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Medical device quality management systems (ISO 13485/EU MDR) and competitive advantage in MedTech: A PRISMA 2020 systematic review and research agenda

Systemy zarządzania jakością wyrobów medycznych (ISO 13485/EU MDR) a przewaga konkurencyjna w sektorze MedTech: systematyczny przegląd literatury PRISMA 2020 i agenda badawcza

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Abstract:

Research objectives and hypothesis/research questions

The review is guided by three primary research questions:

RQ1: Which QMS practices (e.g., ISO 13485 documentation, internal/external auditing, risk management, PMS/quality-data activities) are most frequently studied in MedTech organizations, and how are they operationalized?

RQ2: Which outcome categories dominate (e.g., compliance/market access, time-to-market, cost of quality, innovation, operational performance, competitive outcomes), and how are they measured?

RQ3: Which research designs and methods are most common, and what theoretical and methodological gaps remain for operations and quality management research?

Research methods

Searches were conducted in Web of Science Core Collection and Scopus (time window 2020-2026; peer-reviewed journal articles and conference papers; English). Following PRISMA 2020 procedures (identification, screening, full-text eligibility), 60 records were identified (50 Web of Science; 10 Scopus). After title/abstract screening and full-text retrieval, 13 studies met inclusion criteria from the database search. Forward and backward snowballing of reference lists and citations of included studies identified

one additional eligible study (Linck, Tinoco, Bonato et al., 2025). In total, 14 studies were included. Data were extracted using a structured coding frame (context, QMS domain, operationalisation, outcomes, method, key findings). Study quality was appraised using MMAT 2018, where applicable, acknowledging heterogeneity in design.

Main results

Evidence concentrates on four practice clusters: (1) QMS documentation, certification, and maturity assessment, (2) auditing and audit-readiness as governance of compliance and translation, (3) risk management (including cybersecurity and SME constraints), and (4) quality data and post-market surveillance (including AI-enabled literature surveillance and malfunction reporting barriers). Competitive outcomes are typically proxied rather than measured directly, most often via compliance capability, recall risk mitigation, innovation constraints under regulatory change, and operational efficiency. Quantitative, multi-firm evidence linking specific QMS practices to product competitive advantage remains rare.

Implications for theory and practice

The review consolidates fragmented streams (regulatory, clinical governance, AI-enabled surveillance, SME risk management, QMS maturity assessment) into an integrated capability model: QMS practices enable regulatory market access, organisational learning, and operational reliability, which in turn shape time-to-market, cost of quality, and innovation performance. A research agenda is proposed with testable hypotheses and measurement pathways aligned with operations management standards.

Keywords:

MedTech, ISO 13485, quality management system, competitive advantage, systematic literature review

Abstrakt:

Cel badań i hipotezy/pytania badawcze

Przegląd kieruje się trzema głównymi pytaniami badawczymi:

RQ1: Które praktyki SZJ w organizacjach MedTech są najczęściej badane, np. dokumentacja zgodna z ISO 13485, audyty wewnętrzne i zewnętrzne, zarządzanie ryzykiem, działania PMS i aktywności oparte na danych jakościowych, oraz w jaki sposób są one operacjonalizowane?

RQ2: Które kategorie wyników dominują, np. zgodność i dostęp do rynku, czas wprowadzenia na rynek, koszt jakości, innowacyjność, efektywność operacyjna, wyniki konkurencyjne, oraz jak są one mierzone?

RQ3: Które projekty badań i metody są najczęstsze oraz jakie luki teoretyczne i metodologiczne pozostają w badaniach z obszaru zarządzania operacjami i jakością?

Metody badawcze

Przeszukano bazy Web of Science Core Collection i Scopus (okres 2020-2026; recenzowane artykuły i materiały konferencyjne; język angielski). Zgodnie z procedurami PRISMA 2020 zidentyfikowano 60 rekordów. Po przeglądzie tytułów i abstraktów oraz ocenie pełnych tekstów 13 prac spełniło kryteria włączenia. Metoda kuli śnieżnej (cytowania w przód i wstecz) pozwoliła zidentyfikować jedno dodatkowe badanie (Linck, Tinoco, Bonato et al., 2025). Łącznie włączono 14 prac.

Główne wyniki

Analizowane badania koncentrują się w czterech obszarach: (1) dokumentacja QMS, certyfikacja i ocena dojrzałości, (2) audyty i gotowość audytowa jako mechanizm zarządzania zgodnością, (3) zarządzanie ryzykiem, (4) dane jakościowe i nadzór porejestracyjny. Wpływ na konkurencyjność mierzony jest zwykle pośrednio – najczęściej przez zdolność zapewnienia zgodności regulacyjnej, ograniczenie ryzyka wycofań z rynku, bariery innowacyjne i efektywność operacyjną. Badania ilościowe na próbach wielofirmowych, bezpośrednio łączące praktyki QMS z przewagą konkurencyjną, pozostają rzadkością.

