

Innovation and Regulation of Medical Devices in Brazil: The Case of Rapha

Inovação e Regulação de Dispositivos Médicos no Brasil: O Caso do Rapha

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RESUMO

Objetivo: Analisar o percurso de inovação e regulação do dispositivo médico RAPHA, desenvolvido na Universidade de Brasília e conduzido pela empresa LifeCare Medical, identificando os marcos legais, científicos e tecnológicos que viabilizaram sua certificação e notificação sanitária. **Método:** Estudo de caso qualitativo e documental, baseado em análise normativa e institucional, envolvendo legislações sanitárias vigentes, resoluções aplicáveis e documentos técnicos institucionais. **Resultados:** Foram identificadas seis etapas essenciais: regularização da empresa, implantação de boas práticas de fabricação, certificação compulsória de conformidade, rotulagem e rastreabilidade, peticionamento eletrônico e integração universidade–empresa, evidenciando aderência às normas vigentes e redução de riscos regulatórios. **Conclusão:** O caso RAPHA evidencia a importância do planejamento regulatório integrado à inovação tecnológica, contribuindo para o fortalecimento do ecossistema nacional de inovação em saúde e para a inserção segura de tecnologias no sistema de saúde.

DESCRIPTORES: Certificação; Dispositivos Médicos; Inovação em Saúde; Regulação Sanitária.

ABSTRACT

Objective: To analyze the innovation and regulatory pathway of the RAPHA medical device, developed at the University of Brasília and conducted by LifeCare Medical, identifying the legal, scientific, and technological milestones that enabled its certification and sanitary notification. **Method:** A qualitative documentary case study based on normative and institutional analysis, involving current health regulations, applicable resolutions, and institutional technical documents. **Results:** Six essential stages were identified: company registration, implementation of good manufacturing practices, compulsory certification, labeling and traceability, electronic submission, and university–industry integration, demonstrating compliance with current regulations and reduced regulatory risks. **Conclusion:** The RAPHA case highlights the importance of integrating regulatory planning with technological innovation, contributing to the strengthening of the national health innovation ecosystem and the safe incorporation of technologies into the healthcare system.

DESCRIPTORS: Certification; Medical Devices; Health Innovation; Health Regulation.

RESUMEN

Objetivo: Analizar el recorrido de innovación y regulación del dispositivo médico RAPHA, desarrollado en la Universidad de Brasília y conducido por la empresa LifeCare Medical, identificando los hitos legales, científicos y tecnológicos que posibilitaron su certificación y notificación sanitaria. **Método:** Estudio de caso cualitativo y documental, basado en análisis normativo e institucional, que incluye legislación sanitaria vigente, resoluciones aplicables y documentos técnicos institucionales. **Resultados:** Se identificaron seis etapas esenciales: regularización de la empresa, implementación de buenas prácticas de fabricación, certificación obligatoria, rotulación y trazabilidad, peticionamiento electrónico e integración universidad–empresa, evidenciando adherencia a las normas vigentes y reducción de riesgos regulatorios. **Conclusión:** El caso RAPHA evidencia la importancia de la planificación regulatoria integrada a la innovación tecnológica, contribuyendo al fortalecimiento del ecosistema nacional de innovación en salud y a la incorporación segura de tecnologías en el sistema de salud.

DESCRIPTORES: Certificación; Dispositivos Médicos; Innovación en Salud; Regulación Sanitaria.

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ID Michelle Luciana de Sousa
Master's in Biomedical Engineering, University of Brasília (UnB).
ORCID: <https://orcid.org/0000-0002-9325-1305>

ID Adson Ferreira Rocha
Professor in the Graduate Program in Biomedical Engineering, UnB
ORCID: <https://orcid.org/0000-0003-4532-1791>

ID Suêlia de Siqueira Rodrigues Fleury Rosa
Professor in the Graduate Program in Biomedical

Engineering, UnB
ORCID: <https://orcid.org/0000-0002-1247-9050>

ID Mário Fabrício Fleury Rosa
Professor in the Graduate Program in Biomedical Engineering, UnB
ORCID: <https://orcid.org/0000-0002-4821-9007>

ID Leda Correia Nobre Brandão
Master's in Biomedical Engineering, University of Brasília (UnB)
ORCID: <https://orcid.org/0009-0008-4963-5804>

INTRODUCTION

Technological innovation in health requires coordination between science, industry, and health regulation. In Brazil, this process is supported by a robust regulatory framework established by Law No. 6,360/1976⁽¹⁾ and enhanced by Law No. 9,782/1999⁽²⁾, which created the National Health Surveillance Agency (ANVISA). Complementing this framework is the role of the National Institute of Metrology, Quality, and Technology (INMETRO), responsible for certifying the conformity and safety of medical devices.

