Bridging the Gap from Operational Function to Accreditable Quality: Implementation of a Unified Quality Management System Driven by Automated Processes and Digital SOPs at the MUB Biobank

Anna Michalska-Falkowska[1], Dorota Juchniewicz[1], Karine Sargsyan[2,3,4]

[1]Biobank, Medical University of Bialystok (MUB), Poland

[2]IBD Institute and OncoBiobank, Cedars-Sinai Medical Center, Los Angeles, CA, USA

[3]Office of Vice Rector for Research, Medical University of Graz, Austria

[4]Department of Digital Medicine and AI, and Department of Medical Genetics, Yerevan State Medical University, Yerevan, Armenia

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01 BACKGROUND & PROBLEM

Target Accreditation Standard: ISO 20387:2018

Many academic biobanks operate functionally but rely on informal practices and disparate records — creating a critical gap against ISO 20387 requirements.

The MUB Biobank needed to:

- Formalize operational processes into auditable procedures
- Establish objective, quantifiable performance metrics
- Implement a robust Quality Assurance (QA) framework
- Demonstrate "fit-for-purpose" status for high-impact research

02 THE OPERATIONAL GAP

Informal Practices → Disparate Records → No Formal KPIs → ISO 20387 Gap ✗

Pre-QMS state at MUB Biobank

03 OBJECTIVES

- Design a comprehensive QMS aligned with ISO 20387
- Integrate LIMS with automated cold-storage infrastructure
- Enforce SOPs digitally to eliminate procedural deviations
- Generate irrefutable, automated audit trails
- Track KPIs for continuous quality improvement
- Build the accreditation evidence portfolio

04 QMS IMPLEMENTATION STRATEGY

The cornerstone was the integration of a fully automated -80°C storage system with a centralized LIMS — used as the technological backbone for digital SOP enforcement.

Infrastructure Integration

Automated −80°C cold storage linked directly to centralized LIMS. All sample movements tracked in real time, eliminating manual logging errors.

Digital SOP Implementation

SOPs embedded within LIMS workflows. System enforces predefined protocols for sample processing, storage & retrieval — deviations structurally prevented.

Automated Audit Trails

Every action automatically generates a timestamped, tamper-proof record. Full traceability from collection to use: ready for accreditation inspection.

Continuous QC Monitoring

Real-time temperature monitoring with defined alert/action thresholds. Automated notifications trigger predefined corrective-action workflows.

KPI Dashboard & Reporting

Quantitative performance indicators tracked via the LIMS dashboard. Provides evidence of operational control and trend data for continuous improvement.

Regular Sample Quality Checks

Structured QC program with scheduled integrity assessments. Results feed into the KPI framework and are documented for the accreditation portfolio.

05 SYSTEM ARCHITECTURE FLOW

Automated −80°C Storage ⇄ Centralized LIMS → Digital SOPs & KPIs → ISO 20387 Evidence

06 KEY PERFORMANCE INDICATORS

0
Procedural Deviations
Since digital SOP roll-out

100%
Audit Trail Coverage
All critical processes

24/7
Temperature Monitoring
Alert / action thresholds

≥95%
Retrieval Accuracy
Tracked per LIMS log

Additional KPIs tracked: sample processing turnaround time, incident reporting rates, corrective action closure time.

07 OUTCOMES ACHIEVED

- Automated Audit Trails
- Digital SOP Implementation
- Standardized Operations
- KPI-Driven Quality Assurance
- Accreditation Pathway
- Research Community Trust

08 CONCLUSIONS

Key Findings

Digital SOP enforcement eliminated procedural deviations and standardized pre-analytical workflows across all sample types.

Automated data capture delivers irrefutable, real-time audit trails — replacing subjective assessment with quantitative evidence.

Defined KPIs provide objective performance data that drives continuous improvement rather than reactive management.

The QMS framework delivered the complete foundational evidence portfolio required to pursue formal ISO 20387 accreditation.

FEEL FREE TO CONTACT US!

Anna Michalska-Falkowska, PhD DPharm
MSc Biobanking Clinical Pharm. Specialist
Medical University of Bialystok
anna.michalska@umb.edu.pl