



REVIEW ARTICLE

THE CONVERGENCE OF STATISTICAL PROCESS CONTROL AND QUANTITATIVE MICROBIAL RISK ASSESSMENT: ENHANCING PHARMACEUTICAL QUALITY AND PUBLIC HEALTH SAFETY

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Abstract

Statistical process control (SPC) has become an essential tool for maintaining quality and safety in pharmaceuticals, public health, and other industries. This review critically examines the applications and synergistic potential of SPC applications in pharmaceutical manufacturing and public health risk assessment. The article demonstrates SPC's effectiveness in monitoring microbiological quality, detecting process variations, and assessing public health risks. Key applications include microbiological quality control of pharmaceutical products and water systems, statistical analysis of disinfectant efficacy, and risk assessment for infectious disease outbreaks. SPC can provide a unified analytical framework, facilitates proactive risk management, and supports data-driven decision-making. Future research should focus on developing standardized SPC protocols, integrating SPC with other data analysis tools, and exploring new applications. SPC enables researchers and practitioners to improve pharmaceutical quality and public health outcomes significantly.

Keywords: Data-driven decision-making, infectious disease outbreaks, pharmaceutical quality control, public health risk assessment, risk management, statistical process control.

INTRODUCTION

Ensuring the quality and safety of pharmaceutical products and healthcare services stands as a paramount concern within an increasingly complex regulatory environment and against the backdrop of persistent threats from microbial contamination and disease outbreaks¹⁻⁴. Traditional approaches to quality control and risk management in these sectors have historically relied on standardized procedures, retrospective testing, and qualitative risk assessments⁵⁻⁷. While these methods have provided a foundational level of safety, the escalating demands for higher quality, coupled with the need for more forward-looking and predictive strategies, necessitate the adoption of more sophisticated, data-driven methodologies⁸. Traditional pharmaceutical quality control often involves evaluating raw materials and the final packaged product through analytical tests such as conductivity, pH, thermal analyses, spectroscopy, density, refractometry, and titration, adhering to pharmacopeia guidelines to identify impurities⁹⁻¹⁴. Quality control laboratories play a crucial role in ensuring drug safety and efficacy.¹⁵ Quality assurance (QA) aims to prevent defects proactively, whereas quality control (QC) is a reactive

process that inspects and tests the final product^{15,16}. The regulatory landscape has evolved, with early efforts focusing on standardizing potent drug formulas¹⁷. However, these traditional methods often depend on end-product testing and may not fully reveal issues arising during the manufacturing process¹⁸. Pharmaceutical quality assurance includes both technical and managerial activities across the supply chain¹⁹.

The pharmaceutical industry's regulatory history indicates a growing recognition of the need for comprehensive quality management systems that extend beyond mere end-product testing²⁰. Concepts like Good Manufacturing Practices (GMP) and Quality by Design (QbD) emphasize building quality into the product from its inception and throughout manufacturing²¹. This evolution highlights the importance of more advanced tools like Statistical Process Control (SPC) and Quantitative Microbial Risk Assessment (QMRA) for continuous monitoring and preventive risk evaluation^{22,23}.

In this context, Statistical Process Control (SPC) and Quantitative Microbial Risk Assessment (QMRA) have emerged as powerful tools, gaining increasing recognition for their ability to enhance both quality and

safety across the pharmaceutical and healthcare spectrum²⁴. Statistical Process Control, defined as the application of statistical techniques to monitor and control a process or production method, offers a means to understand and manage variability, identify process issues, and drive continuous improvement²⁵. Its principles, rooted in the ability to distinguish between common cause variation inherent to a process and special cause variation indicating external influences, enable organizations to maintain stable and predictable operations²⁶. Key SPC tools include control charts, Pareto charts, histograms, and capability plots²⁷. Complementing this approach, Quantitative Microbial Risk Assessment provides a framework for estimating the probability of adverse health outcomes resulting from exposure to microorganisms^{28,29}. By integrating data on hazard identification, exposure assessment, dose-response relationships, and risk characterization, QMRA allows for a more informed and proactive approach to managing microbial risks³⁰⁻³².