However, the translation of research results into innovative products still faces significant barriers, known as the “valley of death” in Translational Health Research—a critical phase between scientific validation and technological, industrial, and regulatory feasibility.

In this context, the RAPHA device—a portable, natural latex-based phototherapy system for residual wound healing, designed to treat lower limb lesions resulting from complications of diabetes mellitus—represents a breakthrough in the translational innovation process led by the University of Brasília (UnB).

RAPHA stands as a concrete example

of university–industry cooperation, in which regulatory planning was incorporated from the initial stages of technological development, allowing for the anticipation of technical and regulatory requirements and reducing uncertainties in the certification and health notification process.

Thus, analyzing RAPHA's regulatory journey helps us understand how the integration of technological innovation and regulation contributes to strengthening the national medical device industry, ensuring patient safety, and consolidating the national health innovation ecosystem.

Thus, this study aims to analyze the innovation and regulatory pathway of the RAPHA device, identifying the legal, scientific, and technological milestones involved in its certification and health notification.

METHOD

This is an exploratory-descriptive study with a qualitative approach, based on a bibliographic and documentary review, covering a time frame of the last 10 years. We analyzed current legislation, resolutions, and regulatory instructions from the Brazilian Health Regulatory Agency (ANVISA) and the National Institute of Metrology, Quality, and Technology (INMETRO),

published through December 2024, as well as institutional documents from the University of Brasília (UnB) and technical reports from LifeCare Medical Indústria e Comércio, responsible for the large-scale production of the RAPHA device.

Brazilian health legislation and current regulatory acts from ANVISA and INMETRO, published through December 2024, were considered as inclusion criteria, in addition to institutional documents related to the development, certification, and regulatory approval of the device. Outdated documents or those without direct applicability to the regulatory process under analysis were excluded.

The sample consisted of laws, decrees, resolutions, administrative orders, technical reports, and laboratory test records. Data sources included: health legislation (Laws No. 6,360/1976⁽¹⁾, No. 9,782/1999⁽²⁾ and No. 14,874/2024⁽³⁾; Decrees No. 8,077/2013 and No. 10,178/2019);

ANVISA regulations (RDC No. 560/2021⁽⁴⁾, RDC No. 665/2022⁽⁵⁾, RDC No. 751/2022⁽⁶⁾, RDC No. 848/2024⁽⁷⁾, RDC No. 902/2024⁽⁸⁾ and No. 924/2024⁽⁹⁾); INMETRO regulations (Ordinance No. 384/2020⁽¹⁰⁾ and Normative Instruction No. 283/2024⁽¹¹⁾) and institutional documents, including

technical reports from LifeCare Medical⁽¹²⁾, laboratory test records (CERTBIO/UFCG and LENSE/UnB), and dossiers from NUPITEC/CDT/UnB.

The data were organized chronologically, covering the period from the company's registration to the health notification phase. For analysis, five thematic axes were defined: company registration; certification of compliance; health notification; labeling and traceability; and university–company integration.

The analysis was conducted through triangulation of sources, combined with regulatory mapping and thematic categorization, along with content interpretation, enabling a comparison between the applicable legal requirements and their practical implementation in the regulatory journey of the RAPHA device.

RESULTS

The results were organized into thematic axes defined by the method, covering the stages of company registration, certification of compliance, health registration, labeling and traceability, and university–industry integration. This structure allowed for linking regulatory requirements to practical evidence of their implementation in the regulatory pathway of the RAPHA device.

Company Registration and Good Manufacturing Practices

LifeCare Medical obtained its Operating Authorization (AFE) and Operating License (LF) in accordance with RDC No. 560/2021⁽⁴⁾, meeting the require-

ments for operating in the medical device sector. Concurrently, it implemented the Good Manufacturing Practices system, in accordance with RDC No. 665/2022⁽⁵⁾, ensuring quality control, traceability, and document compliance.

