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Regulatory frame work for biosimilar monoclonal antibodies

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The objective of this paper is to facilitate regulatory requirements for the approval process of Biosimilar Monoclonal antibodies (mAb) in Regulated and Emerging markets. Biosimilars are biological products that are the replicas of their innovator biopharmaceuticals. Monoclonal antibodies have been established as a major product class of biotechnology-derived medicinal products. Specified regulations, and approval process of generic version of mAb exists depending on the country. In European Union, Centralized Procedure is mandatory for Biosimilar (mAb). When compared with other countries EMA (European medicines agency) has proper regulations pertaining to Biosimilar mAbs. In US proper set of guidelines for Biosimilar (mAb) have evolved after "Promoting Innovation and Access to life-saving Medicines Act" introduced, authorized USFDA to approve follow-on biologics/biosimilars in an abbreviated manner. The approval process is abbreviated biosimilar biologics license applications (bBLAs) or 351(k) filings. In India, the product is under new drugs, and follows the Biological drugs submission requirements. In India, apart from Central Drugs Standard Control Organization (CDSCO), the office of Drug Controller General of India (DCGI) the apex regulatory body under Government of India (GoI), two other competent authorities are involved in the approval process of biosimilars or Similar Biologics products (SBPs). It is a big difficulty to Biosimilar mAb potential producers to fallow different approval processes and regulations in different regions. This paper concludes that there is a need that ICH/WHO should come forward and lay down proper and specific regulations for these products.

Biography

I K.Sreekanth Reddy, studying m.ph first year regulatory affairs in jsscp, Mysore. I completed my B.ph at Victoria College of pharmacy, Guntur .I given poster presentation on 63rd IPC held at Bangalore.

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Electronic data capture: Breaking down the barriers in clinical research

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Electronic Data Capture, EDC, a pioneering technology, was a backbone designed to allow all clinical data services to speak to each other. Electronic Data capturing is a flexible tool used by pharmaceutical company to accelerate time to market drug and extend their window of opportunity for realizing revenue ($400 million are used for clinical data acquisition).EDC is intuitive for capture, analysis and reporting of data. The main advantages of EDC are it shortens trial times, connecting teams which enables quick query resolution, discrepancy management and finally fast database lock. 21 CFR part 11 312,314 provides us the regulatory basis for electronic documentation ie., records and signatures. The e-DM Vision (electronic Data Management) entails "3A" which includes Acquisition, Aggregation & Access of data. EDC also helps in archiving of data in persistent and permanent forms for many years. It's role can be extended to pharmacovigilance also for capturing adverse events.EDC training to site staff can be given and assessed by UAT(User Acceptance Test).In this fast growing world with advancing technology, EDC has to be given importance both in academia and industry. The present topic gives an idea of e-DM Vision, and how the EDC trials works in cohesion and different EDC systems used by various vendors and how effective are the EDC trials compared to paper based trials.

Biography

K.Sri Geetha has completed her B.Pharm in Vishwa Bharathi College Of Pharmaceutical Sciences, Guntur. Qualified in GPAT_2011, at present pursuing her M.Pharm (pharmacology) in Jawaharlal Nehru Technological University, Kakinada. Her areas of interest are Clinical Research, Regulatory Affairs and Drug Discovery.

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