Cecil Nick, J Bioanal Biomed 2018, Volume 10
DOI: 10.4172/1948-593X-C1-038

11th EUROPEAN BIOSIMILARS CONGRESS

April 26-27, 2018 Rome, Italy

Meeting the challenges of gaining marketing approval of biosimilars across the globe

Cecil Nick
PAREXEL International, UK

This presentation addresses the challenges sponsors face in developing biosimilars for the global market amidst a myriad of varying regulatory requirements. Differences in approach between CHMP and FDA will be considered with respect to the impact of variances in the regulatory frameworks and conflicting quality and clinical data requirements. Consideration will then be given to the need for inclusion of local patients in order to gain regulatory marketing approval as is the case for example in China, Japan, Russia and India. Also in some regions there is the need compare the biosimilar against reference product sourced from specific regions at the quality and sometimes the clinical level. The timings for clinical trial approval and potential for interaction with regulatory authorities in order to seek feedback on the suitability of the proposed development program will also be discussed.

Biography

Regulatory affairs professional for over 30 years. Has particular expertise in monoclonals and biosimilars, having worked on over 20 such programs, engaged in over 50 interactions and meetings with regulatory agencies in the EU, US, Canada, Australia, Mexico, Brazil and supported 6 submissions in the EU and US. He has also participated extensively in Industry and International meetings on the subject. Prior to joining PAREXEL, Cecil served as Regulatory Manager at Novo Nordisk Ltd. Fellow of TOPRA and has been a guest lecture at Cardiff University MSc in Clinical Research and Greenwich University MSc in Pharmaceutical Sciences courses and Biotech Module leader for the TOPRA MSc course. He was on the editorial panel of SCRIP Clinical Research and has authored many articles on regulatory and clinical development issues. Holds BSc (Hons) in Biochemistry from the University of Cape Town.

cecil.nick@parexel.com

Notes: