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From Traditional to Artificial Intelligence-Based Microbial Contamination Control in Pharma: Driving a New Era

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Attah, F
Department of Microbiology
Federal University of Technology
Minna, Niger State
Nigeria
attahf@custech.edu.ng
Corresponding author

Abalaka, M.E
Department of Microbiology
Federal University of Technology
Minna, Niger State
Nigeria
abalaka.moses@futminna.edu.ng

Aminu, R.F
Department of Microbiology
Confluence University of Science and Technology
Osara, Kogi State
Nigeria
aminurf@custech.edu.ng

Sadiku J. O
Department of Microbiology

Confluence University of Science and Technology
Osara, Kogi State
Nigeria
sadikujo@custech.edu.ng

Adam, H.O
Department of Microbiology
Confluence University of Science and Technology
Osara, Kogi State
Nigeria.
adamsho@custech.edu.ng

David, A. F
Department of Microbiology
Federal University of Technology
Minna, Niger State
Nigeria
aliudf@custech.edu.ng

O.S Omowaye
Department of Microbiology
Federal University Lokoja
Kogi state, Nigeria
jesuniyi4wealth@gmail.com

Ismaila, U
Department of Microbiology
Confluence University of Science and Technology
Osara, Kogi State
Nigeria
ummuhanny2003@gmail.com

Beji, Z.Y
Department of Public Health
Federal University of Technology
Minna, Niger State
Nigeria
zalihayusufbeji@yahoo.com

Abstract

In pharmaceutical production, microbial contamination is the inadvertent presence of bacteria, fungus, or viruses. Microbial contamination poses a threat to pharmaceutical manufacture by lowering product quality, safety, and efficacy. Traditional contamination control methods—staff cleanliness, equipment sterilisation, and environmental monitoring—are essential but increasingly insufficient for modern production concerns. This research examines how AI may change pharmaceutical production by detecting and preventing microbial contamination. The article discusses contamination causes, conventional mitigation strategies, and the benefits of artificial intelligence-driven technologies like predictive analytics, automated quality control, machine learning, regulatory compliance, product safety, and manufacturing efficiency. It also discusses implementation methods, benefits, and drawbacks. This study shows how artificial intelligence may improve microbiological contamination monitoring and pharmaceutical production standards.

Key words: *Traditional, artificial intelligence, contamination, pharmaceutical, new era*

Introduction

Microbial contamination in pharmaceuticals refers to the unexpected presence of microorganisms such as bacteria, fungi, and viruses in pharmaceutical products, production processes, or the surrounding environment. (Gupta et al., 2024). These organisms might come from air, water, raw materials, equipment, or people, threatening product quality, safety, and efficacy.

Formulation, filling, packaging, and storage can all contribute to contamination (Ahmed et al., 2024). Product deterioration, effectiveness loss, and patient health hazards might ensue from such exposure. Under Good Manufacturing Practice (GMP), pharmaceutical goods with complex components must meet quality and microbiological standards

(Ahmed, 2024). Hardcopf and Shah (2023) state that even slight contamination control failures can cause product recalls, health issues, financial loss, and brand harm. Thus, strict processes, clean facilities, and well-trained staff are essential for contamination control. AI is a modern answer to such challenges. Data and algorithms enable artificial intelligence systems to identify patterns and complete tasks without human interaction. The Turing Test, established by Alan Turing, is still regularly used. According to Monett et al. (2020), a computer passes the Turing Test if it can mimic human replies in a text-based debate.

Artificial intelligence includes machine learning, deep learning, and neural networks. Dolgikh (2024) lists reactive machines and speculative self-aware systems as its applications. Artificial intelligence aims to mimic human cognitive processes and aid decision-making. Artificial intelligence is now believed to include computers that can reason logically and think like humans (Korteling et al., 2021).

This article will examine how AI is preventing, detecting, and managing microbial contamination in pharmaceutical production. It will also examine the pros and cons of using AI in pharmaceutical microbiology, including efficiency and accuracy gains and drawbacks.