Implikacje dla teorii i praktyki

Przegląd porządkuje rozproszone wątki badawcze w spójny model: praktyki QMS umożliwiają uzyskanie dostępu do rynku, wspierają uczenie się organizacyjne i zapewniają niezawodność operacyjną – co z kolei przekłada się na czas wprowadzenia wyrobu, koszty jakości i wyniki innowacyjne. Zaproponowano agendę badawczą zawierającą testowalne hipotezy i ścieżki pomiarowe zgodne ze standardami zarządzania operacyjnego.

Słowa kluczowe:

MedTech, ISO 13485, system zarządzania jakością, przewaga konkurencyjna, systematyczny przegląd literatury

Introduction

Medical technology companies compete in an environment where product performance, safety, and regulatory compliance co-evolve. The sector's product space spans hardware devices, implantables, in vitro diagnostics (IVD), and software as a medical device (SaMD), increasingly incorporating AI/ML and connected functionality. As device complexity rises, quality failures translate not only into patient risk but also into recalls, liability, disruption of supply chains, reputational damage, and delayed market access – channels that directly affect competitiveness and firm performance.

In Europe, the Medical Device Regulation (MDR 2017/745) and the In Vitro Diagnostic Regulation (IVDR 2017/746) strengthened requirements related to clinical evidence, traceability, post-market surveillance (PMS), and lifecycle documentation. In practice, these requirements interact with ISO 13485-based QMS design controls, risk management, auditing regimes, and corrective/preventive mechanisms. For manufacturers, QMS practices can therefore be interpreted in two complementary ways: (a) as compliance infrastructure enabling market access, and (b) as an operations capability enabling reliability, learning, and process discipline that can support innovation and performance.

Despite this strategic relevance, the research landscape is dispersed. Many publications emphasize regulatory interpretation, clinical evidence, or technical verification, while fewer studies examine how QMS practices translate into organizational outcomes such as time-to-market, cost of quality, or product advantage. Even when "performance" is discussed, operationalizations vary widely: some studies focus on audit readiness, others on project approvals, the efficiency of PMS literature monitoring, or recall-related risk prediction. This dispersion limits cumulative knowledge building, particularly for operations and quality management research seeking theoretically grounded, measurable links between quality systems and competitive outcomes.

This systematic review addresses this gap by synthesizing recent peer-reviewed evidence (2020-2026) on QMS practices in the MedTech sector, their operationalization, and the outcomes they are associated with. The review culminates in an integrative framework and a research agenda tailored to quality management and operations management scholarship.

1. Research questions

The review is guided by three primary research questions:

RQ1: Which QMS practices (e.g., ISO 13485 documentation, internal/external auditing, risk management, PMS/quality-data activities) are most frequently studied in MedTech organizations, and how are they operationalized?

RQ2: Which outcome categories dominate (e.g., compliance/market access, time-to-market, cost of quality, innovation, operational performance, competitive outcomes), and how are they measured?

RQ3: Which research designs and methods are most common, and what theoretical and methodological gaps remain for operations and quality management research?

2. Contribution

The paper contributes in three ways. First, it provides a consolidated evidence map of QMS practices and outcome types in the medical-device industry. Second, it offers an integrative thematic synthesis highlighting plausible mechanisms that connect medical-device quality-system maturity to competitive advantage under MDR-like institutional pressures. Third, it proposes a research agenda with testable propositions, measurement suggestions, and design recommendations suited to the MedTech sector and aligned with operations management and quality management scholarship.

3. Methods (PRISMA 2020)

3.1. Reporting standard and protocol

This systematic literature review (SLR) follows PRISMA 2020 reporting guidance (Page, McKenzie, Bossuyt et al. 2021), including transparent documentation of databases, search strategies, screening stages, inclusion/exclusion criteria, and synthesis approach. The review design anticipates heterogeneity in empirical designs (qualitative, case study, design science, conceptual/review), which motivates a primarily thematic synthesis, supplemented by structured mapping of contexts, QMS domains and outcomes.

3.2. Information sources

Searches were conducted in Web of Science Core Collection and Scopus. The search date was 16 January 2026. The time window was restricted to 2020-2026 to capture recent dynamics linked to the post-implementation period of MDR-oriented organisational change and the rising role of digital quality intelligence. Following database screening, forward and backward snowballing was conducted: reference lists of all 13 database-included studies were screened (backward snowballing), and citing articles were identified via Google Scholar and Semantic Scholar (forward snowballing). Candidate records were assessed against the same eligibility criteria used for database records.

