TECHNIUM
SOCIAL SCIENCES JOURNAL

www.techniumscience.com

Vol. 66/2024

A New Decade for Social Changes

PLUS COMMUNICATION

International Communication & PR

Technium Social Sciences Journal
Vol. 66, 441-451, December, 2024
ISSN: 2668-7798
www.techniumscience.com

Monitor to Protect: The Proliferation of Bio-Connected Devices in Supply Chains

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Abstract. The use of bio-connected devices (BCDs) in medicine and perishable logistics marks a significant advancement in product traceability and flow security. These devices, equipped with heat-sensitive biosensors, allow for real-time monitoring of storage and delivery conditions. This ensures that medicines, particularly vaccines, and perishable goods are kept within proper temperature ranges, preventing deterioration. Additionally, BCDs play a crucial role in combating counterfeiting through transparent traceability systems, often enhanced with blockchain technology, which guarantees product authenticity throughout the supply chain. However, the adoption of these innovative technologies faces several barriers, including high initial costs, data security concerns, and the need for adequate technical infrastructure. Despite these challenges, BCDs have substantial potential to transform the food and pharmaceutical industries by boosting operational efficiency and ensuring product safety.

Keywords. Artificial intelligence (AI), bio-connected devices (BCDs), biosensors, blockchain, Internet of Things (IoT), medicines, perishables, supply chain, traceability.

1. Introduction

In an increasingly globalized and interconnected world, efficient supply chain management has become more critical than ever, with a growing emphasis on responsiveness and resilience. Among the technological innovations reshaping this sector, bio-connected devices (BCDs) are emerging as essential tools for ensuring product safety and quality, whether for perishables or medicines. By integrating biosensors into connected systems, BCDs enable real-time monitoring of environmental conditions, enhance product traceability, and optimize logistics processes. These biosensors allow companies to not only respond swiftly to issues but also anticipate potential challenges before they become critical. This capability to monitor every link in the supply chain helps build consumer confidence in the products they purchase [24][25]. Ultimately, the goal is *to monitor logistical processes to better protect people*, ensuring that safety standards are met while improving overall supply chain efficiency, benefiting both businesses and consumers alike.

As fundamental components of BCDs, biosensors play a central role in collecting product flow data. By detecting biological signals and converting them into actionable information, biosensors enable the tracking of essential variables such as temperature, humidity, and gas levels within storage units throughout the supply chain. Their ability to provide real-time data is crucial, particularly for sensitive products, where even slight deviations can compromise quality. The integration of BCDs goes beyond simple monitoring; it also allows companies to anticipate and address potential problems before they arise. With enhanced visibility at every stage of the logistical process, businesses can respond swiftly to anomalies, minimizing both technical and financial risks. Additionally, the use of biosensors contributes to resource optimization, facilitating industrial planning and inventory management.

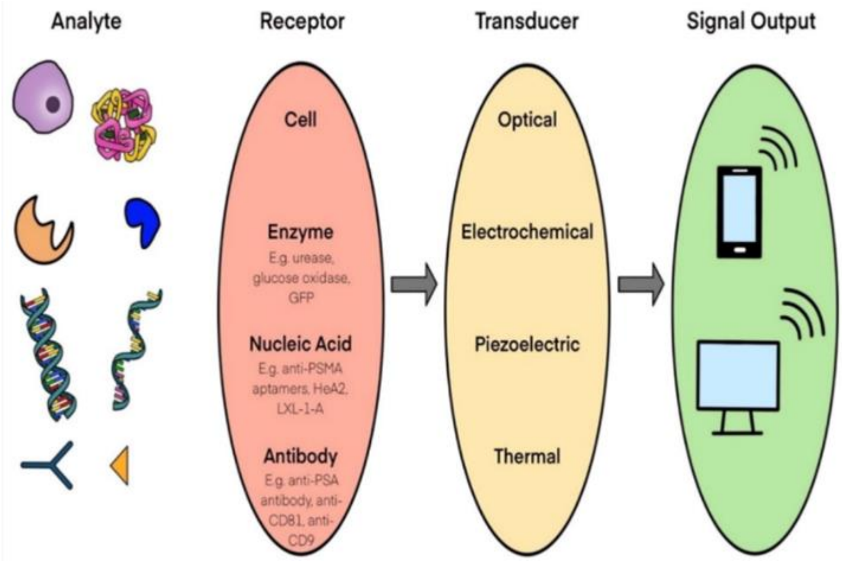
To explore these issues in depth, this research note is structured as follows. First, we examine the concept of BCDs and their functionality, emphasizing the importance of biosensors in modern logistics. Next, we analyze the specific applications of BCDs within the perishables supply chain, demonstrating how these innovative devices enhance the quality and safety of food products. We then assess the impact of BCDs in the pharmaceutical sector, particularly regarding cold chain monitoring for vaccines and efforts to combat counterfeiting. Finally, we address the limitations of BCD usage in the supply chain while considering the challenges that must be overcome. Our analysis aims to illustrate how BCDs represent not only a technological advancement but also a significant lever for improving logistical practices, ultimately contributing to efficiency and reliability, with important implications for public health.

