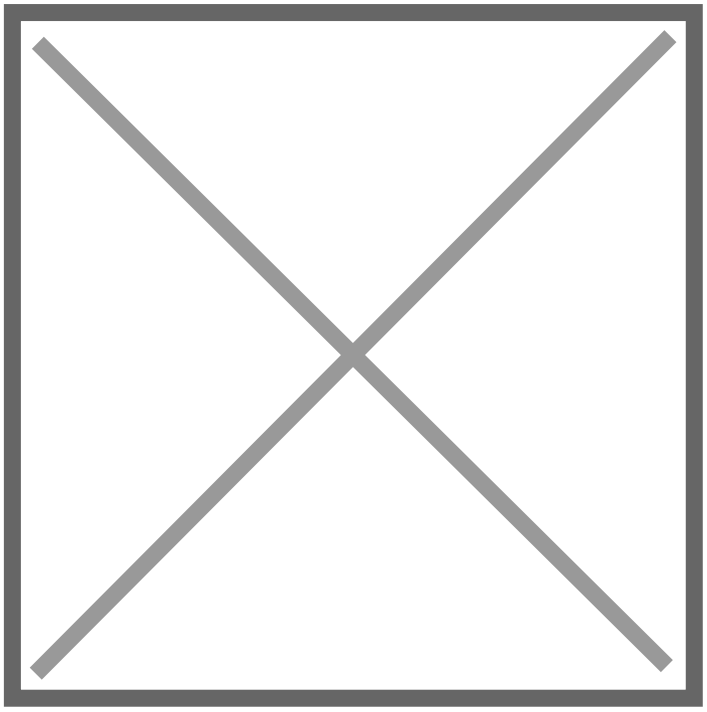
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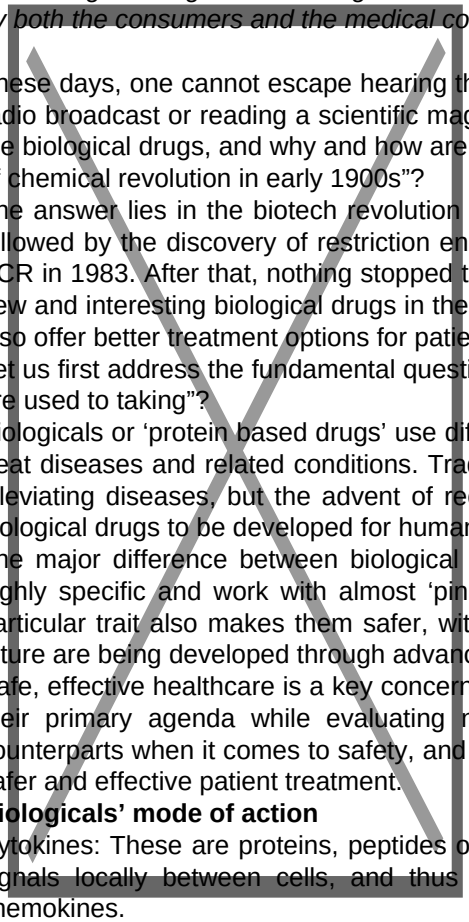
Biological drugs making a difference

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Biological drugs making a difference

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These days, one cannot escape hearing the word, ‘biotechnology’ or ‘biological drugs’ while watching television, listening to a radio broadcast or reading a scientific magazine or a newspaper. One often wonders, “what has biotechnology got to do with the biological drugs, and why and how are they different from the drugs we normally have been taken for years since the start of chemical revolution in early 1900s”?

The answer lies in the biotech revolution that took roots in 1953 with the discovery of DNA structure by Watson and Crick, followed by the discovery of restriction enzymes and hybridoma technology two decades later, coupled with the invention of PCR in 1983. After that, nothing stopped the biological revolution which grew by leaps and bounds, and has given us several new and interesting biological drugs in the last two decades. These drugs not only have made a big difference in our lives but also offer better treatment options for patients than before.

Let us first address the fundamental question, “What are biological drugs and how are they different from the normal drugs we are used to taking”?

Biologicals or ‘protein based drugs’ use different proteins that occur naturally in any living organism, to diagnose, prevent and treat diseases and related conditions. Traditionally, proteins have been isolated from plant and human sources and used for alleviating diseases, but the advent of recombinant DNA technology has enabled large-scale production of these futuristic biological drugs to be developed for human health care.

