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A REVIEW ON RECENT ADVANCES ON BIOSENSORS IN PHARMACEUTICAL INDUSTRY

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Abstract

Biosensors are innovative analytical devices that combine biological recognition elements such as enzymes, antibodies, nucleic acids, or cells with physical transducers to detect and quantify specific substances. In the pharmaceutical industry, biosensors have gained significant attention due to their ability to provide rapid, accurate, and cost-effective results compared to traditional laboratory techniques. Recent technological advancements have revolutionized biosensor applications through the integration of nanomaterials, microfluidic systems, artificial intelligence (AI), and the Internet of Things (IoT). Nanomaterials like graphene, carbon nanotubes, and gold nanoparticles enhance sensitivity and stability, while microfluidic lab-on-a-chip devices enable miniaturized, high-throughput testing with minimal sample volumes. Moreover, AI- and IoT-enabled biosensors allow real-time data collection, analysis, and personalized therapeutic monitoring. These developments have expanded biosensor use in drug discovery, quality control, vaccine development, and therapeutic drug monitoring. Wearable and implantable biosensors further contribute to personalized medicine by providing continuous, non-invasive health monitoring. Despite challenges such as cost, stability, and regulatory compliance, ongoing innovations continue to improve biosensor efficiency, scalability, and reliability. Therefore, biosensors are emerging as indispensable tools in modern pharmaceutical research, ensuring safer, faster, and more effective healthcare solutions.

Keywords: Biosensors, Nanotechnology, Pharmaceutical Industry, Microfluidics, Artificial Intelligence (AI), Internet of Things (IoT), Therapeutic Drug Monitoring, Personalized Medicine, Drug Discovery, Quality Control.

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Introduction

Biosensors are devices that use a biological material (like enzymes, antibodies, or DNA/aptamers) together with a transducer to detect specific substances. In the pharmaceutical industry, they are gaining importance because they can provide fast, accurate, and low-cost detection compared to traditional lab methods such as HPLC or mass spectrometer [1].

Recent advances have made biosensors more useful for drug discovery, quality control, and therapeutic drug monitoring (TDM). For example, wearable biosensors (patches, microneedles) can now measure drug levels in sweat or interstitial fluid without the need for frequent blood sampling. This helps in monitoring medicines with narrow therapeutic ranges and improves patient comfort [2].

Another important development is the use of aptamers and molecularly imprinted polymers (MIPs) instead of antibodies. These recognition elements are more stable, cheaper to make, and work well even in harsh conditions. At the same time, nanomaterials like graphene and metal oxides are improving biosensor sensitivity and making devices smaller and more portable. Overall, these advances show that biosensors can become powerful tools in the pharmaceutical industry, making drug, manufacturing, and personalized treatment faster and more reliable [3].

1.1 Principal of biosensors;

biosensor is an analytical device that combines a biological component with a physicochemical detector to monitor and quantify specific substances (analytes). The fundamental working principle involves the following steps:

1. Biorecognition:

A biological element (such as enzymes, antibodies, aptamers, or cells) specifically interacts with the target analyte [4].

2. Signal Transduction:

The interaction between the bioreceptor and analyte induces a measurable change (e.g., optical, electrochemical, thermal, or mass-related) [5].

3. Signal Processing:

The transduced signal is processed and converted into a readable output, often displayed digital [6].

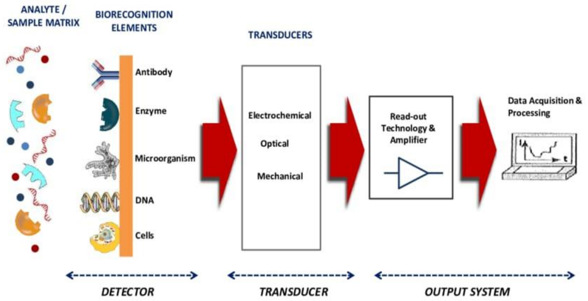

Figure 1: Image of Biosensors.

1.2 Importance of Biosensors in Pharmaceuticals:

Biosensors play a vital role in the pharmaceutical industry by enabling rapid, accurate, and cost-effective analysis of drugs, biomarkers, and contaminants. They enhance drug discovery, quality control, therapeutic drug monitoring, and process analytical technology (PAT). Biosensors offer high sensitivity, specificity, and real-time detection, reducing the need for lengthy laboratory assays [7].

