

Biosensors EEL3050



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Industrial Standards of Biosensors

Commercially available biosensors have become integral tools in various industries, including healthcare, environmental monitoring, food safety, and biotechnology. To ensure their reliability, accuracy, and safety, these devices must adhere to specific industrial standards.

ISO Standards for Biosensors:



1. ISO 13485:2016:

- **Title:** Medical devices — Quality management systems — Requirements for regulatory purposes
- **Purpose:** Specifies requirements for a quality management system (QMS) for medical devices, including biosensors. It ensures that manufacturers consistently produce devices that meet regulatory requirements and are safe and effective.
- **Relevance:** Applies to the development, manufacturing, and post-market activities of biosensors used in medical applications.

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ISO Standards for Biosensors:

2. ISO 15197:2013:

- **Title:** In vitro diagnostic test systems — Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus
- **Purpose:** Defines performance criteria, accuracy, and labeling requirements for glucose monitoring systems used by individuals with diabetes.
- **Relevance:** Ensures that glucose biosensors meet necessary performance standards for accuracy and reliability in self-testing.

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3. ISO 10993-1:2018:

- **Title:** Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- **Purpose:** Covers the biological evaluation of medical devices to assess biocompatibility. It includes testing for cytotoxicity, sensitization, and irritation.
- **Relevance:** Ensures that biosensors, especially those in direct contact with the human body, are safe and do not cause adverse biological reactions.


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ISO Standards for Biosensors:

4. ISO 19227:2018:

- **Title:** Medical devices — Detection of specific pathogens or contaminants
- **Purpose:** Provides guidelines for the performance and testing of biosensors designed to detect specific pathogens or contaminants.
- **Relevance:** Ensures that biosensors used in environmental or food safety applications meet performance standards for detecting harmful agents.

5. ISO/TS 20900-2020:

- **Title:** Medical devices — Guidelines on the development of medical devices
- **Purpose:** Provides guidelines on the development, manufacturing, and testing of medical devices, including biosensors. 
- **Relevance:** Helps ensure that biosensors are developed and manufactured in accordance with best practices and regulatory requirements.

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ISO Standards for Biosensors:

6. ISO 17516:2020:

- **Title:** In vitro diagnostic test systems — Evaluation of the performance of nucleic acid testing systems
- **Purpose:** Focuses on the evaluation of nucleic acid testing systems, which can include biosensors used for genetic testing.
- **Relevance:** Ensures the accuracy and reliability of biosensors designed for detecting genetic material.

7. ISO 20387:2018:

- **Title:** Biotechnologies — Biobanking — General requirements for biobanking.
- **Purpose:** Defines general requirements for biobanking, which can involve biosensors used for sample analysis and monitoring.
- **Relevance:** Ensures the quality and reliability of biosensor data used in biobanking applications.

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ISO Standards for Biosensors:

Key Aspects Covered by ISO Standards:

1. **Performance Specifications:** Standards define the accuracy, sensitivity, specificity, and other performance metrics required for different types of biosensors.
2. **Safety and Biocompatibility:** Ensures that biosensors do not pose risks to users or patients and are compatible with biological systems.
3. **Quality Management:** Establishes requirements for quality control and management practices during the design, manufacturing, and post-market phases.
4. **Testing and Validation:** Outlines procedures for validating the performance and reliability of biosensors through rigorous testing.
5. **Documentation and Labeling:** Provides guidelines for technical documentation, labeling, and instructions for use to ensure clear and accurate information for users.

Adherence to these ISO standards helps ensure that biosensors are effective, reliable, and safe for their intended applications, whether in medical diagnostics, environmental monitoring, or other fields

Industrial Standards of Biosensors

FDA Regulations :

The U.S. Food and Drug Administration (FDA) regulates biosensors as medical devices if they are intended for use in diagnosing, treating, curing, or preventing diseases. The regulatory pathway and requirements for biosensors depend on the specific type of device, its intended use, and its associated risks. Here's a summary of key FDA regulations for biosensors:

1. Classification of Medical Devices

The FDA classifies medical devices, including biosensors, into three categories based on risk:

- Class I** (Low Risk): Subject to general controls (e.g., labeling, registration). Most Class I devices are exempt from premarket notification (510(k)).
- Class II** (Moderate Risk): Require general controls and special controls. Most Class II devices need a 510(k) clearance before entering the market.
- Class III** (High Risk): Require premarket approval (PMA) as they support or sustain human life, prevent impairments, or pose a potential unreasonable risk of illness or injury.

