Chirag Shah, J Bioanal Biomed 2014, 6:2
http://dx.doi.org/10.4172/1948-593X.S1.013

OMICS Group Conferences
Accelerating Scientific Discovery

3rd International Conference and Exhibition on
Biowaivers, Biologics & Biosimilars

October 27-29, 2014 Hyderabad International Convention Centre, Hyderabad, India

Challenges and its resolutions in the conduct of biosimilars clinical development

Chirag Shah
Cliantha Research Ltd., India

Biosimilars offer big opportunities in the global market but with associated great challenges. In reality, the complex molecular structure of biosimilars presents difficulties in the development and subsequently in the regulatory approval. In his presentation, the author would like to highlight the scientific, clinical, regulatory and operational requirement and challenges for the clinical development. He will also cover pharmacokinetic and pharmacodynamic study requirements, its design, endpoint selection and its correlation with efficacy. Moving forward to Phase III trial, target indication, disease mapping for availability of target population, statistical consideration, end point selection, duration of the study, immunogenicity and safety consideration will also be discussed.

After this design, the major challenges lies at the operational front and will provide overview about requirement of trained site, team and investigators, site infrastructure, country specific regulatory environment, competing studies, budgetary expectations, patient compliance and follow up in the large is also of paramount importance for the success of the trial. Along with that, another important aspect is to map competitor's activities and their progress. Ultimately being generic molecules, expectation of the organizations are very quick and high, from the returns on investment and revenue perspective, compare to other NCEs or NBEs, where the horizon is broad. Hence, it is imperative to understand the challenges upfront and work towards the resolutions of those challenges.

Biography

Chirag Shah has rich experience of more than 15 years in multidisciplinary area of Product development in Pharmaceutical, Biotech companies and in Clinical Research Organisation (CRO). His expertise includes in Set up of new department, Global Project Management (Discovery & Clinical-Phase I-IV), Preclinical drug development, Regulatory affairs, Medical Services, Pharmalicensing, Financial Management, System development, Business Development and Marketing. Prior to joining Cliantha Research, he has worked with leading Indian companies such as Cipla, Intas, Alembic, Nicholas Piramal and SIRO Clinpharm. He gained his PhD in Pharmacy from Saurashtra University, Rajkot, India. He is also specialized in the Pharmaceutical Management (PGDPM) from IES's Management College and Research Centre, Mumbai with special focus on Marketing, Operation and Finance. He is an associate member of American College of Clinical Pharmacology (ACCP), American Society of Clinical Oncology (ASCO), Life member of Indian Pharmacological Society (IPS) and Drug Information Association (DIA).

cshah@clianthatrials.com