3.3. Search strategy

Search strings were developed iteratively by combining three conceptual clusters: (1) MedTech/medical device sector (including medical devices, IVD, and software as a medical device), (2) quality systems and practices (QMS, ISO 13485, auditing/internal audit, CAPA, nonconforming product control, quality data/monitoring, risk management, post-market surveillance/vigilance), and (3) competitive and performance outcomes (competitive advantage/product advantage, firm/market performance, innovation, time-to-market, cost of quality, recall risk and resilience). The final database queries are reported in Appendix A.

3.4. Eligibility criteria

Operational definitions and inclusion/exclusion criteria were defined ex ante and applied consistently at screening and full-text stages. MedTech sector is defined here as organisations involved in the development, manufacturing, and supply of medical devices (including IVD) and software as a medical device (SaMD), operating under medical-device regulatory frameworks. QMS is defined broadly to include ISO 13485-oriented or MDR-aligned organisational practices and routines that govern product quality and lifecycle safety, including internal auditing/audit readiness, risk management, post-market surveillance and complaint handling, quality data monitoring and feedback, and process/documentation controls required for regulatory market access.

Inclusion criteria require that studies: (1) focus on medical device/MedTech organizations; (2) examine at least one QMS domain; (3) report or theorize links to competitive advantage or related outcomes; (4) are peer-reviewed journal articles or conference papers indexed in WoS/Scopus; (5) published 2020-2026, English language. Studies were excluded if they were purely clinical without organizational QMS content, purely technical engineering without quality-system context, or editorials/commentaries without methods.

3.5. Study selection process

Selection was performed in two stages: (1) title/abstract screening, and (2) full-text eligibility assessment. Screening decisions were documented in an audit trail; uncertain records were retained for full-text assessment. Screening and extraction were conducted by one reviewer (A.P.) using a structured decision rulebook. A random 20% sample (n = 12) was independently screened by a second reviewer (dr Angelika Pańka, Nicolaus Copernicus University in Toruń). Inter-rater agreement was perfect (Cohen's $\kappa = 1.00$; 12/12 concordant decisions, 7 include, 5 exclude).

3.6. Data extraction and coding

A structured extraction form was applied to all included studies, capturing bibliographic metadata, context, QMS domain, operationalization, outcomes, design/method, and key findings.

3.7. Quality appraisal (MMAT 2018)

Methodological quality was appraised using the Mixed Methods Appraisal Tool (MMAT, 2018; Hong, Fàbregues, Bartlett et al., 2018), enabling consistent assessment across qualitative, quantitative, and mixed-methods designs. For papers that were primarily conceptual/implementation frameworks without evaluative empirical components, MMAT criteria were recorded as not applicable; these papers were retained for mechanism mapping but were weighted accordingly in the quality-of-evidence discussion. Quality appraisal was not used to exclude studies but to inform confidence in evidence streams.

3.8. Synthesis approach

Given heterogeneity in constructs and outcomes, a meta-analysis was not appropriate. The synthesis therefore used: (1) descriptive mapping (study characteristics, contexts, methods, outcome types), and (2) thematic synthesis organized around QMS domains and mechanism–outcome pathways, culminating in an integrative conceptual framework and research agenda.

4. Results

4.1. Study selection (PRISMA flow)

The database search identified 60 records (Web of Science n = 50; Scopus n = 10). No duplicates were detected using DOI and title/year matching. Following title/abstract screening (n = 60), 47 records were excluded as out of scope (primarily clinical/technical studies without QMS organizational content). Thirteen full texts were assessed for eligibility; all 13 met inclusion criteria and were included. Subsequently, forward and backward snowballing of all 13 included studies identified one additional eligible record (Linck, Tinoco, Bonato et al., 2025, identified via forward citations of Kheir, Smedts, Jacoby et al., 2021). In total, 14 studies were included in the synthesis.

