

1st European Training Course on Quality Management for Tissue Establishments

20 October 2021 to 25 November 2021

ONLINE



ADVISORY BOARD

MEMBERS

**Advisory Board members of the 1st European training course
on quality management for tissue establishments**

ADVISORY BOARD MEMBERS

Johan Guns



Johan Guns has been active in the field of human cell and tissue banking and quality assurance for over 20 years and co-founded the Belgian Association for Tissue and Cell Banks. He has worked at the University Hospital Brussels since 2000, first in the Centralised Unit for Pancreatic Islet Cell Transplantation, then as Quality Assurance Manager for medical laboratories, tissue banks and biobanks, a role he took up in 2007. He became Head of the quality department in 2014 and Biobank Manager of the hospital's centralised biobank in 2018. Since 2019, Johan has been Visiting Professor at Vrije Universiteit Brussel, where he lectures on quality assurance in healthcare and bioethical issues surrounding human body materials. He is an appointed expert at the Belgian Superior Health Council, Federal Agency for Medicines and Health Products of Belgium and has been

a member of the working group preparing the Council of Europe Guide to the Quality and Safety of Tissues and Cells for Human Application since the 3rd edition.

Mona Hansson



Mona Hansson obtained her PhD in immunology in 1983 from the Karolinska Institute in the field of natural killer cells and haematopoiesis. She was the Head of the Stem Cell Laboratory and Apheresis Unit at Karolinska University Hospital for 5 years, and for the past 10 years has worked at the Swedish Health and Social Care Inspectorate (IVO) as National Coordinator for Tissues and Cells, Blood and Organs with responsibility for inspections of blood and tissue establishments and their vigilance reporting. She was part of the working group preparing the Council of Europe Guide to the Quality and Safety of Tissues and Cells for Human Application (2nd edition) and chaired the group for the 3rd edition.

Mona currently works as an external expert for the IVO.

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Richard Lomas



Richard Lomas is a clinical scientist, working for the Tissue and Eye Services department of National Health Service (NHS) Blood and Transplant in the UK. He has been a professional tissue banker for more than 25 years, with a special interest in the development and validation of novel processing techniques and the clinical evaluation of allografts. He holds a BSc in genetics from the University of Leeds and a PhD in the preparation of demineralised bone matrices from the same university. He has participated as an expert in EU-funded teaching programs and in international collaborations to develop best practices for tissue banking. He is a member of the working group preparing the Council of Europe Guide for the Quality and Safety of Tissues and Cells for Human Application, and has authored or co-authored 20+ publications in the field of tissue and cell banking, as well as several book chapters in the same area. He is currently a board member of the European Association of Tissue and Cell Banks.

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.

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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 preparing the Council of Europe 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.

Jaime Tabera



Jaime Tabera has an MSc in Biochemistry from the University of the Basque Country and is currently the Operations and Quality Manager at the Barcelona Tissue Bank – Catalonia Blood and Tissue Bank, which he joined in 2009. Prior to this role, he worked as a quality assurance consultant to the pharmaceutical industry for 7 years. He has participated as an expert in several international projects promoted by EU health programmes, including the Technical Assistance and Information Exchange (TAIEX), EU Twinning, the American International Health Alliance and the International Atomic Energy Agency. He has been part of the leadership and coordination team of the Euro Good Tissue Practices I and II projects and has played an active role in preparing several editions of the Council of Europe Guide to the Quality and Safety of Tissues and Cells for Human Application. Jaime is currently a board member of the European Association of Tissue and Cell Banks (EATCB).

Kelly Tilleman



Kelly Tilleman's research career began in the field of proteomics with a PhD in biomarker research in inflammatory arthritides at the University of Ghent in 2007, which she pursued while working as a Quality Manager for an accredited DNA fingerprinting laboratory. Kelly joined the hospital's reproductive medicine department in November 2009 and combined her role as Quality Manager of the fertility centre with scientific research in the area of fertility preservation. Her work over the years that followed combined quality management with project and laboratory process management.

Kelly is currently Director of the Ghent University Hospital IVF lab, where she has the privilege to work with a very dynamic and enthusiastic team. She is a former coordinator of the Safety and Quality in Artificial Reproductive Techniques (SQART) special interest group at the European Society of Human Reproduction and Embryology (ESHRE), Belgian representative to the EDQM and board member of the ICCBBA, an international standards organisation responsible for the ISBT-128 standard on medical products of human origin.

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Nina Worel



Nina Worel is a physician and specialist in transfusion medicine. She has worked in the field of haematopoietic stem cell (HSC) transplantation for more than 25 years and is the Medical Director of the cell & tissue procurement facility and tissue bank at the Medical University of Vienna. She is also a member of the executive committee of the Joint accreditation committee of the International Society for Cell & Gene Therapy (ISCT) and the European Group for Blood and Marrow Transplantation (EBMT), focusing on quality assurance of HSC transplant centres. Nina currently chairs the stem cell donor outcome committee of the EBMT and the donor issue committee of the Worldwide Network for Blood and Marrow

Transplantation (WBMT).

Nina participated in the working group preparing the Council of Europe Guide to the Quality and Safety of Tissues and Cells for Human Application since the 2nd edition.

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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 PhD 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



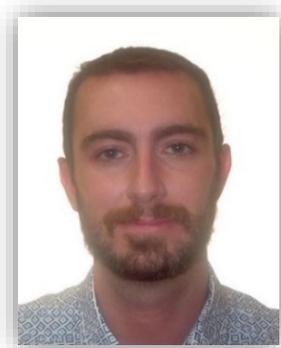
Mar Lomero joined the EDQM in 2016, where she has collaborated on a number of European projects related to organ, tissue and cell donation and transplantation as Principal Scientific Assistant. She is currently responsible for the analysis of serious adverse events and reactions (EU SARE exercise) related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

Mar is a critical care nurse; she has a master's degree in donation and transplantation of organs, tissues and cells from the University of Barcelona, and obtained her PhD 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 was certified as a transplant coordinator by the European Board of Transplant Coordinators in 2016.

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Jaime Marco



Jaime Marco, has been a Principal Scientific Assistant in the EDQM's transplantation team 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 Organisation (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 has been an Administrative and Support Assistant in the organ transplantation team since December 2020.

Prior to joining the EDQM, Christine served in the French army for 30 years, during which she occupied a number of positions in both military and civilian settings. As part of her military career with the French Defence Ministry, Christine was posted to various roles throughout France and abroad, including 4 years at the French Embassy in Tel Aviv (Israel) and 6 years with NATO in Portugal and Italy. She also participated in missions of operational interest in Africa and the Balkans and took part in several multinational exercises in Europe and beyond.