2. Spotlight on BCDs

Biosensors are analytical devices that detect *biological* signals and convert them into measurable data, typically represented as *electrical* signals [13]. These devices comprise a biological recognition element—such as enzymes, antibodies, or nucleic acids—and a transducer that transforms the biochemical reaction into a signal [21] (see Figure 1). In logistics management, biosensors have been employed for several years to monitor changes in temperature, humidity, gas levels, and other environmental factors critical to maintaining the integrity of sensitive products. Furthermore, their ability to provide real-time information facilitates rapid decision-making, enhancing supply chain management and ensuring product quality. The increasing adoption of these technologies highlights their significance in product tracking and tracing. With these devices, it is now possible to anticipate potential issues before they arise, minimizing the risk of economic loss and bolstering consumer confidence in the quality of the supply system, including logistics.

Technium Social Sciences Journal
Vol. 66, 441-451, December, 2024
ISSN: 2668-7798
www.techniumscience.com

Figure 1. Elements of biosensors [21]



BCDs encompass a wide range of devices that integrate biological sensors into larger connected systems, often as part of the Internet of Things (IoT). These devices are considered “connected” because they can transmit data to other devices, cloud systems, or operators, providing real-time information on the status of products in transit. BCDs leverage biosensors and other intelligent technologies to create a biologically aware logistical environment, ensuring that every aspect of a product’s lifecycle is monitored and optimized. Among the sensitive products addressed by BCDs, perishables and medicines stand out, as they face three main challenges: managing environmental conditions, ensuring traceability, and maintaining regulatory compliance—all crucial for guaranteeing their quality and safety. By integrating advanced technologies, BCDs provide innovative solutions to enhance transparency and operational efficiency while minimizing the risks of loss or contamination.

The first challenge is temperature sensitivity: many pharmaceutical products must be stored at specific temperatures to maintain their efficacy. For instance, vaccines typically need to be kept in a positive cold environment. During the Covid-19 pandemic, the extreme logistical conditions for storing and delivering RNA-Messenger vaccines were often highlighted, requiring temperatures of –70°C for the Pfizer/BioNTech vaccine and –20°C for the Moderna vaccine [16]. The second challenge is environmental sensitivity: perishables such as dairy products, meat, and fresh produce are highly affected by environmental factors like humidity, light exposure, and oxygen levels, all of which can alter their quality. Finally, the third challenge involves the presence of counterfeit and fraudulent products. Pharmaceutical supply chains also face the risk of counterfeit medicines, which can jeopardize lives. Therefore, traceability and quality control efforts are crucial for ensuring safe product flows.

