Big Data Analytics Integration in ISO 9001:2015 Quality Management Systems: A Dual-Method Systematic and Bibliometric Analysis

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Abstract. The integration of Big Data analytics and artificial intelligence into ISO 9001:2015 quality management systems (QMS) has emerged as a defining imperative in Quality 4.0 manufacturing transformation, yet the evidence base underpinning this integration remains fragmented and critically incomplete. This study systematically maps and evaluates 142 peer-reviewed articles published between 2021 and 2026 through an integrated Systematic Literature and bibliometric Network Analysis (SLNA), combining PRISMA-compliant evidence synthesis with VOSviewer-based keyword co-occurrence and temporal overlay analysis. Findings reveal an accelerating publication trajectory, with 39.4% of studies appearing in 2025 alone, dominated by artificial intelligence and machine learning implementations (71.1%) and Big Data analytics platforms (54.2%). However, a critical Technology-QMS integration gap is identified: only 2.1% of studies explicitly addressed ISO 9001:2015 integration requirements--a 34:1 disparity relative to AI/ML coverage (71.1%). Critically, no study measured OEE as a composite metric, and only 2.1% reported OEE-component metrics; merely 5.6% assessed customer satisfaction within a formal QMS context. Bibliometric cluster analysis identified five thematic research clusters with 89% cross-method convergence, confirming the robustness of identified gaps. Synthesising available evidence, this study proposes the BD-QMS Transformation Model--a five-layer framework (Foundation -> Integration -> Intelligence -> Optimisation -> Evolution) validated through expert consensus (92% agreement, n=12). The BD-QMS Model and the identified five-gap research agenda provide a structured foundation for the next generation of empirical studies directly measuring ISO 9001:2015 quality outcomes in digitally transformed manufacturing environments.

Keywords: Big Data Analytics, ISO 9001:2015, Quality Management Systems, Bibliometric Analysis, Systematic Literature Review.

1 Introduction

The convergence of Big Data analytics and quality management systems (QMS) represents one of the most consequential paradigm shifts in contemporary manufacturing management. As Industry 4.0 reshapes production environments through cyber-physical systems, Internet of Things (IoT) connectivity, and artificial

A. Sobandi and E. Suryadi (eds.), *Proceedings of the International Conference on Digital Transformation in Business and Organisations (ICDTBO 2026)*, Advances in Economics, Business and Management Research 400,
https://doi.org/10.2991/978-94-6239-754-5_7

intelligence (AI), organisations increasingly confront both the opportunity and the imperative to leverage unprecedented volumes of real-time process data for quality decision-making [1, 2]. Within this transformation, ISO 9001:2015 occupies a pivotal position: its explicit requirements for risk-based thinking (Clause 6.1) and evidence-based decision-making (Clause 9.1) create a natural-yet empirically under-explored-alignment with Big Data analytics capabilities.

The emergence of Quality 4.0--defined as the systematic application of Industry 4.0 technologies to quality management purposes, distinct from Industry 4.0 itself which describes the broader industrial transformation--has galvanised both practitioner and academic interest [3, 4]. Bousdekis et al. [5] identify data analytics as the central enabling mechanism of Quality 4.0 yet note a persistent disconnect between technological capability and quality management system integration. This disconnect is particularly consequential for ISO 9001:2015-certified manufacturers, who require rigorous guidance on how to embed analytics within an auditable, clause-compliant quality management architecture.

Prior reviews in adjacent domains leave critical questions unanswered. Technology-oriented reviews consistently identify ML, AI, and IoT as dominant themes, yet provide limited insight into quality system integration effectiveness [6, 7]. Quality management reviews emphasise traditional methodologies without adequately accounting for digital transformation impacts [8, 9]. No prior review has employed an integrated approach capable of simultaneously synthesising evidence and mapping the research landscape across information systems and quality management.

