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Review of Statistical Process Control (SPC) Methods in the Context of Ensuring Medical Device Reliability

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Abstract

The article examines specific features of ensuring the integration of statistical process control (SPC) into the quality management systems of medical device manufacturers. The significance of the topic is determined by the simultaneous strengthening of regulatory pressure (FDA, ISO 13485) and the need for digital modernization of production loops within the logic of Industry 4.0, since it is precisely the combination of regulatory compliance and digital maturity that becomes a prerequisite for achieving an exceptionally high product reliability. The scientific novelty consists in substantiating a hybrid model in which dynamic risk management based on PFMEA is coupled with SPC instruments and predictive analytics components, forming an end-to-end architecture for monitoring and preventing deviations. Substantial emphasis is placed on an applied case of the Canadian company Umano Medical devoted to the industrialization of medical bed manufacturing, which makes it possible to specify requirements for data, metrology, and managerial decisions when scaling output. The purpose of the study is to analyze the effectiveness of implementing digital quality loops as a means of minimizing production defects and increasing process predictability. To achieve this purpose, Lean Six Sigma tools, methods of correlation analysis of production data, and provisions of systems engineering are applied, ensuring the alignment of technical, organizational, and information components. The analytical basis is formed from materials of publications from recent years. The outcome is the author's concept of risk-oriented digital SPC, interpreted as an integrated system that unites variability management, risk prioritization, and deviation forecasting within a single digital cycle. The material is oriented toward the practical tasks of quality engineers, R&D specialists, and production managers in medical equipment manufacturing.

Keywords: *Statistical Process Control, Medical Device Reliability, ISO 13485, PFMEA, Industry 4.0, Lean Six Sigma, Quality 4.0, FDA Complianc.*

INTRODUCTION

The modern medical industry is developing at the intersection of two dominant vectors: regulatory tightening and accelerated digitalization of production systems. A qualitative change in the regulatory landscape is observed due to the FDA transition to the QMSR model and the entry into force of the EU MDR requirements, which increases expectations for traceability, risk management, and the evidence base of quality throughout the entire product life cycle. In parallel, digital transformation within the logic of Industry 4.0 shifts manufacturing into a mode of continuous data collection and processing, creating prerequisites for more accurate and prompt control of technological parameters. In this configuration, classical Quality Control practices, oriented predominantly toward inspection of finished products, demonstrate limited economic feasibility and create additional exposure to risks: defects are identified post factum, when the cost of correction is maximal, and the probability of nonconformity entering a shipment increases to an unacceptably high level. The stability of characteristics and the reliability of medical devices require a shift in emphasis toward preventive quality management, in which statistical process control (SPC) occupies a central place as an instrument for early detection of drift, control of variability, and maintenance of a state of statistical control [1]. The highest criticality of such a transition is manifested with respect to life-support products and complex hospital equipment, since failure during operation may be associated with a direct threat to patient safety and significant regulatory consequences.

The **objective** is reduced to the development and substantiation of an integrated approach to ensuring the reliability of medical devices through the integration of SPC, PFMEA risk analysis instruments, and digital monitoring systems. Within the framework of this objective, a methodological analysis of the application of SPC under the

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requirements of ISO 13485 and FDA 21 CFR 820 is envisaged, with identification of the limits of applicability of traditional schemes, including constraints associated with the inertia of periodic control, insufficient sensitivity to weak degradation signals, and gaps between process data and managerial decisions. The final vector of tasks is oriented toward the formation of recommendations for the implementation of AI-driven process control aimed at increasing process maturity, ensuring their scalability, and reducing dependence on manual interpretations of data when adopting corrective actions.

Scientific novelty is determined by a conceptual rethinking of PFMEA: an interpretation of this instrument is proposed not as a static form of risk documentation, but as a dynamic mechanism capable, in a near-real-time mode, of controlling the configuration of SPC—selection of monitored characteristics, settings of control charts, response thresholds, and prioritization of signals.

The author's hypothesis is that coupling digital twins of production processes with the classical SPC toolkit ensures a transition from predominantly detection-based control to reliable forecasting of deviations. Such a transformation is considered a key condition for the practical implementability of Zero Defect principles in the medical industry, where value lies not only in identifying a nonconformity, but also in preventing its formation at the level of causal process factors.

MATERIALS AND METHODS

The methodological foundation of the study is a systems approach that combines a conceptual and theoretical elaboration of the problem domain with empirical materials formed in the course of engineering practice. The theoretical platform was formed through a systematic literature review of international publications indexed in Scopus, Web of Science, and IEEE Xplore. To maintain the relevance of the conclusions under conditions of post-pandemic intensification of manufacturing digitalization, the time frame of the search query was limited to 2021–2024, while selected fundamental sources were included as a methodological framework for the interpretation and application of Six Sigma approaches.