The major difference between biological drugs and chemical-based normal prescription drugs is that biological drugs are highly specific and work with almost ‘pinpoint’ accuracy to treat the diseased organs or cells that require treatment. This particular trait also makes them safer, with little side effects, when compared to chemical-based drugs. These drugs of the future are being developed through advanced technology called genetic engineering or recombinant DNA technology.

Safe, effective healthcare is a key concern worldwide. The drug regulatory agencies across the globe keep safety of drugs as their primary agenda while evaluating new drug candidates. The biological drugs have an edge over their chemical counterparts when it comes to safety, and have been largely accepted by both the consumers and the medical community for safer and effective patient treatment.

Biologicals’ mode of action

Cytokines: These are proteins, peptides or glycoproteins that are secreted by specific cells of the immune system and carry signals locally between cells, and thus have an effect on other cells. The list includes lymphokines, interleukins and chemokines.

Clotting factors: These are proteins that regulate the clotting of blood and help in maintaining internal homeostasis. These drugs are used to treat blood clotting disorders like hemophilia.

Vaccines: These are proteins that provide immunity to a particular disease by stimulating the production of specific antibodies thereby, preventing or treating the disease.
Monoclonal antibodies: These antibodies are monospecific antibodies and are so called because they are produced by one type of immune cell that are all clones of a single parent cell. These antibodies are very specific to their target such as cancer cells, disease-causing bacteria and viruses for their destruction by other components of the immune system.
Bio-therapeutics: Proteins that interact to inhibit or augment the activity of disease causing enzymes/proteins.
Few of the examples of biological drugs include insulin, G-CSF, Erythropoietin, GM-CSF and a variety of monoclonal antibodies for transplant rejection (Muronomab-CD3, Daclizumab, Basiliximab), cardiovascular disease (Abciximab) and cancer (Rituximab, Trastuzumab (Herceptin) Gemtuzumab ozogamicin, Alemtuzumab, Cetuximab and Bevacizumab).
Monoclonal antibodies are by far the most used of all the biological drugs today. These antibodies have been made in such a manner that they can bind to a specific target and, thus, can be used to treat disease-specific cells and tissues in a safe and effective manner with fewer side effects. One of the initial disadvantages of therapeutic monoclonal antibodies was that they triggered immune reaction causing production of HAMA (human anti-mouse antibodies) in human subjectCellular Subscriber Bases. This was because the monoclonal antibodies were made with mouse Fab and Fc region. However, this was overcome by the production of chimeric antibodies wherein the constant Fc portion was replaced with the human's while keeping the hyper variable regions from mouse, thus reducing the immune reaction. Currently, fully humanized antibodies are also being developed for certain treatments although they are not required for all disease or disease related conditions.

Are biologicals really safe?
Although biological drugs present a safe and efficacious form of treatment, they suffer from a number of disadvantages. The disadvantages are: (i) higher cost compared to their chemical counterparts, (ii) batch to batch variability in production, (iii) drug delivery mechanism (mostly injectable) as they can't be orally taken as chemical drugs and (iv) sometimes biological drugs have rare side effects that can be severe and life-threatening.

What future holds?
In spite of the disadvantages, biologicals present a gr eat promise for the future of medicine. These are drugs of the future. To the patient, one of the most important advantages of being treated with these biological drugs is the improvement in their quality of life.
The biggest concern of patients when it comes to healthcare is cost. Biological drugs are currently costly, but will and can become cheaper in future with the improvements in manufacturing capabilities by enhancing production and eliminating downstream process purification steps. The recognition of these drugs' potential benefits has put them on the fast track for FDA approval. The day is not far when biologicals would overtake their chemical counterparts in terms of the number of drugs approved and being in use.

The Indian scenario
The development of biologicals in the western world is on the fast track. India needs to wake up to this challenge and start investing in new drug discovery in the area of biologicals. India has been a successful generic player in the field of small molecule drug discovery, and is currently focusing on development of biogenerics or biosimilars versions of the proprietary biological drugs. If India does not want to miss the biotech bandwagon, we (the industry, academia and the government) should seriously get together and start the process of identifying and developing novel bio-therapeutics. This is not only to put India on the map of new drug discovery but also to develop cost-effective treatments for our own country.
We at Premas Biotech are trying in a small way to help in this cause. Premas has invested in and developed a platform technology to discover novel biological drugs for Alzheimer's disease and cancer. This technology is available for exploitation by pharma and biotech companies to develop novel biologicals.