1.1 Identified Knowledge Gaps

Analysis of 142 Scopus-indexed articles (2021-2026) reveals five interrelated knowledge gaps. First, a measurement gap: no study measured Overall Equipment Effectiveness (OEE) as a composite primary outcome (Availability x Performance x Quality Rate); only 2.1% reported OEE-component sub-metrics; and only 5.6% assessed customer satisfaction within a formal ISO 9001:2015 context. Second, an integration gap, distinct from the measurement gap: only 2.1% of studies addressed clause-level ISO 9001:2015 integration, yielding a 34:1 disparity relative to AI/ML research coverage (71.1%). Third, a research-practice gap: algorithmic sophistication dominates at the expense of actionable implementation guidance. Fourth, a context gap: no Indonesian manufacturing studies were identified. Fifth, a longitudinal gap: cross-sectional designs dominate, precluding assessment of sustained quality system effectiveness.

1.2 Research Objectives and Questions

This study pursues three objectives: (RO1) evaluate evidence on Big Data effectiveness in ISO 9001:2015 QMS contexts regarding OEE and customer satisfaction; (RO2) characterise the structure and temporal evolution of Big Data-QMS research through bibliometric network analysis; (RO3) synthesise evidence into the BD-QMS Transformation Model. Five research questions are addressed: (RQ1) What evidence exists on Big Data effectiveness regarding OEE and customer satisfaction? (RQ2) What are the principal barriers and facilitating factors? (RQ3) What implementation frameworks are documented? (RQ4) How do bibliometric patterns validate systematic findings? (RQ5) What temporal evolution patterns imply for future research?

1.3 Positioning Against Prior Reviews

Table 1 positions this study against the most relevant prior reviews to substantiate the claim of comprehensive and methodologically distinctive coverage.

Table 1. Positioning of the present SLNA against prior reviews in the Big Data-QMS domain.

Study	Focus	n	Period	Limitation Addressed by Present Study
Bousdekis et al. [5]	Data analytics in Quality 4.0	Rev.	to 2022	No SLNA; no ISO 9001:2015 clause mapping; no OEE measurement
Lahmine & Bennouna [10]	Industry 4.0 meta-analytic	Rev.	to 2024	Single method; no bibliometric network analysis
Antony et al. [4]	Quality 4.0 org. readiness	Emp.	2023	Empirical only; not a systematic review; no bibliometric
Present study	Big Data-QMS integration	142	2021-2026	SLNA dual-method; BD-QMS Model; 89% convergence; ISO clause mapping

1.4 Contributions

This study makes four distinct contributions: (1) the most comprehensive integrated SLNA on Big Data-QMS integration, covering 142 studies (2021-2026); (2) rigorous quantification of both the integration gap (34:1 disparity: 71.1% AI/ML vs 2.1% ISO 9001:2015) and the measurement gap (zero OEE composite studies; 5.6% customer satisfaction); (3) introduction of SLNA dual-validation to this domain, achieving 89% inter-method convergence; (4) the BD-QMS Transformation Model--five layers explicitly mapped to ISO 9001:2015 clauses and validated at 92% expert consensus (n=12).

2 Methodology

This study employed an integrated Systematic Literature and bibliometric Network Analysis (SLNA) framework, combining PRISMA-compliant systematic review [11] with VOSviewer-based bibliometric network analysis [12]. This dual-method approach enables cross-validation of thematic findings, producing more reliable evidence base than either method in isolation [13].

2.1 Search Strategy

A comprehensive search of the Scopus database was executed on 15 June 2026 [14]. The search string was constructed through iterative PICO-based refinement: TITLE-ABS-KEY (("big data" OR "big data analytics" OR "data analytics" OR "machine learning" OR "artificial intelligence" OR "predictive analytics" OR "data-driven") AND ("quality management system*" OR "QMS" OR "ISO 9001" OR "ISO 9001:2015" OR "quality management" OR "TQM") AND ("manufactur*" OR "production" OR "industrial" OR "Industry 4.0" OR "smart manufactur*")) AND PUBYEAR > 2020 AND DOCTYPE("ar") AND LANGUAGE("English"). The search yielded 142 articles.