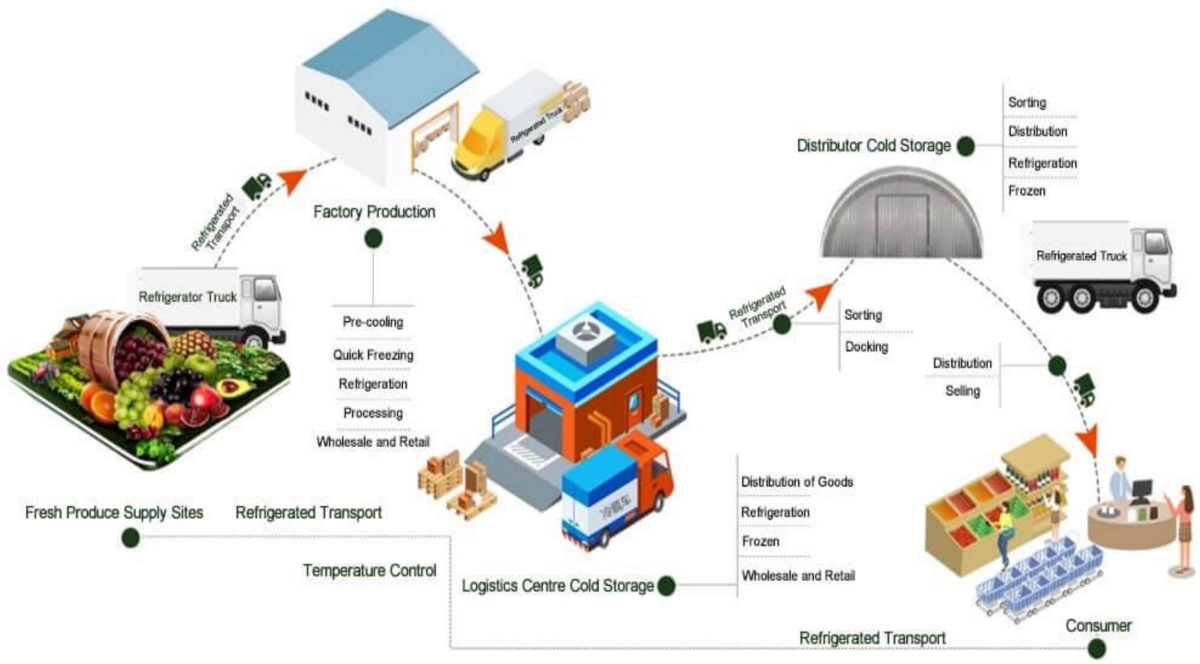
The integration of BCDs into supply chains ensures that real-time data is available for monitoring, tracking, and responding to any deviations from optimal conditions. This technology allows companies to collect precise information on various parameters, including temperature, humidity, and product location. The ability to obtain real-time data significantly reduces risks to product quality and safety, while BCDs also enhance communication among supply chain members, leading to more effective coordination and greater responsiveness. In the event of an issue, alerts can be sent instantly, enabling rapid corrective actions before products are compromised. Additionally, analyzing the collected data can help optimize logistical processes, resulting in cost savings and improved customer satisfaction. The examples of perishables and pharmaceuticals illustrate the importance of these challenges, emphasizing how BCDs can drive innovation and efficiency across multiple industries, ensuring products reach consumers in optimal condition.

3. Application of BCDs to perishables logistics

One of the main advantages of using BCDs in the perishables supply chain is their capacity for real-time monitoring of environmental conditions [9]. For instance, temperature fluctuations during the transport of food products can lead to spoilage or bacterial growth, posing significant health risks for consumers and financial losses for producers and retailers. Media reports have highlighted alarming instances of cold chain breaches in fast-food restaurants, resulting in fatalities among vulnerable individuals with serious illnesses. By integrating biosensors into packaging or loading units such as pallets and containers, it becomes possible to accurately monitor temperature, humidity, and oxygen levels throughout the supply chain (see Figure 2). Continuous monitoring also allows for the optimization of distribution processes and reduces risk management costs [5], all while ensuring the high quality of the delivered goods. Furthermore, this proactive approach enhances overall supply chain transparency and fosters confidence between stakeholders, ultimately leading to improved market competitiveness.