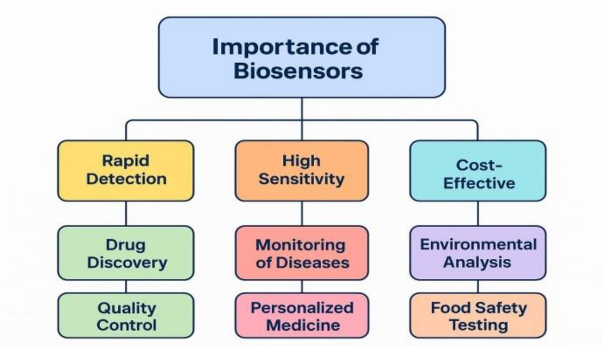

Figure 2: Image of Importance of Biosensors in Pharmaceuticals.

Aim and Objective

Aim:

The aim of this study is to understand the recent developments in biosensors and how they are used in the pharmaceutical industry for drug testing, quality control, and monitoring treatments.

Objectives:

1. To understand the basic principles and components of biosensors used in the pharmaceutical industry.
2. To explore recent technological advancements in biosensors for drug development and quality control.
3. To analyze the role of biosensors in therapeutic drug monitoring and point-of-care testing.
4. To identify the challenges and future prospects of biosensor applications in pharmaceuticals.

2. Classification of biosensors:

2.1 Based on Transduction Mechanism (electrochemical, optical, piezoelectric, thermal, etc)

Biosensors are analytical devices that combine a biological recognition element with a physical transducer to produce measurable signals. They are widely applied in the pharmaceutical industry for drug discovery, quality control, therapeutic drug monitoring, and process control. Depending on the transduction mechanism, biosensors are mainly classified as electrochemical, optical, piezoelectric, and thermal.

1. Electrochemical biosensors:

Electrochemical biosensors are the most widely used. They measure electrical signals such as current, voltage, or impedance when a biochemical reaction occurs. Recent advances include the use of nanomaterials (graphene, carbon nanotubes, metal nanoparticles) to improve sensitivity, as well as portable, smartphone-based devices for real-time therapeutic drug monitoring. These sensors are applied for antibiotic detection, impurity testing, and process monitoring [8].

2. Optical biosensors:

work by detecting changes in light (intensity, wavelength, or resonance). The main progress has been in surface plasmon resonance (SPR), nanoplasmonics, and label-free photonic devices that provide real-time kinetic studies. Multiplexed optical platforms and smartphone-linked systems make them highly useful in drug–target interaction studies, stability testing, and contamination detection [9].

3. Piezoelectric biosensors:

(e.g., quartz crystal microbalance, surface acoustic wave devices) detect changes in frequency when molecules bind to the sensor surface. Advances include QCM with dissipation monitoring (QCM-D), which allows simultaneous measurement of mass and viscoelastic properties. They are important in biologics quality control, vaccine development, and antibody–antigen studies [10].

4. Thermal biosensors:

Measure heat changes in biochemical reactions. Recent developments include miniaturized microcalorimeters and integration with microfluidics for high-throughput enzyme screening. They are mainly used in drug discovery, enzyme inhibitor screening, and fermentation monitoring.

Overall, the integration of nanotechnology, microfluidics, and digital platforms has made biosensors more sensitive, portable, and reliable, enhancing their role in the pharmaceutical industry [11].

2.2 Based on Biorecognition element (enzyme, antibody, nucleic acid, whole cell, etc)

Biosensors are analytical devices that use a biorecognition element to detect a target molecule and convert it into a measurable signal. In the pharmaceutical industry, they are widely used for drug discovery, quality control, and therapeutic drug monitoring. Recent advances focus on improving sensitivity, speed, miniaturization, and cost-effectiveness.

1. Enzyme-based biosensors:

Enzymes are widely used because of their high specificity. Recent improvements include nanozymes (nanomaterials with enzyme-like activity) and enzyme immobilization on nanostructures, which make sensors more stable and reusable. These are applied for monitoring drug metabolites like glucose or L-Dopa during therapy [12].

2. Antibody-based biosensors (Immunosensors):

Antibody sensors provide high selectivity for proteins and drugs. Advances include label-free immunosensors (surface Plasmon resonance, electrochemical impedance) and integration with microfluidics, allowing faster and portable detection. They are useful in monitoring therapeutic drug levels and detecting biomarkers in real time [13].