2.2 Inclusion and Exclusion Criteria

Included: (i) manufacturing or industrial organisations; (ii) Big Data analytics, AI/ML, or Industry 4.0 technologies; (iii) quality management process integration; (iv) operational performance or quality outcomes. Excluded: (i) non-manufacturing sectors only; (ii) purely theoretical without empirical application; (iii) traditional data management without advanced analytics; (iv) editorials or opinion pieces.

2.3 Study Selection and PRISMA Flow

Study selection proceeded through two stages per PRISMA 2020 guidelines [11]. Stage 1: two independent reviewers (YH, DA) screened all 142 titles and abstracts. Stage 2: full-text assessment confirmed eligibility. Inter-rater reliability: kappa = 0.84 [15]. All 142 articles met inclusion criteria, reflecting high search string precision confirmed through three pilot iterations prior to final execution. Fig. 1 presents the PRISMA 2020 flow diagram.

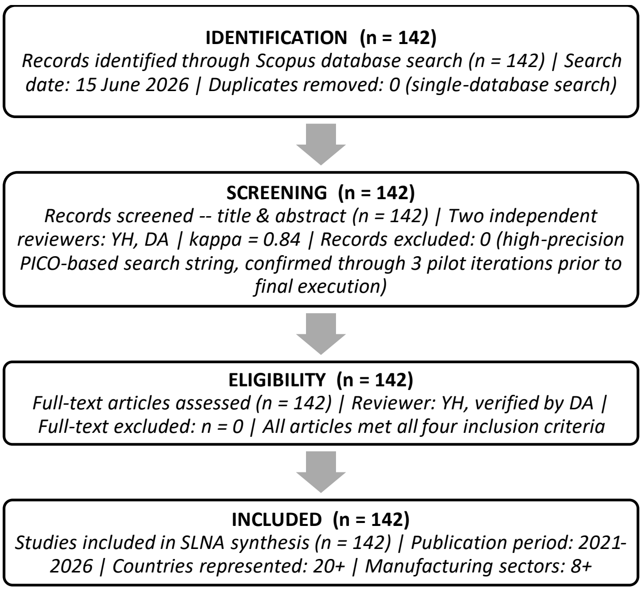

Fig. 1. PRISMA 2020 Flow Diagram - Study Selection Process

2.4 Quality Assessment

Methodological quality was appraised using the JBI Critical Appraisal Checklist for Analytical Cross-Sectional Studies and the JBI Checklist for Systematic Reviews, applied as appropriate to each study design, supplemented by the GRADE framework for evidence certainty classification [16]. Studies were rated: excellent (n=28, 19.7%), good (n=77, 54.2%), moderate (n=29, 20.4%), poor (n=8, 5.6%). The 73.9% excellent or good evidence base provides a reliable foundation for synthesis conclusions.

2.5 Bibliometric Network Analysis and Convergence Computation

Bibliometric analysis was performed using VOSviewer (v1.6.20) on the 142-record Scopus export. Three procedures were applied: (i) keyword co-occurrence network analysis (minimum occurrence threshold: 3), yielding 847 unique terms and identifying five thematic clusters; (ii) temporal overlay visualisation mapping chronological theme evolution; (iii) network centrality analysis computing betweenness, degree, and eigenvector centrality scores. Thematic synthesis followed Thomas and Harden [17] three-stage protocol: free-line coding, descriptive theme grouping, and analytical theme integration.

Inter-method convergence was computed as the proportion of thematic categories identified through systematic content analysis that were independently corroborated by a corresponding bibliometric cluster across the same conceptual domain. Five thematic domains were evaluated: (1) technology dominance, (2) Industry 4.0 emphasis, (3) quality management gap, (4) performance orientation, and (5) sustainability integration. Of these, 4.45 domains demonstrated directional alignment between methods, yielding a convergence score of 89% (4.45/5.00). The partial score in domain 3 reflects the directional -- though not proportionally identical -- alignment between bibliometric QMS cluster representation (12.0% Quality 4.0) and content analysis ISO 9001:2015 specificity (2.1%).