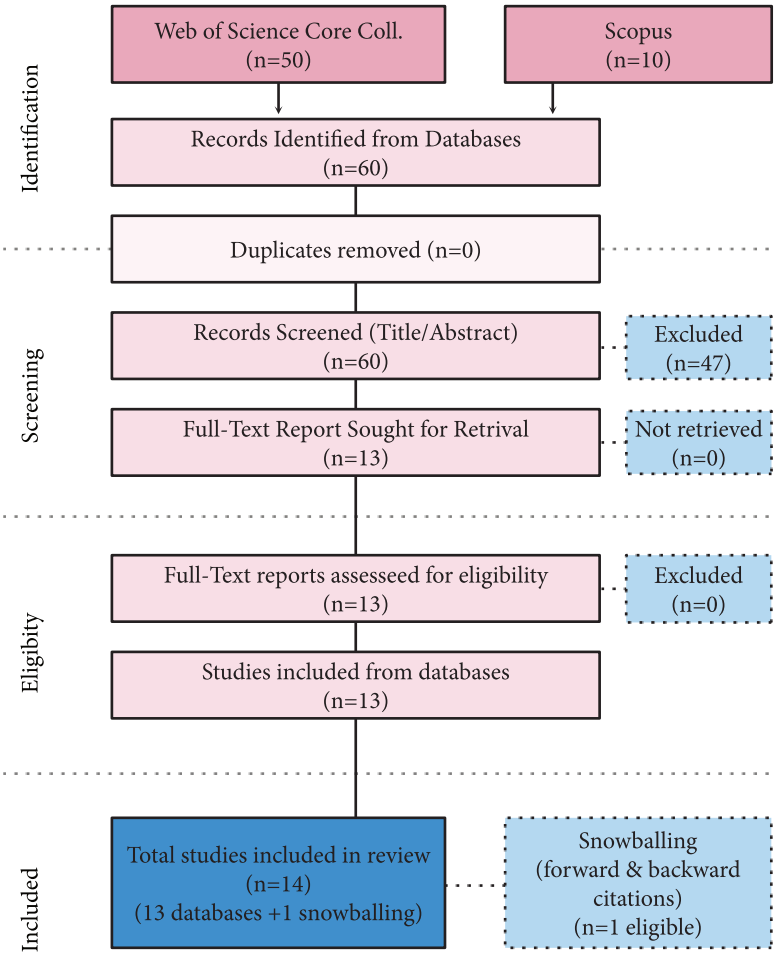

Fig. 1. PRISMA 2020 flow diagram of study selection
Source: own elaboration

Table 1. PRISMA 2020 flow (numerical summary)

PRISMA 2020 item	Count
Records identified from databases (WoS + Scopus)	60
Records removed before screening: duplicates	0
Records screened (title/abstract)	60
Records excluded at screening	47
Reports sought for retrieval (full text)	13
Reports not retrieved	0
Reports assessed for eligibility	13
Reports excluded (with reasons)	0
Records identified via snowballing (forward citations)	1
Studies included in synthesis	14

Source: own elaboration

4.2. Characteristics of included studies

The 14 included studies span 2020-2026, with a concentration in the post-MDR enforcement period. Geographically, the evidence covers Europe (Belgium, Czech Republic, Portugal, Sweden, UK, Ireland/France), Asia (Japan, Pakistan, India), and Latin America (Brazil). Study designs are dominated by qualitative multiple case studies, implementation/case reports, and technical evaluations of quality-data processes; large-sample surveys linking QMS maturity to competitive advantage constructs were not observed in this evidence set.

Thematically, six clusters emerge: QMS documentation and certification for start-ups and academic R&D; QMS maturity assessment and implementation diagnostics; auditing practices; risk management practices; post-market surveillance and quality data analytics; and regulatory turbulence as a strategic constraint.

Table 2. Included studies: context, QMS focus, outcomes, methods, and key findings (n = 14)

Study (year)	Context	QMS domain(s)	Outcome(s)	Method/design	Key finding (condensed)	Type
Kadambi, Alagumalai (2020)	India; MedTech dev. platform	QMS (ISO-aligned); design controls	COMPLIANCE; TTM; PERF	Retrospective QMS record review	Platform supported FDA/CE/India-compliant device development across types.	Conference paper
De Maria, Di Pietro, Lantada et al. (2020)	EU/global; open-source collab.	ISO 13485-inspired; MDR-inspired pathway	INNOV; COMPLIANCE; COQ	Design paper/platform description	E-infrastructure supports collaborative device co-design while promoting compliance.	Conference proc.
Yaqoob, Abbas, Shafqat (2020)	Networked devices; Pakistan	Integrated safety–security–privacy risk assessment	COMPLIANCE; RESILIENCE	Framework + illustrative case	Proposes unified risk assessment for connected devices under regulatory expectations.	Journal
Maresova, Rezny, Peter et al. (2021)	Czech Republic; SME manuf.	MDR-driven QA strengthening	COQ; INNOV; COMPLIANCE	Case study + sector analysis	MDR improves safety/recalls but imposes high cost/admin burden; SMEs may exit MedTech.	Journal
Kheir, Smedts, Jacoby et al. (2021)	Belgium; MedTech start-up	ISO 13485 documentation; QMS set-up	COMPLIANCE; TTM; COQ	Case-based guideline	Documentation roadmap for ISO 13485 compliance in start-ups.	Journal
Mishra, Shukla (2021)	USA; manufacturer audits	AUDIT; QSR; MDSAP	COMPLIANCE; TTM	Narrative review/guideline	Synthesizes audit processes; links compliance to market access.	Journal
Tase, Ni, Buckle et al. (2022)	UK; clinicians + manufacturers	Q-DATA; vigilance reporting	COMPLIANCE; Q-DATA quality; RESILIENCE	Qualitative interviews + surveys	Under-reporting and poor data limit trend detection and learning.	Journal
Reniewicz, Suryaprakash, Kowalczyk et al. (2024)	EU/global; IVD PMS	PMS; Q-DATA analytics (AI/NLP)	EFFICIENCY; COMPLIANCE; COQ	Comparative evaluation	AI/NLP reduced analyst time and improved screening precision for PMS.	Journal