The search strategy was based on combining thematic keyword constructs reflecting the subject domains of the study: Statistical Process Control medical devices, PFMEA integration, Industry 4.0 quality assurance, ISO 13485 digitization. Inclusion of publications in the analytical corpus was determined by a set of criteria: assignment of journals to the first or second quartile (Q1–Q2), the presence of applied implementation case studies, and the prioritization of manufacturing issues relative to clinical aspects. A separate priority was established for works that analyze the possibilities of applying AI and IoT within the quality management and process monitoring loop.

Data collection, aggregation, and analytical processing were performed using specialized software tools: Minitab was applied for statistical calculations and the construction of analytical models, while the enterprise's internal ERP/MES loops were used to extract and structure data streams from production lines. Validation of the proposed methodological solutions was carried out through comparison with the requirements of ISO 13485:2016 Medical devices. Quality management systems and the FDA 21 CFR Part 820 regulations, which ensured the regulatory validity of the presented approach in the context of regulated manufacturing.

RESULTS

The results section is structured according to the logic of the study: from methodological foundations to practical validation and далее — to the assessment of limitations and development directions.

The analysis of contemporary literature [1, 7, 9] demonstrates that the isolated application of SPC (including Shewhart charts) without linkage to the risk profile and the criticality of characteristics loses managerial value in the medical industry. The key conclusion of the theoretical stage was the substantiation of the reliability triad, in which PFMEA, the Control Plan, and statistical process control are considered mutually complementary elements of a unified quality assurance loop. This configuration transforms SPC from a post factum diagnostic tool into a mechanism for targeted control of parameters that determine the safety and functional suitability of the product.

In the context of the requirements of ISO 13485:2016, in particular clause 7.5.6 related to the validation of production processes, the production system must confirm the ability to consistently produce conforming product under specified conditions. The most effective approach is achieved through the integration of PFMEA with digital monitoring systems, since traditionally static risk analysis begins to be updated with real production data. In its classical form, PFMEA is used to identify potential failures and their causes at the process design stage; however, the results [6, 7] show that dynamic PFMEA makes it possible to revise the risk priority number (RPN) based on SPC signals and the actual frequency/severity of defect manifestation. In this framing, risk ceases to be a once-and-for-all expert assessment and becomes a parameter refined empirically.

In the course of the study, a methodology was formalized in which critical-to-quality parameters (CTQ), identified through risk analysis, are automatically transformed into priority measurement points for SPC and embedded in the Control Plan as elements of the control strategy. This ensures the concentration of resources on controlling characteristics that determine the clinical safety and regulatory soundness of the product, instead of costly total control across a broad

range of secondary parameters. An additional effect is achieved through the use of Lean and Six Sigma, primarily DMAIC, already at the stage of developing the process route: baseline variability is reduced prior to series launch, and thus the need for compensatory control after start-up decreases. The application of DFM at early stages совместно with R&D makes it possible to eliminate design prerequisites for instability, including ambiguous fits, sensitivity to material variation, and assembly traps that form hidden causes of defects.

A significant addition to the described PFMEA–SPC linkage is digital traceability as an independent factor of process controllability. When forming a CTQ-oriented measurement architecture, data cease to be disparate records and acquire the status of an evidence base for verification and validation: inspection results, equipment parameters, versions of test-bench software, and deviation statuses can be linked into a single cause-and-effect loop. This improves the quality of investigations and reduces the risk of incorrect localization of the cause of nonconformity, especially in multistage processes where a defect manifests during final testing but is formed much earlier. As a result, a methodologically correct alignment of process capability requirements with the principle of risk-based management is achieved, when evidence of stability is collected precisely where failure has the greatest clinical and regulatory significance.

Practical verification of the proposed approach was carried out at the Umano Medical production site (Canada) during the industrialization of new medical equipment. The production of modern hospital beds represents a combined process chain that includes metalworking, robotic welding, assembly of electronic units, and final functional-safety testing. At critical stages, elements of Industry 4.0 [3, 10] were implemented, ensuring an end-to-end data flow and the possibility of statistical analysis close to the source of variability.

The data collection loop included smart assembly tools with torque and angle control that transmit operation parameters to the MES in real time. At the release stage, automated test stations were implemented, where functional checks (load capacity, actuator operation, electrical safety) are accompanied by the automatic generation of SPC charts and the recording of test results. The most significant result was achieved by forming closed feedback loops: data from control points were analyzed for trends and early drift signals. When the process shifted toward the upper or lower tolerance limit, even while maintaining specification conformance, the system initiated notifications about the need for preventive adjustment. Thus, the practical implementation of risk-based decision making required by modern quality standards was ensured.

