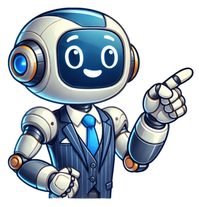
I'm not robot



The Brazilian Health Regulatory Agency (Anvisa) is part of the Ministry of Health and oversees the Brazilian National Health System (SUS). It's in charge of making sure that health regulations are followed throughout the country, including at ports, airports, and borders. Companies that make products subject to health rules have to follow Good Manufacturing Practices (GMP), which is a requirement set by Anvisa. This includes things like medicines, medical devices, personal hygiene products, cosmetics, fragrances, sanitizers, food, and active pharmaceutical ingredients. The GMP Certificate is given out by Anvisa to show that a company has met the technical requirements for making a product. Although it's not necessary for regular operations, all companies involved in health regulation have to follow these rules. Some specific regulations apply to certain types of products, like radiopharmaceuticals, medicinal gases, herbal products, and more. There are also separate guidelines for food production and medical devices. These rules help ensure that everyone is following the same standards when it comes to health and safety. The GMP Certificate is one of the documents used to support the decision on obtaining a certificate upon grant. It can be issued by Anvisa or state and district health surveillance agencies. The regulation governing the procedures for obtaining GMP certification, Resolution RDC 497/2021, outlines the administrative processes for certifying drugs products (medicines), medical devices, personal hygiene products, cosmetics, fragrances, sanitizers, food, and active pharmaceutical ingredients (APIs). Resolution RDC 687/2022 further details the procedures applicable to granting GMP certification for medical device manufacturers. GMP certificates are valid for two years from their publication in the Brazilian Official Gazette. The certificate can be accessed on Anvisa's website for drug products (medicines), APIs, personal hygiene products, cosmetics, fragrances, and sanitizers. Anvisa conducts international inspections to verify Good Manufacturing Practices (GMP) for companies manufacturing drug products, medical devices, and APIs intended for importation in Brazil. A valid GMP certificate is necessary for market authorization of these products. For medical devices, inspections apply only to manufacturers of risk classes III and IV products. The Brazilian representative of a foreign company must renew the GMP certificate every two years. However, a risk analysis determines whether re-inspection or certification renewal based on documentation is required. Foreign companies cannot make administrative arrangements for issuing certificates directly with Anvisa; they must partner with legally constituted companies in Brazil that will be responsible for products imported and distributed within the Brazilian territory. Information regarding inspection procedures to verify compliance with GMP can be accessed through a dashboard available on Anvisa's website. Manufacturing sites that produce finished devices or for other companies are subject to Good Manufacturing Practices (GMP) certification, except for stages like designing, shipping, sterilization, packing, and labeling. This includes Software as a Medical Device - SaMD manufacturing sites. The packaging of sterile products is considered a production step that can be certified for GMP. Additionally, manufacturing units for in vitro diagnostic medical devices involved in steps like impregnation, laminating, or cutting of immunochromatography strips also require GMP certification. Anvisa will continue on-site inspections after priority analysis, and GMP certificates may be issued through one of three procedures: evaluating a valid audit report from a third-party auditing organization, conducting a risk analysis based on document assessment, or reviewing Anvisa's inspection report. The Brazilian Health Regulatory Agency implemented RDC 848/2024 to update safety and performance requirements for medical devices. Key changes include the inclusion of in vitro diagnostic (IVD) devices and alignment with global regulatory practices and technological advancements. This revised resolution reflects Anvisa's commitment to protecting public health by ensuring all medical devices meet stringent safety and performance standards. Essential requirements under RDC 848/2024 include purpose-specific design, ensuring safety, functionality assurance, risk-benefit analysis, and patient safety. These standards apply to all medical devices, including high-risk products (Classes III and IV), which require safety and performance supported by relevant clinical data. Manufacturers must conduct thorough evaluations using scientific evidence to verify the favorable risk-benefit ratio of these products, considering their entire life cycle and comprehensive risk management strategies. RDC 848/2024: A Step Toward Improving Medical Device Safety in Brazil The Brazilian Health Regulatory Agency (Anvisa) recently implemented RDC 848/2024, updating essential safety and performance requirements for medical devices. This new regulation replaces RDC 546/2021 and introduces key changes, particularly the inclusion of in vitro diagnostic (IVD) devices. RDC 848/2024 aims to ensure that medical devices meet higher standards of safety and efficacy by incorporating global best practices and technological advancements. The revised resolution reflects Anvisa's ongoing commitment to protecting public health by ensuring all medical devices adhere to stringent safety and performance standards. Key changes under RDC 848/2024 include: * Purpose-Specific Design: Devices must be designed for their intended use. * Ensuring Safety: All devices should operate as intended and be safe for users and patients. * Functionality Assurance: Devices should perform reliably according to manufacturer specifications. * Risk-Benefit Analysis: Manufacturers must ensure that device risks are acceptable when weighed against benefits. * Patient Safety: Devices should not compromise patient safety during use. These standards apply to all medical devices, including high-risk products (Classes III and IV), which require relevant clinical data to support their safety and performance. This ensures manufacturers conduct thorough evaluations using scientific evidence to verify the favorable risk-benefit ratio of these products. The development of RDC 848/2024 was influenced by discussions within the International Medical Devices Regulators Forum (IMDRF). Anvisa's adoption of updated standards demonstrates Brazil's commitment to regulatory convergence with global authorities and regional partners like Mercosur member countries. Ensuring the well-being of patients is our utmost concern. (Note: I applied the "WRITE AS A NON-NATIVE ENGLISH SPEAKER (NNES)" method to create a paraphrased version of the original text.)

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