cont. tab. 2

Study (year)	Context	QMS domain(s)	Outcome(s)	Method/design	Key finding (condensed)	Type
Lopes, Pinto, Da Silva et al. (2025)	Portugal; SaMD certification	QMS; AUDIT; clinical evaluation	COMPLIANCE; TTM	Regulatory analysis + case	Details MDR certification workflow for SaMD.	Journal
Buist, Ortiz-Catalan (2025)	Sweden; academic MDR QMS	ISO 13485-aligned QMS for academia	COMPLIANCE; INNOV	Implementation case	Tailored QMS enabled MDR-compliant clinical investigation approval.	Journal
Ushimaru, Katoh, Sasaki et al. (2025)	Japan; academia–industry R&D	AUDIT (internal); governance	INNOV; PERF; market expansion	Retrospective audit + stats	50% device success; associated with IP, funding, and sales involvement.	Journal
Hu, Montcolo, Ghadimi (2026)	Industrial; recall risk	Q-DATA analytics; recall prediction	RESILIENCE; COQ; COMPLIANCE	ML framework evaluation	Proactive recall-initiator prediction; best configuration reported weighted accuracy of approx. 89%.	Journal
Xavier, Da Silva, Sampaio et al. (2026)	Brazil/Portugal; SMEs	RISK; QMS audit subjectivity	COMPLIANCE; INNOV	Multiple case study	Risk management varies across risk classes; training and audit standardization needed.	Journal
Linck, Tinoco, Bonato et al. (2025)	Brazil; med. refrigeration manuf.	ISO 13485 maturity assessment; QMS diagnostics	COMPLIANCE; PERF; TTM	Abductive case study	52-requirement maturity tool applied; overall 3.45/5; operations dimension lowest; FDA approval achieved post-intervention.	Journal

Source: own elaboration

4.3. Thematic synthesis

Building QMS capability under resource constraints

A dominant theme is translating regulatory and ISO requirements into workable operating systems under limited resources. Kheir, Smedts, Jacoby et al. (2021) position ISO 13485 as a practical backbone for start-ups, emphasizing that early quality-system structuring creates a trade-off between speed and compliance workload – a classic capacity-allocation problem. The same logic applies to academic-to-market translation: Buist and Ortiz-Catalan (2025) discuss how research environments must increasingly align with MDR-aligned QMS practices. Both studies converge on a mechanism in which QMS adoption creates a routinised regulatory market-access capability that becomes a prerequisite for competing on other dimensions.

Certification and conformity assessment as time-to-market governance

Lopes, Pinto, Da Silva et al. (2025) combine a European regulatory analysis with a SaMD certification case study. They highlight that SaMD certification requires an integrated set of standards (ISO 13485, IEC 62304, IEC 82304-1) and that the certification process can take 1.5-3 years – a direct, measurable time-to-market implication of quality-system requirements in regulated software innovation.

Auditing and audit readiness as quality governance and organisational learning

Auditing appears in three forms: (i) regulatory audit expectations – Mishra and Shukla (2021) map US FDA inspection practices and position audit preparedness as a core compliance competency; (ii) internal auditing as governance – Ushimaru, Katoh, Sasaki et al. (2025) report that external funding and IP acquisition were positively associated with project completion in an academia–industry platform; and (iii) audit variability as a risk – Xavier, Da Silva, Sampaio et al. (2026) show that auditor subjectivity creates unpredictable compliance expectations for SMEs even with similar QMS documentation.

Risk management as a cross-cutting QMS mechanism

Risk management connects QMS practices to competitive outcomes across both pre-market and post-market phases. Xavier, Da Silva, Sampaio et al. (2026) identify persistent implementation challenges in medical device SMEs (11 companies, Brazil and Portugal), noting that SMEs recognise risk management as crucial but difficult under limited resources. Yaqoob, Abbas, and Shafqat (2020) broaden the scope by proposing an Integrated Safety, Security, and Privacy (ISSP) framework for connected devices.