3. Nucleic acid-based biosensors:

Aptamers (short DNA/RNA sequences) and CRISPR/Cas-based biosensors have emerged as powerful tools. Aptamers are easy to synthesize and modify, while CRISPR-based detection provides high sensitivity for nucleic acids. These are being developed for detecting drug resistance genes, contaminants, and biological impurities in pharmaceutical products [14].

4. Whole-cell biosensors:

Engineered microbial or mammalian cells act as "living sensors." They are designed to respond to toxins, metabolites, or drug candidates by producing measurable signals (like fluorescence). Recent work in cell-free biosensors (freeze-dried transcription–translation systems) has improved stability, making them useful for low-cost field testing and pharmaceutical quality control.

Overall, the trend is toward portable, miniaturized, multiplexed biosensors that can work directly at the point-of-care or manufacturing site, improving drug development and patient safety [15].

3. Role of biosensors in the pharmaceutical industry:

3.1 Drug Discovery and Development

1. **Electrochemical Sensors**: Recent developments in electrochemical sensors, such as carbon paste electrodes, glassy carbon electrodes, screen-printed carbon electrodes, and reduced graphene oxide electrodes, have enhanced the sensitivity and speed of drug and metabolite analysis in pharmaceutical and biological samples [16].
2. **Chemiluminescent Biosensors**: Innovations in chemiluminescent biosensing platforms have significantly improved the detection of pharmaceutical compounds, offering high sensitivity and specificity for pharmaceutical analysis [17].
3. **Electrochemical Aptamer-Based Sensors**: Electrochemical aptamer-based biosensors have emerged as promising tools for controlled drug delivery, offering advantages such as reagent-free operation, cost-effectiveness, and reusability, making them suitable for real-time therapeutic monitoring [18].

3.2 Pharmacokinetics and pharmacodynamics studies

1. Electrochemical Sensors:

Advancements in electrochemical sensors, such as carbon paste electrodes, glassy carbon electrodes, screen-printed carbon electrodes, and reduced graphene oxide electrodes, have enhanced the sensitivity and speed of drug and metabolite analysis in pharmaceutical and biological samples [19].

2. Wearable Biosensors:

Innovations in wearable biosensors have enabled continuous monitoring of drug levels and physiological responses, facilitating real-time therapeutic drug monitoring and personalized medicine [20].

3. Microneedle-Based Platforms;

Microneedle-based integrated platforms have been developed for personalized medicine, allowing for continuous dual monitoring of glucose and metformin, thereby enhancing pharmacokinetic and pharmacodynamic evaluations [21].

3.3 Quality Control and Process Monitoring

Recent developments in biosensor technologies have significantly enhanced pharmaceutical quality control and process monitoring. These advancements enable real-time, in-line monitoring of critical parameters, ensuring consistent product quality and regulatory compliance [22].

3.4 Personalized Medicine and Diagnostics

Personalized medicine uses genetic, proteomic, and biomarker data to tailor treatments. Biosensors enable rapid diagnostics, real-time monitoring, and improved patient outcomes [23].

4. Recent advance in biosensors

4.1 Nanomaterial-based biosensors in the [nanoparticles, carbon nanotubes, graphene, and quantum]

1. Nanoparticles (NPs):

Noble metal nanoparticles, such as gold and silver, are utilized for their excellent conductivity and biocompatibility. They enhance signal amplification and enable rapid detection of pharmaceutical compounds [24].

2. Carbon Nanotubes (CNTs):

CNTs possess high surface area and electrical conductivity, making them ideal for electrochemical biosensors. They facilitate efficient electron transfer and are employed in the detection of various pharmaceutical agents [25].

3. Graphene and Graphene Oxide (GO):

Graphene-based materials exhibit remarkable mechanical strength and electrical properties. GO, in particular, is used to modify electrode surfaces, improving the sensitivity and stability of biosensors [26].

4. Quantum Dots (QDs):

QDs are semiconductor nanoparticles that offer size-tunable fluorescence properties. They are employed in optical biosensors for the detection of pharmaceutical compounds, providing high sensitivity and multiplexing capabilities [27].