From an operational perspective, biosensors can be integrated into smart labels or RFID tags attached to products [22], which continuously measure the environmental conditions during transport. The generated data is transmitted wirelessly to cloud-based platforms, making it easily accessible to all supply chain members. If the temperature deviates from the acceptable range, immediate corrective actions can be taken, such as rerouting the shipment to prevent further deterioration or adjusting storage conditions accordingly. This type of continuous monitoring ensures that perishable goods arrive at their destination in optimal condition, thereby significantly reducing food waste. Additionally, enhanced product traceability [3] allows for more efficient resource management and significantly improves responsiveness to potential issues that may arise during transport, ultimately ensuring consumer safety and satisfaction throughout the supply chain.

Figure 2. Biosensors in the food cold chain
(https://www.renkeer.com/, Accessed September 10, 2024)



Another key advantage of using BCDs is their ability to support the implementation of predictive analytics. Biosensors detect early signs of spoilage, such as changes in gas composition within a storage container, which often indicate bacterial activity or enzymatic reactions occurring in food products. Through real-time data analysis, logisticians can predict when products are likely to deteriorate, enabling proactive interventions like adjusting temperature parameters or accelerating delivery times to maintain quality. For instance, some biosensors can detect ethylene, a plant hormone that accelerates fruit ripening. If ethylene levels exceed a certain threshold, it may indicate that the product is ripening faster than expected, necessitating corrective actions such as reducing temperature or adjusting humidity levels. These measures are essential to slow the ripening process and extend the product's shelf life, thereby minimizing waste and ensuring freshness for consumers [17].

Finally, BCDs play a crucial role in traceability, which is essential for regulatory compliance, particularly in the agri-food industry [1]. Government agencies such as the Food & Drug Administration (FDA) in the United States and the European Medicines Agency (EMA) in Europe enforce strict regulations regarding the handling, storage, and transport of perishable and sensitive products. For instance, the FDA's Food Safety Modernization Act imposes stringent traceability requirements on food products to prevent contamination and mitigate potential health risks to consumers and communities. With BCDs, every link in the supply chain can be monitored and recorded in real time, from production and packaging to final delivery to retailers and consumers. This level of traceability is vital not only for ensuring regulatory compliance but also for enabling rapid responses to product recalls or contamination incidents, thereby protecting consumer safety, maintaining confidence in the food supply chain, and ultimately safeguarding public health. As an illustration, Box 1 provides an example of AI application by a major food company.

Box 1. The Nestlé case

Founded in 1905 and headquartered in Vevey, Switzerland, Nestlé is the world's largest food company, according to Forbes' Global 500 ranking. With a strong commitment to AI technologies, Nestlé identifies three key strategic objectives: (1) enhanced logistics efficiency; (2) fully digitalized operations; and (3) improved sustainability. Two particularly significant use cases exemplify this commitment. First, the company aims to enable more efficient inventory management by reducing stock levels and costs, improving the accuracy of demand forecasts, and enhancing supply chain efficiencies through advanced software platforms and machine learning algorithms. Second, Nestlé focuses on predictive maintenance to minimize equipment downtime and extend the lifespan of its machinery, thereby improving health, safety, and environmental standards while maximizing overall equipment uptime. Additionally, Nestlé continues to invest in smart factories, leveraging AI to optimize energy consumption and reduce waste, further solidifying its leadership in sustainable innovation. Moreover, its ongoing research in AI-driven product development allows for faster market adaptation, addressing evolving consumer preferences and accelerating time-to-market for new, healthier, and more sustainable products.

