MAN_02 - Regulatory Intelligence (RI) applied to the registration and post-variation of Bio-Manguinhos vaccines and biopharmaceuticals

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Introduction: Regulatory Intelligence (RI) is an important pillar of Regulatory Affairs. Understanding RI enables an analysis of the company's regulatory landscape. RI allows for strategic mapping and planning through reports, performance indicators, and databases, making the regulatory process more accurate. ANVISA establishes the attributes for evaluating the quality, safety, and efficacy of products, which must be analyzed and approved by the agency. The RDC 49/2011 outlined the technical requirements for post-variation to biological products until 2020. It was revoked by RDC 413/2020 and IN 65/2020. These regulations provide more detailed information on post-variation, including their conditions, mandatory documents, and categorization as major, moderate, minor, or with no impact.

Objectives: Apply RI strategies to map regulatory processes and identify the impacts of IN 65/2020 on post- variation of medicines at Bio-Manguinhos (BM) between 2018 and 2023.

Methodology: The methodology was based on the 4 principles of RI: data collection, analysis, interpretation, and information delivery. For this purpose, it was developed an internal database using Power BI to collect, map, analyze, and characterize medication records, as well as post-records between 2018 and 2023. It was interpreted the impact of regulations RDC 49/2011 and IN 65/2020 through comparative studies. It was also evaluated strategies for disseminating regulatory information within the unit.

Results: Through the survey and analysis of regulatory data, a total of 445 post-variation items were identified for the 25 medications, with 60% falling under the IN 65/2020 regulation. Three new products were added to the portfolio after 2021. There was a 14% reduction in the number of requirements after 2021. There was a 14% reduction in the number of item notifications after 2021. It is worth noting that the COVID-19 (recombinant) vaccine was registered in 2021, accounting for 17% of post-variations after the IN 65/2020 regulation came into effect.

Conclusion: The use of IR allowed for the mapping of the regulatory scenario of BM, making it possible to verify a notable increase in post-variations. This fact is due to certain variables such as the increase of portfolio, with emphasis on the market authorization of the COVID-19 vaccine and the advancement of PDP phases. The regulatory framework of IN 65/2020 enabled greater detail and classification of the processes. From the evolution of IR in the institution, it is expected that more robust and assertive documents will be delivered for post- variation analysis.

Keywords: Regulatory affairs; Pharmaceutical industry; Regulatory Intelligence