This step marks the starting point of the regulatory process and is essential for the continuation of the subsequent phases. Compliance with health standards from the very beginning of the production process underscores the importance of integrating regulatory planning with technological development.

Mandatory certification and compliance testing

In accordance with Ordinance No. 384/2020⁽¹⁰⁾ and IN No. 283/2024⁽¹¹⁾, the device underwent mandatory certification, as required for electromedical equipment. Electrical safety (ABNT NBR IEC 60601-1), performance, and biocompatibility tests were conducted in accredited laboratories, such as CERTBIO (UFCG) and LENSE. R (UnB), which are accredited by INMETRO.

The results demonstrated compliance with the established technical requirements, validating the device's safety and efficacy. This step is crucial for health regulatory approval, as it provides technical evidence of the product's compliance with regulatory requirements.

Health Regulatory Approval

RAPHA was classified as a Class II medical device and is subject to the health notification regime, in accordance with

RDC No. 751/2022⁽⁶⁾. Under this regulatory model, responsibility for technical and documentary compliance rests with the manufacturer, eliminating the need for prior review by ANVISA. The electronic filing is carried out through the DATAVISA system, in accordance with the guidelines of the Guide for Electronic Filing of Health Notifications for Medical Devices (ANVISA, 2023)⁽¹³⁾.

The electronic submission was carried out in accordance with current regulatory guidelines, ensuring the recording of information and product traceability, in accordance with the guidelines of the Guide for Electronic Submission of Health Notifications for Medical Devices (ANVISA, 2023)⁽¹³⁾. This step demonstrates the importance of document organization and prior alignment with regulatory requirements.

Labeling and Traceability

The labeling and instructions for use were prepared in accordance with RDCs No. 902/2024⁽⁸⁾, No. 924/2024⁽⁹⁾, No. 848/2024⁽⁷⁾ and No. 591/2021⁽¹⁴⁾, including warnings regarding natural latex, safety guidelines, and implementation of the Unique Device Identification (UDI) system, in line with WHO guidelines (2022)⁽¹⁵⁾.

The implementation of the traceability system, through unique device identification, contributes to post-market monitoring and patient safety, demonstrating adherence to national and international regulatory guidelines.

Table 1 – Stages and Legal Basis of the Regulatory Process

Stages	RAPHA Status	Legal Basis
Company Registration	Completed	RDC 560/2021 ⁽⁴⁾ ; RDC 830/2024; Lei 6360/76; Decreto 8077/2013
GMP	Completed	RDC 687/2022; RDC 665/2022 ⁽⁵⁾ ; RDC 850/2024
Device classification	Completed	RDC 751/2022 ⁽⁶⁾ ; RDC 423/2020; RDC 777/2023
INMETRO Certification	Completed	Portaria 384/2020 ⁽¹⁰⁾ ; IEC 60601-1; IN 283/2024 ⁽¹¹⁾
Labeling and traceability	Included in the technical dossier	RDC 902/2024 ⁽⁸⁾ ; RDC 924/2024 ⁽⁹⁾ ; RDC 848/2024 ⁽⁷⁾ ; RDC 591/2021 ⁽¹⁴⁾
Electronic petitioning	In progress	RDC 751/2022 ⁽⁶⁾ ; Guia ANVISA 2023 ⁽¹³⁾
Regulatory conclusion	Under review	Lei 6.360/76 ⁽¹⁾ ; RDC 751/2022 ⁽⁶⁾
Post-market	Target	RD 478/2021; RDC 551/2021; Lei 12401/2011

Source: AnvisaLegis; LifeCare Documents.

DISCUSSION

The partnership between the University of Brasília (UnB) and LifeCare Medical Indústria e Comércio was formalized through a technology licensing agreement, with institutional support from the Center for Intellectual Property and Technology Transfer (NUPITEC/CDT). This institutional arrangement complies with the Innovation Law (Law No. 10,973/2004) ⁽¹⁶⁾ and with the guidelines of the National Policy on Science, Technology, and Innovation in Health (Law No. 14,874/2024) ⁽¹⁰⁾, which encourage the transfer of knowledge generated in an academic setting to the productive sector.

