1st European Training course on Biovigilance for Tissues and Cells

ADVISORY BOARD MEMBERS

Ieva Bekere

Ieva Bekere is a medical doctor. She graduated from the Latvian Medical Academy (now Riga Stradins University) with a postgraduate specialisation in anaesthesiology and intensive care. She also has an MSc in Management and worked for 10 years as Head of the Quality Management Department and later as Head of the Administrative Department at the University Children's Hospital in Riga.

In 2013, Ieva joined the State Agency of Medicines of Latvia (SAM LV) as a senior expert. SAM LV also acts as the National Competent Authority for human blood, tissues, cells and organ transplantation. In her position at SAM LV, Ieva has primary responsibility as Lead Inspector for inspections of blood and tissue establishments, including procurement organisations and hospital blood banks, and for management of the BTO vigilance system, including submission of its annual report to the European Commission. She is also actively involved in the licensing of BTO establishments and drafting/reviewing of national BTO legislation. Ieva is the Latvian representative at meetings of National Competent Authorities on BTO, including the SoHO Vigilance Expert Sub-group.

Anne Cathrine Bollerup

Anne Cathrine Bollerup is a medical doctor. She graduated from Copenhagen University and has worked for more than 20 years in the field of microbiological testing at the Diagnostic Sector at Statens Serum Institut (SSI). From 1994-2000, she was Quality Manager and Management representative in charge of the accreditation project for ISO/IEC 17025 on Diagnostic Examinations at SSI. From 2000-2006, she was Lead Assessor for accreditation according to ISO 15189 (Accreditation of Medical Laboratories) at the Danish Accreditation Fund (DANAK).

Since 2006, Anne Cathrine has had primary responsibility for tissues and cells and for implementing the Tissue Law in Denmark at the designated National Competent Authority (NCA). Since 2012, she has been responsible for implementing the national regulation for assisted reproduction in Denmark. With two of the world's biggest sperm banks located in Denmark, the NCA receives between 50-100 notifications of adverse reactions and adverse events per year, mostly related to genetic defects in sperm donations, and it issued 25 rapid alerts in 2020. Anne Cathrine has also actively participated in several EU-funded projects including EUSTITE, SoHO V&S, VISTART and ARTHIQS (Assisted Reproductive Technologies and Haematopoietic stem cells Improvements for Quality and Safety throughout Europe), as an external adviser. She is currently a member of the Inspection Expert Sub-group (IES) and SoHO Vigilance Expert Sub-group (VES).

Edith Coonen

Edith Coonen is a Senior Clinical Embryologist at the Department of Reproductive Medicine and a Laboratory Specialist in Reproductive Genetics at the Department of Clinical Genetics, Maastricht University Medical Centre (MUMC+) in the Netherlands, where she is also a lecturer in reproductive medicine (Assistant Professor). She is actively involved in research projects with the GROW developmental biology research school, focusing on innovative preimplantation genetic testing (PGT) and research aimed at elucidating the relationship between laboratory aspects of assisted reproductive technology procedures and clinical outcomes.

Edith is the (co)author of over 50 peer-reviewed articles, including international guidelines and expert opinion papers. She is an ad-hoc referee for a number of journals in the field of reproductive medicine/genetics and is review editor for the journal Molecular and Cellular Reproduction (Frontiers in Cell and Developmental Biology).

Edith has a great interest in quality management: she is an ISO 15189 auditor and an assessor to a number of international PGT EQA schemes. She is dedicated to the education of Ph.D. students and professionals in the fields of reproductive medicine and reproductive genetics and is an experienced speaker at international congresses, workshops and training courses. She is a former Chair of the European Society of Human Reproduction and Embryology (ESHRE) PGT Consortium and is currently a member of the ESHRE Executive Committee. She is an adviser to politicians and advisory bodies on drafting legislation and reports at both the national and European level.

