

Risk-Based Quality Management in Device Manufacturing

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ABSTRACT

Medical device manufacturing quality management has traditionally relied on end-of-line inspection and batch release testing -- approaches that detect defects after they occur rather than preventing them. Risk-based quality management (RBQM) redirects resources from uniform inspection toward proactive identification and control of the process parameters most likely to affect patient safety, aligning with the ISO 13485:2016 emphasis on risk-proportionate quality processes and the FDA's shift toward process analytical technology. This study presents the Risk-Based Quality Management Assessment Framework (RBQMAF), evaluating five quality management strategies -- traditional inspection-centric QMS, statistical process control (SPC), process analytical technology (PAT), failure mode and effects analysis-driven control (FMEA-DC), and AI-augmented predictive quality -- across four manufacturing quality tasks: incoming material qualification, in-process defect prevention, final product conformance assurance, and CAPA effectiveness. Our Manufacturing Quality Performance Score (MQPS) integrates defect escape rate, process capability index, CAPA closure effectiveness, inspection efficiency, and regulatory audit readiness. AI-augmented predictive quality achieved the highest MQPS (0.932) through gradient-boosted models trained on 2.8 million process parameter records that predict non-conformances 4.2 hours before detection by traditional methods, enabling pre-emptive intervention that reduced scrap rates by 38%. FMEA-driven control achieved the highest regulatory audit readiness (0.960) through systematic risk linkage between process controls and patient safety outcomes.

Keywords: quality management; risk-based; medical device manufacturing; ISO 13485; statistical process control; process analytical technology; FMEA; predictive quality; CAPA; GMP compliance

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1. Introduction

1.1 The Quality Management Evolution in Medical Devices

The quality management paradigm for medical device manufacturing has undergone three generational shifts since the original Good Manufacturing Practice (GMP) regulations. The first generation (1978-1996) emphasised end-of-line inspection and lot sampling, accepting that some defective units would be produced and relying on statistical sampling to catch them before shipment. The Quality System Regulation (21 CFR Part 820), finalised in 1996, introduced the second generation by requiring process validation, design controls, and corrective and preventive action (CAPA) systems that address root causes rather than symptoms (FDA, 1996). The third generation, catalysed by ISO 13485:2016 and the EU MDR 2017/745, adds risk-based thinking throughout the quality system: the intensity of quality controls should be proportionate to the risk that process failures pose to patient safety, rather than applied uniformly across all processes regardless of criticality (ISO, 2016). Despite this regulatory evolution, survey data from the Medical Device Innovation Consortium suggests that 62% of device manufacturers still allocate quality resources primarily based on historical inspection patterns rather than prospective risk assessment, and that only 24% have implemented real-time statistical process monitoring across critical manufacturing operations (MDIC, 2020).

1.2 Five Quality Management Strategies

Five strategies represent the spectrum from reactive to predictive quality management. Traditional inspection-centric QMS (baseline) relies on incoming inspection, in-process visual checks, and final lot release testing with acceptance quality limits (AQL) defined per ANSI/ASQ Z1.4. Statistical process control (SPC) monitors critical-to-quality (CTQ) parameters in real time using Shewhart control charts, Western Electric rules, and process capability indices (Cpk), triggering investigation when processes drift toward specification limits (Montgomery, 2019). Process analytical technology (PAT) extends SPC with in-line and at-line spectroscopic, imaging, and sensor measurements that characterise product quality during manufacturing rather than testing it afterward (FDA, 2004). FMEA-driven control integrates ISO 14971 risk management with manufacturing process control: each process step receives a risk priority number

based on failure severity, occurrence, and detectability, and control intensity scales with RPN (Stamatis, 2003). AI-augmented predictive quality trains machine learning models on historical process and quality data to predict non-conformances before they occur. Section 2 reviews the literature. Section 3 describes RBQMAF. Results in Section 4, discussion in Section 5, conclusions in Section 6.

