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The regulatory affairs as a bridge between government regulatory authorities and pharmaceutical companies

In the middle of 20th century, there was no centralized system for medicinal product authorization; not in Europe, nor in USA, which led on several tragedies, as a result of low regulations (sulfanilamide elixir, thalidomide tragedy and etc.). The contemporary system of drug monitoring, which increases medicinal products quality, safety and efficacy control, was introduced in 1970's. However, despite of strictness of Marketing Authorizations (MA) Law and Good Manufacturing Practice, it became possible to the mid-1980's to get MA for several drugs without the FDA's standard evaluation procedure (for example, authorization of the first antiretroviral drug *Azidothymidine*). Nowadays, all MA are conducted in accordance with the regulations and guidelines established by regulatory authorities. The main scope of Regulatory Affairs functions combines administrative, scientific and technical part of pharmaceutical product development and manufacturing: Administrative legislation of facilities, creation of Standard Operation Protocols (SOP), pharmaceutical development, manufacturing, registration, and pharmacovigilance and post-marketing activities. This multiply diversity in functions holds the regulatory professionals team in a unique position with deep responsibilities. The scope of Regulatory Affairs functions differs from country to country, but, if countries have not their own regulations, it follows the World Health Organization guidelines and World Trade Organization. The Pharmaceutical Law of Georgia which regulates the scope of Regulatory Affairs in Georgia is as following: There are two regimes of registration in Georgia – Recognition and National one. Under the Recognition regime it is possible to register pharmaceutical products, which are already authorized in USA, Canada, EU countries and other countries from official List of countries, during 7 working days. The submission of additional labeling is by Notification with submission of required documents. The National regime requires submission of documents from list of documents for registration, after official submission registration lasts 3 months, if process is postponed, for the applicant is given 2 months for submission of additional documents. As soon as required documents are submitted, process is continued. The renewal registration process lasts 2 months, required documents should be submitted not less 2 month prior the expiration of registration in Georgia (preferable to submit 4 months prior the expiration date). The registration process of change of II rank (of high importance) lasts 3 months, I rank b type – 1 month, 1 a type – 10 working days. The Regulatory Affairs activities, which are reducing time for product reaching on the market, have considerable economic importance for any pharmaceutical company. The new drugs developing and clinical research are expensive, therefore, postponed authorization of this drug even for some months, has considerable financial costs. The contact between the Government Regulatory Authorities and the pharmaceutical company is carried out by the Regulatory Affairs department. Being the bridge between two structures, the Regulatory Affairs department follows up the product registration process. The Regulatory Affairs department has continued in response of product post-marketing safety. As a conclusion Regulatory Affairs professionals are involved in regulatory strategy for drug product approval by global regulators, and in pharmaceutical company's activities, from pharmaceutical development, through non-clinical and clinical research to post-marketing studies. Therefore Regulatory Affairs professionals play important role in a pharmaceutical industry.

Biography

Elene Chikobava is a Master Chemistry, with 10 years of working experience as a biochemist in the Scientific-Research Centre of Biophysics and Biotechnology, where she has completed her PhD in Biologic Science. She became a senior specialist of the Pharmacopoeia Committee of Drug Agency of the Ministry of health, Labor and Social affairs of Georgia after its creation in 2003. After being actively involved in renovation of the Pharmacopoeia Committee, where she worked as a senior specialist of Pharmacopoeia Department. Then she started to work as a Head of Regulatory Affairs specialist for the domestic manufacturer of generic and herbal products - "Biopolus" Ltd (Georgia), along with it she was consulting Georgian wholesaler "GPC" about pharmaceutical products registrations of pharmaceutical products in Georgia and different companies; clinical researches and manufacturing technology. She had been a participant of numerous scientific conferences, including those conducted by WHO. She has published more than 20 scientific papers.

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