Through this integration, the protection of intellectual property,

technology transfer, and UnB's institutional participation in the industrialization phase of the RAPHA device⁽¹³⁾ are ensured. The adopted model reinforces the concept of the Quintuple Helix, which links university, government, industry, society, and the environment in support of sustainable innovation.

This coordination was crucial for RAPHA to advance in the technological maturity process, enabling it to cross the so-called “valley of death”—a critical phase of Translational Health Research (T3 stage). This is a strategic stage involving technology transfer to the productive sector, certification by INMETRO, health regulatory approval by ANVISA, and preparation for the safe availability of the product within the healthcare system⁽¹²⁾.

The data show that RAPHA has moved beyond the initial stages (T0 to T2) and is currently in the T3 phase. This progress demonstrates the University of Brasília's institutional commitment to advancing an innovation originating in academia, guided by criteria of safety, quality, and social responsibility, with the potential for a positive impact on the Unified Health System.

CONCLUSION

The study shows that the success of the regulatory pathway for the RAPHA device stems from the integration of technological innovation, regulatory planning, and inter-agency cooperation. The incorporation of regulatory requirements from the earliest stages of development was critical to technical compliance and to the feasibility of certification and health notification. The findings reinforce the role of health regulation as a strategic tool for safe innovation in health. The collaboration between universities, the private sector, and regulatory agencies demonstrates the consolidation of a national innovation ecosystem capable of transforming scientific knowledge into technological solutions with practical applications.

The RAPHA case highlights that regulatory planning integrated with research and development contributes to risk reduction, process optimization, and the safe integration of technologies into the healthcare system, with the potential for a positive impact on the Unified Health System and the strengthening of national technological sovereignty.

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Figure 1 – Phases of Translational Health Research

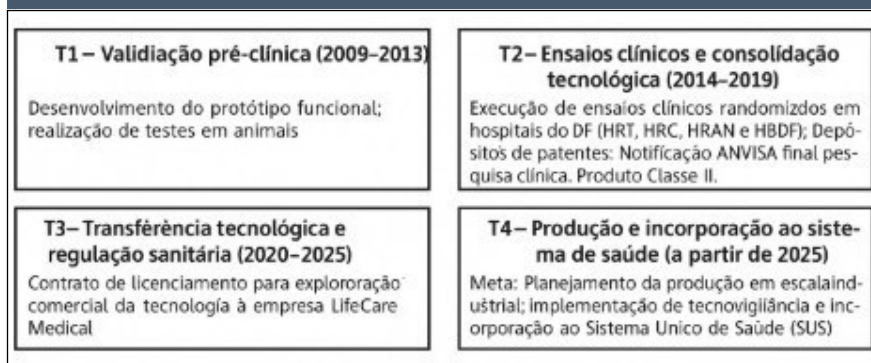


Source: Silva (2021), adapted by the author.

The development of the first three stages of THR can span more than a decade, requiring significant investment and carrying a substantial risk of failure (Bosio, 2019)⁽¹⁷⁾. In this context, the findings of this study corroborate the

literature by demonstrating that integration between universities and companies not only accelerates the innovation process but also promotes greater regulatory efficiency and contributes to the consolidation of a national health technology ecosystem.

Figure 2 - PTS stages already achieved by RAPHA



Source: (Rosa, 2025). Prepared by: the author

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AMENDMENT/UNB/FCTE – CHIP-Eny/UnB: Organ-on-a-Chip platform for angiogenesis aimed at accelerating clinical trials in health technologies, and 8032 – AMENDMENT/UNB/FCTE – Functional improvement in the preclinical phase of a latex intraesophageal device with thermal conduction for the prevention of atrioesophageal fistula in radiofrequency cardiac ablation; as well as from Senator Leila Barros, whose support made possible Bill 7763 – UNB/FGA/AMENDMENT – Expansion of angiogenesis and vasculo-

genesis activities using Organ-on-a-Chip, with a focus on analyzing the regulatory and health aspects of Equipment RAPHA for the treatment of diabetic. This research is characterized by its interdisciplinary and cross-cutting nature, integrating knowledge from the fields of biomedical engineering, biotechnology, materials science, and health, fostering the integration of basic research, technological development, and clinical application, with a view to generating innovative solutions with high scientific, social, and economic impact.

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