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## **Review on Quality Assurance and Risk Management in Pharmaceuticals**

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### **ABSTRACT:**

Quality assurance and risk management are critical components of the pharmaceutical industry. Pharmaceutical companies are responsible for ensuring that their products are safe, effective, and of the highest quality. Quality assurance is the process of ensuring that all aspects of the manufacturing process meet established quality standards, while risk management involves identifying, assessing, and mitigating potential risks that could impact product quality or patient safety.

This review article explores the relationship between quality assurance and risk management in the pharmaceutical industry, including how risk assessments are used to identify and mitigate potential quality issues, and discusses some of the best practices for implementing effective risk management strategies. The article begins by defining quality assurance and risk management and explaining how they are related in the pharmaceutical industry. It then discusses the role of risk assessments in quality assurance and risk management, including how they can be used to identify potential quality issues in pharmaceutical manufacturing and distribution. Examples of different types of risk assessments that are commonly used in the industry are provided, and the benefits and limitations of these assessments are discussed.

The article also outlines some of the key best practices for implementing effective risk management strategies in the pharmaceutical industry. These include establishing clear goals and objectives, assigning roles and responsibilities, implementing robust processes for identifying and managing risks, and monitoring and reviewing risk management activities over time. Examples of companies or organizations that have successfully implemented these best practices are provided, and their benefits are explained.

**KEYWORDS:** Quality assurance, Risk management, Pharmaceutical industry, Risk assessment, Best practices, Product safety.

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### **INTRODUCTION:**

The pharmaceutical industry is organized and complex, with a focus on producing drugs that are safe, effective, and of high quality. Quality assurance and risk management are the two critical components of the pharmaceutical industry that are essential for ensuring patient safety and product quality. Quality assurance is a set of procedures and processes that are implemented throughout the drug development, manufacturing, and distribution process to ensure that drugs meet specific quality standards [1]. Risk management involves identifying, assessing, and mitigating potential risks associated with the use of drugs [2].

The pharmaceutical industry is highly regulated, and regulatory agencies such as the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have established guidelines and regulations to ensure that drugs are safe and effective for use [3]. These guidelines outline the specific requirements for quality assurance and risk management in the pharmaceutical industry.

The importance of quality assurance and risk management has become increasingly evident in recent years, with numerous drug recalls and safety concerns highlighting the need for improved processes and procedures. By implementing effective quality assurance and risk management strategies, pharmaceutical companies can reduce the likelihood of product defects and safety issues, ensuring that patients receive safe and effective drugs.

Quality assurance and risk management are critical areas of focus in the pharmaceutical industry for several reasons.

Firstly, drugs are highly complex products that can have significant impacts on patients' health and well-being. Ensuring that drugs are manufactured, distributed, and used safely and effectively is therefore of paramount importance. Quality assurance processes help to ensure that drugs are manufactured to specific quality standards and that they meet regulatory requirements before they can be marketed and used by patients [3].

Secondly, the pharmaceutical industry is highly regulated, with strict requirements for quality and safety. Failure to comply with these regulations can lead to significant financial and reputational damage for companies, as well as harm to patients. Effective risk management is therefore essential for identifying and mitigating potential risks associated with drug development, manufacturing, and use [4].

Finally, the pharmaceutical industry is more competitive, with companies vying for market share and seeking to develop new and innovative drugs. Implementing effective quality assurance and risk management processes can help companies to differentiate themselves from their competitors by ensuring that they are providing safe, effective, and high-quality products [5].

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## II. RELATIONSHIP BETWEEN QUALITY ASSURANCE AND RISK MANAGEMENT

In the pharmaceutical industry, quality assurance and risk management are closely related, as both are essential for ensuring that products are safe and effective for use by patients. Quality assurance measures, such as implementing standard operating procedures (SOPs), good manufacturing practices (GMPs), and quality control testing, help to minimize the risk of quality issues arising during drug development and manufacturing. Risk management strategies, such as risk assessments and risk mitigation plans, help to identify and manage potential risks that could impact product quality or patient safety [6].

