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SPECIAL FOCUS PAPER

# Nanosensor Integration for Adulterant Detection: Cross-Country Thematic Comparison

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## ABSTRACT

Adulterants, such as diethylene glycol in syrups, compromise drug safety globally. This study explores nanosensors (nanoscale electrochemical/optical devices) for real-time contaminant detection at parts-per-billion levels in active pharmaceutical ingredients (APIs). The study uses thematic analysis of secondary literature to compare nanosensor adoption across four contexts: the U.S. (FDA gold nanoparticle pilots), the EU (graphene platforms under the European Medical Association), China (state-backed heavy metal sensors), and India (IIT-developed adulterant detectors). Coding reveals patterns in sensitivity, scalability gaps, and regulatory hurdles, contrasting U.S./EU lab-to-market pipelines. The study applies qualitative thematic analysis to peer-reviewed literature published between 2021 and 2026. The findings indicate substantial potential for high detection accuracy using nanosensors, offering a blueprint for resilient global pharma quality control. Management benefits include faster quality alerts, unified compliance dashboards, and cross-border standardization, addressing the EU's serialization maturity vs. Asia's fragmented testing.

## KEYWORDS

nanosensors, adulterant detection, cross-country comparison, supply chain management

## 1 INTRODUCTION

A major persistent concern in global public health is pharmaceutical adulteration, particularly toxic component contamination. The case of diethylene glycol (DEG) and ethylene glycol (EG) contamination in oral liquid and syrup formulation is among the most crucial cases. Even a small amount of these contaminants can cause acute kidney failure, metabolic acidosis, neurological impairment, and fatal effects, more so in the pediatric population [1]. As a response to a mass poisoning incident associated with contaminated medicinal syrups, the regulatory scrutiny has been strengthened. The permissible impurity threshold is tightened with EG and DEG levels restricted to a maximum of 0.1% [1]. This shows the urgent need for strict quality control across excipients and final pharmaceutical products.

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The conventional approach involved in the detection of EG and DEG is mainly based on the laboratory-based technique, which includes Gas Chromatography with Flame Ionization Detection (GC-FID), Thin Layer Chromatography (TLC), and High-Performance Liquid Chromatography (HPLC). One of the most precise and suggested methods is GC-FID. These conventional methods are, however, time-consuming and labor-intensive, and require particular instrumentation and trained personnel. The rapid field screening and real-time quality assurance are constrained because of such infrastructure limitations [2]. The issue is all the more serious in low- and middle-income countries. The existing chromatographic methods are reliable, but they are usually inaccessible in decentralized supply chains. This reflects the requirement of fast, budget-friendly, and portable detection methods.

The nanoscale electrochemical and optical biosensors are produced using advanced nanotechnology. These have high selectivity and high sensitivity to analytes. With some of the most superior electrochemical sensors, the surface area, stability, and efficiency of electron transfer increase, resulting in improved analytical performance in both pharmaceutical drug identification and quantification efforts [3]. The superior electrochemical sensor design incorporates nanomaterials, such as metal nanoparticles, quantum dots, metal oxides, and carbon nanoparticles. These nanomaterials enhance selectivity, limit of detection (LOD) and response time [4]. Such sensors are also designed as a wearable, mobile phone-compatible, and disposable platform, therefore, demonstrating the high potential of the field-deployable and real-time analysis of pharmaceuticals.

Nano-assisted biosensors have transformative properties in many fields, such as medical care, food security, and environmental protection. Such a transformation is achieved with the help of signal transduction and surface functionalization [5]. Early biomarker detection, real-time contaminant identification, and integration with digital tools are possible because of nanotechnology advances. Optical nanosensor have Localized Surface Plasmon Resonance (LSPR), colorimetric strategies, Surface-Enhanced Raman Scattering (SERS), and photoluminescence that provides an additional detection pathway [6]. Gold nanoparticle-based sensors have exceptional electronic and optical properties that provide high detection sensitivity [7]. Their conductivity, strong plasmonic interaction, and stability support biosensing usage.

