The Importance of Validating New *in vitro* Medical Devices

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Currently, technological innovations are increasingly gaining ground in all fields, and especially in medicine, the validation process is one of the essential requirements for the approval of new medical devices (MDs) and *in vitro* diagnostic devices (IVDs). For a new device to be introduced into the market, it must meet specific requirements, and it is in this context that validation emerges. All IVDs and MDs must be approved by the National Health Surveillance Agency (ANVISA) or the relevant health authority of the country to ensure that the device is safe and effective for the population, and that its use will cause minimal harm compared to the benefits it can bring. In this context of Health Technology Assessment (HTA), this study aims to highlight, through a literature review, the importance of the validation process for IVDs and its impact on the market and the healthcare network.
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An *in vitro* diagnostic device (IVD) is an instrument used outside the human body capable of analyzing human body samples, such as blood, urine, and other biological materials. They are used to store biological materials, determine diseases, or assess the condition of an organism. Therefore, they are handy for preliminary diagnoses and disease prevention [1].

New health technologies, including IVDs, must follow criteria established by ANVISA and several Normative Instructions (IN), and Collegiate Board Resolutions (RDC). Each device has different criteria depending on its functionality, the material it works with, and its operating principle. Given this wide range of possibilities, the validation process is not trivial [2].

The validation process of a new device involves testing reliability, precision, consistency, and whether it meets the requirements established by the applicable standards. One of the fundamental stages in the development of an *in vitro* diagnostic device is preclinical validation, which involves a series of laboratory tests to verify performance and safety using animal models or chemical formulations.

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In biomedical equipment innovation projects, the regulation and validation stage of new devices is noteworthy. Although these innovations require significant investment to develop and implement [3], and despite the evolution of biomedical devices through the emergence of new equipment, techniques, and algorithms aimed at improving health and well-being, various strategic management issues persist within institutions [4]. The validation process for new equipment is a frequently encountered issue and impacts the approval of new technologies and market adoption, thus deserving attention and study. In this context, this study aims to highlight the importance of validating new *in vitro* diagnostic devices, considering the significant impact that such validation has on the incorporation of new health technologies into the market. To achieve this goal, perspectives from several authors on the topic will be discussed, aiming to clarify the benefits of a structured validation method in innovation projects.

Materials and Methods

A literature review was conducted, based on exploratory research and bibliographic methods, from October 2024 to February 2025. Articles were found in Google Scholar, MDPI, and Scielo databases. They were filtered based on the year of publication (from 2018 onward) and the following keywords: biomedical devices, *in vitro* devices,

validation, and regulatory frameworks. Articles that addressed biological *in vitro* processes rather than devices were excluded, as well as those focusing on IVD maintenance. After applying the inclusion and exclusion criteria, 7 articles were selected. Some were directly related to validation, while others were included for their conceptual contributions.

Table 1 below presents a systematization of the content extracted from each article for qualitative analysis on the importance of *in vitro* medical device validation.

Theoretical Framework

As theoretical knowledge does not always translate into practical results, strict control is necessary over which devices can be introduced into the market and public health networks. Regulatory agencies aim to protect patients and society from unsafe devices, striking a balance between protection and market needs. Their primary goal is to promote public health [4].

Moreover, ANVISA defines the criteria for risk classification of medical devices and health products

Table 1. Selected articles.

Author	Title	Year	Source	Summary
Murilo Contó and Luciene Bonan	Legal framework for the incorporation and access to medical devices in Brazil: structure, types of evaluation, and opportunities for progress	2020	Google Scholar	Provides relevant information on testing and classifications.
Tina Morrison and colleagues	Modeling and simulation in biomedical engineering: regulatory science and innovation for advancing public health	2023	Google Scholar	Contextualizes the field, highlighting the importance of regulation.
Rosa Mayelin Orcid and colleagues	Impact of regulations on innovation in the field of medical devices	2018	Sciel Reviews	Conflicting issues in the evaluation of biomaterials and devices, and stresses the need for a method.
Lei Wang and colleagues	Methods and Advances in the Design, Testing and Development of *in vitro* Diagnostic Instruments	2023	MDPI	Summarizes related technologies and key R&D aspects.
Pernille Fauskanger and colleagues	Quantification of Difference in Nonselectivity Between In Vitro Diagnostic Medical Devices	2025	Google Scholar	Proposes a metric for quantifying non-selectivity differences in IVD-MDs.
Joana Freitas	Organization and management of biomedical equipment maintenance focusing on patient risk	2018	Google Scholar	Summarizes biomedical equipment management issues.
José Silva	Biomedical Engineering Center of the Brazilian Air Force: support and development	2019	Google Scholar	Discusses challenges in biomedical device development.

through INs and RDCs. These are mandatory prerequisites for IVD registration. ANVISA works with laboratories and Product Certification Bodies (OCPs) accredited by INMETRO [1]. Access to health technology is often limited by the difficulty in validating and regulating new devices, due to the lack of specific policies and literature on regulation. Each device has specific legislation and requirements that must be carefully analyzed and fulfilled [1].

Validation is also essential in the module planning stage, as it is used to develop product prototypes. IVD projects integrate several fields of engineering and technology: mechanical, electronic, optical, inspection, computer science, and control [2].

MDs and IVDs must maintain high precision even under external factors, justifying the need for rigorous validation before market acceptance [5]. Selectivity is a critical parameter that defines the device's capacity to accurately measure the target analyte without interference from other substances [5].

A crucial point is that, despite advances in human physiology research, applying this knowledge presents challenges, resulting in a treatment device approval rate below 50%. Increasing this rate improves quality of life and supports healthcare systems. Model-based development gathers diverse data to reduce uncertainty and failure rates, providing insights that would otherwise be unattainable. Computational methods thus offer viable alternatives to ease validation [6]. Each device has unique features that make validation a complex process. Nonetheless, sufficient clinical evaluations must be conducted to ensure safety [7].

Conclusion

This study examines the complexity and importance of the validation process for *in vitro* medical devices. It highlights the importance of validating new IVDs, as validation determines the acceptance of new proposals. Validation ensures the efficacy, reliability, and safety of treatments for patients and professionals. Structuring validation from the product's conception increases the likelihood of regulatory approval and optimizes development time. This research continues with a literature review on innovation in IVD equipment and regulatory frameworks for validation.

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