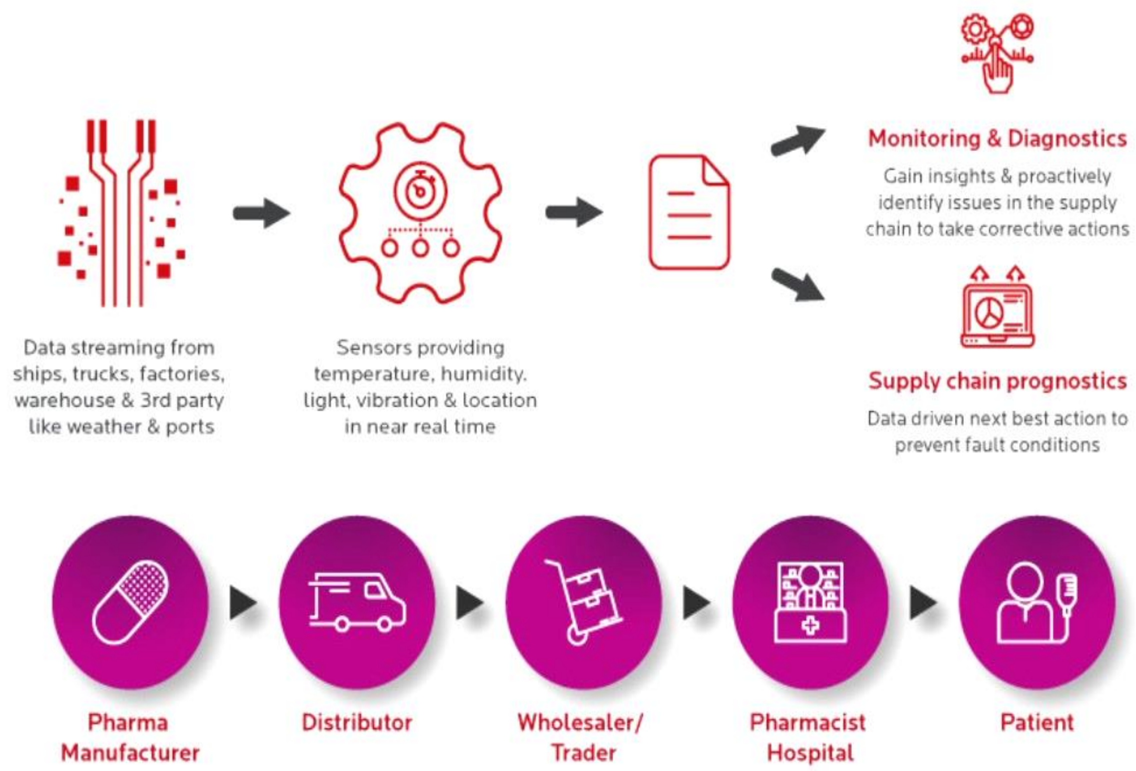
Source: Adapted from https://emerj.com/ (Accessed July 6, 2024).

4. Application of BCDs to medicines logistics

The pharmaceutical industry, especially in the context of vaccines and biologics, relies heavily on cold chain logistics to ensure product efficacy [2]. Many vaccines and medicines must be stored within a narrow temperature range, typically between 2°C and 8°C, to maintain their effectiveness. As mentioned earlier, the RNA-Messenger vaccines developed during the Covid-19 pandemic had even more stringent requirements. Even minor deviations from these specified temperature ranges can cause irreversible damage to the products, rendering them completely unusable. In this regard, BCDs provide a robust solution for monitoring the integrity of the pharmaceutical cold chain, from manufacturer to patient (see Figure 3). By integrating temperature-sensitive biosensors into shipments, companies can track the environmental conditions that products are subjected to in real time [15]. This data is then transferred to a cloud platform accessible to logisticians, allowing them to detect and address any issues during transit. Additionally, some biosensors are designed to trigger alarms if temperatures approach critical thresholds, enabling rapid corrective actions to be taken, such as transferring the shipment to a refrigerated warehouse or adjusting storage conditions to safeguard product integrity [26].

Medicines are also—and above all—victims of a significant problem with potentially dramatic consequences: counterfeiting [6]. According to the World Health Organization, approximately 10% of medicines sold in low-income countries are counterfeit and often produced under deplorable conditions or, at best, of mediocre quality. Counterfeit medicines can have devastating effects on public health, as they frequently contain harmful ingredients and lack the essential active components needed for effective patient treatment. BCDs play a crucial role in combating this issue by providing a continuous traceability system that verifies the authenticity of pharmaceutical products [7]. Biosensors embedded in medicine packaging are linked to a blockchain, ensuring that every step in the product's journey is recorded and authenticated. Any alterations or deviations from the intended supply chain are immediately detected, reassuring patients that the products they receive are genuine and safe. This level of transparency not only strengthens consumer confidence in the healthcare system but also promotes secure access to essential treatments for millions of people worldwide [11].