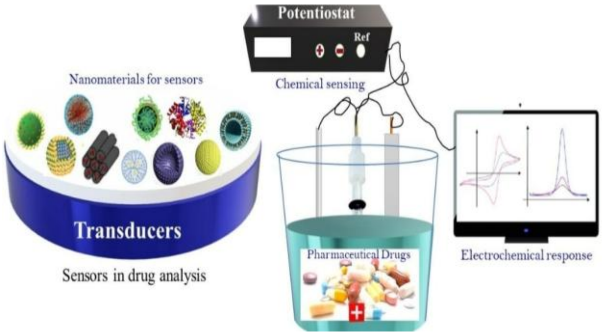

Figure 3: Image of Nanoparticles, carbon nanotubes, graphene, and quantum.

4.2 Lab-on-a-Chip and Microfluidic Biosensors.

Lab-on-a-chip (LoC) and microfluidic biosensors have recently advanced as powerful tools in the pharmaceutical industry for drug discovery, quality control, and personalized medicine. These systems allow miniaturized, rapid, and highly sensitive testing with very low sample volumes [28]. Recent studies report integration of electrochemical and optical sensors directly into microchannels, enabling real-time analysis with excellent sensitivity and accuracy. For example, microfluidic immunosensors achieved detection of sepsis biomarkers such as TNF-α and IL-6 within minutes, with limits of detection in the pg/mL range, validating their superiority over conventional ELISA assays. Organ-on-chip systems, such as liver-on-a-chip, now combine microfluidics with embedded biosensors to monitor drug metabolism and hepatotoxicity dynamically. Furthermore, advances in fabrication (3D printing, lab-on-PCB) and artificial intelligence-assisted data analysis are accelerating translation to pharmaceutical quality control and personalized therapy [29]. Overall, LoC and microfluidic biosensors are key enablers of validated, sensitive, and accurate pharmaceutical applications [30].

4.3 Wearable and implantable biosensors

Wearable and implantable biosensors enable continuous, real-time monitoring of physiological signals and drug levels with high sensitivity and accuracy. Recent advances integrate flexible materials, wireless data transfer, and validated biocompatible designs, supporting personalized therapy, pharmacokinetics, and disease management in the pharmaceutical field [31].

4.4 smartphone-integrated biosensors and point-of-care devices

Smartphone-integrated biosensors and POC devices are transforming pharmaceutical diagnostics by enabling rapid, sensitive, and validated testing [32]. Recent innovations include electrochemical sensors for sepsis biomarkers achieving limits of detection in the picogram range and strong correlation with clinical assays.[33] Additionally, AI-enhanced paper-based cartridges with field-effect transistors enable multiplexed biomarker detection with high reproducibility. These advancements support real-time therapeutic drug monitoring, personalized medicine, and decentralized clinical testing [34].

4.5 AI and IoT Enabled Biosensors

AI (Artificial Intelligence) and IoT (Internet of Things) enabled biosensors are modern innovations that combine intelligent data processing with real-time digital connectivity. These biosensors collect biological information such as glucose levels, heart rate, or drug concentrations and transmit the data through IoT systems for continuous monitoring. AI algorithms analyze this data to identify patterns, detect early signs of disease, and provide predictive insights for personalized treatment. In the pharmaceutical industry, AI–IoT integrated biosensors play a vital role in clinical trials, drug monitoring, and precision medicine. They enhance patient safety, reduce errors, and improve decision-making through automated data analysis and cloud-based access [35].

Fluorescence Spectroscopy

Determines single intensity changes in fluorescent biosensors

Fluorescence spectroscopy is a highly sensitive and widely used analytical technique for studying signal intensity changes in fluorescent biosensors. It works on the principle that certain molecules emit light (fluorescence) when excited by a specific wavelength. In fluorescent biosensors, biological recognition elements such as enzymes, antibodies, nucleic acids, or aptamers are tagged with fluorescent dyes or nanomaterials. When the target analyte interacts with these fluorophores, the fluorescence emission intensity or wavelength changes due to mechanisms such as fluorescence quenching, enhancement, or energy transfer (FRET) [36]. These variations directly correspond to the analyte concentration, enabling accurate and real-time detection.