2. Literature Review

2.1 Statistical Process Control and Process Validation

SPC adoption in medical device manufacturing has been slower than in automotive and semiconductor industries, partly due to the lower production volumes typical of medical devices and partly due to regulatory frameworks that historically emphasised lot release testing over process monitoring. Woodall (2000) demonstrated that control chart monitoring reduced out-of-specification rates by 35-55% in semiconductor fabrication, findings later replicated in medical device contexts by Chen et al. (2014) who reported a 42% reduction in non-conformance reports after implementing multivariate SPC across 15 critical process parameters in a catheter manufacturing facility. The FDA's 2011 process validation guidance explicitly endorsed continuous process verification -- ongoing SPC monitoring during routine production -- as the third stage of a lifecycle approach to validation, replacing the legacy concept of three validation batches followed by assumed process stability (FDA, 2011). Arafat et al. (2018) found that manufacturers implementing Stage 3 continuous monitoring detected process drift an average of 6.4 weeks earlier than those relying solely on periodic revalidation, preventing an estimated 12-18% of non-conformances from reaching final product.

2.2 FMEA and Risk-Based Approaches

Process FMEA (pFMEA) has become the standard tool for linking manufacturing risk to quality control intensity. The AIAG-VDA FMEA handbook, adopted by the medical device industry through the GHTF/IMDRF framework, provides a structured methodology for identifying failure modes, assessing their severity, occurrence, and detectability, and assigning risk priority numbers that drive control plan development (AIAG, 2019). However, Sharma et al. (2018) identified significant limitations in traditional FMEA practice: the ordinal RPN scale is mathematically

arbitrary (a severity 10 x occurrence 1 x detection 1 = 10 receives the same RPN as severity 1 x occurrence 2 x detection 5 = 10, despite radically different risk profiles), and inter-rater reliability for FMEA scoring is poor (ICC 0.41-0.58). Liu et al. (2019) proposed a fuzzy-logic enhancement to FMEA that addressed the RPN sensitivity problem by treating severity, occurrence, and detection as fuzzy linguistic variables with non-linear aggregation rules, improving correlation with actual field failure rates from $r = 0.52$ (traditional RPN) to $r = 0.81$. Table 1 maps the key studies.

2.3 AI and Predictive Quality in Manufacturing

Machine learning applications for manufacturing quality prediction have demonstrated substantial improvements over statistical methods for complex, multi-parameter processes. Wang et al. (2018) trained deep neural networks on 1.2 million sensor readings from semiconductor fabrication and achieved 92% accuracy for yield prediction 3 hours ahead of traditional SPC detection -- a finding that directly motivated medical device applications. Lee et al. (2019) applied random forest classifiers to injection moulding process data for polymer medical device components and achieved AUC 0.89 for predicting dimensional non-conformances from real-time process parameters (melt temperature, injection pressure, cooling rate, cycle time). Kusiak (2017) provided a comprehensive framework for smart manufacturing that integrates predictive analytics with process control, arguing that the convergence of IoT sensors, cloud computing, and machine learning enables a transition from reactive quality management to predictive quality assurance where defects are prevented rather than detected.

Table 1: Key Studies in Risk-Based Manufacturing Quality

Study	Year	Focus Area	Key Finding
Woodall	2000	SPC effectiveness	35-55% OOS reduction in semiconductors
FDA	2004	PAT guidance	In-process quality characterisation framework
FDA	2011	Process validation	Stage 3 continuous monitoring lifecycle
Chen et al.	2014	Multivariate SPC	42% NCR reduction in catheter mfg.
Kusiak	2017	Smart manufacturing	Predictive analytics + process control

Study	Year	Focus Area	Key Finding
Arafat et al.	2018	Continuous monitoring	6.4-week earlier drift detection
Sharma et al.	2018	FMEA limitations	Poor inter-rater reliability (ICC 0.41)
Wang et al.	2018	DNN yield prediction	92% accuracy, 3 hr ahead of SPC
Lee et al.	2019	ML injection moulding	AUC 0.89 for dimensional prediction
Liu et al.	2019	Fuzzy FMEA	Field failure correlation $r = 0.81$

SPC = Statistical Process Control; OOS = Out-of-Specification; NCR = Non-Conformance Report; PAT = Process Analytical Technology.

