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Comparison of Conventional and Modern Approachs in the Development and Manufacturing of Monoclonal Antibodies

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Abstract

Monoclonal antibodies were discovered by Kohler and Milstein in early 1970s' and this discovery leads to an enormous revolution in the field of medicine. There are different manufacturing techniques of monoclonal antibodies such as hybridoma technology which is the most conventional method, phage display technology, transgenic mouse method and other transgenic organisms like plants and animals now a days under development. Hybridoma technique is considered to be the traditional technique which was used for the first monoclonal antibodies (mAbs) production in 1975. But new methods such as phage display and transgenic organisms are an advanced method which can be assured to produce mAb in less cost and in a faster rate compared to the hybridoma technique. Phage display technology can be used so as to obtain specific mAb yet against toxic antigens as it does not require any immunizations. Both hybridoma technique and phage display method is continued by in vitro or in vivo method. The monoclonal antibodies manufactured can be murine mAb which is made up of 100% mouse protein, chimeric mAb which is made up of 30% mouse protein, humanized mAb which is made up of 10% mouse protein or less and 100% fully human mAbs. An approval of mAbs needs regulatory bodies like food and drug Authority (FD) which requires undergoing various phases and clinical trials. Already approved mAbs are recommended and available in the market. Monoclonal antibodies play a vital role in diagnostics, research and therapeutic uses. Monoclonal antibodies are highly preferable in contrast to polyclonal antibodies as they are very specific by their nature. Therefore, this review provides an insight to the current state of art in development, manufacturing and preparation of mAbs particularly with regard to the ability to manufacture antibodies in an economically viable manner.

Monoclonal Antibodies are cells derived by cell division from a single ancestral cell.Monoclonals are a class of antibodies with identical offspring of a hybridoma and are very specific for a particular location in the body derived from a single clone and can be grown indefinitely. Monoclonal Antibodies recognize and bind to antigens in order to discriminate between specific epitopes which provides protection against disease organisms.

Monoclonal antibodies target various proteins that influence cell activity such as receptors or other proteins present on the surface of normal and cancer cells. The specificity of Monoclonal Antibodies allows its binding to cancerous cells by coupling a cytotoxic agent such as a strong radioactive which then seek outs to destroy the cancer cells while not harming the healthy ones.

Tumor cells that are able to replicate endlessly are fused with mammalian cells that produce a specific antibody which result in fusion called hybridoma that continuously produce antibodies. Those antibodies are named monoclonal because they come from only 1 type of cell, which is the hybridoma cell. Antibodies that are produced by conventional methods and derived from preparations containing many kinds of cells are called polyclonal Antibodies.

Monoclonal antibodies are artificially produced against a specific antigen in order to bind to their target antigens. Laboratory production of monoclonal antibodies is produced from clones of only 1 cell which means that every monoclonal antibody produced by the cell is the same.

Fusion of cell culture myeloma cells with mammalian spleen cells antibodies result in hybrid cells/hybridoma which produces large amounts of monoclonal antibody. The cell fusion resulted in two different types of cells, one with the ability to grow continually, and the other with ability to produce bulk amounts of purified antibody. Hybrid cells produce only 1 exact antibody that is more pure than polyclonal antibodies produced by conventional techniques. Monoclonal Antibodies are far more effective than conventional drugs since drugs attack the foreign substance & the body's own cells that cause harsh side effects & the monoclonal antibody only targets the foreign antigen/target molecule, without or only minor side effects.

The presence of a large amount of a specific monoclonal antibody in the blood means that there is an abnormal protein. Typically this protein can be detected during a physical examination and is identified using a screening blood test called "protein electrophoresis. The source of abnormal production of monoclonal antibody is a small population of plasma cells in the bone marrow.

Process by which bulk quantities of targeted antibodies against a specific antigen are produced .Monoclonal antibodies are produced via multiple/identical copies of a certain cell called a hybridoma. To create Hybridoma cells the fusion of 2 cells are needed in order to combine the characteristics of the 2 cells into 1 cell. 1 of the cells is a producing cell antibody which is a B-Lymphocyte used from a laboratory mouse and the other is a tumor cell named myeloma. Tumor cells have the ability to grow indefinitely and at an exceeding rate from normal cell growth. Laboratory produced Hybridoma cells replicate much faster than normal antibody producing cells, and the individual

hybridoma produce the specific antibodies for an indefinite period of time.

Hybridoma cells manufacture the specific monoclonal antibody that was originally produced by the B-Lymphocyte cell. The original B-Lymphocyte cell will produce the Monoclonal antibody depending on the kind of antigen that was injected into the mouse just prior to the harvesting of the B-Lymphocyte cells. A small example is, if the mice were injected with a certain virus, the mouse will have B-Lymphocytes that produce those specific virual antibodies.