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Biosimilars development - Overview

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Biosimilars are increasingly being developed by many companies and used as therapeutics for various diseases worldwide. There is a lot of scope to improve in biosimilar story. Biosimilar products are approved through stringent regulatory pathways in highly regulated markets such as the US, EU, Japan, Canada and Australia following loss of exclusivity of their originator reference product. The development of biosimilar product possesses various challenges such as comparable quality, safety and efficacy to a reference product in addition to other challenges in product development from laboratory to manufacturing scale. Biosimilar from process development, pre-clinical trials and clinical trials up to fill finish meets number of challenges. Quality attributes of monoclonal antibody or bio therapeutic proteins are highly affected by both process and product related impurities. There should be an efficient upstream as well as downstream process to overcome all the bottlenecks and establishing appropriate standards for biosimilarity remains an important area for scientific, legislative and regulatory debate. Cost-effective manufacturing process is a key factor to deliver a biosmilar product into the clinic and the clinical performance of biotherapeutics are highly influenzed by manufacturing process. The key factors help in reducing the cost includes the overall manufacturing process time, high titer producing cells, less number of purification steps, higher recovery and yield of clinically active product. Manufacturing process should be consistent & highly robust. The process includes modern QC & QA procedures, in-process control & process validation. Most importantly, manufacturing process should meet the same standard of originator products and the originator product should be extensively studied during the biosimilar product development. Single use technology applications should be evaluated thoroughly before initating the uses in a manufacturing facility. The manufacturing processes should be clearly defined, controlled and validated to ensure compliance, clear records, and any deviations found, that should be investigated and well documented. Manufacturer comprehensively design the production process taking all relevant guidelines into account. I would like to give an overview on biosimilar development espcially the manufacturing process starting from the laboratory and current scenario. My discussion is intended for audience from biopharma industry as well as active collaborators from various institutes and universities.

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