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Overview of the Regulatory Framework for Radiopharmaceuticals

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Abstract

Radiopharmaceuticals are products that have the particularity of combining two very restrictive regulatory requirements depending on two different authorities: that of the drug in the pharmaceutical sense and that of a radioactive source linked to a specific authorization system.

Radiopharmaceuticals are a new reality in the pharmaceutical industry and are considered to be an indicator of modern medicine and the technological industry. The exponential increase in their use is attributed to their dual use as diagnostic and therapeutic agents. They represent a group of pharmaceutical preparations, which contain radionuclides with short half-lives and are mainly administered intravenously. Maximum care should be taken during their production, distribution, storage, and disposal because their radiant nature is a concern for both patients and medical staff. All stages of production must be done by the requirements of Good Manufacturing Practice. Therefore, radiopharmaceuticals must meet the requirements of the pharmaceutical regulator, the same as those of the nuclear regulator. The largest number of regulatory bodies in the world have different perspectives in terms of their production, distribution, transportation, storage, and disposal. However, in developed countries, the regulator of radiopharmaceuticals is in its infancy.

In this article, we will shed light on the various regulatory limitations imposed by these statutes, emphasizing that these regulations are therefore

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likely to evolve in the years to come and to demonstrate the importance of their development, proper use, and perspective.

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