

2nd European Training Course on Quality Management for Tissue Establishments

26 September 2022 to 9 November 2022

ONLINE



ADVISORY BOARD

MEMBERS

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on quality management for tissue establishments**

ADVISORY BOARD MEMBERS

María José de los Santos



María José de los Santos started her career in 1991 in the IVF laboratory of IVI Valencia. She received her PhD in Biology from the University of Valencia in 1996, and from 1996-1999 she carried out her postdoctoral fellowship in Reproductive Immunology at Fearing Research Laboratory at Harvard Medical School. She also worked as a Clinical Embryologist at Brigham and Women's Hospital.

María is a Senior Clinical Embryologist and researcher certified by the European Society of Human Reproduction and Embryology (ESHRE) and the Association for the Study of Reproductive Biology (ASEBIR). Her main study focus is embryo quality, embryo development, and in vitro embryo culture conditions and quality management. Currently, she is the Director of the Clinical Embryology Laboratory at IVI Valencia. She 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. She is the author or co-author of over 50 original peer-reviewed articles published in leading reproductive journals and has written more than 20 book chapters.

During her career, she has also participated as a researcher in competitive projects funded by the Government of the Valencian Community (IMPIVA), the Spanish Government (CDTI) and Carlos III Health Institute.

María has been involved in teaching since early in her career, delivering courses since 1996. Presently she is the Coordinator of two modules (The Clinical Embryology Laboratory and Improving Embryo Quality) of the Master's degree in Biotechnology of Assisted Human Reproduction (former doctorate degree of the Pediatrics, Obstetrics and Gynaecology Department at University of Valencia).

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.

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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.

Borut Kovačič



Borut Kovačič started his career in 1989 as a Clinical Embryologist. He received his PhD from the University of Ljubljana Faculty of Medicine in 1999. For more than 25 years he has been the Head and Quality Control Manager of the Medically Assisted Reproduction (MAR) laboratory at the University Medical Centre Maribor, Slovenia. Since 2019 he has been a full professor of Cell Biology at the Faculty of Medicine in Ljubljana and Maribor. Borut is a member of the European Society of Human Reproduction and Embryology (ESHRE) Committee for the UEMS-CESMA accredited examination in Clinical Embryology. Within ESHRE he is a member of the Steering Committee for the accreditation of MAR centres

for embryologist training, a member of the Committee for the certification of MAR centres for good clinical and laboratory practice and ESHRE assessor of MAR centres in this programme. He is also a member of the ESHRE EU Affairs group and represented ESHRE in the VISTART project.

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.

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Renza Monteleone



Renza Monteleone has been a Quality Manager since 2006, working in the Stem Cell Transplant Program, Cord Blood Bank and Transfusion Service of “Bianchi-Melacrino-Morelli” Hospital in Reggio Calabria, Italy. She took on this role after gaining experience as a Clinical Research Coordinator at Thomas Jefferson University Hospital in Philadelphia, USA. Renza is an active inspector, in the area of Quality Management, for the Joint Accreditation Committee for ISCT Europe and EBMT (JACIE) and the National Transplant Center of the Italian Ministry of Health. She is the Chair of the JACIE Quality Managers Committee and a member of the JACIE Accreditation Committee. She was a member of the working group

preparing and reviewing FACT-JACIE Accreditation Standards, and was also a contributing author to the publication “Quality Management and Accreditation in Hematopoietic Stem Cell Transplantation and Cellular Therapy: The JACIE Guide”.

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).

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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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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

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.

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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.