Nano sensors are mainly explored in the context of food safety and environmental contaminants. However, the underlying principles of the technology are transferable to pharmaceutical adulterant detection. Nano-biosensors have shown low detection limits and high sensitivity in contaminant and adulterant identification in food material [8]. Nanomaterial-based calorimetric portable detection tools are developed for environmental toxins and illicit drugs, showing real-time field usage potential [9]. Apart from that, graphene-based electrochemical biosensors are explored for the detection of contamination [10]. However, the adoption of nanosensors does not solely depend on technological feasibility. As per jurisdiction, the regulations related to health products vary. The regulatory pathways in the European Union and the United States highlight challenges like a lack of a standard nanotechnology definition, an extended approval timeline, and complicated physicochemical requirements [11]. Thus, the structured evaluation program focuses on the standardization of the testing process.

Regulatory frameworks for medical devices using nanomaterials continue to evolve in China. National authorities issue documents to guide physicochemical characterization, safety evaluation, and biological assessment [12]. The regulatory refinement needs to influence the translation of innovation in clinical and commercial applications. Computational approaches like natural language processing (NLP) are used to analyze regulatory alignment and deviance across the European Union, the US, and China. It shows similarities and differences in regulatory priority. These aspects reveal the complication of cross-jurisdictional technology application.

Despite this broad literature base conducted independently on nanosensor techniques and regulatory science, there exists scarce literature on nanosensor analysis combined with cross-country implementation in the pharmaceutical supply chain. The available academic literature addresses either sensor engineering or the regulatory framework primarily. It fails to analyze how national regulations can affect the use of nanosensors in the detection of adulterants. Therefore, the proposed study is aimed at filling the gap between nanotechnology engineering and cross-country studies in the pharmaceutical sector. The primary aims include the following:

- Synthesize recent studies in nanosensor technologies related to adulterant detection.
- Compare nanosensor adoption across the US, the European Union, China, and India.
- Identify infrastructural, scalability, and framework components that influence deployment.
- Present an integrative framework to link the regulatory ecosystem with the nanosensor pathway.

# 2 LITERATURE REVIEW

## 2.1 Optical and gold nanoparticle biosensors

Photonic signal transduction provides detection capabilities to optical sensors. Localized Surface Plasmon Resonance (LSPR), photoluminescence (PL), surface enhanced Raman scattering (SERS), electrochemiluminescence, and chemiluminescence are used by these optical nanosensors [6]. Furthermore, low-dimensional nanomaterials improve signal amplification and sensitivity in pharmaceutical applications. The portability, minimal requirement of attachments, and rapid responsiveness of the optical biosensor favor its usage for continuous monitoring. They are also integrated into smart pharmaceutical monitoring systems. An advanced subset of optical and electrochemical platforms is gold nanoparticle (AuNP)-based biosensors. These biosensors have good stability, strong plasmonic interactions, and high conductivity, increasing detection sensitivity [7]. LSPR, fluorescence, SERS, colorimetric detection, and surface plasmon resonance (SPR) are largely explored for the detection of AuNP biosensors. Although it's extensively researched in the context of diagnosing infectious diseases, its detection processes are directly extended to the pharmaceutical sector. Its rapid response time and strong signal amplification support screening of impurities.

## 2.2 Nanomaterial-based electrochemical sensors

The possible future of the electrochemical sensing platforms in the detection of pharmaceutical analytes lies in their high sensitivity, compatibility, and easy operation. It is also possible that the nanomaterial-based electrochemical sensors enhance the surface area, selectively functionalize surfaces, and enhance the electron transfer kinetics, thus enhancing the analytical capability [3]. These systems are mobile, affordable, and accurate and thus can be used to control the quality of pharmaceuticals. The emerging trends in electrochemical sensor technology are sophisticated nanostructures, metal oxides, quantum dots, and carbon nanomaterials [4]. The methods of its fabrication, such as screen printing and sol-gel processing, are optimized to provide enhanced scalability and reproducibility. Barhoum et al. [4] also demonstrate that the performance rates, such as selectivity, LOD, and stability, are enhanced in the case of nanofabrication strategies.

Malode et al. [3] state that electrochemical nanosensors have key potential for drug analysis in pharmaceutical and biological matrices because of high specificity and stability. Modern sensor designs are smartphone compatible. They also include wearable platforms and disposable paper-based devices. This reflects a shift towards field-deployable methods. The portability is advantageous for rapid adulterant detection. A major advancement in this domain is graphene-based electrochemical biosensors. The high conductivity, large surface-to-volume ratio, and mechanical strength of graphene account for its cost-effectiveness and high sensitivity [10]. It thus has better detection efficiency, making it suitable for the detection of even trace-level pharmaceutical impurities like EG and DEG.

