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Regulatory submissions for blood products at Saudi FDA

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Abstract

The Saudi FDA is a government administration that regulates food, drug, as well as medical devices, whether they are imported or locally manufactured. The drug sector oversees and controls human and veterinary medicines, and cosmetic products through constructive regulation policies and guidelines. The main purpose is to ensure the safety, quality, efficacy and availability of all medicines including pharmaceutics and biologics. Thereof, biological products or biologics are medicinal products derived from a variety of natural sources such as human or animal tissues, or microbiological origins, they were created with biotechnology and can be manufactured through diversity of biotech based-methods; they are complex in structure and not fully characterized, and mainly composed of sugar, protein, or nucleic acids or a combination of these substances, they may also be living entities. Like pharmaceutical products, biologics intended to prevent or treat diseases and medical conditions, and can be categorized into a wide range of medicinal products including vaccines, blood and blood components, allergenic extracts, immunosera, somatic cells, gene and cellular therapy, human cells and tissues, and biosimilars. However, biological products intended to be marketing in Saudi Arabia must obtain a marketing authorization approval. The approval for biological products can be achieved once the applications meet the requirements. The applications of biological products can be classified based on the purpose of the application, as follows: new registration, variation, and renewal. These applications shall go through multi steps process, which starts with the validation and ends with the final decision of approval of rejection. For that, the drug sector has developed and adopted many guidelines for industry of biological product. My goal is to provide an overview of this process in Saudi Arabia and share my experience with it.

Biography

Ali M. Alsamil has completed his Master's of biomedical laboratory science at the age of 27 years from Quinnipiac University and Bachelor's of science in biochemistry from King Saud University. He is specialist in blood bank and transfusion services. Currently, he is an assessor of blood products, a senior biomedical laboratory specialist, in the product evaluation and standards setting at drug sector, Saudi FDA.