Post-market quality data, surveillance, and the learning loop

The post-market phase is where QMS routines become learning systems. Tase, Ni, Buckle et al. (2022) identify under-reporting and normalised workarounds that restrict system learning in malfunction reporting. Reniewicz, Suryaprakash, Kowalczyk et al. (2024) evaluate an AI/ML tool for PMS literature surveillance, reporting substantial reductions in screening time. The implication: firms that detect signals earlier may reduce recall risk and improve responsiveness.

Regulatory change as a structural shock

Maresova, Rezny, Peter et al. (2021) analyse regulatory change effects in the Czech Republic, reporting a dual outcome: improved patient safety but increased financial and administrative burdens for small companies. This implies a contingent logic: QMS capability may become a selection mechanism, rewarding firms with compliance economies of scale and penalising smaller innovators.

QMS maturity assessment as a diagnostic and improvement tool

Linck, Tinoco, Bonato et al. (2025) develop and validate a maturity assessment methodology for ISO 13485:2016, constructing a five-level scale across 52 certifiable requirements in four categories: quality policies, planning, operations, and business process improvement. Applied in a Brazilian medical refrigeration manufacturer (Class II), the assessment revealed overall maturity of 3.45/5, with operations scoring lowest (3.11) – primarily due to insufficient digitalisation and incomplete procedure standardisation. Notably, the company achieved FDA approval months after the methodology was applied. This study provides one of the few empirically grounded instruments for measuring the gap between QMS presence and QMS capability, and the explicit linkage to subsequent regulatory market access represents a rare observable competitive outcome in the included evidence set.

4.4. Mapping outcomes across studies

Direct measurement of competitive advantage (market share, price premium, growth, ROI, customer loyalty, product advantage) is largely absent. Instead, the evidence uses proxies tightly aligned with operations and regulatory realities: market access and audit/certification success, time-to-market constraints, cost and administrative burden, resilience and recall risk, operational efficiency in surveillance, and innovation throughput and project conversion.

Table 3. Evidence map: QMS domains and outcome categories (number of studies addressing each intersection)

Quality domain	Competitive/ market	Operational perf.	Innovation	TTM/ cert. speed	Cost/ burden	Compliance	Resilience (recall)
ISO 13485/ QMS impl.	0	1	2	5	2	7	0
Internal audit/ inspection	1	1	0	2	0	3	0
Risk management	0	0	1	0	0	2	2
PMS/quality data analytics	0	1	0	1	1	3	2
Recall prevention	0	0	0	0	1	1	1

Source: own elaboration

4.5. Quality appraisal (MMAT 2018)

Table 4. MMAT 2018 appraisal summary

Study	Design	MMAT applic.	Key strengths	Key limitations	Overall
Kadambi, Alagumalai (2020)	Retrospective QMS review	Yes	Uses QMS records as evidence	Single setting; limited method detail	Moderate
Yaqoob, Abbas, Shafqat et al. (2020)	Framework + case	Partial	Rigorous framework design	Limited empirical validation	Low-Mod
De Maria, Di Pietro, Lantada et al. (2020)	Design paper	N/A	Practical design science	No evaluative study	N/A
Maresova, Rezny, Peter et al. (2021)	Case + sector analysis	Yes	Company and sector data	Context-specific; forecast assumptions	Moderate
Kheir, Smedts, Jacoby et al. (2021)	Case-based guideline	Partial	Pragmatic for practitioners	Limited evaluative metrics	Low-Mod
Mishra, Shukla (2021)	Narrative review	N/A	Comprehensive audit synthesis	No primary data	N/A
Tase, Ni, Buckle et al. (2022)	Mixed methods	Yes	Multiple stakeholders; triangulation	Sampling limitations; self-report	Mod-High

cont. tab. 4

Study	Design	MMAT applic.	Key strengths	Key limitations	Overall
Reniewicz, Suryaprakash, Kowalczyk et al. (2024)	Quant. comparative	Yes	Clear AI vs manual comparison	Task-specific; external validity limits	Mod-High
Lopes, Pinto, Da Siva et al. (2025)	Reg. analysis + case	Partial	Detailed SaMD certification steps	Case specificity	Moderate
Buist, Ortiz-Catalan (2025)	Implementation case	Yes (qual.)	Concrete MDR QMS steps	Context-specific	Moderate
Ushimaru, Katoh, Sasaki et al. (2025)	Retrospective eval.	Yes	Operational metrics	Single platform	Mod-High
Hu, Monticolo, Ghadimi (2026)	ML modelling	Yes	Formal modelling; replicable	Advantage inferred; data limits	Mod-High
Xavier, Da Silva, Sampaio et al. (2026)	Multiple case study	Yes	Cross-country; SME focus	Interview-based; small n	Mod-High
Linck, Tinoco, Bonato et al. (2025)	Abductive case study	Yes (qual.)	Validated maturity tool; multi-source data; post-intervention outcome	Single case; convenience sampling of experts	Moderate

Source: own elaboration

5. Discussion

5.1. From compliance to competitive advantage

Across the included studies (2020-2026), quality management in MedTech appears primarily as a compliance-driven capability anchored in ISO 13485 and the EU MDR, but with clear signals that it can be leveraged beyond regulatory hygiene toward measurable strategic outcomes. The most consistent pattern is that the same set of QMS practices that ensures conformity (documentation, traceability, risk management, internal audits, post-market surveillance and vigilance, corrective actions) also creates organizational mechanisms that can translate into competitive advantage when deliberately managed as learning and execution systems rather than as bureaucratic overhead.