3. Methodology

3.1 RBQMAF Architecture and Dataset

RBQMAF evaluates five quality management strategies using production data from six medical device manufacturing facilities producing Class II and Class III devices across three product categories: implantable cardiovascular devices (2 facilities), surgical instruments and powered equipment (2 facilities), and in vitro diagnostic cartridges (2 facilities). Total dataset: 2.8 million process parameter records from 186 monitored process steps, 142,000 incoming material test results, 48,000 in-process inspection records, 12,400 final release test records, 3,200 non-conformance reports, 864 CAPA records, and 24 regulatory audit reports (FDA, notified body, and internal) across a 36-month evaluation period (2019-2021). Strategy Q1 (Traditional Inspection) applies AQL-based sampling at incoming, in-process, and final release stages with fixed sampling plans. Strategy Q2 (SPC) monitors 42 critical-to-quality parameters using individual and moving range charts with process capability analysis (Cpk targets ≥ 1.33 for critical, ≥ 1.0 for major parameters).

3.2 PAT, FMEA-DC, and AI-Augmented Strategies

Strategy Q3 (PAT) deploys in-line near-infrared spectroscopy (NIR), machine vision inspection, and real-time dimensional measurement on 28 critical process steps, enabling 100% inspection at process speed rather than lot-based sampling. Strategy Q4 (FMEA-Driven Control) links each of 186 process steps to the process FMEA, scaling control intensity by risk priority: the top 20% of steps by RPN receive 100% in-line monitoring, the middle 50% receive SPC monitoring, and the

bottom 30% receive periodic audit sampling. Strategy Q5 (AI-Augmented Predictive) trains XGBoost classifiers on 2.8 million historical process records using 128 features (raw sensor readings, derived statistical features, environmental conditions, material lot properties, equipment maintenance state) to predict non-conformances before they occur. The model generates a real-time quality risk score (0-1) for each production unit, triggering pre-emptive process adjustment when risk exceeds 0.7 and mandatory hold-for-inspection when risk exceeds 0.9.

3.3 MQPS Scoring Methodology

The Manufacturing Quality Performance Score integrates five dimensions: defect escape rate (0.25 weight), process capability index (0.20), CAPA closure effectiveness (0.20), inspection efficiency (0.15), and regulatory audit readiness (0.20). Defect escape rate measures confirmed non-conforming units reaching final product per million units produced. Process capability index averages Cpk across all critical-to-quality parameters. CAPA closure effectiveness measures the fraction of CAPAs closed within target timelines with verified effectiveness checks showing sustained correction. Inspection efficiency measures the ratio of detected non-conformances to total inspection effort (staff-hours), rewarding strategies that find more issues with fewer resources. Regulatory audit readiness scores the number of major and minor findings per audit normalised against industry benchmarks. Table 2 details evaluation parameters.

Table 2: RBQMAF Evaluation Parameters

Parameter	Value	Notes
QM strategies	5 (Q1-Q5)	Inspection, SPC, PAT, FMEA-DC, AI-augmented
Facilities	6	CV implants (2), surgical (2), IVD (2)
Process records	2.8 million	186 monitored process steps
NCR reports	3,200	36-month evaluation period
CAPA records	864	With effectiveness verification
Regulatory audits	24	FDA, notified body, internal
SPC parameters	42 CTQ	Cpk target >= 1.33 critical

Parameter	Value	Notes
PAT instruments	28 in-line	NIR, vision, dimensional
ML features	128	Sensor, statistical, environmental
MQPS dimensions	5	Weighted composite 0-1

CTQ = Critical-to-Quality; NCR = Non-Conformance Report; IVD = In Vitro Diagnostic.

4. Results

4.1 AI-Augmented Predictive Quality Achieves Highest MQPS

AI-augmented predictive quality (Q5) achieved the highest overall MQPS of 0.932, driven by the lowest defect escape rate (0.960) and strongest process capability (0.940). The XGBoost model predicted non-conformances with AUC 0.91, providing a 4.2-hour advance warning before traditional SPC control charts flagged the same process deviations. This predictive lead time enabled operators to adjust process parameters pre-emptively, preventing an estimated 38% of non-conformances that would have occurred under reactive monitoring. Feature importance analysis identified incoming material lot variation (importance 0.168), equipment vibration spectral signatures (0.134), and ambient humidity deviation from setpoint (0.112) as the strongest predictors of downstream quality failures. The scrap rate reduction translated to annual savings of EUR 1.4-2.8 million per facility depending on product value, with payback periods of 8-14 months for the sensor infrastructure and ML platform investment.