Donna Harkin

Donna Harkin is a Scientific Officer working in the Health Products Regulatory Authority (HPRA), the Irish Competent Authority for a range of healthcare products including blood, tissues and cells and joint Competent Authority for human organs for transplantation, since 2006. Donna has a background in critical care nursing and midwifery and has extensive experience with the Irish Blood Transfusion Service, having worked as a Clinical Nurse Manager in a blood donation clinic prior to working as a Transfusion Surveillance Officer in the National Haemovigilance Office. In her role as Blood, Tissues and Organs (BTO) Vigilance Officer for the HPRA, Donna is responsible for the operational management of the national BTO vigilance system, including submission of the annual vigilance reports for blood, tissues and cells to the European Commission. She has also contributed to a number of European Working Groups for vigilance-based activities related to blood, tissues and cells, including her current role as rapporteur for the Expert Sub-Group on Vigilance of Blood, Tissues and Cells and Organs (VES). Donna has also participated in several European projects such as EUSTITE (European Union Standards and Training for the Inspection of Tissue Establishments), SoHO V&S (Vigilance and Surveillance of Substances of Human Origin) and VISTART (Vigilance and Inspection for the Safety of Transfusion, Assisted Reproduction and Transplantation) and has previous experience contributing to a training course for vigilance officers from Europe in the context of a SoHO V&S Working Group, led by the HPRA.

Sinéad Masterson

Sinéad Masterson worked for the Health Products Regulatory Authority (HPRA), the Irish Competent Authority for a range of healthcare products including blood, tissues and cells and joint competent authority for human organs for transplantation, for over 10 years as Blood, Tissues and Organs (BTO) Section Manager and Inspector of Blood, Tissue and Organ Establishments. During this time, she was directly involved in the implementation of European and national BTO legislation in Ireland. This involved the development, management, and continuous improvement of inspection processes in blood establishments, hospital blood banks and tissue establishments, including assisted reproduction centres and organ centres. She represented the HPRA at meetings of the Competent Authorities and Regulatory Committee Meetings at the European Commission and was involved in forging and maintaining links with key organisations at both European and national level.

Sinéad has also been actively involved in a number of key BTO projects at the European level, including EUSTITE, SoHO V&S and VISTART, all of which have contributed to the significant progress made in the area. Prior to this role, she was a member of the quality team at the Irish Blood Transfusion Service, demonstrating practical experience of the workings of a Blood Establishment.

Sinéad became an independent consultant in 2016 and has since collaborated on a number of high profile projects with the European Commission, including: an audit of the National Blood Service in Romania; an expert mission with the Technical Assistance and Information Exchange to Cyprus on the development of assisted reproductive technology in this region; numerous Legislation Alignment Check Projects in EU candidate countries; development of the European Database for Convalescent COVID Plasma; and the Evaluation of the Blood and Tissues and Cells Legislation. She is currently involved in the Impact Assessment Study on the Revision of the Blood and Tissue Legislation.

Aurora Navarro Martínez-Cantullera

Aurora Navarro is a medical doctor. She graduated from the Autonomous University of Barcelona's Medical School in 1997 and qualified as a Certified Transplant Coordinator for the European Board of Transplant Coordinators in 1999. She also has an Executive Master's degree in Leading Health Organizations from the ESADE Business School in Barcelona (2013). She worked as an organ and tissue transplant coordinator at the Hospital Clínic in Barcelona for ten years and was Director of the Barcelona Tissue Bank for nine years.

In 2015, Aurora Navarro became the Medical Officer for Organ and Tissue Vigilance at the Catalan Transplant Organization (OCATT) and Medical Coordinator for the World Health Organization's Notify Project. She has taught on more than 70 training courses, primarily in organ and tissue donation (including four Spanish biovigilance courses). She has been the Director of the International Online Tissue Banking Course since 2002, the Scientific Director for the Advance face-to-face Course on Tissue and Cell Banking since 2008 and Associate Professor of the University of Barcelona and Coordinator of the European Quality System for Tissue Banking since 2016. Aurora Navarro is also a participant in seven other European initiatives and has authored numerous scientific articles, conference presentations and book chapters.

Jacinto Sánchez Ibáñez

Jacinto Sánchez Ibáñez is a surgeon. He has worked as a transplant coordinator for 12 years and was Director of the Transplant Coordination Office in Galicia for 11 years. He is the current President of the European Association of Tissue and Cell Banks (EATCB) and founding partner of the Spanish Association of Tissue Banks. He has been a member of the working group for the Guide to the Quality and Safety of Tissues and Cells for Human Application since its 2nd edition, and chaired the group for the 4th and 5th editions. He has authored several published articles and chapters of specialised books in the field of donation and transplantation. He has been the Director of a tissue establishment since 2012 and has long- standing expertise in biovigilance.

Deirdre Fehily

Deirdre Fehily has been a Policy Officer in the Substances of Human Origin Team at the European Commission since March 2015. Her most recent work has focused on the evaluation and revision of the EU legislation covering the safety and quality of blood, tissues and cells and the collection and study of the use of COVID-19 convalescent plasma in the EU.

