialists, laboratory professionals, regulatory authorities, scientific societies, industry, and patient associations.

Only through a multidisciplinary and collaborative approach will we be able to build a strong European network capable of supporting innovation while maintaining the highest standards of quality and patient safety.