This review aims to explore the innovative applications of SPC and QMRA in addressing contemporary challenges within pharmaceutical and healthcare settings. Specifically, it will delve into the synergistic potential of integrating these two methodologies to achieve a more comprehensive and effective approach to quality and safety. The scope of this review encompasses the application of SPC in microbiological quality control, the use of statistical methods in evaluating disinfectant efficacy, the role of both SPC and QMRA in monitoring and analyzing disease outbreaks, and their broader applications in diverse healthcare-related areas, as evidenced by a significant body of research in this field. The increasing complexity of pharmaceutical manufacturing and healthcare delivery systems necessitates more sophisticated and predictive approaches to quality and safety than traditional methods alone can provide. Regulatory bodies are continuously updating guidelines, reflecting a greater emphasis on preventive contamination control³³. The European Medicines Agency's (EMA) revised Annex 1, set for full implementation by 2025, emphasizes quality risk management, advanced cleanroom technology, and stringent environmental monitoring for contamination control³⁴. This evolution suggests that traditional reactive approaches might not be sufficient to meet these evolving standards and ensure patient safety^{35,36}. Furthermore, SPC and QMRA, while distinct in their focus, share a common foundation in data analysis and a proactive orientation towards preventing problems rather than just reacting to them^{30,37}. SPC focuses on monitoring and controlling processes to prevent deviations, while QMRA aims to predict and quantify risks before they materialize. This shared proactive nature suggests potential for powerful synergy³⁵⁻³⁷.

Statistical process control

A key aspect of SPC is its capacity to provide a real-time, data-driven understanding of how processes behave³⁸. Defined as the utilization of statistical techniques to monitor and regulate manufacturing processes, SPC aims to maintain consistency, reduce variability, and proactively identify deviations that

could impact product quality³⁹. By visually representing process data on control charts, manufacturers and healthcare providers can detect deviations from expected performance and understand the nature of the variation⁴⁰⁻⁴². This distinction between common cause variation, which is inherent and predictable within a stable process, and special cause variation, which arises from external factors and indicates an unstable or out-of-control process, is crucial for implementing appropriate corrective actions. To achieve this, SPC employs a range of graphical and analytical tools⁴³. Control charts, such as Shewhart charts, Individual-Moving Range (I-MR) charts, and Laney charts, are central to SPC, providing a visual representation of process data over time with statistically determined control limits that help distinguish between these two types of variation⁴⁴⁻⁴⁷. These charts, initially developed by Walter Shewhart, allow for the identification of special causes when data points fall outside control limits or exhibit non-random patterns⁴⁸. Other valuable tools include Pareto charts, which prioritize improvement efforts by highlighting the most frequent issues; histograms, which display the distribution of data; and capability plots, which assess whether a process can consistently meet specifications^{49,50}. The American Society for Quality (ASQ) defines SPC as the use of statistical techniques to control a process, emphasizing its role in monitoring process behavior and identifying issues²⁵.

In the context of pharmaceutical manufacturing, the application of SPC is crucial for ensuring product consistency across batches, reducing manufacturing defects, and identifying potential process deviations before they lead to quality issues^{51,52}. Research has demonstrated the direct application of SPC to various aspects of pharmaceutical production^{53,54}. For instance, studies have explored the use of variable and attribute control charts for monitoring active pharmaceutical components, demonstrating their utility in assessing process efficiency and facilitating comparative studies⁵⁵. Furthermore, SPC has been applied to the analysis of drug recall trends, offering a multidimensional perspective on product safety and quality management⁵⁶. Analysis of FDA recall data using SPC tools over a three-year period revealed that major contributors to recalls include microbiological quality issues, problems with product compositions, and packaging defects⁵⁶. The implementation of statistical process control in the inspection of active medicinal compound quality has also been investigated, showcasing its role in maintaining the integrity of pharmaceutical ingredients^{9-14,45}. SPC helps move beyond reactive quality control to a predictive approach focused on preventing defects and ensuring consistent product quality^{57,58}. The industry's move towards continuous process verification (CPV), where SPC is vital, highlights the importance of ongoing process monitoring over reliance on final product testing⁵⁹. An illustrative graph (Figure 1) shows FDA recall trend analysis⁶⁰. Beyond general manufacturing, SPC plays a vital role in microbiological quality control within pharmaceutical facilities⁶¹⁻⁶³.