This technique is highly advantageous because it offers exceptional sensitivity, selectivity, and rapid response time. It allows the detection of analytes even at nanomolar or picomolar levels, making it ideal for pharmaceutical, biomedical, and clinical applications [37]. In the pharmaceutical field, fluorescence spectroscopy-based biosensors are used for drug–receptor interaction studies, enzyme kinetics, protein conformational changes, DNA hybridization, and detection of disease biomarkers. Additionally, nanotechnology has enhanced this technique's capabilities through the use of quantum dots, carbon nanodots, and fluorescent nanoparticles, improving stability and brightness.

Overall, fluorescence spectroscopy provides a precise method to evaluate signal intensity changes, ensuring the effective design, optimization, and validation of biosensors for drug development, therapeutic monitoring, and diagnostic applications [38].

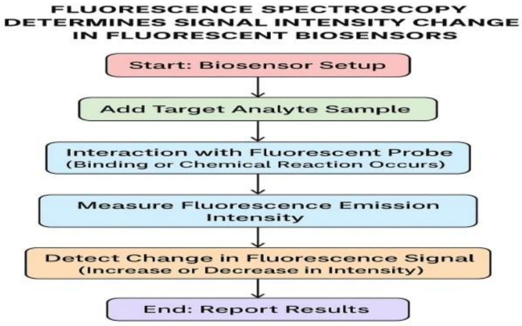

Figure 4: Image of Fluorescence Spectroscopy.

5. Application in pharmaceutical analysis

5.1 Drug Detection and Quantification Using Biosensors

Biosensors are emerging as powerful analytical tools for drug detection and quantification in the pharmaceutical industry. They integrate selective biorecognition elements (enzymes, antibodies, aptamers) with transducers to identify and measure drug molecules with high sensitivity and specificity. Recent advances focus on nanomaterial-based biosensors (graphene, carbon nanotubes, quantum dots, and metal nanoparticles), which enhance detection limits and improve signal stability. These biosensors are particularly useful for therapeutic drug monitoring (TDM), pharmacokinetic studies, and clinical diagnostics. Furthermore, integration with AI and IoT platforms enables real-time monitoring, remote data analysis, and improved decision-making, making them highly applicable for modern pharmaceutical research and personalized medicine [39].

5.2 Detection of impurities and contamination

Recent advancements in biosensor technology have significantly enhanced the pharmaceutical industry's ability to detect impurities and contamination, ensuring drug safety and quality. A comprehensive review by Bounegru et al. (2025) high lights key developments in this field:

Key Advances in Biosensors for Pharmaceutical Contaminant Detection

1. Electrochemical Sensors and Biosensors;

Electrochemical sensors and biosensors have emerged as powerful tools for detecting pharmaceutical contaminants in natural waters, including surface water, wastewater, and bottled water. Recent innovations have focused on enhancing sensitivity, selectivity, and detection limits through the use of advanced electrode-modifying materials such as nanomaterials and conductive polymers. These advancements enable the detection of a wide range of pharmaceutical substances, including anti-inflammatory drugs (e.g., diclofenac, ibuprofen), hormones (e.g., 17α-ethinylsteaddiole and antibiotics (e.g., sulfamethoxazole, ciprofloxacin). The integration of these sensors with Internet of Things (IoT) systems allows for continuous, real-time monitoring of environmental media quality, contributing to public health safety.

2. Microfluidic Biosensors;

Microfluidic biosensors have been developed for the on-site detection of mycotoxins in food samples, offering high efficiency and outstanding detection performance. These biosensors utilize microfluidic platforms to integrate sample preparation, reaction, and detection processes, enabling rapid and sensitive analysis of contaminants. The application of microfluidic biosensors in food safety monitoring enhances the ability to detect and quantify mycotoxins, ensuring the safety of pharmaceutical raw materials.

3. Optical Biosensors;

Optical biosensors, including surface plasmon resonance and fluorescence-based methods, have shown promise in detecting microbial contaminants in pharmaceutical products. These techniques offer label-free detection and can be integrated into portable devices for on-site testing. Recent advancements have focused on enhancing the sensitivity and specificity of these sensors to detect low levels of microbial contamination, ensuring the safety and efficacy of pharmaceutical products [40].

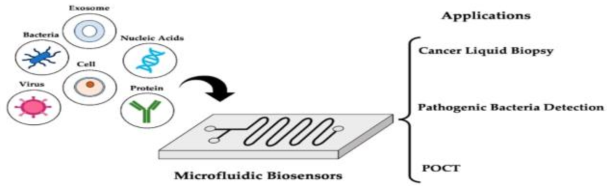

Figure 5: Image of Microfluidic Biosensors.