Prospects for scaling are associated with the expansion of intelligent analytics tools, as indicated by sources [5, 8]. Predominantly reactive control models are being replaced by AI-driven process control, where the objective function shifts from recording realized deviations to the early identification of degradation patterns. Unlike classical SPC, AI algorithms are capable of accounting for nonlinear interactions of factors (for example, the combination of micro-drift of settings, temperature, vibration, and load mode), forming a risk forecast before parameters go beyond control limits. In the context of Umano Medical, a transition to predictive maintenance is being considered, where SPC data arrays and equipment telemetry (vibration, temperature of drives and assemblies) are used to plan repairs based on failure probability rather than calendar periodicity.

At the same time, the key barrier remains the digital maturity of enterprises in the medical profile. Computer software validation (CSV), especially when using AI components, forms a complex regulatory loop: demonstrable model correctness, reproducibility of results, change controllability, and controllability of data sources are required. The FDA is indeed in the phase of forming approaches to the validation of black-box AI in production, which strengthens requirements for documentation, version control, model-drift monitoring, and ensuring the traceability of decisions to the source data. Despite this, the scalability of digital SPC solutions retains high practical value: an architecture for data collection and processing, once developed and linked to CTQ and PFMEA, is relatively easily replicated to new lines provided that unified principles of measurements, calibrations, and change management are in place.

DISCUSSION

A synthesis of the obtained results was performed with their comparison to current practice, and an authorial quality management model was formed. The totality of practical experience obtained at Umano Medical and the data from the literature analysis make it possible to reasonably conclude that the prospects for improving the reliability of medical devices are determined by the transition to full end-to-end integration of data generated at the stages of R&D and manufacturing execution.

Within the proposed approach, statistical process control (SPC) loses the status of an autonomous, isolated discipline and is considered a functional element of a unified system that closes the loop between development, verification, release, and subsequent interpretation of production quality signals. As a conceptual solution, the model of the Dynamic Reliability Loop was formulated, based on the continuous circulation and alignment of data between R&D and production, which ensures adaptive control of process parameters and stable reproduction of the required product characteristics. Let us consider the proposed process architecture in Figure 1 below. Traditionally, the flow of information in production is linear: from R&D to production. A cyclical model is proposed, in which SPC data directly update the risk analysis.

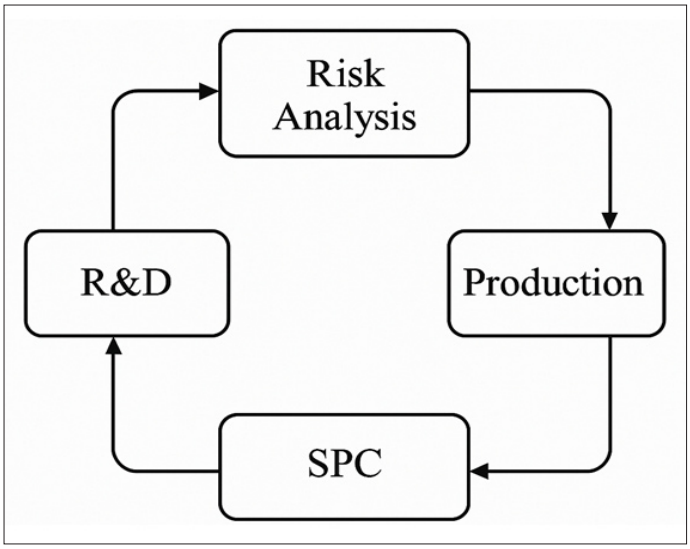

Figure. 1. Scheme of integration of PFMEA and SPC within a unified digital ecosystem (Quality 4.0) [1, 4].

The key system-forming mechanism is a feedback loop that ensures the coupling of the results of statistical process control with managerial decisions in the areas of risk management and design. When high process stability is confirmed based on SPC data, a formal basis is established for the automated adjustment of the occurrence probability indicator in the PFMEA downward, which, in turn, creates prerequisites for rationalizing the Control Plan by eliminating redundant inspections while maintaining the required level of risk controllability. When signs of instability are identified based on SPC metrics, a trigger is initiated for an in-depth engineering reassessment, including a revision of decisions in the logic of DFM, since process variability in this case is interpreted as an indicator of design–process misalignment or insufficient robustness of the selected parameters.

The next stage of validating the proposed transition is substantiating its economic viability. For this, a comparison of the traditional model of organizing SPC and digital SPC is applied, presented in Table 1, which makes it possible to identify differences in cost structure, operational workload, and the effects of variability controllability.

Table 1. Comparative analysis of traditional and digital approaches to SPC in medical manufacturing [2, 3, 5, 8].