Sources of Microbial Contamination in Pharmaceutical Manufacturing

The presence of microorganisms in pharmaceutical products poses a considerable risk to the health of patients, as well as to the safety and effectiveness of the medicines themselves (Dao et al., 2018). Contamination can occur during production. Gupta et al. (2024) reported the following sources of contamination during manufacturing:

i. **Raw Materials and Water:** Ingredients, especially those of natural origin (e.g., plant-derived excipients), may harbour microbial contaminants if not adequately sterilised in formulation (Singh et al., 2021). Water, particularly in its purified or distilled forms, is a major

potential source of contamination if not properly maintained within pharmacopeial standards (Gupta et al., 2024).

ii. **Personnel:** Human operators are among the most significant sources of microbial contamination, shedding skin flora, respiratory droplets, and other microorganisms (Dinçoğlu et al., 2024). Inadequate hygiene practices, improper gowning, and poor aseptic techniques can lead to direct or indirect contamination of products and equipment.

iii. **Manufacturing Environment**: The cleanliness of the facility plays a crucial role. Airborne microorganisms, poorly maintained cleanrooms, contaminated surfaces, and inadequate environmental monitoring can all introduce microbes during various stages of production (Mohammed, 2023).

iv. **Equipment and Instruments**: Production equipment, especially those with complicated designs or hard-to-clean parts, can harbour microorganisms if not properly sanitised and validated. Biofilm formation in water systems and transfer lines can be particularly challenging to control (Jebichi, 2018).

v. **Packaging Materials**: Contaminated primary or secondary packaging materials can compromise the sterility of the final product (Ansari and Datta, 2003). Packaging that is not adequately sterilised or stored under controlled conditions may serve as a vector for microbial entry (Das et al., 2025).

Traditional Methods of Preventing Microbial Contamination in Pharmaceuticals

Preventing microbial contamination is a critical concern in pharmaceutical manufacturing, requiring a thorough understanding of how microbes can infiltrate various stages of production (Hashim and Celiksoy, 2025).

Raw Materials: Raw materials may introduce microbial contamination into pharmaceutical processes, endangering product safety and quality (Gupta et al., 2024). To prevent this, materials should be handled carefully upon delivery. This involves inspecting and analysing raw

materials upon delivery, taking sterile samples, and preventing microbial growth during storage. Manufacturers must also implement vendor certification methods to ensure that suppliers provide microbiologically compatible goods (Gupta et al., 2024). To detect contamination early, all incoming goods must be microbiologically examined. Testing cell lines and process media for mycoplasma and associated viruses is critical for biologic products since these bacteria may silently affect the manufacturing system and jeopardise product safety (Kapoor et al., 2020).

Air Quality: Airborne microbes, including moulds like *Penicillium* and *Aspergillus*, can contaminate products. To mitigate this, clean rooms with sterile air circulation are used, supported by Heating, Ventilation, and Air Conditioning (HVAC) systems with High-Efficiency Particulate Air (HEPA) filters (95–99.9% efficiency) (Hama, 2023). These systems must deliver single-pass, non-recirculated fresh air to prevent cross-contamination.

Equipment: Equipment must be designed for easy cleaning and sterilisation. Fixed machinery, such as mixing tanks, should support proper drainage and sterilant accessibility (Chakraverty and Kundu, 2025). Designs should minimise horizontal surfaces to prevent particle accumulation and ensure airflow is not obstructed, especially in aseptic environments (Ashtekar, 2021).

Personnel: Staff involved in production must be properly trained and follow strict hygiene protocols (Aarnisalo et al., 2006). Wearing protective gear—head, face, and hand coverings—is mandatory to avoid contaminating products, especially during aseptic operations (Sharman and Silver-MacMahon, 2023).

Water: Water promotes microbial growth (Peleg, 2022). Drying methods or additives like sugars and polyethylene glycol can reduce microbial risks

in aqueous formulations (Patel et al., 2025). High humidity during storage may lead to moisture films on products, increasing the risk of mould.

Temperature Management: Microbial growth tends to be most active between 20°C and 60°C, making this range particularly favourable for contamination (Hamad, 2012). To reduce the risk of microbial proliferation, it is important to store products at temperatures outside this range. Keeping products at lower temperatures, such as 8–12°C, slows down microbial metabolism and reproduction, thereby limiting growth. Conversely, maintaining temperatures above 80°C, such as in the case of injection water, effectively kills most microbes, further minimising the chance of contamination (Hamad, 2012).

pH: The pH is important for preventing germs from contaminating pharmaceutical products by creating conditions that limit the growth and survival of microorganisms (Gopalakrishnan et al., 2024). Most bacteria, yeasts, and moulds flourish within a limited pH range, often close to neutrality (pH 6–8) (Aliganza et al., 2025). Modifying the pH of a pharmaceutical formulation to values outside the ideal range—either acidic (low pH) or alkaline (high pH)—can effectively inhibit microbial growth (Kumadoh et al., 2024). Also, alkaline environments can stop microbes from living, but they are not used often because some medicines can become unstable in those conditions (Nasaj et al., 2024).

