IDENTIFYING OF KEY BARRIERS TO THE DIGITAL TRANSFORMATION OF QUALITY MANAGEMENT SYSTEMS

Iryna Lazko[1]

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Digital transformation (DT) of quality management systems (QMS) (Quality 4.0 / Digital QMS) offers significant opportunities – improved quality control, real-time analytics, predictive defect diagnostics, and increased productivity. However, implementation faces numerous interrelated barriers: human, technological, organizational, and economic. A review of scientific publications identified ten key barriers to the digital transformation of QMS. Based on the results of practical activities, practical measures to mitigate them were proposed.

1. **Organizational cultural resistance and fear of change.** Managers and staff resist new work practices, automation, and analytics tools; this is reflected in low system adoption, sabotage of initiatives, or underutilization of implemented tools. In DT QMS projects, this can lead to formal implementation "on paper" without real quality improvement. Sony et al. [1] identify cultural/human factors as one of the leading barriers to Quality 4.0 implementation; Elg et al. [2] examine in detail the role of QM practitioners in ensuring the adoption of digital initiatives. Many studies rely on surveys and qualitative interviews, which provide a good picture of perceptions but are limited in quantifying the scale of impact across sectors and regions. Barrier mitigation measures can include: change management programs (user engagement, change champions), pilots with end users, usage measurement, and adoption metrics.

2. **Lack of competencies and digital literacy.** Quality personnel often lack skills in data analysis, machine learning, and data management; without these competencies, digital tools fail to deliver the expected impact. Shao et al. [3] highlight the "talent team" and skills as a key factor in their model for medium-sized manufacturing enterprises (SMEs); Sony et al. [1] confirm the importance of personnel readiness. An analysis of scientific publications revealed that talent factors are often measured by self-declaration; a more rigorous assessment of actual skills and training effects is needed. The following measures are proposed to mitigate this barrier: targeted training programs, mixed teams (internal and external experts), and training metrics (hours, certifications, retention).

[1] LTD Research and Design Institute, Ukraine

3. Outdated IT infrastructure and legacy systems. Existing ERP/MES/PLM and on-premises databases often integrate poorly with modern analytical platforms – the complexity of integration increases project costs and timelines. Elg et al. [2] analyze the technical challenges of integration and the role of QM in digitalization; Calvo-Mora et al. [4] also note the technical barriers to scaling Quality 4.0. Most scientific papers describe the problem, but fewer provide ready-made architectural recipes; the impact depends heavily on industry systems and the degree of customization. Suggested measures to mitigate the barrier include API-oriented integrations, middleware, staged refactoring, and pilots on a limited set of integrations.

4. Data Quality, Availability, and Integration. Analytics and predictive models depend on correct, complete, and synchronized data; poor telemetry, inconsistent data dictionaries, and lack of data governance render projects useless or misleading. Calvo-Mora et al. [4] identify data barriers as a separate cluster; Sony et al. [1] also point to data readiness as a readiness factor. Operational data quality metrics and their thresholds are rarely standardized – research often provides qualitative recommendations without specific target metrics. Suggested barrier mitigation measures include data stewards, ETL/ELT processes, data quality level agreements (SLAs), automated quality monitoring.

5. Financial constraints and ROI uncertainty. High initial investments (hardware, software, integration, training) and uncertainty about the return on investment are a serious barrier, especially for SMEs. Shao et al. [3] argue that economic factors are critical for SMEs; Tu et al. [5] demonstrate that digital technologies increase TFP, which is a positive argument, but the relationship between ROI in a specific QMS project remains project-dependent. Macro studies [5] show the overall benefits of digitalization, but do not replace a detailed business case for individual pilots. Suggested measures to mitigate the barrier include staged funding, pilots with measurable KPIs, and financial models for 12–24 months.

6. Lack of strategic support from management. Without sponsorship at the top management level, projects are low priority, with limited budgets and personnel support. This reduces the chances of changing processes and quality management. Studies [1], [2] emphasize the importance of leadership and linking digital initiatives to business goals. The role of leaders is often inferred from surveys and case studies; more empirical evidence is needed on the causal link between sponsorship and the success of Quality 4.0. Suggested measures to mitigate this barrier include formalizing sponsorship, establishing KPIs for management, developing internal business cases, linking to key business metrics.

7. Security, privacy, and regulatory constraints. Data exchange between systems, cloud solutions, and analytics create risks of leaks and non-compliance with requirements (GDPR, etc.), which hinders the use of cloud/IoT solutions in QMSs. Elg et al. [2] highlight the risks and requirements of digitalization; Sony et al. [1] highlight security/privacy as a readiness factor. Regulatory specifics vary by country; general studies rarely provide step-by-step compliance guidelines. Suggested mitigation measures: privacy by design, data anonymization, security audits, and compliance with industry standards.

8. Inconsistent processes and weak governance of digital initiatives. The lack of standardized implementation processes, clear roles, and procedures for implementation leads to duplication, conflict, and low sustainability of solutions. Elg et al. [2] describe the need for new QM roles in the digital landscape; Calvo-Mora et al. [4] demonstrate that governance and process barriers constitute a separate cluster of problems. Practical guidance on governance is often context-dependent; templates must be adapted to the specific organization.

Suggested measures to mitigate this barrier include setting up RACI, release management, and cross-functional boards for digital initiatives.

9. Specific barriers for SMEs: personnel and resource constraints. Small and medium-sized enterprises (SMEs) have smaller available budgets, limited HR resources, and weak negotiating power with suppliers, which slows down the digitalization of their QMS. Shao et al. [3] provide a quantitative model of factors for SMEs; Sony et al. [1] and Calvo-Mora et al. [4] also note differences in barriers for SMEs and large firms. The results presented for China [3] have regional specifics, but the general conclusions are often replicable. Suggested measures to mitigate this barrier include the use of cloud-based SaaS solutions with PAYG models, regional support programs, joint initiatives (cooperation).

10. Supplier Limitations, Compatibility, and Vendor Lock-in Risks. Incompatibility between solutions from different vendors or dependence on a single vendor limits flexibility and increases risks when changing architectures. For example, [2] notes the role of the vendor ecosystem as a barrier. There is less quantitative data on the impact of vendor lock-in on the success of specific QMS projects; conclusions are more often empirical/descriptive. Suggested measures to mitigate this barrier include: striving for open standards, choosing vendors with open APIs, and including exit clauses and data portability in contracts.

Based on the analysis of scientific publications, the following conclusions can be drawn: there is a consistent consensus that the main barriers are a combination of human (culture, skills) and technical (data, infrastructure) factors; new studies use multivariable methods for more rigorous validation of

barrier clusters; macro-studies provide an economic justification for investments. Many studies rely on surveys/qualitative case studies, which provide a good understanding of perceptions but require further validation across different sectors and countries; there are comparatively few long-term controlled studies demonstrating the causal effects of specific mitigation measures.

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