JACIE Supports Quality Managers: the Critical Role of Quality Managers in Stem Cell Transplantation and Cellular Therapies

The Joint Assurance Committee of ISCT-Europe and EBMT (JACIE) is established as Europe's only official certification body in haematopoietic stem cell transplantation (HSCT) and cellular therapy and is committed to promoting high-quality patient care and continuous improvement through its profession-led, voluntary certification scheme. Since its inception in 1999, JACIE has evolved to meet the increasingly complex regulatory and certification demands associated with cell therapies while maintaining its core mission of promoting excellence in patient care.

JACIE-certified centres must meet the rigorous requirements within the FACT-JACIE Standards framework, which requires not only Standards compliance, but active engagement in continuous quality improvement. Quality managers are at the very heart of the effort required to achieve this, ensuring that process control becomes part of business-as-usual activity through the quality management systems they design, implement, and maintain to meet clinical and laboratory regulatory and certification demands.

Scientific data from the European Society for Blood and Marrow Transplantation (EBMT) confirm that patients treated in JACIE-certified centres experience significantly improved relapse-free and overall survival[1,2]. JACIE certification has also been shown to improve the management of related donors[3]. These outcomes correlate with the presence of robust quality management systems, managed and overseen by experienced Quality professionals.

The responsibilities of quality managers extend beyond documentation and compliance. They encompass system-wide leadership in quality assurance[4], risk management[5], training[6], incident reporting[7], and the integration of emerging regulatory requirements such as the forthcoming SoHO (Substances of Human Origin) Regulation[8], the **EU Health Technology Assessment Regulation (EU) 2021/2282**[9] and evolving frameworks for Advanced Therapy Medicinal Products[10] (ATMPs).

JACIE believes that dedicated quality manager resource is essential for the delivery of safe, effective, and high-quality care in HSCT and cellular therapy. These quality manager professionals with a specialist interest in, and knowledge of, cellular therapies are integral to the implementation and sustainability of quality management systems that uphold FACT-JACIE Standards[11] and directly enhance patient outcomes, regulatory compliance, and operational excellence. Without dedicated, specialist and protected quality manager resource, quality management system working becomes an afterthought and soon disappears from business-as-usual activity, patient (and staff) safety is compromised, and a culture of continuous improvement is lost.

JACIE supports a sector-wide environment in which certified HSCT and cellular therapy centres

1. have designated quality management personnel within the cellular therapy service who have specialist knowledge of process control within cell therapies , and who are appropriately educated, trained and experienced to transact this specialist quality management role
2. provide adequate and ring-fenced resources to transact quality management activities, including staffing, technology, and other necessary resources
3. establish clear reporting structures that ensure quality managers have appropriate authority within the cellular therapy service, and access to senior leadership
4. implement comprehensive training programs for quality management staff to maintain competency in evolving standards and technologies

As the healthcare landscape continues to change with the advent of ever-increasing new therapeutic modalities, regulatory frameworks, and technological capabilities, the role of quality managers becomes increasingly vital. The rapid advancement of cellular therapy technologies requires quality managers to adapt quality systems to accommodate novel therapeutic approaches and to ensure compliance with evolving regulatory frameworks.

Quality managers should not be considered a 'nice to have' addition to the core team, but instead recognised, and celebrated, for what they are – an indispensable component of the cellular therapy delivery team and a core mechanism that ensures the safety of processes within a complex treatment context and enhanced patient outcomes

JACIE calls upon all stakeholders - healthcare institutions, regulatory bodies, professional organisations, and funding agencies - to recognise, support and invest in the essential role of quality managers in delivering safe, effective, and high-quality cellular therapy services across Europe and beyond.

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4 2007 No. 1523 HUMAN TISSUE The Human Tissue (Quality and Safety for Human Application) Regulations 2007

5 HTA Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment. 2021.

6 DIRECTIVE 2004/23/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

7 Snowden, J. A., McGrath, E., Orchard, K., Kröger, N., Sureda, A., & Gratwohl, A. (2021). Visions for a JACIE Quality Management System 4.0. *Bone Marrow Transplantation*, 56, 2876–2881. https://doi.org/10.1038/s41409-021-01467-8

8 Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application

9 Regulation (EU) 2021/2282 on health technology assessment

10 Regulation (EC) No 1394/2007 on advanced therapy products and amending Directive 2001/83/EC and Regulation (EC) No 726 /2004

11 FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration, 8th Edition. 2021.

This position statement reflects JACIE's commitment to excellence in hematopoietic stem cell transplantation and cellular therapy through comprehensive quality management systems. For more information about FACT-JACIE Standards and certification processes, please visit www.ebmt.org/jacie-accreditation.