### 2.3 Nanosensors for adulterant and contaminant detection

The pharmaceutical-dedicated nanosensor deployment is an emerging area, yet studies from food safety and environmental monitoring show the feasibility of nanoscale impurity detection. Kaur et al. [8] chalk up that nano-biosensors have better sensitivity and a lower detection limit for identifying impurities and adulterants in diverse matrices. It further offers better selectivity because of functionalized nanoparticles and allows the detection of hazardous materials in a complex environment. Hemdan et al. [5] also indicate that pollutant and pathogen detection is done with nano-enhanced biosensors. This is indicative of real-time capabilities and portable capabilities. Biosensors have further capabilities after signal transduction and surface functionalization, as well as the incorporation of specialized technologies. The integration also facilitates the formation of an intelligent monitoring system, which is applicable in the supply chain. The colorimetric detection using nanomaterials is also created to detect illegal drugs, as presented by Hossain et al. [9]. It possesses on-site detection, despite the minimum technical expertise requirements. Such platforms expect real-time response, ease of operation, and portability, thus making it very essential in the screening of pharmaceutical adulterants. The change to embedded sensing technologies also reflects the increasing attention paid to the systems of intelligent packing. Mkhari et al. [13] disclose that smart packaging comprises RFID units, sensors, and indicators presenting real-time visibility. Although this is primarily being used in the food preservation context, the strategy of including nanosensors in packaging or distribution can be applied in a pharmaceutical environment.

### 2.4 Cross-country adoption

Even after significant technological advances, the translation of nanotechnology health products in commercial and clinical settings is dependent on regulatory frameworks. As the comparison of the United States and European Union regulatory systems reveals, there are enduring problems, such as the absence of a common definition of nanomaterials, prolonged approval processes, and complex physicochemical characterization requirements [11]. Existing rules tend to apply existing medical equipment or pharmaceutical models to nanotechnology to allow products to contribute to the complexity of the procedures. The regulations of medical equipment with nanomaterials have developed in China on the basis of documents that are devoted to safety assessment, physicochemical characteristics, and biological assessment [12]. Despite the presence of prescribed evaluation courses, regulatory sciences must undergo continuous innovations to achieve clinical translation. An analysis of the regulatory documents in the United States, China, and the European Union revealed semantically comparable differences in regulatory focus by Han and Bergmann [14]. The authors also employed natural language processing and machine learning to demonstrate the existence of dissimilar levels of alignment between jurisdictions; this indicates that there is inconsistency in regulatory convergence. The regulatory differences also determine the way the nanosensors can be commercialized. In spite of the fact that lab-level innovation can be more or less similar in its analytical capacity at the global level, the level of deployment maturity could be shaped by the national regulatory transparency, harmonization process, and validation scheme to a great extent.

## 3 MATERIALS AND METHODS

### 3.1 Research design

This study uses qualitative thematic analysis of secondary literature to understand the integration of nanosensors in pharmaceutical adulterant detection across different regulatory settings. The research approach is comparative and analytical. It concentrates on nanosensor technological evolution, nanosensors' interaction with the condition of scalability, regulatory science, and commercialization. Nanosensors have been developed through the fields of electrochemical engineering, regulatory science, optical biosensing, and intelligent packaging. So, a structured comparative review was selected to get diverse details. Peer-reviewed articles covering nanomaterial sensing platforms [3], [4], [6], [7], contaminant detection [8], [9], [10], and DEG/EG analysis [1], [2] are synthesized in this research.

### 3.2 Inclusion and exclusion criteria

The inclusion criteria for the selection of articles in this study are the following:

- Published between 2021 and 2026
- Articles published in peer-reviewed journals
- Relevance to core themes such as nanomaterial-based electrochemical sensors, contaminant and adulterant detection, optical and nanoparticle-based biosensors, DEG/EG detection, intelligent sensing integration, and regulatory science and cross-country analysis.

The exclusion criteria were the following:

- Published in any other language except English
- Articles not accessible through academic databases

The planned inclusion criteria ensure consistency and reliability in the findings of the study.

