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Bio-similar development and production

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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. Bio-similar 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. I would like to give an overview on biosimilar development in various countries and current scenario. My discussion is intended for audience from biopharma industry as well as from active collaborators from various institutes and universities.

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XTEN – A biodegradable alternative to PEG enabling biopharmaceuticals with precisely controlled structure

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PEGylation is commonly used to generate long-acting biologics (Bio-betters). However, there are increasing concerns about the safety of PEG resulting from its resistance to being metabolized resulting in the accumulation in various organs including the kidney and brain. PEG is further limited by its poly-dispersity as well as an increasing risk of pre-exposure caused by the use of PEG in many cosmetics. Amunix has developed XTEN, a protein-based polymer that mimics the biophysical properties of PEG. XTEN is easily metabolized, thereby eliminating the risk of tissue accumulation. Proteins and peptides can be genetically fused to XTEN in a precisely controlled locations to increase biological half-life. XTEN polymers can also be produced by large scale microbial fermentation enabling chemical conjugation similar to PEGylation. XTEN has been successfully applied to a wide range of bio-therapeutics and the most advanced product, human growth hormone-XTEN, VRS-317, is currently in late stage clinical testing.

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