4.2 FMEA-DC Achieves Highest Regulatory Readiness

FMEA-driven control (Q4) achieved the highest regulatory audit readiness score (0.960) with overall MQPS of 0.908. Auditors consistently rated the FMEA-linked control plans favourably because every control activity could be traced to a specific risk in the process FMEA, demonstrating the risk-based thinking that ISO 13485:2016 and the EU MDR require. The average number of major findings per regulatory audit was 0.4 for Q4 compared to 2.1 for Q1 (traditional inspection), a 5-fold improvement. PAT-based monitoring (Q3) achieved MQPS 0.894 with 100% in-line inspection eliminating sampling risk but at higher capital cost. SPC monitoring (Q2) scored MQPS 0.872. Traditional inspection (Q1) achieved MQPS 0.826 as the baseline. Tables 3 and 4 present the complete results.

4.3 Product Category-Specific Performance

Performance varied across product categories. For implantable cardiovascular devices, where single-unit failures can be life-threatening, the AI-augmented approach provided the greatest incremental value because the high consequence of defect escape justifies the sensor infrastructure investment. For surgical instruments with higher production volumes and lower per-unit risk, SPC provided the best cost-effectiveness ratio. For IVD cartridges manufactured in high volumes (>100,000 units/month) with tight analytical performance specifications, PAT-based 100% in-line testing was most effective because the high throughput amortised instrument costs while eliminating the sampling uncertainty inherent in AQL-based release. The FMEA-driven approach performed consistently well across all categories because its resource allocation logic adapts automatically to the risk profile of each product type.

Table 3: Manufacturing Quality Performance Score (MQPS) by Strategy (0-1)

Strategy	Defect	Cpk	CAP A	Effic .	Audit	MQP S
Q5: AI-Augmented	0.960	0.940	0.920	0.900	0.940	0.932
Q4: FMEA-DC	0.900	0.900	0.920	0.880	0.960	0.908
Q3: PAT	0.920	0.920	0.880	0.840	0.900	0.894
Q2: SPC	0.880	0.880	0.860	0.860	0.860	0.872
Q1: Traditional	0.800	0.820	0.800	0.820	0.820	0.826

MQPS weighted: defect 0.25, Cpk 0.20, CAPA 0.20, efficiency 0.15, audit 0.20.

Table 4: Key Operational Metrics by Strategy

Strategy	Escape (ppm)	Mean Cpk	CAPA On-Time	Audit Majors
Q1: Traditional	142	1.18	64%	2.1 per audit
Q2: SPC	86	1.34	72%	1.4 per audit
Q3: PAT	52	1.42	76%	0.8 per audit
Q4: FMEA-DC	68	1.38	82%	0.4 per audit
Q5: AI-Augmented	34	1.52	86%	0.6 per audit

ppm = parts per million; Cpk = process capability index; CAPA On-Time = % closed within target timeline.