Packaging: Proper packaging prevents microbial entry and extends shelf life (Arshad et al., 2025). Innovations include self-sealing wads for injectable containers and replacing wide-mouthed jars with narrow, sealed tubes

Artificial intelligence in Pharmaceutical Manufacturing

AI is transforming pharmaceutical production by improving patient outcomes and innovation (Bhatt et al., 2024). AI is transforming medicine research, quality control, and supply chain management by improving efficiency, accuracy, and decision-making (Guo, 2023). The industry is using AI for automation and predictive analytics to reduce mistakes and speed up operations (Adekunle et al., 2021). Artificial intelligence can quickly analyse large datasets and find patterns and insights that conventional approaches cannot (Rachakatla et al., 2023). AI-powered image recognition systems accurately detect product

faults, guaranteeing safety and compliance (Ghelani, 2024). AI monitors output in real time and forecasts deviations to help predict maintenance and resource optimisation (Keleko et al., 2022).

Implementing AI in Pharmaceutical Manufacturing

Successfully integrating artificial intelligence into pharmaceutical manufacturing requires a structured and strategic approach as shown in Figure 1 below. Each step in the process plays a critical role in ensuring that AI delivers meaningful value while adhering to strict regulatory standards.

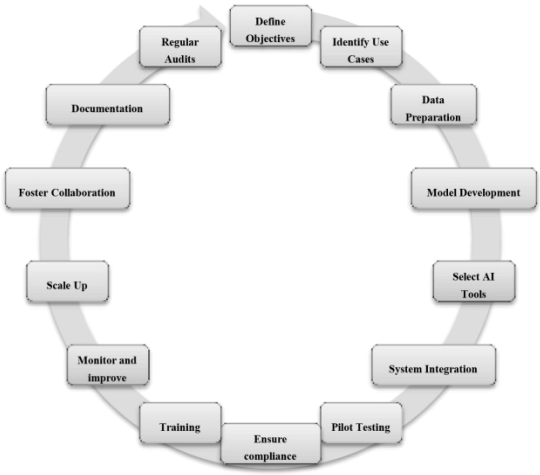

Figure 1: The flow chat of AI implementation in Pharmaceutical Manufacturing

1. Define Objectives

The first step is to establish clear goals for AI adoption. Objectives may include improving quality control, enhancing production efficiency, predicting equipment failures, or optimising supply chains (Bhattacharya, 2021). A well-defined objective provides direction and helps measure return on investment.

2. Identify Use Cases

After setting goals, manufacturers must determine where AI can add the most value. Important uses of AI include predicting when machines need maintenance using IoT sensor data, recognising images in realtime for quality checks, forecasting demand, and spotting unusual patterns in production batches (Kliestik et al., 2023). Prioritising impactful applications ensures focused and efficient implementation.

3. Data Preparation

Quality data is foundational to effective AI. The process involves collecting, cleaning, and structuring datasets from sources such as sensors, batch records, quality assurance logs, and supply chain systems (Subramanian, 2023). Without relevant and well-organised data, AI models cannot be trained effectively.

4. Select AI Tools

Choosing the right technology is critical. Machine learning models are ideal for predicting trends, while deep learning and computer vision are suited for image analysis and visual inspections (Mahadevkar et al., 2022). Natural language processing (NLP) can analyse unstructured data such as lab notes or maintenance reports (Benício et al., 2022).

5. Model Development

AI models are trained on the prepared data to perform specific tasks, such as identifying defective tablets or optimising mixing times. Model accuracy must be validated to ensure reliability before deployment in production environments (Heymann et al., 2022).

6. System Integration

AI systems must be embedded within existing manufacturing execution systems (MES), process control platforms, or enterprise resource planning (ERP) tools. Integration often requires collaboration with IT departments to ensure interoperability and real-time data flow (Kadadi et al., 2024).

7. Pilot Testing

Before full deployment, pilot projects are essential to test AI models under real-world conditions. Pilots help identify potential issues, adjust algorithms, and ensure models perform as expected within the production environment (Paul et al., 2024).

8. Ensure compliance.

Compliance with good manufacturing practices (GMP), FDA regulations, and global standards is non-negotiable. AI systems must ensure data integrity, traceability, and security (Kabir et al., 2024). This includes meeting requirements for electronic records and validating software performance (Moy et al., 2021).

9. Training

Staff must be trained to understand and interact with AI tools. Training should cover the basic principles of AI, how to interpret model outputs, and procedures for escalating unexpected results (Bellini et al., 2022). A workforce equipped with digital skills ensures smooth AI adoption (Babashahi et al., 2024).

