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Systematic shortlisting of candidate molecules and biosimilar/biobetter product development: An undergraduate research effort

Balram Pani, Pooja Gupta, Ranjeet S Thakur, Avneesh Mittal, Purnima Anand, Deepika Bhaskar and Uma Chaudhry
Bhaskaracharya College of Applied Sciences- University of Delhi, India

Pioneered at Stanford University in the 1970s, the recombinant DNA technology has made possible the modern biopharmaceutical industry. Biotherapeutics have revolutionised the treatment of various life-threatening and chronic conditions, but they are very expensive and therefore remain out of the reach of millions across the world. As these products lose patent protection, follow-on biologics like biosimilars and biobetters are poised to drastically expand patient access by increasing affordability. India, already home to a robust generics industry, also has multiple players developing as well as manufacturing biosimilars for both the domestic and global markets. In order to identify potential biotherapeutics for biosimilar development, we manually annotated the US-FDA CDER and CBER lists, extracted biologics with therapeutic applications in humans, classified these on the basis of their patent status and biomolecule categories, and then checked which ones had comparable biosimilars in the Indian market. Since the objective was to use a microbial expression system, we further eliminated products with extensive post-translational modifications, and arrived at enzyme candidates like asparaginase, collagenase, and monoclonal antibody candidates like Ranibizumab. Asparaginase, indicated for the treatment of acute lymphoblastic leukemia, was expressed in *E. coli*, purified and was assayed in the CEL and Kasumi cell lines. Its physicochemical biosimilarity with the reference product was also established. In the next phase of our study, cysteine-specific PEGylation of the ranimizumab Fab' fragment (expressed in *E. coli*) would be carried out in an attempt to develop a biobetter version of the same (PEGylation improves efficacy, stability and antigenicity).

Biography

Balram Pani, the Principal of Bhaskaracharya College of Applied Sciences, is also a faculty in the Department of Chemistry, University of Delhi. He obtained his PhD from Jawaharlal Nehru University. He has 20 years of research and teaching experience in the field of Chemistry and Environmental Science. He has also authored various books on Environmental Science and Engineering Chemistry, which have been adopted by several universities, and Engineering and Science Colleges.

chaudhry.uma@gmail.com

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