

Biotherapeutics: An Overview **Chih-Chang Chu***

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Editorial

Biotherapeutics are a rapidly growing portion of the total pharmaceutical market accounting for almost one-half of recent new drug approvals. A major portion of these approvals each year are monoclonal antibodies (mAbs). During development, non-clinical pharmacology and toxicology testing of mAbs differs from that done with chemical entities since these biotherapeutics are derived from a biological source and therefore the animal models should share the same epitopes as humans to elicit a pharmacological response.

Biotherapeutics or biologicals are drug therapy products where the active substances are produced from a biological source. These products include recombinant proteins and hormones, cytokines, monoclonal antibodies (mAbs), growth factors, gene therapy products, vaccines, gene-silencing, cell-based products, tissue-engineered products and stem cell therapies. Many of the biotherapeutic molecules in development or recently approved are mAbs and these are considered the most rapidly growing drug class in anti-immunity, oncology and chronic inflammatory diseases.

A monoclonal antibody (mAb or moAb) is an antibody made by cloning a unique white blood cell. All subsequent antibodies derived this way trace back to a unique parent cell. Monoclonal antibodies are laboratory-produced molecules engineered to serve as substitute antibodies that can enhance, restore, or mimic the immune system's attack on cancer cells. They are designed to bind to antigens which are generally more in number on the surface of cancer cells than healthy cells.

moAbs can have monovalent affinity, binding only to the same epitope. Polyclonal antibodies bind to multiple epitopes and are usually made by several different antibody secreting plasma cell lineages. Bispecific monoclonal antibodies can also be engineered

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by increasing the therapeutic targets of one monoclonal antibody to two epitopes.

It is possible to produce monoclonal antibodies that specifically bind to virtually any suitable substance; they can then serve to detect or purify it. This capability has become an important tool in molecular biology, biochemistry and medicine.

moAbs are identical copies of an antibody that targets one specific antigen. Scientists can make monoclonal antibodies by exposing white blood cells to a particular antigen. They can then select a single white blood cell or clone and use this as the basis to produce many identical cells, making many identical copies of the monoclonal antibody.

Biotherapeutics have the ability to target specific molecules within the human body, and have a good track record with patient safety. Manufacturing biotherapeutics is complex, as they are larger compounds in both size and structure, and can be sensitive to environmental conditions. Moreover, they require sophisticated production and control processes and are dependent upon the host cells of living organisms to produce the necessary active pharmaceutical substances.