Adriana Kiedzierska-Mencfeld, J Bioanal Biomed 2023, Volume 15

Adriana Kiedzierska-Mencfeld

Polpharma Biologics S.A., Poland

From development to commercial phase: A case study on Ranibizumab biosmilar

Approval of FYB201- ranibizumab product (Lucentis biosimilar) is key milestone for Polpharma Biologics, which is an international biotechnology company with integrated operations in the European Union (EU), developing and manufacturing biosimilar medicines. Using state-of-the-art platform technologies, Polpharma Biologics develops biosimilar products to treat a range of conditions in major therapeutic areas. Programs at Polpharma Biologics start in cell line development and transition through technical and clinical development to commercial-scale production, preparing drugs for future commercial partnerships with global pharmaceutical organizations. The company pipeline contains more than six biosimilars in different stages. FYB201 was developed by Bioeq, a Joint Venture between Polpharma Biologics and Formycon. The production of biosimilars is a process with high levels of scientific rigor and the approval of FYB201 (Ranivisio®, CIMERLI™ (ranibizumab-eqrn), is the culmination of years of dedication by Polpharma Biologics. Starting from technology transfer and process optimization, method transfer and then process validation, Polpharma Biologics actively participated in development of ranibizumab biosimilar. Currently being commercial manufacturer of drug substance ranibizumab, experienced transformation from development to commercial organization. FYB201 is highly similar to the reference product Lucentis® in terms of comparable efficacy, safety, pharmacokinetics and immunogenicity in patients with age-related neovascular (wet) macular degeneration. FDA-approval and interchangeability designation are based on a totality of evidence including analytical, nonclinical, clinical and manufacturing data. Manufacturing of product for various markets (e.g. UK, US, Europe) requires expertise in many areas, high level of GMP awareness and quality culture.

Biography

Adriana Kiedzierska-Mencfeld has more than 15 years' experience in recombinant protein chemistry and over 10 years' experience in biosimilars development and manufacturing. Working in Polpharma Biologics S.A. for over 8 years she has actively participated in development of biosimilars. Her career in Biosmilars she started from development than moving into production for clinical trials and currently being in commercial phase. As a part of the site leadership team, she has participated in several GMP inspections, customer audits and successfully passing the FDA-PLI (Pre-License Inspection) inspection, gaining experience in a regulated environment. Going through various phases of the product life cycle, she participated in the preparation of registration dossiers for various agencies, as well as in the product approval process. Currently, as a Member of the Management Board and Head of the Polpharma Biologics Branch in Gdańsk, she is responsible for all operations in Gdańsk, managing over 500 employees. Her focus is team building, people development and knowledge sharing.

Received: January 29, 2023; **Accepted**: January 31, 2023; **Published**: April 03, 2023