Overall, effective quality assurance and risk management programs are essential for ensuring that pharmaceutical products meet regulatory requirements and are safe and effective for use by patients. By implementing robust quality assurance and risk management processes, pharmaceutical companies can help to minimize the risk of product recalls or other quality issues, and build trust with regulators and patients alike.

### *The key principles that underpin effective quality assurance and risk management strategies*

Effective quality assurance and risk management strategies in the pharmaceutical industry are based on several key principles. These principles are designed to ensure that products are manufactured consistently and safely, and that risks are identified and managed throughout the product lifecycle. Here are some of the key principles that underpin effective quality assurance and risk management strategies:

**Quality culture:** An effective quality assurance and risk management strategy requires a strong culture of quality within the organization. This means that everyone involved in the development, manufacture, and distribution of pharmaceutical products is committed to quality and understands its importance. A strong quality culture is essential for ensuring that quality is embedded in all aspects of the product lifecycle, and that everyone is working towards the same goal.

**Risk assessment:** A thorough risk assessment is a critical component of effective quality assurance and risk management. Risk assessments are used to identify potential hazards or sources of variability in the manufacturing process, as well as to understand the potential risks associated with product use and distribution. By identifying and assessing risks, pharmaceutical companies can take steps to mitigate or eliminate them, and ensure that products are safe and effective for use by patients [7].

**Quality systems:** Effective quality assurance and risk management strategies require the establishment of robust quality systems throughout the organization. This includes the development and implementation of standard operating procedures (SOPs), good manufacturing practices (GMPs), and quality control testing. These systems are designed to ensure that products are manufactured consistently and to the required quality standards.

**Continuous improvement:** An effective quality assurance and risk management strategy requires a commitment to continuous improvement. This means that organizations must be willing to review and evaluate their processes and systems on an ongoing basis, and make changes as needed to improve product quality and patient safety [8,9].

**Regulatory compliance:** Pharmaceutical companies must comply with a range of regulatory requirements and guidelines, such as those set by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Compliance with these regulations is essential for ensuring that products are safe and effective for use by patients, and for maintaining the trust of regulators and the public [8].

**Document control:** Document control is an essential component of effective quality assurance and risk management. This involves ensuring that all documents related to product development, manufacturing, and distribution are accurate, up-to-date, and easily accessible. Document control helps to ensure that processes are followed consistently, and that changes are made in a controlled and documented manner [9].

**Supplier management:** Pharmaceutical companies must work closely with suppliers to ensure that raw materials and other components meet the required quality standards. This involves establishing clear specifications for suppliers, as well as monitoring and auditing supplier performance on an ongoing basis [10].

**Training and development:** Effective quality assurance and risk management strategies require a skilled and knowledgeable workforce. This means providing employees with the necessary training and development opportunities to ensure that they are equipped to carry out their roles effectively [8,9,10].

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## III. THE RISK ASSESSMENTS IN PHARMACEUTICAL INDUSTRIES

Risk assessment is a critical tool in pharmaceutical manufacturing and distribution to identify potential quality issues that could impact the safety, efficacy, and quality of drug products. The process involves identifying potential hazards, analyzing their likelihood and severity, evaluating the overall level of risk, and implementing strategies to mitigate or control the identified risks.

### Types of Risk Assessments in the Pharmaceutical Industry

There are different types of risk assessments are used in the pharmaceutical industry to identify potential hazards and mitigate or control risks associated with manufacturing, distribution, and administration of drug products. Each type of risk assessment has its benefits and limitations.