Three cross-cutting mechanisms emerge. First, credibility and market access as a strategic asset: certification readiness and auditability are treated as prerequisites for regulated markets (Lopes, Pinto, Da Silva et al., 2025; Buist, Ortiz-Catalan, 2025). Second, speed and efficiency through structured execution: quality infrastructure standardizes development and post-market routines (Kheir, Smedts, Jacoby, 2021; Linck, Tinoco, Bonato et al., 2025). Third, learning and risk reduction via data and analytics: continuous data flows are essential for detection and risk mitigation, but practical barriers remain (Tase, Ni, Buckley et al., 2022; Reniewicz, Suryaprakash, Kowalczyk et al., 2024).

5.2. Methodological gaps

The dominant pattern is explanatory ambition paired with descriptive evidence. The field lacks: (i) multi-firm quantitative studies with validated QMS practice scales, (ii) longitudinal designs linking QMS change to performance change, (iii) econometric isolation of regulatory-shock effects, and (iv) operationalisations connecting to strategy literature. Competitive advantage in MedTech operates through mediating mechanisms (market access, reliability, surveillance responsiveness) that are rarely modelled or tested quantitatively.

5.3. Research agenda

Measurement agenda

Future studies should differentiate between QMS presence (certification, documented procedures) and QMS capability (how effectively the system enables learning, speed, and risk reduction). Building on Linck, Tinoco, Bonato et al.'s (2025) foundational maturity assessment, an expanded capability-maturity instrument could span: audit effectiveness, CAPA effectiveness, nonconforming product control, quality data analytics maturity, management review governance, risk management integration, and digital quality readiness.

Testable propositions

Based on the mechanisms observed in the included studies, the following testable propositions can structure quantitative and mixed-method research:

- Proposition A (compliance-to-speed pathway): Higher QMS capability maturity is associated with shorter certification and change-approval cycle times (time-to-market), mediated by documentation completeness and audit readiness;

- Proposition B (data-to-learning pathway): Quality data analytics maturity is associated with lower post-market risk (complaints, malfunctions, recalls), mediated by faster detection and CAPA closure effectiveness;
- Proposition C (regulatory pressure as moderator): MDR-related regulatory pressure strengthens the relationship between QMS capability and performance for SMEs up to a threshold, after which compliance costs may crowd out innovation investment (an inverted-U effect);
- Proposition D (digital quality as productivity lever): Adoption of AI-enabled surveillance and analytics tools improves PMS process productivity and completeness, which in turn improves compliance outcomes and reduces cost of quality;
- Proposition E (audit as coordination capability): Internal audits function as cross-boundary coordination mechanisms in ecosystems (academia--industry, suppliers), improving development throughput and reducing rework.

Methodological agenda

Three design types are particularly valuable. First, multi-respondent surveys linking capability measures (audit, CAPA, risk management) with objective outcomes (recall frequency, time-to-CE marking, complaint rates), controlling for risk class and firm size. Second, longitudinal case comparisons around MDR transition, tracing QMS investments against development speed and survival. Third, quasi-experiments comparing PMS productivity before/after AI-enabled surveillance implementation.

Theoretical agenda

A publishable theoretical contribution for operations management can be built by explicitly positioning QMS as: an institutionalized baseline capability required for legitimacy in regulated markets (institutional theory), a firm-specific dynamic capability that enables reliable execution, learning, and rapid adaptation to changes (dynamic capabilities), and a mechanism that converts compliance costs into strategic assets when integrated with digital tools and data-driven governance (RBV and operations strategy). This framing helps reconcile the cost-burden narrative observed for SMEs under regulatory change with the capability-advantage narrative implied in studies that treat QMS as a structured learning system.

6. Practical implications

For MedTech executives and quality leaders, three implications follow. First, manage QMS as a performance system, not just a compliance requirement – firms using QMS routines as organizational memory can standardize development and reduce rework. Second, strengthen the post-market intelligence loop: under-reporting undermines continuous improvement and increases regulatory exposure (Tase, Ni, Buckle et al., 2022). Third, invest selectively in digital quality capabilities: AI-enabled surveillance can increase efficiency and completeness of regulatory work (Reniewicz, Suryaprakash, Kowalczyk et al., 2024; Hu, Monticolo, Ghadimi et al., 2026).