### 3.3 Analytical coding

The selected articles were coded across five analytical dimensions that were derived from recurring performance. The first dimension is detection sensitivity. The key performance metrics derived from various literature are selectivity, LOD, signal amplification, and analytical precision [3, 4, 6]. The next dimension is deployment maturing. The reported implementation stages in literature are laboratory-level validation, prototype development, field-deployable or portable system, and regulatory-approved or commercial platform. These indicators were decided on the basis of a wearable, disposable platform and smartphone compatibility [4], [5]. Scalability and cost feasibility are the third dimension. Material accessibility, fabrication method, and suitability for a limited resource setup are indicators of scalability. Cost considerations were reflected in the rapid portable DEG/EG assay [2] and the graphene-based sensor platform [10]. The next dimension is regulatory compatibility, which evaluates characterization needs, approval pathways, and harmonization issues. The last dimension is digital integration potential. The multi-dimensional coding framework allows evaluation beyond analytical performance.

### 3.4 Cross-country mapping

The cross-country aspect has been obtained through the study of the technological potential and regulatory environments under four settings, including the United States, the European Union, China, and India. Regulatory ecosystems in the U.S. and the European Union are characterized by physicochemical characterization requirements and product evaluation organized around nanotechnology. In China, it is defined by the shift of regulatory science, recommendations on nanomaterial-based medical products, and the amount of regulatory variation between jurisdictions in China and in the West. In India, the particular nanotechnology laws are not well arranged, yet the new patterns are manifested in developing research based on cost-sensitive sensors [8], [10] as well as the use of portable screening techniques.

## 4 RESULTS AND DISCUSSION

### 4.1 Detection sensitivity and analytical performance

Thematic analysis of the sampled articles depicted high levels of analytical detection abilities. Nanostructured materials contain more sensitive, selective, and low LOD electrochemical sensors and are, therefore, useful at the trace level in the pharmaceutical sector [3], [4]. The structure of the body is better functionalized due to the enhanced electrode surface area, fineness of surface functionalization, and enhanced electron-transfer kinetics. Other parallel improvements are also seen in optical biosensors. LSPR, SERS, and photoluminescence enable the amplification of signals at a high rate and efficient detection [6]. AuNP biosensors have enhanced the ability to detect biorelevant molecules because of the high plasmonic and conductive properties [7]. It also allows high sensitivity and fast detection that highly conform with a stringent impurity level of DEG and EG impurities [1]. The nanosensors designed for food safety as well as environmental contaminant identification [8], [9] in the appropriate range and response time are compatible with the screening of pharmaceutical adulterants, and, therefore, such investigations are pertinent.

## 4.2 Regulatory stringency and commercialization

Regulatory science has a decisive role in deciding nanosensor adoption maturity. Substantial procedural complications are present in nanotechnology-enabled health product frameworks in the U.S. and the European Union [11]. The major challenges are extensive physicochemical characterization needs, a lack of harmonized nanomaterial definition, and long approval times. Although it adds to the structure, it slows down commercialization. The regulatory guidance for nanomaterial-based medical devices in China focuses on biological assessment, physicochemical characterization, and safety assessment [12]. There are defined evaluation plans, but regulatory science continues to evolve to improve the translation of nanotechnology-enabled devices. Further, computational analysis shows measurable semantic differences in regulatory priority across the U.S., the European Union, and China. Thus, there is partial alignment but incomplete harmonization.

## 4.3 Gaps in scalability and field deployment

The laboratory-scale nanosensor performance is strong, but its scalability and deployment are uneven. Modern electrochemical sensors include a wearable, disposable format and smartphone compatibility. It shows a shift towards portable monitoring systems. Nano-enhanced biosensors show compatibility with intelligent monitoring systems [5]. The translation of a laboratory-level system to a field-deployable system requires operational protocols and cost-effective production. The importance of low cost and field-deployable usage is reflected in rapid screening assays for DEG and EG [2]. Further, even though the chromatographic gold standard methods are precise, they are inaccessible in many limited-resource environments. This highlights the requirement for simple detection methods. Graphene-based electrochemical sensors provide a cost advantage because of simple fabrication and material accessibility [10]. The major barriers in the path of widespread pharmaceutical integration are large-scale industrial manufacturing, regulatory validation, and quality assurance standards.

## 4.4 Intelligent monitoring with digital integration

One such cross-cutting theme that came out of the analysis is digital integration. Nano-biosensors can be integrated with artificial intelligence (AI), Internet of Things (IoT), and real-time data systems [5]. Modern technology is integrated to facilitate remote data transfer, predictive monitoring, and an automatic alert system. The sensors in intelligent packaging systems are supporting the constant check of the product integrity through the supply chain [13]. This is mainly applied to food preservation, but a similar approach may be implemented in the pharmaceutical supply chain. Regulatory science is also changing with the computational analysis and digital modeling. As an example, NLP usage concerning regulatory content demonstrates the possibility of harmonizing the cross-jurisdictional regulatory standards. In such a way, the integration of nanosensors within a pharmaceutical context is not limited to the field of analytical chemistry and includes the domain of digital quality infrastructure.