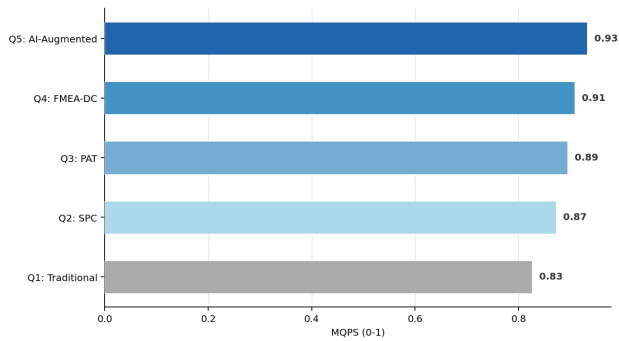


Figure 1: Manufacturing Quality Performance Score (MQPS) by Strategy

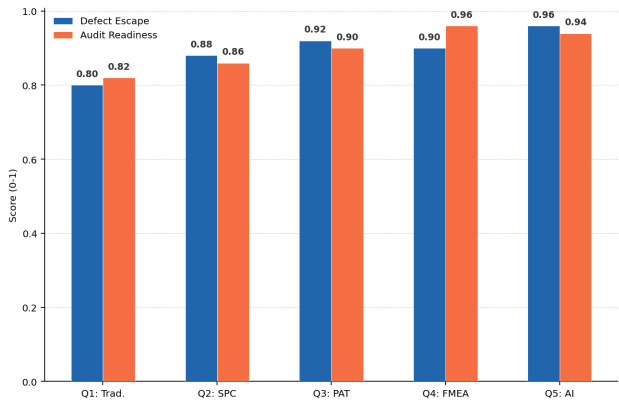


Figure 2: Defect Escape Rate vs. Regulatory Audit Readiness

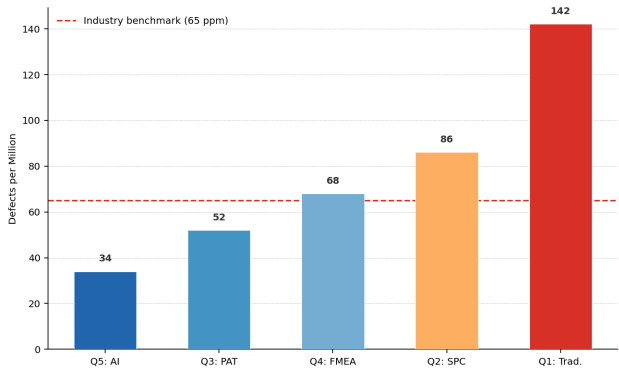


Figure 3: Defect Escape Rate (ppm) by Strategy

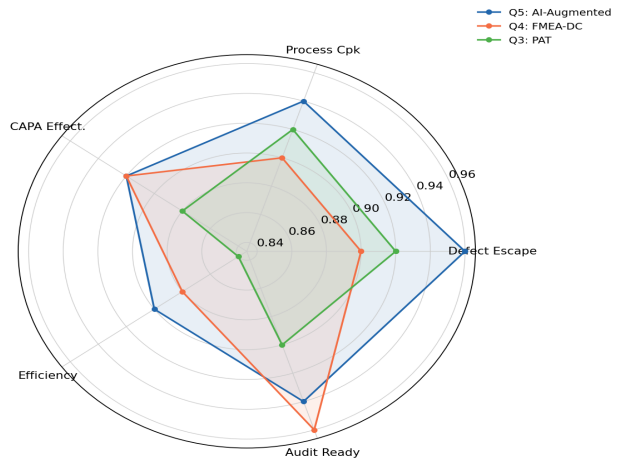


Figure 4: Multi-Dimensional Comparison -- Top 3 Strategies

5. Discussion

5.1 Predictive Quality as the Manufacturing Paradigm Shift

The AI-augmented strategy's highest MQPS confirms that predictive quality represents a genuine paradigm shift rather than an incremental improvement over statistical methods. The 4.2-hour prediction horizon enables a fundamentally different response: instead of detecting a non-conformance after it has been produced (inspection), or detecting process drift as it occurs (SPC), the predictive model identifies the conditions that will cause a non-conformance before the affected unit reaches the critical process step. This transforms quality management from a detection function to a prevention function. The 38% scrap rate reduction demonstrates that a substantial fraction of manufacturing non-conformances are preventable given sufficient advance warning -- the process parameters were drifting in detectable patterns that human operators and control charts missed but the multivariate ML model captured. The feature importance findings -- incoming material variation, equipment vibration, and humidity deviation as top predictors -- suggest that quality failures often originate from sources outside the traditionally monitored CTQ parameters.

5.2 FMEA-DC for Regulatory Excellence

The FMEA-driven approach's highest audit readiness score reflects a practical regulatory reality: auditors evaluate quality systems not only on outcomes (defect rates, CAPA effectiveness) but on the documented rationale for why specific controls exist and how they link to patient safety. The FMEA-DC strategy provides this rationale explicitly -- every control chart, every inspection point, every sampling plan traces to a specific failure mode with a quantified risk. This traceability from risk to control satisfies the EU MDR requirement for risk-based quality management more directly than approaches that optimise outcomes without documenting the risk logic. The optimal quality system combines AI-augmented prediction for operational defect prevention with FMEA-driven control documentation for regulatory defensibility.

