JACIE/FACT Accreditation

An introductory guide to the accreditation process for Haematopoietic Stem Cell Transplant Programmes

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CHAPTER 1

Certification vs — Accreditation

A fundamental distinction

In the landscape of healthcare quality, certification and accreditation are often confused. Understanding the difference is essential for choosing the right path and accurately communicating your level of quality to patients, institutions and international partners.

ISO 9001 certification is an organisational standard. It verifies that the organisation has implemented a quality management system — policies, procedures, internal audits, management review — but does not assess the quality of the product or the clinical service delivered. A transplant centre certified to ISO 9001 has demonstrated structured organisational processes, but this does not guarantee that the cellular product is safe, effective and traceable.

JACIE/FACT accreditation is a technical standard specific to Haematopoietic Stem Cell Transplant Programmes. It goes beyond verifying the organisation: it assesses staff competence, cellular product quality, patient and donor safety. It ensures that the product and service meet internationally recognised standards of excellence.

International recognition

The standard is jointly promoted by JACIE (Joint Accreditation Committee ISCT-Europe & EBMT) for Europe and FACT (Foundation for the Accreditation of Cellular Therapy) for North America. The accreditation is recognised in over 50 countries and is an increasingly common requirement for participation in international clinical trials and for the delivery of advanced cellular therapies such as CAR-T.

In summary: ISO 9001 certifies that an organisation has a quality system; JACIE accreditation certifies that the quality system produces excellent clinical outcomes.

CHAPTER 2

The four pillars — of the standard

A quality system compliant with the JACIE/FACT standard is founded on four fundamental pillars. Each must be documented, implemented, verified and continuously improved. The absence of even one pillar compromises the entire system.

Human resources

Staff are the heart of every transplant programme. The standard requires that every operator has documented qualifications consistent with their role, participates in structured continuing education programmes and has competencies periodically assessed using objective tools. Staffing levels must be adequate for activity volumes, with coverage plans for absences and turnover.

Documentation

The document system is the backbone of quality. It includes the quality manual, standard operating procedures (SOPs), work instructions, recording forms and training plans. Every critical activity must be clearly described, formally approved, distributed to competent staff and subject to periodic review. Document traceability must cover the entire lifecycle of the cellular product.

Infrastructure and equipment

Environments and instruments must be qualified and maintained according to defined protocols. Critical equipment (cell separators, programmable freezers, incubators) requires IQ/OQ/PQ qualification, periodic calibration, preventive maintenance and emergency plans for breakdowns. Environments must have documented environmental controls.

Continuous improvement

- Planned and systematic internal audits across all areas of the standard
- Measurable performance indicators, monitored and compared against benchmarks
- Structured error and near-miss management with root cause analysis
- Corrective and preventive actions (CAPA) with effectiveness verification
- Annual management review with trend analysis and improvement plan

CHAPTER 3

The three areas — of the standard

The JACIE/FACT standard covers three distinct but interconnected operational areas. Each area has specific requirements, but the quality system must ensure coherence and traceability throughout the entire patient and cellular product pathway.

Clinical Programme

The clinical area covers the entire patient pathway: from eligibility assessment to conditioning, from infusion to long-term follow-up. Requirements include documented selection protocols, structured informed consent, management of acute and chronic complications, and a follow-up system ensuring systematic outcome collection at 100 days, 1 year and beyond.

Collection

The collection area encompasses therapeutic apheresis (for peripheral blood stem cells), bone marrow harvesting and donor management. Requirements concern donor qualification, eligibility criteria, standardised collection procedures, management of donation-related adverse events and product traceability from donor to laboratory.

Processing Laboratory

The cell processing laboratory is the technical heart of the programme. Requirements cover processing procedures (selection, depletion, expansion), cryopreservation with validated protocols, product quality control (viability, cell count, sterility, markers), method validation and complete traceability from collection to thawing and infusion.