**Table 1: Common Types of Risk Assessments in the Pharmaceutical Industry**

Sr. No.	Type of Risk Assessment	Description	Benefits	Limitations
01	Hazard Analysis and Critical Control Points (HACCP)	A systematic approach to identifying and controlling hazards in the manufacturing process.	Improves product quality and safety; provides a systematic approach to identifying potential hazards.	Requires specialized knowledge and expertise; may be time-consuming to implement.
02	Failure Modes and Effects Analysis (FMEA)	A systematic approach to identifying potential failure modes in a process or system and developing strategies to mitigate or eliminate the risk of those failure modes.	Improves product quality and safety; provides a systematic approach to identifying potential failure modes.	Requires specialized knowledge and expertise; potential for subjective ratings of likelihood and severity.
03	Fault Tree Analysis (FTA)	A structured approach to identifying the causes of a potential failure or hazard and the effectiveness of controls to mitigate or eliminate the risk.	Identifies potential failure modes before they occur; develops strategies to mitigate or eliminate potential hazards; improves product quality and safety.	Requires specialized knowledge and expertise; potential for subjective ratings of likelihood and severity.
04	Risk Ranking and Filtering (RRF)	A qualitative approach to prioritizing hazards or risks based on their likelihood and severity.	Prioritizes resources based on risk; straightforward and easy-to-use approach; quickly identifies high-priority hazards.	Potential for subjective ratings of likelihood and severity; inability to account for unexpected hazards.
05	Process Mapping and Failure Mode Analysis (PFMEA)	A structured approach to identifying potential failure modes in the manufacturing process and developing strategies to mitigate or eliminate the risk of those failure modes.	Provides a systematic approach to identifying potential failure modes; improves product quality and safety.	Requires specialized knowledge and expertise; potential for subjective ratings of likelihood and severity.
06	Preliminary Hazard Analysis (PHA)	A systematic approach to identifying hazards early in the design phase of a product or process.	Improves product safety and quality; identifies potential hazards early in the design process.	Requires specialized knowledge and expertise; may not capture all hazards or risks.
07	Quantitative Risk Assessment (QRA)	A method of measuring risk by assigning numerical values to the likelihood and consequence of a hazard.	Provides a more objective assessment of risk; can be used to compare different types of risks.	Requires specialized knowledge and expertise; may be time-consuming and resource-intensive to conduct.
08	Probabilistic Risk Assessment (PRA)	A method of assessing risk that takes into account uncertainties and variability in the system or process being analyzed.	Provides a more comprehensive assessment of risk; can help identify areas where additional data or analysis is needed.	Requires specialized knowledge and expertise; may be time-consuming and resource-intensive to conduct.
09	Bowtie Analysis	A visual tool that helps to understand and communicate the relationships between	Provides a clear and concise way to communicate risk information; can	Requires specialized knowledge and expertise;

		hazards, their causes, and the controls that are in place to prevent or mitigate them.	help identify gaps in control measures.	potential for subjective ratings of likelihood and severity.
10	Risk Assessment and Mitigation Strategy (RAMS)	A systematic approach to identify and control potential risks associated with drug products. It involves assessing the risk of each identified hazard, determining the appropriate risk mitigation strategy, and implementing controls to prevent or mitigate those risks.	Ensures that the benefits of the drug outweigh its risks; improves product safety and quality; meets regulatory requirements.	Requires specialized knowledge and expertise; potential for subjective ratings of likelihood and severity.

This table summarizes common types of risk assessments used in the pharmaceutical industry, including a description of each type, its benefits, and its limitations [6,11,12,13].

Each type of risk assessment has its benefits and limitations, and the selection of the appropriate type of risk assessment depends on the specific situation and context. A combination of different risk assessments may be used to identify potential hazards and mitigate or control risks associated with manufacturing, distribution, and administration of drug products.

### *Process and role of Risk Assessments in the Pharmaceutical Industry*

**Hazard identification:** The first step in the risk assessment process is to identify potential hazards. In pharmaceutical manufacturing and distribution, potential hazards can include contamination, cross-contamination, equipment failure, human error, and environmental factors. For example, the use of raw materials that are not properly sterilized can introduce microbial contamination into the manufacturing process, which can impact the quality of the drug product.

**Risk analysis:** The second step in the risk assessment process is to analyze the likelihood and severity of harm that could result from each identified hazard. This involves assigning a risk score based on the analysis. For example, the risk of microbial contamination may be rated as high if the manufacturing process is not adequately controlled.

**Risk evaluation:** The third step in the risk assessment process is to evaluate the overall level of risk associated with the activity or situation being assessed, based on the identified hazards and their associated risks. For example, if the risk of microbial contamination is rated as high, the overall level of risk associated with the manufacturing process may be deemed unacceptable.

**Risk management:** The final step in the risk assessment process is to implement strategies to mitigate or control the identified risks. For example, implementing validated cleaning procedures, conducting regular environmental monitoring, and establishing quality control measures can help to minimize the risk of microbial contamination.

