SPEAKERS AND CHAIRPERSONS

Vanessa Agostini, Italian Society of Haemapheresis and Cellular Manipulation (SIDEM), Italy

Ruth Barrio, Organización Catalana de Trasplantes (OCATT), Spain

Mariadonata Bellentani, Directorate General for Health Programming, Ministry of Health, Italy

Massimo Cardillo, Italian National Transplant Centre, Italy

Vincenzo De Angelis, Italian National Blood Centre, Italy

Giuseppe Feltrin, Regional Transplant Centre, Veneto Region, Italy

Francesco Fiorin, Italian Society of Transfusion Medicine and Immunohaematology (SIMTI), Italy

Richard Forde, European Directorate for the Quality of Medicines & HealthCare (EDQM)

Béatrice Marquez Garrido, DG SANTE – SoHO Team

Birgit Gathof, Department of Transfusion Medicine, University Hospital of Cologne, Germany

Laura Hickey, Health Products Regulatory Authority (HPRA), Ireland

Johann Kurz, Senior Advisor to EU projects, regulatory bodies in the field of inspections, audits and regulatory compliance of SoHO, Austria

Letizia Lombardini, Italian National Transplant Centre, Italy

Verena Plattner, Department Blood, Tissue & Vigilance - Institute Surveillance, Austria

Simonetta Pupella, Italian National Blood Centre, Italy

Jaime Tabera Fernandez, Blood and Tissue Bank (BST), Spain

Fewzi Teskrat, European Blood Inspection System (EuBIS) Academy

Monica Troiani, Regional Blood Centre, Veneto Region, Italy

Jeroen van Baare, Netherlands Association of Tissue Banks/ Health and Youth Care Inspectorate (IGJ), The Netherlands

The European directives on blood, tissues and cells (2002/98/EC and 2004/23/EC) have significantly helped to ensure safety and quality of care in the blood transfusion, cell and tissue transplantation and medically assisted reproduction fields. Despite this, the need for this legislation to be more responsive to new scientific and technological developments has emerged. Since 2010, the Italian system has been adapted accordingly resulting in the adoption of both common minimum requirements of quality and safety of blood and blood components and in the organisation of harmonized regional inspection systems. The new national legislation (November 5th, 2021) aimed at strengthening the oversight system at regional level and at improving its independence and impartiality. Simultaneously, the EC has promoted and finalised two European key initiatives aimed to strengthen and harmonise Member States (MSs) Substances of Human Origin (SoHO) oversight activities: VISTART (Vigilance and Inspection for the Safety of Transfusion, Assisted Reproduction and Transplantation) and GAPP (FacilitatinG the Authorization of Preparation Process for blood, tissues and cells).
These Joint Actions developed a guideline for the conduction of inspections for the authorisation/accreditation/licensing of Blood and Tissue Establishments as well as guidelines for the authorisation of processes and products based on SoHO, with particular reference to innovative products/processes, respectively.
In consideration of the forthcoming European regulatory framework, an overview on the guidelines, recommendations and tools produced at European level will be given, in order to move towards a European common approach of the oversight activities.

SCIENTIFIC COORDINATOR

Vincenzo De Angelis

SCIENTIFIC BOARD

Livia Cannata, Ursula La Rocca, Simonetta Pupella

ORGANIZING SECRETARIAT

Laura Di Marco, Francesca Martini, Anna Palmieri, Cinzia Scagliarini, Giacomo Silvioli

OFFICIAL LANGUAGE

The official language is English.
A simultaneous English-Italian translation service will be available.

CERTIFICATES

A Certificate of attendance will be provided to all the attendees. A Certificate of participation will be provided upon request only to those who have attended at least 75% of the event.

This event does not provide any CME credits.

CENTRO NAZIONALE SANGUE

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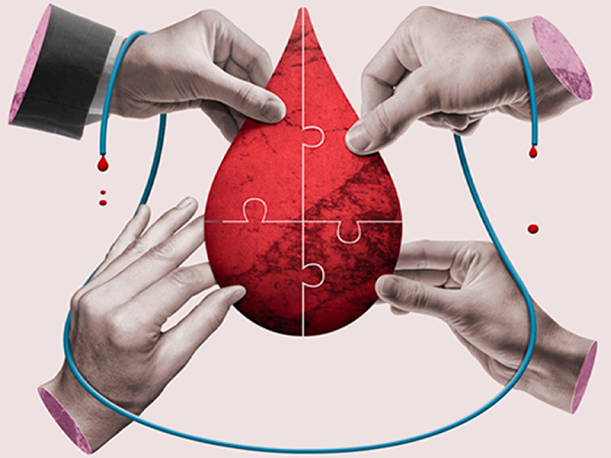
SoHOs OVERSIGHT SYSTEM:
A FOCUS ON INSPECTION AND AUTHORISATION PROCESS AT NATIONAL AND EUROPEAN LEVEL



March 28th, 2023
Acquario Romano,
Piazza Manfredo Fanti 47
Rome

PROGRAMME

09:00 Arrival and registration

09:45 Welcome address
Vincenzo De Angelis, Italian National Blood Centre
Gianni Rezza, Ministry of Health
Sergio Iavicoli, Ministry of Health
Silvio Brusaferro, Istituto Superiore di Sanità
Béatrice Marquez Garrido, DG SANTE – SoHO Team

SESSION 1 – ITALIAN OVERSIGHT SYSTEM

CHAIRPERSONS
VINCENZO DE ANGELIS , MASSIMO CARDILLO

10:15 The authorisation process of the healthcare systems: the Italian context
Mariadonata Bellentani

10:45 The inspection and authorisation processes of the Italian blood system
Simonetta Pupella

11:15 The inspection and authorisation processes of the Italian tissue and cells and MAR systems.
Letizia Lombardini

11:45 Blood oversight system: a regional experience
Monica Troiani

12:00 Tissue, cells and MAR oversight system: a regional experience
Giuseppe Feltrin

12:15 Discussion

12:30 LUNCH BREAK

SESSION 2 – PREPARATORY TOOLS TOWARDS A EUROPEAN COMMON APPROACH OF THE OVERSIGHT ACTIVITIES

CHAIRPERSONS
RUTH BARRIO, RICHARD FORDE

13:30 European Inspection Guidelines (IES – WC1)
Fewzi Teskrat

13:45 Overall guideline on Preparation Process Authorization (PPA)
Laura Hickey

14:00 Risk Assessment approach
Jaime Tabera Fernandez

14:15 An example of Preparation Process Authorization: eye-drops
Birgit Gathof

14:30 Discussion

14:45 COFFEE BREAK

SESSION 3– FORTHCOMING EUROPEAN OVERSIGHT SYSTEM: PRINCIPLES AND TOOLS

CHAIRPERSONS
JOHANN KURZ, VINCENZO DE ANGELIS

15:00 New Regulation perspectives
Béatrice Marquez Garrido

15:20 Inter-Member State audit (IES – WC4)
Verena Plattner

15:40 Inspectors/Assessors/Vigilance Officers European training – SIGHTSoHO "strengthening overSIGHT through training and networking on Substances of Human Origin (SoHO)" (IES – WC2)
Simonetta Pupella

16:00 Round Table
New European regulation impact
Béatrice Marquez Garrido, Massimo Cardillo, Francesco Fiorin, Vanessa Agostini

Quality Management System
Richard Forde, Jeroen van Baare

16:45 Closing remarks - Take home messages

17:00 End of the meeting