

Drug Regulatory Affairs

Humans have always made efforts for staying fit and healthy. But the complex physiological mechanisms of the human body, negative environmental factors (could be radiations, micro-organisms, temperature and humidity, etc.) and modern lifestyle, inevitably manage to defeat the efforts. Drugs which are used for diagnosis, cure, mitigation, treatment or prevention of diseases are amongst the most significant way to get the human body back to a fit and healthy state.

Drugs and medical devices are among the most stringently regulated products in the developed world. The fundamental purpose of regulation is the protection of public health. Regulatory authorities across the world have been working their way to develop regulations which can ensure that only safe and effective products, of high quality and purity, reach into the markets for commercial distribution. Most of the landmark advances in the regulatory development were triggered by adverse events. A keen look into the history of different regulatory authorities will clarify the fact that the current regulations are actually based on the distilled wisdom of bitter past experiences.

US and EU are two parts of the developed world where drugs are the most stringently regulated. The following text describes the history, organization and responsibilities of the regulatory authorities of US and EU region. The chapter will discuss the drug approval and development process, mechanisms used to regulate manufacturing and

marketing, as well as various violation and enforcement schemes adopted by US and EU regulatory authorities. Methods and tools for protecting industrial property and product liability are also discussed at the end of the chapter.

DEFINITIONS

The terms most commonly used in this chapter are defined as they are in the Act:

Drug

Sec. 201(g) (1): The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B) or (C); but does not include devices or their components, parts, or accessories.

Label

Sec. 201(k): The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appearing on the label shall not

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