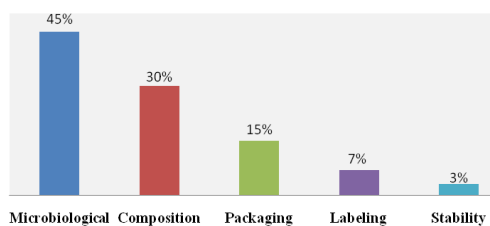


Figure 1: Major contributors to pharmaceutical recalls, emphasizing microbiological issues and composition errors as leading causes.

Monitoring trends in microbiological data, such as the levels of bioburden in purified water, air quality within cleanrooms, and surface microbial counts, is essential for maintaining a sterile and controlled environment⁶⁴⁻⁶⁷. Control charts are particularly useful for establishing baseline microbiological levels, detecting significant shifts or trends that indicate a potential loss of control, and setting appropriate alert and action limits to trigger investigations and corrective actions⁶⁸⁻⁷¹. Researchers have observed that microbiological distributions often follow the Poisson or Negative Binomial model, and data trending provides a comprehensive way to assess water quality and stability⁷². Research highlights the practical application of SPC in this domain, including the monitoring of microbiological environmental conditions, the assessment of purified water quality using control charts, and the evaluation of cleaning efficacy in pharmaceutical facilities through statistical process control^{54,71}. A study using SPC and Six Sigma tools to analyze surface cleanliness in a class C manufacturing facility found that most areas followed non-Gaussian distributions, requiring transformation for analysis^{67,71}. Material and personnel airlocks showed the highest risk of microbial excursions^{67,71}. The application of specific control chart types, such as the Laney control chart, has also been explored for assessing the microbiological quality of oral pharmaceutical filterable products⁴⁵. These charts can be particularly useful for non-normal data often encountered in microbiology⁷²⁻⁷⁴.

The utility of SPC extends to monitoring and analyzing broader trends within pharmaceutical processes and healthcare data^{73,75-78}. In the pharmaceutical industry, SPC has been employed to analyze the stability of active pharmaceutical components, ensuring their quality and efficacy over time⁷⁹. It has also been used to optimize inventory management of goods quality, particularly in healthcare facilities, by enabling a data-driven approach to supplier evaluation⁸⁰. SPC analysis of raw materials used as excipients in healthcare products allowed for prioritization and quantitative evaluation based on material mass, rejection factor, delivery intervals, and lag time⁷⁵⁻⁷⁸. Furthermore, SPC principles and tools have found significant application in healthcare settings for overall quality improvement^{80,81}. They are used to monitor patient outcomes, analyze variations in healthcare processes, and identify areas for potential improvement^{82,83}. Many research articles further demonstrate this versatility, with studies applying SPC to monitor long-term cancer mortality rates, analyze the morbidity and mortality

patterns of the COVID-19 pandemic, and track trends in surgical site infections⁸⁴⁻⁸⁷. SPC has also been used to improve first case start times in interventional radiology departments, aiming to enhance efficiency and patient care⁸⁸. Furthermore, SPC methodologies have been applied to reduce unexpected variations in postoperative length of stay, which can negatively impact resources and patient outcomes⁸⁹.

The consistent application of various Statistical Process Control (SPC) tools across a wide range of topics demonstrates a strong recognition of these methods' adaptability and effectiveness in addressing diverse challenges within both the pharmaceutical and healthcare domains⁹⁰⁻⁹⁴. This widespread utility highlights that SPC is not merely a technical quality control tool but rather a comprehensive philosophy for continuous improvement, applicable across countless processes in both sectors^{25,94}.