Characteristic	Traditional SPC	Digital SPC (Industry 4.0)
Data collection	Manual, periodic (sampling)	Automated, continuous (monitoring)
Response	Reactive (after defects occur)	Predictive (forecasting deviations)
Link to risks	Static (PFMEA is reviewed once per year)	Dynamic (Live PFMEA)
Cost of quality	High costs for inspection and rework	Investments in IT, low operating costs
Validation	Paper-based IQ/OQ/PQ protocols	Digital records, continuous process verification (CPV)

A critically significant condition for effective implementation is the transformation of the physical architecture of the production line, since the digitalization of SPC and the closure of feedback loops require a different configuration of measurement points, data-flow routing, and alignment of inspection operations with process transitions. Within this logic, the line is viewed not as a set of disparate sections, but as a cyber-physical system in which the placement of measurement means, the selection of characteristics for monitoring, the sampling frequency, and the mechanisms for recording deviations must be constructively embedded in the process and synchronized with the parameters of equipment, tooling, and environmental conditions. Such restructuring increases process observability, reduces the latency of drift detection, and ensures the reproducibility of managerial responses through a standardized loop for registering and interpreting quality signals.

Table 2 reflects the impact of implementing SPC and Six Sigma methods on risk indicators. The presented data demonstrate that structural changes in the line architecture, when measurement and analytical components are correctly integrated, lead to a measurable reduction in the risk profile due to early identification of sources of variability and a more precise linkage of corrective actions to causal factors.

Table 2. Impact of implementing SPC and Six Sigma methods on risk indicators [2, 3, 5, 8]

Process	Initial RPN (Risk Priority Number)	Applied method	New RPN
Frame welding	High	Robotization + SPC by current and voltage	Low
Scale calibration	Medium	Automatic Gage R&R + X-bar chart	Low
Actuator assembly	High	Poka-yoke + Force monitoring	Low

A promising direction of development is associated with the implementation of artificial intelligence tools that expand the traditional boundaries of statistical control. A neural-network model within this loop operates not only with process output indicators but also with parameters of the input environment and raw-material variability, including, in particular, humidity and принадлежность to a specific material batch. Through joint analysis of these factors, a forecast of probable deviations is formed, and the control action is implemented preventively: the parameters of machine tools are adapted even before processing begins, which shifts quality management from a response mode to a prevention mode.

The formulated methodology and the presented data set confirm that coupling SPC with digital tools and formalized risk analysis is in fact the only sustainable trajectory solution for ensuring the reliability of medical equipment. This approach ensures fulfillment of regulatory requirements (compliance) not as a formal procedure, but as a result of controlled reproducibility of processes, while simultaneously creating conditions for achieving operational efficiency by reducing variability, minimizing losses, and increasing the predictability of production output.

CONCLUSION

In the presented work, a comprehensive review and critical analysis of approaches to statistical process control (SPC) was carried out with respect to ensuring the reliability of medical devices. The outcomes of the conducted study make it possible to fix several fundamental statements.

The analytical part demonstrates that traditional SPC tools, formed in the logic of periodic sampling inspection, require substantive adaptation to the architecture of Industry 4.0. The transition to real-time data flows generated by IoT infrastructure, as well as coupling with end-to-end dynamic PFMEA, creates a methodological basis for overcoming the limitations of discrete control. Such a loop is not reduced to accelerating measurements: there is a shift in emphasis from recording deviations to their early detection and to managing sources of variability at the level of cause-and-effect relationships.

The digital transformation of quality control loops restructures the very logic of industrial activity: from retrospective quality control to proactive reliability assurance. Within this paradigm, quality is interpreted as an emergent property of a controlled system, where evidentiality is ensured by data continuity, reproducibility of analytics, and traceability of changes in process parameters throughout the product life cycle.

Additionally, it should be noted that increasing the maturity of digital SPC requires the formalization of measurement-system data and unified rules for their governance. Metrological validity of data sources, validation of digital measurement means and analytical models, as well as ensuring the integrity and traceability of records in accordance with regulatory expectations, acquire critical importance. In this context, SPC becomes not an isolated set of statistical charts, but part of a digital quality system, where statistical signals are linked to risk management, changes, deviations, and corrective actions.

The prospective vector of industry development is associated with the widespread implementation of AI algorithms for predictive control of variability. The most significant aspect appears to be the transition from signaling rules to hybrid models combining classical statistics, anomaly detection methods, and cause-oriented analytics, which makes it possible to forecast process drift and prevent excursions beyond tolerances before product nonconformities are formed. As a result, the capability is formed to manage reliability as a measurable and planned outcome, rather than as a consequence of post factum corrections.

Thus, the article confirms the authorial hypothesis that risk-oriented digital SPC serves as a fundamental element of the modern quality system of medical device manufacturers. The obtained results have applied significance and can be used in the development of digitalization strategies for enterprises in the sector, including the construction of integrated loops for monitoring, risk management, and data-driven decision-making.

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