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Comparison of regulatory requirements for marketing authorization of biologics in United States and European Union

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The aim of the present study was to compare regulatory requirements for the approval of biological products in United States (US) and European Union. USFDA (United States Food and Drug Administration) and EMEA (European Medicines Evaluation Agency) were the regulatory agencies which are responsible for safety regulation of the food and drug products in US and Europe. All biologic medicinal products must be approved by the respective regulatory agency governing the respective market before a particular product can be introduced into the market. The fundamental differences identified during the study between United States and European Union. In US, biologics are regulated as per the Food, Drugs and Cosmetics Act, 1938, and the Public Health Service Act, 1944. The Biologics License Application (BLA) is a request for permission to introduce, for introduction, of a biologic product into interstate commerce (21 CFR 601.2). Quality of biological products in European Union is regulated in accordance with the scientific guidelines issued by Committee for Medicinal Products for Human use (CHMP). Based on our comparison, regulation in all countries are almost similar, however between country to country some differences exist due to regional reasons or language differences. To rectify the difference of the dossier formats, we need to go for harmonizing the dossier format so that we can expect the quality of drug product worldwide. It can be concluded that by practicing the particular dossier requirements, the pharmaceutical companies not only comply regulatory requirement but also provide quality medicine with the needy and sufferers.

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