An example of how risk assessment can be used in pharmaceutical manufacturing and distribution is in the production of sterile injectable products. The manufacturing process for these products involves several potential hazards, such as contamination from equipment or raw materials, improper storage, and human error. By conducting a risk assessment, the potential hazards can be identified, and the risks associated with each hazard can be evaluated. The risk management strategies implemented can include measures such as strict cleaning and sterilization procedures, frequent environmental monitoring, and the use of automated manufacturing equipment.

Another example of how risk assessment can be used in pharmaceutical distribution is in the transportation of temperature-sensitive products. The transportation process involves potential hazards such as exposure to extreme temperatures, improper handling, and storage. By conducting a risk assessment, potential hazards can be identified, and the risks associated with each hazard can be evaluated. The risk management strategies implemented can include measures such as using temperature-controlled vehicles, monitoring the temperature during transportation, and ensuring that products are packaged appropriately [7,9].

Risk assessments play a crucial role in informing decision-making on quality assurance and risk management in the pharmaceutical industry. By systematically identifying potential risks and their likelihood and impact, risk assessments can help manufacturers and regulators prioritize their efforts and allocate resources effectively to manage risks and ensure product quality and safety.

First, risk assessments can inform decisions around quality control and quality assurance measures. By identifying potential quality issues and their severity, risk assessments can guide the development of appropriate quality control measures, such as testing protocols and acceptance criteria. For example, if a risk assessment identifies a potential contamination risk from a particular raw material, the manufacturer may implement additional testing or screening procedures to ensure that the raw material meets the required quality standards before it is used in production.

Second, risk assessments can inform decisions around product design and process validation. By identifying potential failure modes and their associated risks, risk assessments can guide the design of products and processes to minimize the likelihood of quality issues arising. For example, a risk assessment

may identify a potential safety risk associated with a specific drug delivery mechanism, leading the manufacturer to modify the design to minimize the risk of adverse events.

Third, risk assessments can inform decisions around supply chain management and distribution. By identifying potential risks associated with suppliers, transportation, and storage conditions, risk assessments can guide decisions around sourcing and logistics to ensure that products are delivered to the end user in a safe and effective manner. For example, a risk assessment may identify a potential temperature excursion risk during shipping, leading the manufacturer to select a different transportation method or implement additional monitoring and control measures to maintain product quality [14-17].

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#### **IV. BEST PRACTICES FOR IMPLEMENTING EFFECTIVE RISK MANAGEMENT STRATEGIES**

##### **Establishing clear goals and objectives:**

The first step in developing an effective risk management strategy is to establish clear goals and objectives. This involves defining what the company hopes to achieve with its risk management activities, such as reducing the likelihood of product defects, minimizing the impact of adverse events, or improving overall patient safety. By establishing clear goals and objectives, the company can ensure that everyone is aligned around a shared vision and can work together to achieve it. Additionally, having clearly defined goals and objectives can help guide decision-making throughout the risk management process, making it easier to prioritize activities and allocate resources [18].

##### **Assigning roles and responsibilities:**

Once the company has established its goals and objectives, it's important to assign specific roles and responsibilities to individuals or teams who will be responsible for carrying out various aspects of the risk management strategy. This helps to ensure that everyone knows what they are responsible for and can be held accountable for their actions. For example, a risk management team might be responsible for conducting risk assessments and developing risk mitigation strategies, while individual departments or teams might be responsible for implementing specific risk controls. By assigning roles and responsibilities in this way, the company can ensure that risk management is integrated into day-to-day operations and is not viewed as a separate function [6].

##### **Implementing robust processes for identifying and managing risks:**

Effective risk management requires a structured process for identifying and managing risks. This might include techniques such as Failure Modes and Effects Analysis (FMEA) or Hazard Analysis and Critical Control Points (HACCP), which are commonly used in the pharmaceutical industry to identify potential risks and develop risk mitigation strategies. The risk management process should be iterative, with ongoing monitoring and review to ensure that the company is identifying and addressing new risks as they arise. Additionally, the company should establish clear procedures for documenting and communicating risks and risk management activities, so that everyone is aware of potential risks and the steps being taken to mitigate them [18].