### 4.5 Cross-country adoption pattern

The implementation of nanotechnology in the pharmaceutical environment presents some unique features, as highlighted in Table 1. The U.S. and the European Union are considered to be regulatory structured ecosystems. This ecosystem focuses on strict physicochemical characterization and safety validation [11]. It also possesses clear analytical performance requirements; however, it is characterized by procedural complexity that is likely to cause a delay in the approval timeline. China has developed regulatory guidance for nanomaterial-based devices, and it increases its ability to innovate [12]. With regard to the Indian context, particular nanotechnology regulatory structures are less organized. Research, however, demonstrates the significance of portability and affordability in new markets such as India [2], [10].

**Table 1.** Cross-country pattern analysis

| Dimension | United States/European Union | China | Cost-Constrained Contexts (e.g., India) | Key Supporting References |
|---|---|---|---|---|
| **Analytical Capability** | High-performance electrochemical and optical nanosensors; strong characterization standards | Rapid innovation in nanomaterial-based sensing devices | Increasing use of graphene and simplified electrochemical platforms | [3] [6] [7] [10] |
| **Detection Sensitivity** | ppb-level detection aligned with impurity thresholds | Comparable high sensitivity under evolving standards | Sensitive detection demonstrated in low-cost formats | [1] [2] |
| **Regulatory Clarity** | Structured but complex nanotechnology evaluation pathways | Defined guidance but evolving harmonization | Limited standardized nanotechnology-specific frameworks | [11] [12] [14] |
| **Approval Timelines** | Rigorous validation; potentially longer approval cycles | Accelerating innovation with regulatory refinement | Faster informal adoption but limited harmonization | [11] [12] |
| **Scalability & Manufacturing** | Advanced fabrication techniques; quality-controlled scaling | Expanding production capacity for nanomaterials | Emphasis on affordability and simplified fabrication | [4] [10] |
| **Digital Integration Potential** | Integration with AI/IoT-enabled monitoring systems | Growing digital-health integration | Emerging digital infrastructure in decentralized settings | [5] [13] |
| **Adoption Archetype** | Regulatory-Structured Ecosystem | State-Guided Innovation Ecosystem | Cost-Constrained Innovation Ecosystem | Synthesized from thematic analysis (By author) |

*Source:* Compiled by authors.

### 4.6 Regulatory-technology alignment framework

According to the results obtained in the discussion of the chosen papers, it is concluded that the maturation of nanosensor adoption is interdependent on the product of analytical ability, regulatory ability, the feasibility of scalability, and the integration of digital infrastructure, as is the case in Figure 1. Convergence of the technical performance occurs throughout the literature, and there is still commercialization divergence. For instance, jurisdictions with structured regulations have standardized deployments, whereas areas focusing on cost sensitivity might opt for portable systems and encounter harmonization barriers.

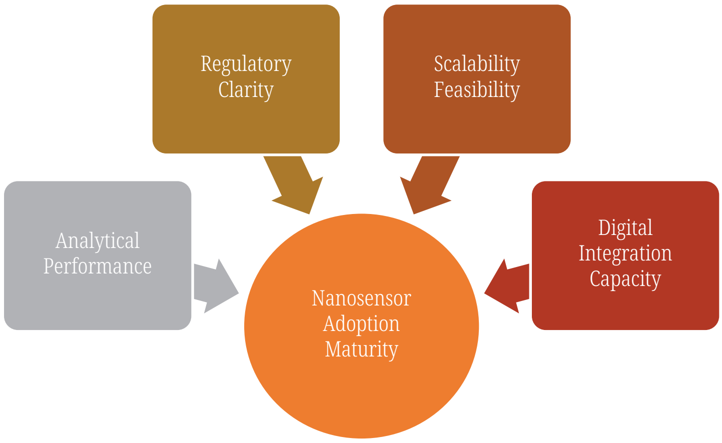


**Fig. 1.** Regulatory-technology alignment framework

*Source:* Compiled by authors.

