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REQUIREMENTS FOR MODIFICATIONS TO THE SANITARY REGISTRATION OF BIOLOGICAL PRODUCTS ARE ESTABLISHED

On June 28, 2024, Exempt Resolution No. 1,160 of May 31, 2024 was published in the Official Gazette, which approved the "Technical Guideline of the Public Health Institute that establishes the requirements for the application for modifications to the sanitary registration of biological products (M-MOBI)".

The Public Health Institute (ISP) has issued guidance for sanitary registration holders regarding the background information required for modification applications, in order to facilitate their correct submission, with complete and updated information to support the type of modification required.

The Technical Guideline M-MOBI includes aspects of the current regulations, as well as the recommendations of the WHO, FDA, EMA and ICH on the subject, leaving the applicant responsible for the veracity of the documents and information provided in the registration application and its subsequent modifications.

Thus, Technical Guideline M-MOBI describes the following:

• Classification of modifications to the sanitary registration of biological products, the last two of which are addressed in this Guideline:

• Legal modifications
• Technical modifications
• Therapeutic modifications
• Modifications to quality aspects

• Within the modifications of quality aspects, there is a subclassification into three levels or categories of analytical quality modifications based on the risk analysis study:

• Major or Level 3
• Moderate or Level 2

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• Minor or Level 1

The categorization of these levels is carried out by the holder of the sanitary registration, specifically by the laboratory in charge of the production or manufacturing processes. Whenever a modification is requested, the application of a comparability study must be considered.

Likewise, the Technical Guideline M-MOBI states:

• Requirements and background information to be submitted for therapeutic modifications.
• Requirements and background information to be submitted for modifications of quality aspects.
• List of the corresponding procedures and services.
• Detailed and exemplified description to guide applicants on the risk classification of those modifications to be performed on biological products.

For more information, please visit the following website.

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