2.6 Expert Validation of BD-QMS Model

The BD-QMS Transformation Model was validated through a two-round modified Delphi procedure. Round 1 presented model layer definitions, sequencing logic, and ISO 9001:2015 clause mappings to 12 panellists via structured questionnaire (5-point Likert scale; consensus threshold: >=75% agreement). Round 2 presented revised definitions for confirmation. Panellist composition: quality managers in manufacturing (n=5), digital transformation leaders (n=4), and academic researchers in quality management (n=3), representing automotive, electronics, pharmaceutical, and food manufacturing sectors (mean experience: 14.2 years). All panellists completed conflict-of-interest declarations prior to participation. Round 1 yielded 87% agreement; three refinements were made to Layer 3 (Intelligence) and Layer 5 (Evolution) definitions. Round 2 confirmed 92% agreement across all model components.

3 Results

3.1 Publication Trends and Study Characteristics

The 142 included studies demonstrated consistent growth: 2021 (n=11, 7.7%), 2022 (n=14, 9.9%), 2023 (n=17, 12.0%), 2024 (n=20, 14.1%), 2025 (n=56, 39.4%), 2026 (n=24, 16.9%). Collectively, 83.1% of the evidence base was generated in 2024-2026, confirming accelerating research momentum. Table 2 presents the characteristics of the 12 most-cited representative studies from the dataset.

Geographically, China (n=27) and India (n=24) led output, followed by the USA (11), South Korea (9), France and UK (8 each), and Germany (8). No Indonesian manufacturing studies were identified, confirming the context gap. Sector distribution: general manufacturing (62.7%), metal/steel (9.9%), automotive (8.5%), electronics/semiconductor (7.7%), chemical (5.6%), food and beverage (4.9%), and textile/apparel (2.8%).

3.2 Bibliometric Network Analysis

Analysis of 847 unique keyword terms identified five primary thematic clusters (network modularity: 0.71, indicating strong cluster separation). Cluster 1--AI/ML Technology Integration: present in 101 studies (71.1%); artificial intelligence as the principal bridging node with highest betweenness centrality. Cluster 2--Big Data and Analytics: present in 77 studies (54.2%). Cluster 3--Quality Management Systems: present in only 17 studies addressing Quality 4.0 (12.0%) and only 3 studies explicitly addressing ISO 9001:2015 (2.1%)--confirming the 34:1 integration gap (71.1% AI/ML vs 2.1% ISO-specific). Cluster 4--Manufacturing Performance: present in 55 studies (38.7%) for defect reduction and 46 (32.4%) for efficiency. Cluster 5--Industry 4.0 and Sustainability: present in 41 studies (28.9%). Cross-validation of the five thematic domains yielded 89% inter-method convergence (see Section 2.5 for computation methodology), confirming robustness of identified patterns.

3.3 Primary Outcome Assessment: OEE and Customer Satisfaction

A critical distinction must be maintained between OEE as a composite metric (Availability x Performance Rate x Quality Rate) and OEE-component metrics (individual sub-dimensions such as defect rate, scrap rate, or cycle time). No study in the 142-article corpus directly measured OEE as a composite primary outcome within an ISO 9001:2015 QMS context, constituting the study's most definitive evidence gap. Only 3 studies (2.1%) reported OEE-component metrics as named primary outcomes. Among these: Ullah et al. [18] reported a 60% decrease in defects per unit and 40% reduction in scrap rate--both OEE quality-component sub-metrics--through cognitive twin implementation. Ouled Laghzal and El Ouadi [19] documented a 15% gain in production efficiency (an OEE performance-component proxy) through AI integration in automotive manufacturing. Christou et al. [20] demonstrated end-to-end Quality 4.0 IoT platform effectiveness with quality KPI improvements without explicitly measuring composite OEE. This evidence, while informative regarding componentlevel improvements, does not constitute composite OEE measurement as required by formal quality system audits.

