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JOINT EVENT

14th International Conference on Generic Drugs and Biosimilars 8 9th Global Experts Meeting on Neuropharmacology

November 15-16, 2018 | Berlin, Germany

Comparison of stelara biosimilar with originator using a PK ELISA

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Psoriasis is a chronic inflamatory condition affecting 2-4% of human population. Scientific evidence suggests that it is an autoimmune disease caused by a combination of genetic and environmental factors. Psoriasis manifests itself as skin inflammation and scaling however; it may also lead to arthritis and death. Though incurable, it can be effectively treated with topical agents (e.g. steroids), phototherapy and systemic drugs like Stelara. In this study we used our highly sensitive PK ELISA for the comparison between Stelara originator and biosimilar. The applied approach was based on Marini, et al. publication from 2014. The `single assay setup` (both compounds tested on the same plate) that we have chosen proved to be suitable and sufficient to properly evaluate the biosimilar in reference to the originator. Total three main parameters have been tested: standard curve overlap, precision and accuracy of QC samples. All these parameters met the pre-defined acceptance criteria thus proving the similarity between tested biologics.

Biography

Arkadiusz Wyrzucki has completed his PhD at University of Zurich in Molecular Virology. After his studies, he started to work as a Scientist at Humabs BioMed where he was selecting therapeutic antibodies. Currently, he is a Senior Scientist at Celerion Switzerland where he develops assays for pre-clinical and clinical studies.

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