Quality in ART Centres

Standards and quality systems for Assisted Reproductive Technology centres

ICMED Magazine ISSN 3103-1943

Editore ICMED S.r.l.

July 2026

Free promotional guide

www.icmed.net

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CHAPTER 1

The regulatory — framework

A complex regulatory landscape

Assisted Reproductive Technology centres operate within a layered regulatory framework comprising national legislation, European directives, implementing decrees and region-specific requirements.

- Law 40/2004: the Italian ART law, establishing fundamental principles, prohibitions, authorisation requirements and the surveillance system
- Directive 2004/23/EC (Tissue & Cells Directive): the European standard for quality and safety in the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells
- Legislative Decree 191/2007 and Legislative Decree 16/2010: Italian transposition of the European directive, with specific requirements for reproductive tissues and cells
- Regional requirements: each Italian Region may add specific authorisation and accreditation requirements for ART centres

Why a structured quality system

A quality system is not merely a regulatory obligation: it is the tool that enables improvement of clinical outcomes, error reduction, process standardisation, complete gamete and embryo traceability, and cross-centre comparison through shared indicators.

CHAPTER 2

The ICMED — 4-dimension methodology

ICMED has developed a methodology specific to ART centres that addresses quality across four integrated dimensions. Each dimension has its own objectives, tools and indicators, but all converge towards a single goal: the safety and effectiveness of treatment.

Organisational dimension

This concerns the centre's structure, roles and responsibilities, communication flows, and quality system governance. It includes the functional organisation chart, the responsibility matrix, the delegation system and the management review.

Technical-scientific dimension

This covers clinical and laboratory protocols, adopted guidelines, patient selection criteria, fertilisation techniques, cryopreservation protocols and outcome evaluation criteria. References include ESHRE guidelines, ISS recommendations and data from the national ART Registry.

Structural dimension

This addresses environments, equipment and environmental control systems. The embryology laboratory requires particularly stringent conditions in terms of air quality, temperature, humidity and absence of volatile organic compounds (VOCs) that can damage gametes and embryos.

Training dimension

This concerns the continuing education of medical, biological, technical and nursing staff. Each role has specific competencies that must be documented, assessed and updated. ICMED delivers role-specific ECM training for each professional profile.

CHAPTER 3

The process — map

The process map of an ART centre is organised into four categories. Each process has inputs, outputs, responsible parties, indicators and interfaces with other processes.

Treatment processes

These are the centre's core processes: informed consent, patient and donor management (where applicable), ovarian stimulation, oocyte retrieval, semen sample collection and preparation, fertilisation, embryo culture, transfer, cryopreservation, and follow-up.

Management processes

These are the governance processes: management review, personnel management, strategic planning, complaint handling, patient communication and continuous improvement.

Quality processes

These are the processes governing the quality system: document management, performance indicators, internal audits, error and near-miss management, method validation, quality control and external assessment.

Support processes

These are the infrastructure processes: equipment and maintenance management, laboratory safety, reagent and materials management, disaster recovery and business continuity planning.

CHAPTER 4

The embryology — laboratory

Environmental qualification

The embryology laboratory is the most critical environment in an ART centre. Environmental qualification must cover particulate air classification, controlled temperature and humidity, volatile organic compound (VOC) concentration and microbiological monitoring. Every parameter must be continuously monitored and recorded.

Method validation

Every technique used in the laboratory must be validated before clinical use. Validation covers conventional IVF, ICSI, embryo culture at various stages, and vitrification and thawing of oocytes and embryos. Acceptability criteria and revalidation protocols must be defined for each method.

Equipment management

Critical laboratory equipment — incubators, operating microscopes, micromanipulators, cryopreservation systems, laminar flow hoods — requires IQ/OQ/PQ qualification, periodic calibration, scheduled preventive maintenance, malfunction alarms and backup plans.

Key Performance Indicators (KPIs)

Laboratory KPIs follow ESHRE standards and ISS ART Registry data:

- Fertilisation rate (IVF and ICSI)
- Blastocyst formation rate
- Post-thaw survival rate
- Clinical pregnancy rate per transfer
- Benchmarking against ESHRE data and the ISS national registry

CHAPTER 5

Traceability — and witnessing

Complete traceability

Gamete and embryo traceability is both a regulatory requirement and a safety imperative. Every sample — oocyte, sperm, embryo — must be bidirectionally traceable from retrieval to final destination (transfer, cryopreservation, disposal), with every intermediate step recorded.

The witnessing system

Witnessing is the double-verification system for sample identity at every critical step in the laboratory. It prevents mix-up errors — which, as news cases demonstrate, can have devastating consequences for the couples involved.

- Identity verification at oocyte retrieval and semen sample collection
- Double-check at insemination or microinjection (ICSI)
- Verification during embryo transfers between dishes, at cryopreservation and at thawing
- Recording of operator and witness for every critical step

Witnessing is not a bureaucratic formality: it is the most effective barrier against identification errors, the most feared adverse event in an ART laboratory.

CHAPTER 6

The pathway — with ICMED

ICMED supports ART centres in building, improving and maintaining a comprehensive quality system, with a pragmatic, evidence-based approach.

- Comprehensive gap analysis against regulatory requirements (Law 40, Legislative Decree 191/2007, European directives, regional requirements)
- Documentation system development: quality manual, SOPs, work instructions, forms, records
- ECM training for medical, biological and technical staff on quality, safety and traceability
- Implementation of quality and performance indicators to ESHRE standards
- Benchmarking against ISS ART Registry data and ESHRE benchmarks
- IAAPP: digital management of documents, NC, CAPA, audits, indicators, staff training
- Support for regional inspections and CNT audits

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Magazine

Quarterly scientific publication (ISSN 3103-1943)

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www.icmed.net

www.iaapp.net

Editore ICMED S.r.l.

ICMED Magazine — ISSN 3103-1943

ISO 9001 — Quality Management System

ISO/IEC 27001:2024 — Information Security

UNI/PdR 125:2022 — Gender Equality

ECM Provider AGENAS — ID 7158

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