5.3 Monitoring therapeutic drug levels

Monitoring therapeutic drug levels is crucial for optimizing treatment efficacy and minimizing adverse effects. Recent advancements in biosensor technologies have significantly enhanced the precision and accessibility of therapeutic drug monitoring (TDM). Recent Advances in Biosensor Technologies for TDM

1. Electrochemical Aptamer-Based Sensors (E-ABs)

E-ABs utilize synthetic DNA or RNA aptamers that undergo conformational changes upon binding to target drugs, facilitating real-time, reagent-free detection. These sensors offer high specificity and sensitivity, making them suitable for continuous monitoring of drugs with narrow therapeutic windows, such as vancomycin. Their integration into wearable devices allows for autonomous feedback-controlled drug delivery systems [41].

2. Wearable "Lab-on-a-Patch" Devices

Companies like Nutromics have developed skin patches embedded with DNA-based biosensors capable of detecting multiple biomarkers simultaneously. These devices can monitor drug levels, such as vancomycin, in real-time, providing clinicians with continuous data to adjust dosages promptly. Currently undergoing ICU trials, these patches aim for FDA approval by 2028.

3. Surface-Enhanced Raman Spectroscopy (SERS) Sensors

SERS-based biosensors offer non-invasive, label-free detection of molecular signatures through skin. Their scalability and sensitivity make them promising for continuous monitoring of various biomarkers, including therapeutic drug levels. These sensors can be integrated into wearable devices for real-time health monitoring [42].

4. Nano-Optical and Electrochemical Biosensors

Advancements in nano-optical and electrochemical biosensors have enabled the detection of therapeutic drug levels with high sensitivity and specificity. These sensors can be integrated into point-of-care devices, facilitating rapid and accurate monitoring of drug concentrations in patients.

Integration with Artificial Intelligence (AI)

AI algorithms are increasingly being employed to analyze data from biosensors, optimizing drug dosing regimens and enhancing personalized medicine approaches. By integrating patient-specific factors, such as genetics and comorbidities, AI can predict optimal drug concentrations, minimize adverse effects and improve therapeutic outcomes [43].

Impact on Pharmaceutical Industry Practices

Personalized Medicine: Biosensors enable tailored drug dosing, improving efficacy and reducing side effects.

Real time monitoring; Continuous data collection allows for timely adjustments in therapy, enhancing patient safety.

Regulatory Advancements: Innovations in biosensor technologies are influencing regulatory frameworks, facilitating the approval of novel monitoring devices [44].

5.4 Biosensors in vaccine development

Biosensors have become pivotal in vaccine development, enhancing both the efficiency of research and the effectiveness of immunization strategies.

Applications in Vaccine Development

1. **Antigen Detection and Characterization:**
   Biosensors facilitate the rapid identification and analysis of viral antigens, enabling the assessment of immune responses and the design of targeted vaccines [45].
2. **Vaccine Efficacy Monitoring:**
   Post-vaccination, biosensors are employed to detect specific antibodies, providing insights into the immunogenicity and protective efficacy of vaccine candidates [46].
3. **High-Throughput Screening:**
   Advanced biosensor platforms allow for the simultaneous screening of multiple vaccine candidates, accelerating the preclinical phase of vaccine development.
4. **Point-of-Care Diagnostics:**
   Portable biosensor devices enable real-time monitoring of immune responses, facilitating timely adjustments in vaccination strategies, especially in resource-limited settings [47].

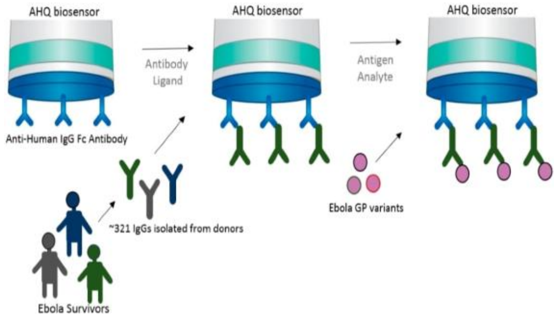

Figure 6: Image of Biosensors in vaccine development.

