SIdEM
Società Italiana
di Emaferesi e
Manipolazione
Cellulare

Simultaneous Translation

New frontiers in SoHO regulation:
the impact on apheresis and cell manipulation laboratories in Europe

Turin (Italy), October 20-21, 2026

Welcome to Turin for this international meeting 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 centres 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.

SCIENTIFIC COMMITTEE

Vanessa Agostini – Azienda Ospedaliero-Universitaria di Modena

Claudia Del Fante – IRCCS Policlinico San Matteo di Pavia

Angelo Ostuni – Presidente SIdEM – Policlinlico di Bari

SCIENTIFIC PROGRAM

TUESDAY, OCTOBER 20

01.30 p.m. Registration

02.00 p.m. Welcome Coffee

02.30 p.m. Introduction
Ostuni A. (Bari)

SESSION 1
Chairs: *Del Fante C., Koh M.*

02.45 p.m. The new jouney of cell therapy products under the umbrella of SoHO regulation. The good, the bad and the ugly
Alvarez M. (Madrid)

03.05 p.m. Discussion

03.15 p.m. Ethical and Legal Considerations in Apheresis under the SoHO Regulatory Framework
Agostini V. (Modena)

03.35 p.m. Discussion

03.50 p.m. Quality Management and Risk Control for cell collection for ATMPs under the SoHO Regulation
Henschler R. (Leipzig)

04.10 p.m. Discussion

04.20 p.m. Practical Implementation of the SoHO Regulation in Apheresis Services: challenges and new opportunities
Worel N. (Wien)

04.40 p.m. Discussion

05.00 p.m. Sponsored Speech (non-CME accredited speech)

05.30 p.m. Cocktail

SCIENTIFIC PROGRAM

WEDNESDAY, OCTOBER 21

SESSION 2

Chairs: *Teofili L., Feltrin G.*

09.00 a.m. The SoHO Regulation: Implications for Advanced Cell Therapies
Mazzanti B. (Rome)

09.20 a.m. Discussion

09.30 a.m. Impact of SoHO regulation on the cell manipulation laboratory
Chabannon C. (Marseille)

09.50 a.m. Discussion

10.00 a.m. Coffee Break

10.30 a.m. Results of the Coherence study approach for cell collection and manipulation for ATMPs
La Rocca U. (Rome)

10.50 a.m. Discussion

11.00 a.m. Technological Innovation and Digitalisation in stem cell laboratory manipulation in the Context of the SoHO regulation
Vassanelli A. (Verona)

11.20 a.m. Discussion

11.30 a.m. Closing Remarks

12.00 p.m. Light Lunch

GENERAL INFORMATION

Congress Venue

NH HOTEL TORINO CENTRO
Corso Vittorio Emanuele II, 104 – Torino

Congress Fees (VAT included)	SIdEM Member	Non Member
• Physician / Biologist / Pharmacist	€ 122,00	€ 150,00
• Nurse / Biomedical Laboratory Technician	€ 75,00	€ 100,00

Registration Procedure

To register, please fill in the form on the event website: **www.selenecongressi.it**
Following pre-registration, the Organizing Secretariat will send an email outlining payment instructions. For registrations made by Italian Public bodies (hospitals, university departments, etc.), fees are VAT-exempt pursuant to Art. 10, p. 20 of Presidential Decree 633/72 and Art. 14, p. 10 of Law 537 of 24/12/93. Please contact the Organizing Secretariat regarding administrative procedures and electronic invoicing.

Italian CME Accreditation

4.2 CME Credits for the following healthcare professionals:

- **Physician:** Allergology and Clinical Immunology, Hematology, Oncology, Genaral Surgery, Pathological anatomy, Transfusion Medicine
- Biologist
- Biomedical Laboratory Technician
- Nurse
- Pharmacist

Simultaneous Translation

Official event languages: Italian and English.

Simultaneous interpretation will be provided. Headsets can be collected at the registration desk upon presentation of a valid ID.

Organizing Secretariat

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