##### **Monitoring and reviewing risk management activities over time:**

Risk management is an ongoing process that requires regular monitoring and review in order to ensure that it remains effective. Companies should establish metrics for evaluating the success of their risk management activities and use these to inform ongoing improvements. For example, a company might track the number and severity of adverse events associated with a particular product or process, and use this information to identify opportunities for improvement. Additionally, companies should establish a process for periodic review and update of their risk management strategy, in order to ensure that it remains relevant and effective over time [7].

##### **Incorporating risk management into the overall quality management system:**

Risk management should be integrated into the overall quality management system of the company, rather than being viewed as a separate function. This helps to ensure that risk management is aligned with other quality-related activities and can be more easily integrated into day-to-day operations [7].

##### **Ensuring adequate resources for risk management:**

Companies should ensure that they have adequate resources (e.g. personnel, time, budget) to carry out their risk management activities effectively. This includes providing appropriate training and development opportunities for staff who will be involved in risk management [18].

##### **Involving all relevant stakeholders:**

Effective risk management requires input from all relevant stakeholders, including employees, customers, suppliers, and regulators. Companies should establish mechanisms for engaging with these stakeholders and soliciting their feedback and input [6].

##### **Establishing a culture of continuous improvement:**

Companies should foster a culture of continuous improvement, in which everyone is encouraged to identify and report potential risks, and to work together to develop and implement strategies for mitigating these risks. This requires a commitment to ongoing learning and development, as well as a willingness to adapt and evolve over time [7].

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## V. EXAMPLES OF COMPANIES THAT HAVE SUCCESSFULLY IMPLEMENTED BEST PRACTICES:

Roche:

Roche is a Swiss multinational pharmaceutical company that has established clear goals and objectives for its risk management activities, including a focus on patient safety and regulatory compliance. The company has assigned specific roles and responsibilities to a dedicated global risk management team, which is responsible for conducting risk assessments and developing risk mitigation strategies. Roche has also implemented robust processes for identifying and managing risks, including the use of FMEA and HACCP techniques. The company monitors and reviews its risk management activities on an ongoing basis and has seen benefits such as improved patient safety and regulatory compliance, as well as increased efficiency and cost savings [19].

Pfizer:

Pfizer is an American multinational pharmaceutical company that has established clear goals and objectives for its risk management activities, including a focus on patient safety and product quality. The company has assigned specific roles and responsibilities to a global risk management team, which is responsible for identifying and managing risks across the organization. Pfizer has implemented robust processes for identifying and managing risks, including the use of FMEA and other risk assessment techniques. The company monitors and reviews its risk management activities on an ongoing basis and has seen benefits such as improved product quality and patient safety, as well as increased regulatory compliance and customer satisfaction [20].

Novo Nordisk:

Novo Nordisk is a Danish multinational pharmaceutical company that has established clear goals and objectives for its risk management activities, including a focus on patient safety and product quality. The company has assigned specific roles and responsibilities to a dedicated global risk management team, which is responsible for conducting risk assessments and developing risk mitigation strategies. Novo Nordisk has implemented robust processes for identifying and managing risks, including the use of FMEA and other risk assessment techniques. The company monitors and reviews its risk management activities on an ongoing basis and has seen benefits such as improved product quality and patient safety, as well as increased efficiency and cost savings [21].

Johnson & Johnson:

Johnson & Johnson is an American multinational medical device, pharmaceutical, and consumer goods company that has established clear goals and objectives for its risk management activities, including a focus on patient safety and product quality. The company has assigned specific roles and responsibilities to a global risk management team, which is responsible for identifying and managing risks across the organization. Johnson & Johnson has implemented robust processes for identifying and managing risks, including the use of FMEA and other risk assessment techniques. The company monitors and reviews its risk management activities on an ongoing basis and has seen benefits such as improved product quality and patient safety, as well as increased regulatory compliance and customer satisfaction [22].