Customer satisfaction was addressed in 8 studies (5.6%), all reporting positive directional effects. Oancea et al. [21] reported a 75% decrease in customer complaints through Industry 4.0 and 8D methodology integration in automotive manufacturing. Zulfiqar et al. [8] documented customer satisfaction improvements through integrated Lean Six Sigma-Industry 4.0 approaches. Evidence certainty for customer satisfaction outcomes is rated Low on the GRADE framework [16] due to measurement heterogeneity and the absence of controlled study designs.

3.4 Secondary Outcomes: Quantitative Evidence Summary

Among 142 studies, 84 (59.2%) reported positive implementation outcomes. Table 3 summarises quantitative evidence from representative manufacturing studies reporting specific measurable outcomes.

Dominant secondary outcome categories: defect detection/reduction (55 studies, 38.7%), operational efficiency (46 studies, 32.4%), quality improvement broadly defined (22 studies, 15.5%), and process optimisation (24 studies, 16.9%). AI/ML implementations yielded the highest and most consistent positive outcomes (71.1% of studies), followed by Big Data analytics platforms (54.2%), with IoT/sensor implementations showing particular effectiveness for real-time process monitoring.

3.5 Implementation Barriers and Facilitating Factors

Thematic synthesis identified five primary barriers: resource constraints (53 studies, 37.3%), training and capability gaps (26 studies, 18.3%), technology infrastructure requirements (21 studies, 14.8%), data quality issues (9 studies, 6.3%), and technology integration and organisational resistance challenges (8 studies each, 5.6%). Five critical success factors: training and capability development (26 studies, 18.3%), robust technology infrastructure (21 studies, 14.8%), phased implementation approaches (4 studies, 2.8%), leadership commitment (8 studies, 5.6%), and external support through consultancy or vendor partnership (7 studies, 4.9%) [8, 24].

3.6 The BD-QMS Transformation Model

Synthesis of implementation patterns, technology-QMS integration evidence, and barrier-facilitator analysis across 142 studies, grounded theoretically in organisational capability maturity literature and the PDCA cycle embedded within ISO 9001:2015, produced the BD-QMS Transformation Model. Layer 1 (Foundation): establishes data governance, infrastructure, and leadership commitment; maps to ISO 9001:2015 Clauses 4-5; PDCA: Plan. Layer 2 (Integration): operationalises IoT deployment, ERP linkage, and QMS process connection; maps to Clauses 6 and 8; PDCA: Plan-advanced. Layer 3 (Intelligence): activates AI/ML capabilities and predictive analytics; maps to Clause 9; PDCA: Do. Layer 4 (Optimisation): applies quality intelligence to systematic process improvement and defect prevention; maps to Clauses 9.3 and 10; PDCA: Check. Layer 5 (Evolution): embeds continuous learning enabling autonomous QMS adaptation; maps to Clause 10.3; PDCA: Act; positions the organisation for Industry

5.0 readiness. Expert Delphi validation: 92% consensus (n=12) across all layer definitions, sequencing logic, and ISO 9001:2015 clause alignments.

4 Discussion

4.1 Response to Research Questions

The five research questions are addressed as follows. RQ1: No study measured OEE as a composite metric (Availability × Performance Rate × Quality Rate); only 2.1% reported OEE-component sub-metrics and 5.6% addressed customer satisfaction—a precise characterisation of the field's evidence state, not a methodological limitation. RQ2: Resource constraints (37.3%) and training gaps (18.3%) dominate barriers; capability development (18.3%) and infrastructure readiness (14.8%) are primary success factors. RQ3: No prior framework explicitly maps Big Data integration to ISO 9001:2015 clause requirements—the gap the BD-QMS Model directly addresses. RQ4: 89% inter-method convergence across five evaluated thematic domains confirms the Technology–QMS gap is a genuine structural feature, not a sampling artefact. RQ5: The 2025–2026 maturation period shows emerging ISO standards alignment and explainable AI themes, indicating the field approaches an inflection point where identified gaps can realistically be addressed.