Integration across the three areas is the true test of quality: cellular product traceability must be guaranteed without interruption from collection to infusion.

CHAPTER 4

The ICMED — 5-phase methodology

The path to JACIE/FACT accreditation requires a structured methodology adaptable to each centre's reality. The typical duration ranges from 12 to 24 months, depending on the starting level and organisational complexity. ICMED has developed a 5-phase methodology, refined over more than 20 years of direct experience.

Phase 1: Assessment

Thorough evaluation of the centre's current status against all standard requirements. Each gap is classified by criticality and impact. The output is a detailed report showing compliance levels for each section and a prioritised list of necessary actions.

Phase 2: Planning

Definition of a customised roadmap with milestones, responsible parties and realistic deadlines. The plan accounts for available resources, organisational constraints and the centre's clinical priorities. Each milestone is verifiable and measurable.

Phase 3: Implementation

Development and implementation of the documentation system (quality manual, SOPs, work instructions), staff training programmes, equipment and environment qualification, and indicator system. ICMED works alongside the centre with specialised consultants who operate side by side with staff.

Phase 4: Verification

Systematic internal audits, mock inspections simulating the real inspection, correction of residual non-conformities and consolidation of staff competencies. This phase is crucial for arriving at the inspection with maximum preparation.

Phase 5: Inspection and follow-up

Support in preparing documentation for the accreditation application, assistance during the official JACIE/FACT inspection, management of any post-inspection observations and launch of the maintenance and continuous improvement programme for the next cycle.

CHAPTER 5

Who is accreditation — for?

JACIE/FACT accreditation is not reserved for large transplant centres. The standard is designed to be applicable to facilities of varying sizes, each with specific needs.

New transplant centres

Centres launching a transplant programme that want to build their quality system from the outset according to international standards. Starting with the right foundations is more efficient than adapting an existing system.

Existing centres

Already operational transplant programmes seeking accreditation for the first time, or those needing to renew an expiring accreditation while adapting to the requirements of the new edition of the standard.

Cell processing laboratories

Cell Factories and processing laboratories operating as standalone facilities or as part of a transplant programme. The laboratory-specific requirements demand highly specialised competencies in GMP-like environments.

Apheresis units

Peripheral blood stem cell and bone marrow collection services. Accreditation of the collection unit can be pursued independently from the clinical programme.

ICMED operates in Europe, Africa and the Middle East. The team has direct experience with the regulatory and cultural specificities of each context.

CHAPTER 6

Why choose — ICMED

ICMED combines two decades of experience, direct expertise and proprietary technology tools to deliver comprehensive, personalised support throughout the accreditation journey.

Experience and track record

Over 100 healthcare facilities supported across 5 countries on 3 continents. A team of JACIE/FACT consultants with direct experience in preparing centres for inspections. Every project is led by professionals who know the standard in both theory and daily practice.

Proprietary tools

- IAAPP: ISO/IEC 27001:2024 certified digital platform for complete quality system management — documents, audits, NC, CAPA, indicators, training
- AGENAS-accredited ECM training (Provider ID 7158) with courses specific to each role in the transplant programme
- ICMED Magazine (ISSN 3103-1943): quarterly publication with scientific and regulatory updates

The ICMED approach

Every centre is unique. We do not apply standardised models: we build a tailored pathway together with the centre that respects the timelines, resources and organisational culture of each facility. Support does not end with accreditation: ICMED accompanies centres in maintenance and continuous improvement.

LEARN MORE

Want to explore this topic further?

ICMED offers accredited ECM training programmes, specialised consulting and the IAAPP platform for complete quality management system oversight.

ECM Training

AGENAS-accredited courses (Provider ID 7158)

Consulting

Accreditations, quality systems, regulatory compliance

IAAPP

AI-powered quality management platform — ISO/IEC 27001

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ISO 9001 — Quality Management System

ISO/IEC 27001:2024 — Information Security

UNI/PdR 125:2022 — Gender Equality

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