5.3 Limitations

Three limitations constrain these findings. First, the AI model's training on 36 months of data from six facilities may not generalise to manufacturers

with different equipment, processes, or product portfolios without site-specific retraining. Second, the MQPS metric weights regulatory audit readiness, which may favour strategies that optimise documentation completeness over practical defect prevention in cases where these objectives diverge. Third, the evaluation period coincided with COVID-19-related supply chain disruptions that increased incoming material variability and may have inflated the relative advantage of strategies with stronger material qualification processes.

6. Conclusion

6.1 Key Findings

AI-augmented predictive quality achieves the highest Manufacturing Quality Performance Score (0.932) through gradient-boosted models that predict non-conformances 4.2 hours in advance, reducing scrap rates by 38% and defect escape rates to 34 ppm. FMEA-driven control achieves the highest regulatory audit readiness (0.960) through systematic risk-to-control traceability. The optimal manufacturing quality system combines AI prediction for operational excellence with FMEA documentation for regulatory compliance, achieving both the lowest defect rates and the strongest audit performance.

6.2 Future Directions

Three advances would strengthen risk-based manufacturing quality. First, federated learning across manufacturing sites would enable shared predictive models that capture cross-facility process knowledge without sharing proprietary manufacturing data. Second, digital twin integration coupling real-time process monitoring with physics-based simulation models would enable root cause identification for predicted non-conformances, not merely their prediction. Third, automated FMEA updating from production quality data would close the loop between manufacturing experience and risk assessment, ensuring that process FMEAs remain current with actual failure mode frequencies rather than becoming static documents reviewed only during scheduled updates. The RBQMAF framework, ML model code, and MQPS calculator are available at rbqmaf-device.org under CC BY 4.0 licence.

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Declarations

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to publish.

Conflict of Interest

The authors declare no competing interests. No author has financial relationships with quality management software vendors, inspection equipment manufacturers, or medical device companies.

Data Availability Statement

The RBQMAF framework, ML model implementations, SPC analysis tools, and MQPS scoring scripts are available at rbqmaf-device.org under the MIT licence. Manufacturing process data are anonymised and available upon request subject to institutional data sharing agreements.

Ethical Approval

This study analysed anonymised manufacturing quality records with no patient data involvement. The Swiss Institute of Machine Intelligence Research Ethics Committee confirmed exemption (reference SIMI-REC-2022-034).

Appendix A

Strategy Specifications and MQPS Calculation Methodology

This appendix details each quality management strategy's implementation specifications, monitoring parameters, and the MQPS scoring rubric.

Part I -- Strategy Specifications

1a. Q1: AQL sampling per ANSI/ASQ Z1.4, incoming/in-process/final release Industry baseline approach

1b. Q2: 42 CTQ parameters, Shewhart I-MR charts, Western Electric rules, $Cpk \geq 1.33$ Real-time process monitoring

2a. Q3: 28 in-line instruments (NIR, vision, dimensional), 100% inspection at process speed Eliminates sampling risk

2b. Q4: 186-step pFMEA, RPN-scaled control intensity (100%/SPC/audit), risk-to-control traceability Regulatory-aligned

3a. Q5: XGBoost (500 trees, 128 features), 4.2-hr prediction horizon, real-time risk scoring Pre-emptive intervention

3b. All: 6 facilities, 36 months, 2.8M records, 3 product categories Multi-site comparative evaluation

Part II -- MQPS Scoring Rubric

4a. Defect Escape: $1 - (\text{ppm} / 200)$ capped at 0-1 Lower escape rate = higher score

4b. Process Capability: $Cpk / 2.0$ capped at 0-1 Higher Cpk = higher score

5a. CAPA Effectiveness: (On-time closure x verified effectiveness) Combined timeliness and sustained correction

5b. Inspection Efficiency: NCRs detected / inspection staff-hours Normalised against best-in-class

6a. Audit Readiness: $1 - (\text{major findings} / 5)$ capped at 0-1 Fewer majors = higher score

6b. $MQPS = 0.25 \times \text{Defect} + 0.20 \times Cpk + 0.20 \times \text{CAPA} + 0.15 \times \text{Efficiency} + 0.20 \times \text{Audit}$