In healthcare, SPC is utilized to monitor various clinical outcomes, including infection rates, postoperative complications, and overall surgical performance⁹²⁻⁹⁴. However, successful SPC implementation, particularly in specialized fields like pharmaceutical microbiology, requires a deep understanding of the specific characteristics of the data being analyzed⁷². Microbiological data frequently exhibit non-normal distributions (Figure 2), and even low-level contamination can be highly significant^{45,46}. Therefore, standard SPC methodologies often need to be adapted^{95,96}. Specific control charts, such as those designed for attribute data or low-count processes, must be employed for effective analysis. For instance, Laney control charts have proven useful for handling non-normal microbiological data^{79,82}.

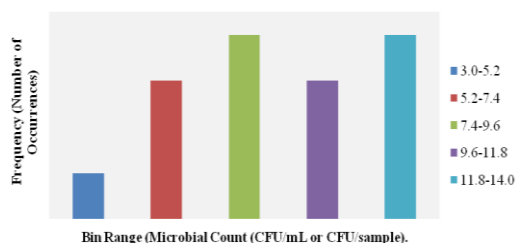


Figure 2: Histogram of microbial count distribution.

Ultimately, the effective deployment of SPC leads to an enhanced understanding of processes, the early detection of performance deviations, a reduction in overall variability, and, consequently, the delivery of improved patient outcomes and the manufacture of higher-quality pharmaceutical products^{69,77}. SPC provides a data-driven approach to root cause analysis, allowing for the implementation of targeted solutions for process enhancement^{60,63}. It is also crucial for sustaining continuous improvement by validating the success of enhancements and helping to maintain achieved gains.

QMRA

QMRA is considered a significant improvement over traditional qualitative risk evaluation¹⁸. It offers a structured and quantitative methodology for assessing microbial risks by using mathematical modeling to estimate the risk of infection and illness from

environmental exposure to microorganisms²²⁻²⁴ (Figure 3). By integrating mathematical models and data on hazard, exposure, and dose-response, QMRA provides a more precise estimation of the likelihood of adverse health outcomes²²⁻²⁴.

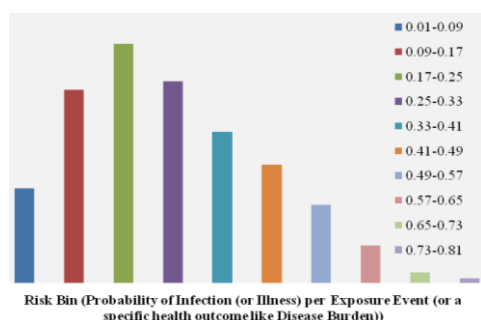


Figure 3: QMRA Risk Distribution (Monte Carlo Simulation).

This quantitative output supports a more informed and forward-looking approach to risk management in pharmaceutical and healthcare settings, facilitating the identification of critical control points and the creation of targeted interventions to minimize microbial contamination and subsequent health risks⁹⁷. The probabilistic nature of risk characterization also enables the consideration of uncertainty and variability, leading to more robust and reliable risk estimates. The QMRA framework generally follows four classical working steps⁹⁸⁻¹⁰¹:

1. **Hazard Identification:** Involves identifying the specific microorganisms of concern and the diseases they can cause, including symptoms and severity.
2. **Exposure Assessment:** Focuses on determining the dose (the amount of a microorganism an individual is exposed to) by measuring the concentration of microorganisms in the environmental medium and the extent of contact.
3. **Dose-Response Assessment:** Uses existing outbreak data or laboratory studies to establish the relationship between the exposure dose and the likelihood of a health outcome, often requiring the selection of appropriate mathematical models.
4. **Risk Characterization:** Integrates the information from the previous steps to calculate the likelihood of the health outcome, frequently employing Monte Carlo simulations to account for variability and uncertainty.