7. Limitations

This review has limitations. First, the 2020-2026 window may under-represent earlier foundational work. Second, competitive advantage is measured indirectly in most studies. Third, only WoS and Scopus were searched; grey literature was excluded. Fourth, snowballing relied on Google Scholar and Semantic Scholar, which may not capture all citing works. Fifth, screening was primarily single-reviewer (A.P.) with 20% inter-rater reliability check (Cohen's $\kappa = 1.00$; 12/12 concordant decisions, performed by dr Angelika Pańka, Nicolaus Copernicus University in Toruń); full dual independent screening is recommended for replication.

8. Conclusions

This PRISMA 2020-based systematic review synthesizes evidence from 14 studies (2020-2026) on ISO 13485/MDR-aligned quality systems and competitive outcomes in MedTech. The evidence consistently shows that quality systems create organizational mechanisms beyond compliance that can plausibly generate competitive advantage through market access credibility, faster execution, and learning-based risk reduction. However, the field lacks validated measurement instruments and causal models linking specific QMS practices to explicit competitive outcomes. The proposed research agenda prioritizes capability-based measurement, theory integration (institutional plus RBV/dynamic capabilities), and empirical designs connecting QMS maturity to time-to-market, cost of quality, and market performance.

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Appendix A. Final search strategies (as executed)

Web of Science Core Collection (Topic; TS), time filter: 2020-2026

TS = ((“medical device*” OR medtech OR “medical technolog*” OR “health technolog*” OR SaMD OR “software as a medical device”) AND (“quality management system*” OR QMS OR “quality control” OR “quality assurance” OR “ISO 13485” OR TQM OR “Quality 4.0” OR “digital quality”) AND (performance OR “firm performance” OR “market performance” OR “competitive advantage” OR competitiveness OR “product advantage” OR innovation OR “time-to-market” OR “cost of quality” OR compliance OR certification OR recall))

Scopus (TITLE-ABS-KEY), time filter: 2020-2026

TITLE-ABS-KEY(((“medical device*” OR medtech OR “medical technolog*” OR “health technolog*” OR SaMD OR “software as a medical device”) AND (“quality management system*” OR QMS OR “quality control” OR “quality assurance” OR “ISO 13485” OR TQM OR “Quality 4.0” OR “digital quality”) AND (performance OR “firm performance” OR “market performance” OR “„competitive advantage” OR competitiveness OR “product advantage” OR innovation OR “time-to-market” OR “cost of quality” OR compliance OR certification OR recall)))

Appendix B. PRISMA 2020 checklist (completed with section/page references)

Table B1. PRISMA 2020 checklist item locations

PRISMA item	Checklist element	Reported in section
Title	Identifies report as systematic review	Title
Abstract	Structured summary	Abstract
Introduction: Rationale	Background and need for synthesis	Introduction
Introduction: Objectives	Explicit review questions	Research questions
Methods: Eligibility	Inclusion/exclusion criteria	Eligibility criteria
Methods: Info sources	Databases and dates	Information sources
Methods: Search strategy	Complete strings	Search strategy + Appendix A
Methods: Selection	Screening process	Study selection process
Methods: Data collection	Extraction and coding	Data extraction and coding
Methods: Risk of bias	Quality appraisal tool	Quality appraisal (MMAT 2018)
Methods: Synthesis	Synthesis approach	Synthesis approach
Results: Study selection	PRISMA numbers	Study selection/PRISMA flow (Table 1)
Results: Characteristics	Descriptive mapping	Characteristics of included studies (Table 2)
Results: Risk of bias	Appraisal summary	Quality appraisal results (Table 4)
Results: Synthesis	Themes and mechanism map	Thematic synthesis + Mapping outcomes (Table 3)
Discussion	Interpretation and limitations	Discussion + Limitations
Other: Funding	Funding statement	Declared above
Other: Competing int.	Competing interests	Declared above

Appendix C. Studies excluded at full-text stage (with reasons)

All 13 records that proceeded to full-text screening from the database search met the eligibility criteria and were included. No records were excluded at the full-text stage. In the snowballing phase, 13 backward-referenced and citing articles were screened at title/abstract level; 12 were excluded (primarily due to scope mismatch: clinical trial methodology, pure regulatory commentary without QMS operational content, or publication date outside the 2020-2026 window). One record (Linck, Tinoco, Bonato et al., 2025) met all criteria and was included. Detailed exclusion reasons for all 47 records excluded at title/abstract stage are available from the corresponding author upon request.