Leiden University Medical Center

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ISO 9001 as a pathway to SRL excellence: strengthening quality, service, and operational stability

Background

Flow cytometry core facilities operate in an increasingly demanding environment, where researchers expect consistent data quality, reliable instrumentation, and transparent processes.

While many facilities rely on internal quality systems or clinical frameworks such as CAP/CLIA, these models are not always optimized for research settings. The ISO 9001 quality management standard offers a flexible structure that emphasizes process control, risk management, and continuous improvement, yet it remains underused in academic core facilities.

The LUMC Flow Cytometry Core Facility applies ISO 9001 principles solely to its internal processes, not for certification, but to establish a sustainable and user-focused quality system that fits our workflows.

Objectives

Our goal was to strengthen operational consistency, improve documentation, enhance training, and reduce instrument downtime by embedding ISO 9001 concepts into daily practice. We aimed to create a system that supports both scientific rigor and operational efficiency, while remaining lightweight enough for a dynamic Research environment.

Approach

Process Mapping and Optimization

We began by mapping all major workflows from user registration to data delivery to identify bottlenecks, redundancies, and unclear responsibilities.

This mapping exercise allowed us to redesign processes with a focus on clarity, efficiency, and traceability.

Each workflow was translated into a controlled, versioned document accessible to all staff.

Document Control System

A centralized document management system was introduced to ensure that SOPs and workflows, log lists, and forms were consistent, up to date, and easy to locate.

Version control and scheduled reviews improved transparency and reduced variability in daily operations.

Maintenance Program

We implemented a tiered QC program with daily, weekly, and monthly routines.

Instrument performance trends were monitored over time using our **FlowMonitor** application enabling earlier detection of deviations and more effective preventive maintenance.

Competency-based Training

Operator training was redesigned into a competency-based program combining vendor instruction with specialized modules for advanced troubleshooting and experimental support.

Operators develop expertise in flow cytometry, mass cytometry, and/or cell sorting, and cross-training ensures full instrument coverage.

This structure promotes consistent proficiency and maintains clear, auditable training records.

Continuous Improvement

User feedback was systematically collected through surveys and informal channels.

Feedback was incorporated into a structured corrective and preventive action (CAPA) process, enabling us to address issues, track improvements, and close the loop with users.

Regular PDCA (Plan–Do–Check–Act) cycles helped embed continuous improvement into routine operations.

Key Outcomes

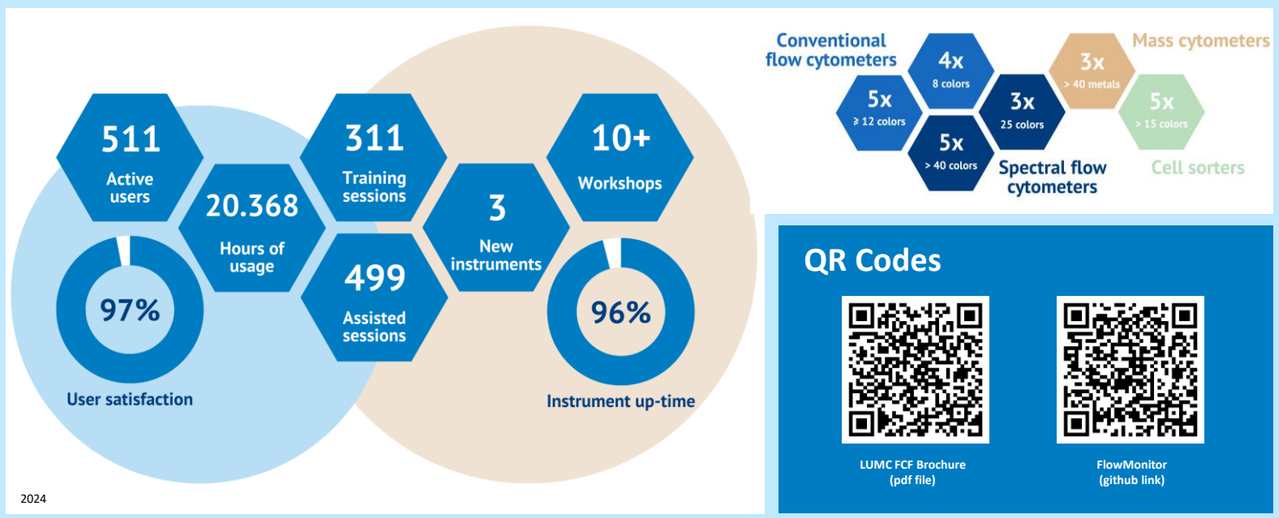
The implementation of ISO 9001 principles led to measurable improvements across the facility. Instrument uptime increased due to more proactive maintenance and earlier detection of performance drift.

Documentation became more consistent and accessible, reducing errors and improving onboarding of new staff.

The ISO-based framework also strengthened collaborations with academic and industry partners by providing a transparent, professional operational structure that supports reproducibility and data integrity.

Users reported higher satisfaction, citing clearer communication, more predictable service quality, and improved instrument reliability.

FCF in Numbers



QR Codes

LUMC FCF Brochure (pdf file)

FlowMonitor (github link)

Conclusion

Our experience shows that the principles of ISO 9001 can work well in research core facilities, even without formal certification.

By improving processes, documenting procedures, providing proper training, and regularly reviewing how we work, facilities can deliver more consistent services, reduce mistakes, and better support researchers.

This poster shares practical **roadmap** that other core facilities can use to introduce ISO-based quality management in a way that fits their own scale and needs.

ISAC RECOGNIZED
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ISO 9001:2015 certified management system