The wide array of applications for QMRA highlights its versatility in addressing microbial risks across various industries^{18,24}. QMRA is used to assess the microbial safety of drinking water, quantify health risks associated with bioaerosol exposure in wastewater treatment plants, and is applied to various exposure routes, including food, water, and air, providing a preventive approach to risk management^{28,98}. Furthermore, it can be utilized to develop failure prevention strategies in water treatment systems, and its rapid, routine application was highlighted as critical for public health protection during the coronavirus disease 2019 pandemic⁹⁸⁻¹⁰¹.

The synergistic convergence of SPC and QMRA

The combination of SPC and QMRA creates a powerful synergy for enhancing pharmaceutical quality by providing a more holistic and proactive strategy for managing microbiological risks. SPC can continuously monitor critical process parameters affecting microbiological quality, such as temperature, humidity, and bioburden levels in water systems^{90,93}. The reliable data generated by SPC can then serve as a vital input for QMRA models, enabling a dynamic and quantitative assessment of the potential risks associated with these parameters^{98,99}. For example, if SPC detects an upward trend in purified water bioburden levels, this information can be integrated into a QMRA model to estimate the potential impact on product sterility and patient safety^{40,77}. This integration allows for timely corrective actions before a critical threshold is breached, facilitating a shift from reactive testing to preventive risk management and resulting in higher-quality pharmaceutical products with enhanced microbial safety⁹⁷.

The convergence of SPC and QMRA also significantly improves healthcare safety by providing a robust, data-driven approach to managing microbiological risks^{68,69}. SPC can monitor healthcare processes that impact microbial safety, such as hand hygiene compliance, sterilization procedures, and environmental controls in hospital settings^{70,71}. The resulting SPC data can be fed into the QMRA framework to quantify the risk of healthcare-associated infections (HAIs) and other adverse outcomes stemming from microbial exposure^{28,68}. This combined strategy enables healthcare facilities to pinpoint high-risk areas, implement targeted interventions, and use SPC to continuously monitor the effectiveness of those interventions^{47,70}. By integrating process control with risk assessment, healthcare organizations can adopt a more forward-looking and evidence-based approach to patient safety and infection prevention^{35,36}.

Challenges and future directions

Implementing and integrating SPC and QMRA in pharmaceutical and healthcare settings face several challenges^{34,101}. These include the requirement for specialized expertise in both statistical analysis and microbiology, the difficulty of validating QMRA models with limited data, and the need to develop robust data collection methodologies^{100,101}. Standardizing SPC protocols across different pharmaceutical manufacturing processes and healthcare settings remains another significant hurdle^{33,37}. Future research should prioritize developing standardized guidelines and protocols for the integrated application of SPC and QMRA^{34,101}. Furthermore, exploring new applications of this convergence in emerging areas, such as personalized medicine and advanced pharmaceutical manufacturing technologies, could yield substantial benefits^{21,59}.

CONCLUSIONS

The SPC and QMRA represent a significant advancement in ensuring pharmaceutical quality and healthcare safety. SPC provides a robust statistical

framework for monitoring and controlling critical processes, enabling the early detection of deviations and the reduction of variability. QMRA offers a quantitative approach to assessing microbial risks, allowing for more informed and proactive management of potential hazards. By integrating these two powerful methodologies, the pharmaceutical and healthcare industries can move beyond traditional reactive approaches to embrace predictive, data-driven strategies for preventing contamination, ensuring product quality, and safeguarding public health. Continued research, robust case studies, and the development of standardized protocols will further enhance the utility and impact of this synergistic convergence and accelerate its adoption across the industry.

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None to declare.

AUTHOR'S CONTRIBUTION

Eissa ME: designed the study, performed the statistical re-analysis, manuscript writing, microbiological interpretation, critically reviewed.

DATA AVAILABILITY

Data will be made available on request.

CONFLICT OF INTEREST

No conflict of interest is associated with this work.

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