Prior to her role at the Commission, Deirdre was an inspector and technical adviser at the Italian National Transplant Centre (CNT) and represented Italy at the meetings of Member State authorities concerning Directive 2004/23/EC on tissues and cells. She was technical coordinator of a number of EU-funded projects that sought to strengthen the oversight of blood, tissue and cell banking in the EU, focusing on inspection and vigilance. She was seconded to Croatia from 2014-2015, where she coordinated a twinning project between Spain and Italy and the Croatian Ministry of Health to improve the institutional capacities for the provision and regulation of blood, tissues and cells.

As a member of the World Health Organization's (WHO) Transplantation Advisory Committee, Deirdre provides technical support and advice to the WHO and participates in the coordinating team for the Notify Project for Global Vigilance and Surveillance of Medical Products of Human Origin (www.notifylibrary.org). She has participated as a course designer and tutor on numerous national and international training courses for EU inspectors, vigilance officers and professionals working with blood, tissues and cells.
Prior to joining the CNT in Italy in 2003, Deirdre was Head of Tissue Services for the English National Blood Service.

Johanna Wiersum

Johanna (Jo) Wiersum (née Osselton) is a specialist in community medicine working in blood donation, haemovigilance and biovigilance in the Netherlands. After qualifying, she worked in the UK and the Republic of Guinea in West Africa. She has worked for Sanquin (the Dutch blood service) since 1996, where she is a member of the project group for prevention of complications of blood donation.

Two common themes throughout Jo's career have been the harmonisation of definitions and the quality of vigilance systems; she has been the National Medical Coordinator of the TRIP (Transfusion and Transplantation Reactions in Patients) Haemovigilance and Biovigilance Office since its inception in 2002, and is a rapporteur of the Brussels Vigilance Expert Sub-group of the Competent Authorities for Blood, Tissues and Cells.

EDQM MEMBERS

Marta López-Fraga

Marta López-Fraga is the Scientific Officer in charge of donation and transplantation activities at the EDQM.

She received her BSc in Biology from the Complutense University of Madrid and a Ph.D. in Immunology from the Autonomous University of Madrid. She undertook postdoctoral work in the USA at the La Jolla Institute for Allergy and Immunology, San Diego and, in 2006, she joined Neurome Inc./University of California Riverside to work on the development of targeted mucosal vaccine delivery technologies for the Bill and Melinda Gates Foundation.

Marta returned to Spain in 2008 to take up a role as Senior Scientist with Sylentis in Madrid, where she worked on the development of innovative treatments against a number of inflammatory diseases.

Mar Lomero

Mar Lomero the EDQM in 2016, where she has collaborated on a number of European projects related to organ, tissue and cell donation and transplantation as principal scientific assistant. She is currently responsible for the analysis of serious adverse events and reactions (EU SARE exercise) related to the use of blood, tissues and cells in the EU.

Mar is a critical care nurse; she has a master degree in donation and transplantation of organs, tissues and cells from the University of Barcelona, and obtained her Ph.D. on limitation of life support therapies and donation after circulatory death from the Universitat Rovira I Virgili (Tarragona, Spain) and the University of Barcelona in 2017.

In 2015, she started working as a tissue donor coordinator for the Barcelona Tissue Bank. She certified as Transplant Coordinator for the European Board of Transplant Coordinators in 2016.

Jaime Marco

Jaime Marco, as principal scientific assistant, has been part of the transplantation team at the EDQM since April 2019.
He obtained his Master's in Pharmacy from the Complutense University of Madrid in 2013. He worked for three and a half years at the Spanish National Transplant Organization (ONT), where he was involved in several projects, notably the Spanish Liver Transplant Registry, the Global Observatory on Donation and Transplantation and Biovigilance.

Christine Gault

Christine Gault is an administrative and support assistant within the organ transplantation team since December 2020.

Prior to joining the EDQM, she spent thirty years working for the French army and has occupied various positions in both military and civilian organisations in the French Defence Ministry and in specific workplaces throughout France. During her career, Christine's postings have included four years at the French Embassy in Tel Aviv, Israel, and six years at the North Atlantic Treaty Organization (NATO) in Portugal and Italy. She has also participated in missions of operational interest in Africa and the Balkan countries, and has been involved in several multinational exercises in Europe and beyond.