GlaxoSmithKline:

GlaxoSmithKline is a British multinational pharmaceutical company that has established clear goals and objectives for its risk management activities, including a focus on patient safety and product quality. The company has assigned specific roles and responsibilities to a dedicated global risk management team, which is responsible for conducting risk assessments and developing risk mitigation strategies. GlaxoSmithKline has implemented robust processes for identifying and managing risks, including the use of FMEA and other risk assessment techniques. The company monitors and reviews its risk management activities on an ongoing basis and has seen benefits such as improved product quality and patient safety, as well as increased efficiency and cost savings [23].

Sanofi:

Sanofi is a French multinational pharmaceutical company that has established clear goals and objectives for its risk management activities, including a focus on patient safety and product quality. The company has assigned specific roles and responsibilities to a global risk management team, which is responsible for identifying and managing risks across the organization. Sanofi has implemented robust processes for identifying and managing risks, including the use of FMEA and other risk assessment techniques. The company monitors and reviews its risk management activities on an ongoing basis and has seen benefits such as improved product quality and patient safety, as well as increased regulatory compliance and customer satisfaction [24].

Dr. Reddy's Laboratories:

Dr. Reddy's Laboratories is an Indian multinational pharmaceutical company that has established clear goals and objectives for its risk management activities, including a focus on patient safety and product quality. The company has assigned specific roles and responsibilities to a global risk management team, which is responsible for identifying and managing risks across the organization. Dr. Reddy's has implemented robust processes for identifying and managing risks, including the use of FMEA and other risk assessment techniques. The company monitors and reviews its risk management activities on an ongoing basis and has seen benefits such as improved product quality and patient safety, as well as increased efficiency and cost savings [25].

Sun Pharmaceutical Industries:

Sun Pharmaceutical Industries is an Indian multinational pharmaceutical company that has established clear goals and objectives for its risk management activities, including a focus on patient safety and product quality. The company has assigned specific roles and responsibilities to a dedicated global risk management team, which is responsible for conducting risk assessments and developing risk mitigation strategies. Sun Pharma has implemented robust processes for identifying and managing risks, including the use of FMEA and other risk assessment techniques. The company monitors and reviews its risk management activities on an ongoing basis and has seen benefits such as improved product quality and patient safety, as well as increased regulatory compliance and customer satisfaction [26].

Biocon Limited:

Biocon Limited is an Indian biopharmaceutical company that has established clear goals and objectives for its risk management activities, including a focus on patient safety and product quality. The company has assigned specific roles and responsibilities to a global risk management team, which is responsible for identifying and managing risks across the organization. Biocon has implemented robust processes for identifying and managing risks, including the use of FMEA and other risk assessment techniques. The company monitors and reviews its risk management activities on an ongoing basis and has seen benefits such as improved product quality and patient safety, as well as increased efficiency and cost savings [27].

In summary, these companies have benefitted from implementing best practices for risk management in the pharmaceutical industry by improving patient safety, product quality, regulatory compliance, and efficiency. By establishing clear goals and objectives, assigning roles and responsibilities, implementing robust processes for identifying and managing risks, and monitoring and reviewing risk management activities over time, these companies have been able to effectively mitigate potential risks and achieve their strategic objectives.

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## V. Conclusion

In conclusion, this review article has explored the important relationship between quality assurance and risk management in the pharmaceutical industry. We have discussed how risk assessments are used to identify and mitigate potential quality issues, and explored some of the best practices for implementing effective risk management strategies.

Overall, it is clear that quality assurance and risk management are critical areas of focus for pharmaceutical companies, as they can help ensure that products are safe and effective for patients, and can help companies meet regulatory requirements and maintain a competitive edge in the marketplace.

In terms of future research or initiatives, there are several areas that could be explored further. For example, researchers could investigate new technologies or methodologies for conducting risk assessments, or could explore how risk management strategies could be applied in new areas of the pharmaceutical industry, such as gene therapy or personalized medicine.

Additionally, there may be opportunities to collaborate more closely with regulatory bodies or other stakeholders to ensure that best practices in quality assurance and risk management are being shared and implemented effectively across the industry. By doing so, we can help ensure that patients receive the highest quality products and services, and that the pharmaceutical industry continues to thrive and innovate in the years to come.

### CONFLICT OF INTEREST:

The authors have no conflicts of interest regarding this investigation.

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