10. Monitor and improve.

AI models must be continuously monitored for accuracy, reliability, and compliance. Over time, they should be refined based on new data, evolving manufacturing needs, and performance feedback (Babashahi et al., 2024). This iterative process ensures models remain effective and relevant.

11. Scale Up

Once a pilot has proven successful, AI solutions can be scaled across additional production lines or facilities. Scalability must be carefully managed to avoid data fragmentation or system incompatibilities (Keskar, 2024).

12. Foster Collaboration

Collaboration across departments including operations, quality assurance, IT, and data science is essential. Engaging all stakeholders fosters a shared understanding of AI's goals and ensures smoother implementation. Ongoing collaboration also keeps teams informed about advancements in AI capabilities (Jony and Hamim, 2024).

13. Documentation

Maintaining comprehensive documentation of AI models, datasets, decision logic, and validation procedures is critical (Mökander et al., 2023). Proper records support regulatory audits, future updates, and knowledge transfer. Documentation also demonstrates compliance with GMP and quality standards (Patel and Chotai, 2011).

14. Regular Audits

Periodic internal and external audits validate that AI systems continue to meet regulatory and performance standards (Raji et al., 2020). These evaluations should assess not only technical accuracy but also data handling, model governance, and user accountability (Xia et al., 2024).

Application of AI in Detecting Microbial Contamination in Pharmaceutical Manufacturing

Artificial intelligence (AI) has become an increasingly valuable tool in pharmaceutical manufacturing, especially in enhancing microbial contamination detection and control (Tsitou, et al., 2024). By integrating AI technologies, manufacturers can significantly improve product safety, quality, and regulatory compliance. Key applications include:

Predictive Modelling for Contamination Risk

Artificial intelligence can quickly analyse massive datasets and discover trends and insights that traditional methods cannot (Rachakatla et al., 2023). AI-powered image recognition systems detect product faults, ensuring compliance and safety (Ghelani, 2024). AI helps predictive maintenance and resource optimisation with real-time production monitoring and deviation predictions (Keleko et al., 2022). As AI use rises, data security, legal compliance, and worker training are needed. Regulators, industry professionals, and AI specialists must collaborate to integrate breakthroughs with industry norms (Kashefi et al., 2024).

Real-Time Microbial Monitoring

Industrial and clinical microbiology is being transformed by AI-powered real-time microbial surveillance (Ayoub et al. 2024). AI-powered sensors and analytical systems monitor microbial populations in food production lines, pharmaceutical clean rooms, and water treatment facilities (Sharma et al., 2024). AI-enabled systems handle data quickly using sophisticated algorithms and machine learning models, unlike conventional microbiological procedures that take hours or days for sample, culture, and manual analysis (Santhanagopalan et al., 2024). These systems can detect tiny microbial load or composition changes utilising optical, biochemical, or biosensor inputs (Taha et al., 2024). The gadget may alert for rapid bacterial count increases or fatal infections. Such detection lets you stop production, separate unsafe batches, and clean and disinfect immediately.

Monitoring in real time guarantees regulatory compliance, product safety and quality, recall risk reduction, and operating downtime (Akano et al., 2024). AI integration is essential because microbial contamination creates serious financial or public health hazards (Mohseni and Ghorbani, 2024).

Automated Microbial Identification

Machine learning (ML) algorithms and modern technologies like mass spectrometry, spectrum analysis, and genome sequencing may swiftly and correctly identify pollutants and diseases (Dakal et al., 2025). This method is much faster than raising and analysing microorganisms manually (Abayasekara et al., 2014). This approach yields data much faster than culture-based methods, which need microbe cultivation and hand analysis (Abayasekara et al., 2014).

Machine learning methods that use large sets of microbial data can find specific patterns in complicated information like genetic sequences or mass spectra (Weis et al., 2020).These algorithms can immediately identify novel microbial samples by comparing them to established profiles after training. ML combined with MALDI-TOFMS may differentiate close relatives of bacteria. AI-augmented genomics can categorise bacteria based on genetic markers in whole-genome sequencing data (Suster et al., 2024).

This automation improves microorganism detection, identification, and test efficiency in clinical, food safety, and environmental monitoring (Tsitou et al., 2024). This technology also eliminates human error and the necessity for expert microbiologists to undertake routine identification tasks, according to Alsulimani et al. (2024).