Figure 3. BCDs present throughout the pharmaceutical supply chain (https://www.birlasoft.com/, Accessed May 14, 2024)



The final point concerns quality control for biopharmaceutical products, which include highly sensitive items such as monoclonal antibodies and cell therapies. These products are extremely sensitive to environmental conditions, and even slight variations in temperature or pH can lead to irreversible degradation, rendering them ineffective or even dangerous. Traditional quality control methods, such as batch testing at the end of production, are inadequate for ensuring the consistent quality of biopharmaceutical products throughout the supply chain. In contrast, BCDs facilitate continuous quality control by providing real-time data on the environmental conditions encountered during storage and transportation. Biosensors monitor not only temperature but also critical parameters such as pH, humidity, and light exposure, offering a more comprehensive and accurate picture of the product’s condition [14]. The collected data is then analyzed to identify trends or anomalies that could signal quality issues, enabling proactive interventions to protect product integrity and ensure patient safety. As an illustration, Box 2 provides an example of AI application by a major pharmaceutical company.

TECHNIUM SOCIAL SCIENCES JOURNAL
Technium Social Sciences Journal
Vol. 66, 441-451, December, 2024
ISSN: 2668-7798
www.techniumscience.com

Box 2. The Merck case

The pharmaceutical company Merck began utilizing AI in its supply chain upon recognizing the increasing complexity of data flows. AI identifies manufacturing issues and proposes solutions, such as procuring additional materials, altering production processes, or adjusting distribution routes. This prescriptive approach significantly reduces the workload of demand planners, who would otherwise have to address these challenges manually. Machine learning algorithms continuously refine the system to minimize errors that could disrupt the supply chain for both Merck and its customers, including hospitals, wholesalers, and pharmacies. The company estimates that nearly 4,000 employees use Aera's software to analyze 1.2 billion rows of supply chain data daily, enhancing operational performance by ensuring the timely and complete delivery of their entire product range. Furthermore, Merck employs another AI solution from TraceLink to optimize the last-mile distribution process to its customers. These AI-driven innovations also allow for faster response times to unforeseen disruptions, such as raw material shortages or shifts in regulatory requirements, minimizing delays and improving resilience. Additionally, Merck's AI systems are designed to enhance collaboration between suppliers and partners, further driving efficiencies across the global supply chain network.

Source: Adapted from https://www.enjeuxlogistiques.com/ (Accessed April 16, 2024).

5. What are the limits to the use of BCDs in the supply chain?

BCDs have emerged as powerful transformative tools in the supply chain, significantly improving tracking, tracing, and monitoring of products, particularly in sensitive sectors such as perishables and pharmaceuticals. Despite their advantages, the use of BCDs presents several notable limitations that can hinder their effectiveness. One primary limitation is their dependence on cutting-edge technologies. Effectively implementing BCDs requires substantial investments in infrastructure, including IoT technologies, cloud storage facilities, and data analytics platforms [18]. Many organizations, especially SMEs, often lack the financial resources or technical expertise needed to fully adopt these advanced technologies. As a result, there is a disparity in the adoption process; only large companies tend to reap the benefits brought by BCDs, leaving smaller players at a significant competitive disadvantage. Furthermore, integrating BCDs into existing supply chains is complicated by the fact that current systems may not be compatible with the new technologies, creating challenges in interoperability and requiring additional resources for system upgrades.

The implementation of BCDs also involves the continuous collection and transmission of data, which raises significant concerns about data security and confidentiality. Supply chains are often prime targets for cyber-attacks, and the integration of connected devices increases vulnerability to these threats, as evidenced by the recurring cyber-attacks on French hospitals [10]. A data breach not only risks compromising sensitive information, including customer details, but can also lead to substantial financial losses and long-lasting damage to a company's reputation. Additionally, the processing of personal data, particularly within healthcare supply chains, raises serious ethical concerns [4][8]. The use of BCDs must adhere to various regulations, such as the General Data Protection Regulation (GDPR) in Europe, which govern the collection and processing of personal data. Non-compliance with these regulations can result in hefty fines, which may discourage companies from fully utilizing BCDs. Furthermore, the situation is complicated by the fact that different regions may have specific regulations concerning the use of connected devices, particularly in sensitive sectors like healthcare and food safety. This variability creates challenges for companies striving to meet legal requirements across multiple jurisdictions.