Industrial Standards of Biosensors

FDA Regulations :

2. Premarket Submission Pathways

- **510(k) Submission:** For devices substantially equivalent to a legally marketed device (predicate). Many biosensors fall under Class II, so they require 510(k) submission. The applicant must demonstrate that the device is as safe and effective as the predicate.
- **Premarket Approval (PMA):** Required for Class III devices. This is a more rigorous process, involving clinical trials and in-depth review to demonstrate the safety and effectiveness of the device.
- **De Novo Classification:** For novel low-to-moderate risk devices without a legally marketed predicate. This process allows for classification into Class I or II, based on safety and effectiveness data.

3. Performance and Safety Requirements

- **Biocompatibility:** Biosensors that interact with the body must meet FDA standards for biocompatibility to ensure they do not cause harm.
- **Sterility and Hygiene:** Devices that are used invasively or in contact with the body need to be sterile, following FDA guidelines.
- **Electrical Safety and Electromagnetic Compatibility (EMC):** Biosensors with electronic components must comply with safety standards for electrical devices.
- **Software Verification and Validation:** For biosensors with integrated software, the FDA requires verification and validation to ensure that the software functions safely and correctly.

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FDA Regulations :

4. Clinical Evaluation

- The FDA may require clinical data to support the biosensor's safety and efficacy. This can involve bench testing, animal studies, or human clinical trials, depending on the device's classification and intended use.

5. Labeling Requirements

- Instructions for Use:** Clear and comprehensive instructions must be provided.
- Warnings and Precautions:** Any potential risks or adverse effects must be included.
- Intended Use:** The device's labeling must accurately describe its intended use, and the manufacturer cannot promote off-label uses.

6. Postmarket Requirements

- Adverse Event Reporting:** Manufacturers must report any adverse events or malfunctions through the FDA's Medical Device Reporting (MDR) system.
- Postmarket Surveillance:** The FDA may require manufacturers to conduct postmarket surveillance studies to monitor the biosensor's long-term performance.
- Quality System Regulation (QSR):** Manufacturers must follow the FDA's QSR (21 CFR Part 820), which covers design, production, installation, and servicing processes to ensure the device's quality and consistency.



Industrial Standards of Biosensors

FDA Regulations :

7. Risk Management

- The FDA emphasizes risk management throughout the product lifecycle, from design to postmarket activities. Manufacturers must identify potential risks, mitigate them, and document the process to ensure patient safety. By adhering to these regulations, biosensor manufacturers can ensure their products are compliant with FDA standards and are safe for public use.

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FDA Regulations:

- **21 CFR Part 820 (Quality System Regulation):** Focus: The FDA's Quality System Regulation (QSR) outlines the Good Manufacturing Practices (GMP) that manufacturers must follow in the design, manufacture, packaging, labeling, storage, installation, and servicing of medical devices, including biosensors.
- **Application:** Any biosensor marketed in the United States must comply with these regulations. Examples include glucose sensors like the FreeStyle Libre by Abbott and Dexcom CGM systems.

CE Marking :

- **Focus:** CE marking indicates that a product meets the health, safety, and environmental protection standards for products sold within the European Economic Area (EEA).
- **Application:** Biosensors such as blood glucose monitors and point-of-care testing devices must meet these standards to be sold in Europe.

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CLIA (Clinical Laboratory Improvement Amendments) :

- **Focus:** CLIA regulations ensure the quality of laboratory testing, including tests performed with biosensors. The standard is crucial for point-of-care biosensors used in clinical settings. SR
- **Application:** Point-of-care devices, such as those used for rapid blood glucose or cholesterol testing, must meet CLIA standards to ensure accurate and reliable results.