Optimising Cleaning and Sanitisation Procedures

According to Jebbor et al. (2024), AI has the potential to revolutionise the way sanitation and cleaning protocols are created and enhanced. According to Palla and Iwunwa (2025), artificial intelligence can determine the best sanitisation strategies by analysing massive amounts of data using various methods. This data encompasses elements such as contamination rates, surface types, chemicals used, and the frequency of treatment application. By employing data to inform protocol adjustments, facilities may stop wasting money on ineffective or out-of-date methods and start putting their efforts into what works (Palla and Iwunwa, 2025). Not only is the likelihood of contamination greatly reduced, but efficiency is increased, expenses are decreased, and hygiene requirements are more consistently applied.

Implementing Risk-Based Contamination Control Strategies

Artificial intelligence makes it possible to prioritise hazards according to their severity, probability, and potential effects, allowing for a more intelligent and strategic approach than considering all contamination concerns equally (Ibrahim et al., 2025). AI can help design targeted actions where they are needed most by looking at things like how equipment is used, the surrounding conditions, previous contamination patterns, and how work is done. According to Abdulameer et al. (2025), AI enables organisations to better allocate resources, proactively control contamination hazards, and ensure safer production environments. With the use of predictive analytics and real-time information, hygiene management is shifting from reactive to proactive.

AI-Driven Expert Systems for Contamination Management

Expert systems driven by AI are transforming how businesses handle contamination hazards by providing intelligent, real-time assistance (Naseem and Rizwan, 2025). These systems use built-in knowledge and decision-making rules to guide users in finding, identifying, and responding to contamination, mimicking how human experts think. These technologies ensure that everyone on the team, from workers to managers, can quickly make informed and consistent decisions, whether they are spotting problems in production data, recommending specific safety measures, or leading cleanup efforts. This approach is particularly helpful in high-stakes settings where mistakes or delays can have major repercussions, such as in the manufacture of food or pharmaceuticals (Canatan et al., 2025). Even without on-site specialists, organisations may maintain high standards of safety and hygiene by using AI as a virtual advisor (Demaerschalk et al., 2023).

Machine Learning Techniques in Contamination Detection

Modern machine learning (ML) algorithms have substantially improved contamination detection, particularly in complicated and large-scale datasets (Varun et al., 2025). Convolutional neural networks (CNNs) excel at analysing visual data, such as microscope pictures or video feeds, to detect microbial growth or anomalies that the human eye cannot see (Dhal a Kar, 2025). Similarly, recurrent neural networks (RNNs) are excellent at handling data that comes in a sequence, like sensor logs, environmental measurements, and genomic sequences, which helps them find small patterns that might indicate contamination. These AI models constantly learn and improve as they encounter new data, becoming quicker and more accurate over time (Zha et al., 2025). The outcome is a powerful, automated detection system that lowers human error, speeds up reaction times, and allows more reliable contamination management across industries (Ellahi et al., 2025).

Challenges of AI in Microbial Contamination Detection and Control

As AI adoption grows, challenges such as data security, regulatory compliance, and workforce training must be addressed. Effective integration requires collaboration among AI specialists, industry professionals, and regulators to align innovations with industry standards (Kashefi et al., 2024).

1. **Validation and Testing**: AI models used to detect microbial contamination must undergo rigorous validation to ensure accuracy, sensitivity, and specificity (Tsitou et al., 2024). This process can be both resource-intensive and time-consuming, especially when aligning with regulatory requirements for microbiological quality assurance.

2. **Expertise Gap**: The development and deployment of AI for microbial detection require interdisciplinary expertise in microbiology, data science, and machine learning (Alsulimani et al., 2024). However, such specialised knowledge may be limited to many pharmaceutical or clinical microbiology settings.

3. **Change Management**: Transitioning from traditional microbial detection methods to AI-based systems often necessitates a cultural shift.

Resistance to change among personnel accustomed to established protocols can hinder adoption and affect implementation outcomes (Murire, 2024).

4. **Integration Complexity**: Incorporating AI tools into existing laboratory information systems (LIS), environmental monitoring platforms, or quality control workflows can be technically complex. It demands strong collaboration between microbiology, IT, and quality assurance teams to ensure seamless data flow and compliance with industry standards (Ain et al., 2024)

Conclusions

Artificial intelligence in microbial contamination management changes pharmaceutical production. Traditional approaches are essential but limited in scalability, reactivity, and accuracy. Real-time monitoring, predictive modelling, and data-driven decision-making with AI reduces contamination risks and improves product integrity. From predictive maintenance to automated microbial identification, AI helps industries meet strict quality and regulatory criteria. Data needs, regulatory adaptations, and labour preparedness are still issues, but AI's efficiency, accuracy, and safety surpass them. As pharmaceutical production evolves, AI will help ensure product sterility, optimise operations, and protect public health.

Conflict of interest

The authors declared no conflict of interest.

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