6. Challenges and limitations

6.1 Sensitivity and specificity issues

Sensitivity Issues

Low Analyte Concentrations:

Detecting analytes present at low concentrations in complex biological matrices requires biosensors with high sensitivity. For instance, microRNA biosensors face challenges due to the low abundance of miRNAs in samples like blood, necessitating enhanced sensitivity to detect miRNAs at femtomolar concentrations [48].

Signal Interference:

Complex biological fluids can introduce noise and nonspecific signals, complicating the detection of the target analyte. This interference can reduce the effective sensitivity of biosensors.

Specificity Issues: Cross-Reactivity:

Biosensors may exhibit cross-reactivity with substances other than the target analyte, leading to false positives. This is particularly problematic in complex samples where multiple similar compounds may be present [49].

Biorecognition Element Limitations:

The specificity of biosensors heavily depends on the biorecognition elements used, such as antibodies or aptamers. Variations in these elements can lead to reduced specificity and potential interference from structurally similar molecules.

Strategies to Overcome These Challenges

Signal Amplification Techniques: Employing methods like enzyme amplification or rolling circle amplification can enhance the sensitivity of biosensors by increasing the detectable signal from low-abundance analytes [50].

Advanced Materials:

Utilizing nanomaterials with tailored properties can improve both sensitivity and specificity. For instance, functionalizing graphene with specific receptors can enhance selectivity towards target molecules [51].

Optimization of Biorecognition Elements:

Designing and selecting biorecognition elements with high affinity and specificity for the target analyte can reduce cross-reactivity and improve overall sensor performance.

Environmental Control;

Implementing systems to regulate environmental conditions during biosensor operation can minimize the impact of external factors on specificity [52].

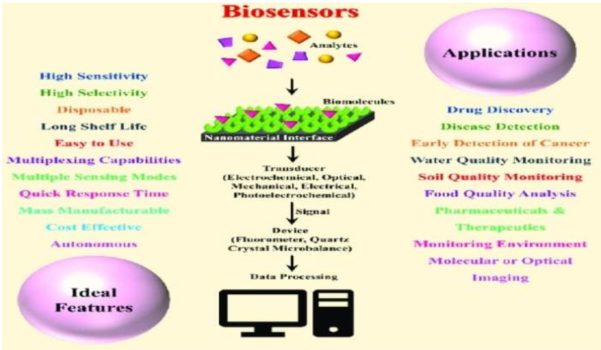

Figure 7: Image of Optimization of Biorecognition Elements.

6.2 Stability and Reproducibility

Stability and reproducibility are critical parameters for biosensors used in the pharmaceutical industry to ensure accurate and consistent results over time. Stability refers to the ability of a biosensor to maintain its performance under varying environmental conditions, while reproducibility indicates the ability to obtain consistent results across multiple measurements or sensor batches [53].

Recent advances have focused on improving biosensor stability through nanomaterial coatings, such as gold nanoparticles, carbon nanotubes, and graphene, which enhance enzyme or antibody immobilization and protect biorecognition elements from denaturation. Polymer-based encapsulation and cross-linking techniques also extend biosensor shelf life and operational durability [54].

For reproducibility, microfabrication and 3D printing technologies enable uniform electrode construction, reducing batch-to-batch variation. Additionally, machine learning algorithms are used for real-time drift correction and signal calibration, improving long-term measurement consistency. Antifouling surface modifications using polyethylene glycol (PEG) or zwitterionic polymers minimize nonspecific adsorption, further improving sensor performance in complex pharmaceutical matrices [55].

These improvements ensure reliable use of biosensors in quality control, drug analysis, and process monitoring, meeting regulatory standards for accuracy and repeatability in pharmaceutical manufacturing [56].

6.3 Cost and Scalability in Biosensors

Cost and scalability are major factors influencing the commercial success and industrial adoption of biosensors in the pharmaceutical industry. Cost refers to the overall expenses involved in biosensor fabrication, including materials, biorecognition elements, transducers, and signal processing components.

Scalability is the ability to manufacture biosensors in large quantities while maintaining performance consistency and affordability [57].

Recent advances have focused on low-cost materials such as paper-based substrates, screen-printed electrodes, and polymer composites that significantly reduce production costs. Microfabrication and 3D printing technologies enable mass production with high precision, improving scalability. Nanomaterials (e.g., graphene, carbon nanotubes, metal nanoparticles) enhance sensor performance while requiring smaller amounts of costly biological components.

