Law

Relevant laws and regulations (domestic)

1. The Constitution has no corresponding introduction

2. Scientific and technological achievements transformation method:

Article 12 The State encourages research and development institutions, institutions of higher learning and other institutions to combine with production enterprises to jointly implement the transformation of scientific and technological achievements. Research and development institutions, institutions of higher learning, etc., may participate in bidding and tendering activities for relevant government departments or enterprises to implement the transformation of scientific and technological achievements.

Article 15 Completion units for scientific and technological achievements, units for the transformation of scientific and technological achievements, and investment units for scientific and technological achievements shall cooperate in the follow-up test, development, application and production and operation of scientific and technological achievements, and shall sign contracts to stipulate the rights and commitments of the parties. risk.

Article 20 The test products transformed by scientific and technological achievements shall be tested and sold in the approved trial sales period in accordance with the provisions of the State's relevant test-selling products and approved by the relevant departments. The trial production and trial sale of the above products shall conform to the relevant national standards for technology, quality, safety and hygiene.

3. Environmental Protection Law:

Article 19 The preparation of relevant development and utilization plans and the construction of projects that have an impact on the environment shall be carried out in accordance with the law. Development and utilization plans that have not been carried out in accordance with environmental impact assessment shall not be organized and implemented; construction projects that have not carried out environmental impact assessment according to law shall not start construction.

4. Science and Technology Progress Law

Article 8 The State establishes and perfects a scientific and technological evaluation system that is conducive to independent innovation. The scientific and technological evaluation system shall carry out classified evaluation according to the characteristics of different scientific and technological activities and in accordance with the principles of fairness, justice and openness.

Article 29 The State prohibits scientific and technological research and development activities that endanger national security, harm public interests, endanger human health, and violate ethics.

5. Drug Administration Law

Article 4 The State encourages the research and creation of new drugs to protect the legitimate rights and interests of citizens, legal persons and other organizations in researching and developing new drugs.

Article 29 In the development of new drugs, relevant materials and samples such as development methods, quality indicators, pharmacological and toxicological test results must be submitted in accordance with the provisions of the drug regulatory authority under the State Council, and only after approval by the drug regulatory authority under the State Council. Clinical Trials.The method for determining the qualification of a drug clinical trial institution shall be jointly formulated by the drug regulatory department of the State Council and the health administrative department of the State Council.The new drug that has completed the clinical trial and passed the examination and approval shall be approved by the drug regulatory department of the State Council and issued a new drug certificate.

Article 30 The non-clinical safety evaluation research institutions and clinical trial institutions must separately implement the quality management norms for drug non-clinical research and the quality management specifications for drug clinical trials.The quality management norms for drug non-clinical research and the quality management regulations for drug clinical trials shall be formulated by the department determined by the State Council.

Article 31 The production of new drugs or drugs with national standards shall be subject to the approval of the drug regulatory authority under the State Council and the drug approval number shall be issued; however, except for the production of Chinese herbal medicines and Chinese herbal medicines without the approval of the approval number management.The catalogue of Chinese herbal medicines and traditional Chinese medicine decoction pieces for the implementation of the approval number management shall be formulated by the drug regulatory department of the State Council in conjunction with the Chinese medicine administration department of the State Council.The pharmaceutical manufacturer can only produce the drug after obtaining the drug approval number.

Article 102 The meanings of the following terms in this Law are: drugs, which are used to prevent, treat, and diagnose human diseases, purposefully regulate human physiology and stipulate indications or functions, usage, usage and dosage. Substances include Chinese herbal medicines, Chinese herbal medicines, Chinese patent medicines, chemical raw materials and their preparations, antibiotics, biochemical drugs, radioactive drugs, serum, vaccines, blood products and diagnostic drugs.

Relevant documents: "Pharmaceutical Production License", "Pharmaceutical Business License" or "Medical Agency Preparation License"

Related rules and regulations

Drug Clinical Trial Quality Management Regulations (2003 implementation)

The Fifth There must be sufficient scientific evidence for conducting clinical trials of drugs. Before conducting a human trial, the purpose of the trial and the problems to be solved must be

carefully considered. The benefits and risks of the subject and public health expectations should be weighed. The expected benefit should exceed the possible damage. The choice of clinical trial methods must meet scientific and ethical requirements.