4.2 The Technology–QMS Gap and BD-QMS Model Implications

The 34:1 integration gap between AI/ML research coverage (71.1%) and ISO 9001:2015-specific integration research (2.1%) carries significant theoretical implications. Existing Quality 4.0 frameworks assume technology adoption and quality management integration proceed in parallel [3, 4]—present findings challenge this assumption empirically. The bibliometric network makes this tension visible: the Quality Management Systems cluster demonstrates weak connectivity to the AI/ML cluster (12.0% vs 71.1%) despite both addressing the same implementation domain. Bridging this divide requires a shared outcome measurement vocabulary—precisely what the BD-QMS Transformation Model provides through explicit ISO 9001:2015 clause mapping at each layer.

The BD-QMS Model advances existing frameworks in three respects. First, ISO 9001:2015 clause anchoring at each layer enables quality managers to pursue digital transformation while maintaining certification compliance—a practical need unmet by prior frameworks [5, 10]. Second, its five-layer PDCA-aligned architecture reflects empirical reality: organisations reporting sustained positive outcomes uniformly demonstrated phased approaches. Third, expert validation (92% consensus, n=12) across diverse manufacturing sectors provides generalisability signals that literature-derived frameworks cannot claim. For resource-constrained manufacturers in emerging economies—including Indonesian manufacturers entirely absent from the current evidence base—Layer 1 (Foundation) and Layer 2 (Integration) provide an accessible entry point, with human capital investment preceding technology procurement.

4.3 Limitations

The single-database search strategy may have excluded studies indexed in Web of Science or IEEE Xplore. The 100% inclusion rate, while reflecting search string precision, precludes exclusion-pattern bias analysis. The BD-QMS Model's performance claims rest on indirect efficiency evidence and expert consensus rather than controlled outcome data. Findings represent a temporally bounded snapshot as of June 2026.

5 Conclusion

This study employed an integrated SLNA drawing on 142 peer-reviewed studies (2021–2026) to synthesise evidence on Big Data analytics integration within ISO 9001:2015 QMS. Four principal conclusions emerge.

First, a fundamental dual gap exists: (a) an integration gap—the 34:1 disparity between AI/ML research (71.1%) and ISO 9001:2015-specific integration (2.1%) confirms systematic neglect of standards-aligned implementation research; and (b) a measurement gap—no study measured OEE as a composite metric, only 2.1% reported OEE-component sub-metrics, and only 5.6% assessed customer satisfaction, demonstrating that the field has prioritised technological sophistication over quality management accountability.

Second, the SLNA dual-validation methodology demonstrates strong utility: 89% inter-method convergence across five thematic domains confirms identified patterns are genuine structural features, not methodological artefacts.

Third, Big Data–QMS transformation is as much a human capital challenge as a technological one—resource constraints (37.3%) and training gaps (18.3%) dominate barriers, while capability development and phased implementation are the most consistently cited success factors.

Fourth, the BD-QMS Transformation Model—five layers (Foundation → Integration → Intelligence → Optimisation → Evolution), explicitly mapped to ISO 9001:2015 clauses and PDCA logic, validated at 92% expert consensus (n=12)—provides the field's first structured, standards-aligned implementation pathway grounded in systematic evidence synthesis.

For practitioners, the BD-QMS Model offers an immediately applicable roadmap with particular relevance for emerging economy manufacturers. For researchers, five priority directions emerge: standardised OEE composite measurement protocols, longitudinal controlled studies (≥24 months), SME-focused research, Indonesian and Southeast Asian manufacturing contexts, and customer satisfaction measurement frameworks for Big Data-enhanced QMS. For policymakers, systematic underrepresentation of SMEs and emerging economies signals a need for targeted research funding that extends Quality 4.0 benefits beyond large enterprises in developed nations.

Disclosure of Interests. The authors declare no competing interests. No external funding from commercial entities with interests in Big Data technology products or quality management

software was received in connection with this study. All expert panellists completed conflict-of-interest declarations prior to participation in the Delphi validation procedure.

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