Additionally, lab-on-a-chip and point-of-care biosensors integrate multiple functions into miniaturized platforms, reducing reagent use and cost per test. Advances in automation and batch manufacturing ensure uniformity and reproducibility, making biosensor production more scalable for pharmaceutical applications such as drug development, quality control, and real-time monitoring [58].

6.4 Regulatory and Ethical Concerns in Biosensors

The integration of biosensors into the pharmaceutical industry raises several regulatory and ethical challenges that must be addressed to ensure safety, accuracy, and data integrity.

Regulatory Concerns:

Biosensors used in drug development, quality control, or clinical diagnostics must meet standards set by authorities like the U.S. FDA, EMA, and ISO (International Organization for Standardization). These standards ensure accuracy, reliability, reproducibility, and patient safety [59].

Key issues include validation, calibration, data transparency, and compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP).

Ethical Concerns:

Ethical issues focus on data privacy, patient consent, and responsible use of biosensor data, especially in personalized medicine and wearable biosensors. Ensuring confidentiality, preventing data misuse, and promoting equitable access to biosensor technologies are essential.

Biosensors must be developed and applied ethically to protect human rights and ensure public trust in pharmaceutical innovations [60].

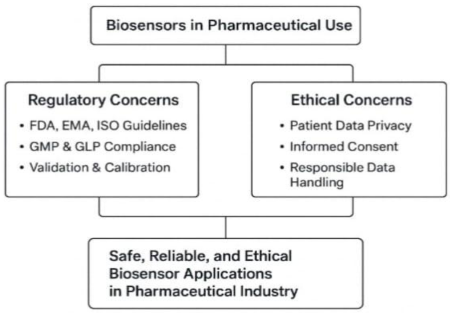

Figure 8: Image of Biorecognition Pharmaceutical use.

7. Future perspectives

7.1 Integration with artificial intelligence and big data

Integrating AI and Big Data into biosensors enhances real-time diagnostics, personalized treatment, and predictive analytics in pharmaceuticals [61]. AI algorithms process vast datasets from wearable devices and electrochemical sensors, enabling precise drug monitoring and early disease detection [62]. This synergy accelerates drug development and improves patient outcomes.

7.2 Personalized Drug Therapy Monitoring

Personalized drug therapy monitoring uses biosensors, artificial intelligence (AI), and big data to measure drug concentrations in real time and adapt treatment to each patient's needs. Wearable biosensors enable continuous monitoring of drug levels in body fluids, especially for drugs with narrow therapeutic windows, improving safety and efficacy [63]. AI analyzes patient data-including genetics, physiology, and previous responses-to support precision dosing and clinical decision-making. This integration allows dynamic adjustments to drug regimens, improving outcomes for conditions like cancer, cardiovascular disease, and chronic illnesses. Challenges include data privacy, regulatory compliance, and technology integration across healthcare systems. Continued development in AI algorithms, biosensor materials, and point-of-care devices promises a future where drug therapy is fully tailored to individual patients [64].

7.3 Biosensors in next-generation pharmaceuticals

Next-generation biosensors integrate nanomaterials, AI, and wearable technology to enable precise drug monitoring, real-time diagnostics, and personalized therapy. These innovations improve treatment efficiency, patient safety, and early disease detection, paving the way for smarter, patient-centered pharmaceutical solutions [65].

8. Conclusion

Biosensors are becoming one of the most powerful tools in the pharmaceutical industry. They help in detecting and measuring biological substances quickly, accurately, and at a lower cost. With the help of biosensors, scientists can monitor drug levels, diagnose diseases early, and ensure the safety and quality of medicines.

Recent advancements-such as the use of nanotechnology, microfluidics, and artificial intelligence (AI)-have made biosensors even more sensitive and reliable. These modern biosensors can work with very small samples and give real-time results, which saves both time and resources during drug development.

In the future, biosensors are expected to play a major role in personalized medicine, where treatments can be customized for each person based on their body's response. They will also support remote health monitoring and rapid disease detection, making healthcare more efficient and accessible.

Overall, biosensors are revolutionizing how the pharmaceutical industry develops and tests drugs. Their continuous improvement will lead to faster, safer, and more effective medical solutions for people worldwide.

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Conflicts of Interest

The authors declare no conflicts of interest.

Author Contribution

All are contribute equally

Financial Support

None

Ethical Considerations and Informed Consent

Not Applicable

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