Finally, from an operational perspective, the need for constant data monitoring and analysis places significant strain on existing resources and necessitates additional staff training. Employees must be equipped not only to manage new technologies but also to interpret data effectively, which calls for investments in training programs and initiatives aimed at facilitating change management [20]. This issue becomes even more pressing when considering that the effectiveness of BCDs hinges on the reliability of the data collected; inaccurate or incomplete data can lead to poor decision-making, negatively impacting overall supply chain performance. For instance, if a BCD fails to accurately report temperature fluctuations for perishable goods, it can result in financial losses and significant product deterioration. Indeed, this reliance on technology emphasizes the importance of robust data quality management practices, which will undoubtedly require considerable material and intangible resources to ensure optimal efficiency and effectiveness in supply chain operations [27].

Despite these limitations, the future of BCDs within supply chains appears promising. Advances in biosensor technology are expected to lead to the development of more affordable and efficient equipment that can be deployed on a larger scale, making it accessible to a wider range of industries and businesses. Furthermore, improvements in blockchain technology are significantly enhancing the security and traceability of product flows within supply chains, thereby providing better protection against counterfeiting and fraud [12]. Additionally, the integration of AI and machine learning with biosensors presents another exciting opportunity for the future. By analyzing the vast amounts of data generated by biosensors, AI algorithms can identify patterns and anomalies that may not be immediately apparent to human operators, who can be influenced by emotional biases [23]. This capability enables more accurate predictions regarding spoilage, product degradation, and other potential issues. Ultimately, these advancements should lead to even greater optimization of supply chains, reduced waste, and improved operational efficiency across various sectors.

6. Conclusion

The integration of BCDs and biosensors into the supply chains of perishables and medicines represents a paradigm shift in flow management. This advancement leads to significant improvements in traceability, product quality, and safety, effectively addressing some of the most pressing challenges faced by industries dealing with highly sensitive products. By enabling real-time monitoring of environmental conditions, BCDs empower supply chain members to make informed decisions swiftly. The ability to ensure the integrity of the cold chain for medicines and to prevent spoilage in perishable goods has been shown to enhance public health outcomes considerably. As consumers become increasingly aware of the associated risks—particularly through extensive media coverage on social networks—the demand for transparent and reliable supply chains is bound to grow. This trend paves the way for BCDs to address these concerns, thereby bolstering consumer confidence in the products they consume. Furthermore, regulatory bodies are likely to implement stricter standards, which will encourage companies to adopt these technologies while ensuring compliance with emerging safety and quality protocols.

Although implementing BCDs presents several challenges—such as high costs, data security concerns, and the necessity for robust technological infrastructure—the potential

Technium Social Sciences Journal
Vol. 66, 441-451, December, 2024
ISSN: 2668-7798
www.techniumscience.com

benefits far outweigh these obstacles. Advances in biosensor, blockchain, and AI technologies are expected to reduce costs and enhance the capabilities of BCDs, making them more accessible to companies of all sizes. Over time, the ongoing evolution and adoption of biologically connected systems will not only redefine long-established logistical practices but also contribute to the development of more sustainable economies, combined with appropriate sustainable reporting [19]. By minimizing food waste, reducing the risk of counterfeiting, and ensuring that sensitive products are stored and delivered under optimal conditions, biologically connected systems are currently playing—and will increasingly play—a crucial role in safeguarding public health and well-being. They foster greater transparency throughout the supply chain while stimulating radical innovations in customer service. This transformative shift undoubtedly represents a significant contribution to a major evolution in supply chain management, the full consequences of which are yet to be thoroughly examined.

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