# 5 PRACTICAL AND MANAGERIAL IMPLICATIONS

## 5.1 Implications for pharmaceutical organizations

Nanosensor technologies are capable of trace-level contamination detection [1]. This presents an opportunity for pharmaceutical companies to shift from batch-based quality checks to semi-continuous or continuous monitoring. Electrochemical nanosensors fabricated through scalable techniques can be included in the production process for monitoring of active pharmaceutical ingredients (APIs). The cost-effectiveness and sensitivity of graphene-based biosensors make it suitable for decentralized manufacturing infrastructure. The rapidly deployable detection system for DEG/EG screening reveals the feasibility of low-cost screening at both procurement and distribution stages. Thus, manufacturing firms operating in multi-tier supply chains could use portable nanosensor kits at supplier validation checkpoints. It reduces dependence on centralized laboratory confirmation.

## 5.2 Implication for regulatory bodies

Regulatory agencies have a central role in the maturity of nanosensor maturity. The research landscape shows physicochemical characterization and safety validation for nanotechnology-enabled health products and services [11] [12]. This is important for patient safety, but a timeline approval delay results in a delay in the deployment of portable technologies. Regulatory bodies can consider structured pilot validation programs and extend them as per the findings of the same. Cross-border recognition of nanosensor data can be enhanced by establishing harmonized performance standards. Computational approaches to regulatory alignment provide a potential path for the identification of areas of convergence and divergence.

## 5.3 Digital integration and smart compliance

Combining nanosensors with IoT and AI has a transformative potential in pharmaceutical supply chains [5]. Continuous monitoring can be facilitated by a real-time dashboard of quality data transmission, predictive analytics, and automatic alerts. An example of current intelligent packaging in food preservation [13] demonstrates that embedded intelligent sensing devices can network their presence to detect chemical and environmental variations. The same infrastructure can be used in the packaging of pharmaceuticals to offer a contaminant-sensitive and tamper-evident solution. The biosensor that was developed as an ultra-compact biochemical sensor based on a 2D photonic crystal cavity is known for altering its spectrum [15]. Moreover, digital technologies in healthcare can focus more on open data on health and the latest biomedical research developments to enhance patients' treatments, making them more accessible and available [16]. For multinational pharmaceutical companies, the unified digital compliance dashboard improves standardized reporting across diverse regulations. These systems can improve transparency and quality assurance decision-making.

### 5.4 Implications for emerging economies

Portability and affordability are important determinants of adoption in cost-constrained situations. A rapid, low-cost detection assay and a graphene-based electrochemical platform show a scalable pathway. Thus, investment in such an environment should focus on low-cost nanomaterial fabrication, training for field-level quality staff, a simple user interface, and a modular sensor kit adaptable to diverse supply chain infrastructure. Emerging economies should thus focus on cost-sensitive engineering solutions to improve pharmaceutical safety without exclusively depending on central laboratory infrastructure.

## 6 CONCLUSION

Adulteration in pharmaceutical products involves toxic impurities like EG and DEG. It poses major health concerns locally and globally. The traditional analytical methods are precise, but they are largely labor- and infrastructure-intensive. They are also not suitable for decentralized real-time monitoring. The recent studies and advancement of nanomaterials and electrochemical and optical biosensors reflect low detection limits, high sensitivity, and good potential field deployments. This paper adopted thematic-comparative research of nanosensor technologies on a variety of regulatory ecosystems. The results further imply a similarity in the analytical performance and indicate also the differences in the commercialization directions due to regulatory clarity, scalability possibility, and the capacity of the digital infrastructure.

The suggested model, which is referred to as the Regulatory-Technology Alignment Framework, describes the flexibility of nanosensor adoption and maturity as the connection between analytical capacity, regulatory context, the condition of scalability, and the readiness of digital integration. Contexts that are cost-constrained in terms of the framework focus on affordability and portability. The con side is, on the other hand, slower deployment yet faster validation in regions that have arranged and backed regulatory systems. Nanosensors in pharmaceutical supply chains could be introduced to increase the strength of the global quality control systems. Resilient border-spanning contaminant detection methods, compatible consolidation protocols, and scalable fabrication protocols and smart digital monitoring platforms can also be supported by nanosensors. The study also proposes the research directions, including that the research needs to be concentrated on pilot implementation studies, harmonization of cross-jurisdictional validation, and AI-assisted performance modeling to hasten the process of safe and effective implementation of nanosensors in pharmaceutical manufacturing systems. The integrated systems embraced during the modern era make use of the greatest of the existing technologies, and this proves to be an advantage in regard to the current study.

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