Research & Reviews in Pharmacy and Pharmaceutical Sciences e-ISSN:2320-1215

Biotechnology in Pharmaceutical Production

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Commentary

Received: 03-Jan-2022, Manuscript No. JPPS-22-51487; **Editor assigned:** 05-Jan-2022, PreQC No. JPPS- 22-51487 (PQ); **Reviewed:** 17-Jan -2022, QC No JPPS- 22-51487; **Revised:** 20-Jan-2022, Manuscript No. JPPS-22-51487 (R); **Published:** 27-Jan-2022, DOI: 10.4172/2320-0189.11.1.004

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DESCRIPTION

Biotechnology is frequently used in modern pharmaceutical manufacturing processes. The use of recombinant DNA technology to transform *Escherichia coli* bacteria to manufacture human insulin, which was done at Genentech in 1978, is one of the early biotechnology applications in pharmaceutical manufacturing. Insulin was collected from the pancreatic glands of cattle, pigs, and other agricultural animals prior to the advent of this technology. While animal-derived insulin is generally effective in the treatment of diabetes, it is not indistinguishable from human insulin and can cause allergic reactions in some people.

Artificial genes were created by Genentech for each of the two protein chains that make up the insulin molecule. The fake genes were "then introduced into plasmids among a set of lactose-activated genes". Lactose activated the insulin-producing genes as a result, the bacteria were "driven to manufacture 100,000 molecules of either chain A or chain B human insulin" after the recombinant plasmids were put into them. After that, the two protein chains were joined to make insulin molecules.

A chemically produced DNA 'adaptor' fragment with an ATG start codon..." follows. The codons for the first through 23rd amino acids in human growth hormone were used to generate. "Two DNA fragments joined to generate a synthetic-natural 'hybrid' gene," according to the researchers due to the considerable length of the amino acid sequence in human growth hormone, using purely synthetic methods of DNA manufacture to develop a gene that could be translated to human growth hormone in *E. coli* would have been extremely time consuming. However, if the DNA for human growth hormone was directly placed into the plasmid introduced into *E. coli*, the bacteria would translate parts of the gene that are not translated in humans, resulting in a "pre-hormone containing an extra 26 amino acids" that would be difficult to remove.

Human blood clotting factors were previously manufactured from donated blood that had been inadequately screened for HIV before the invention and FDA approval of a method to produce those using recombinant DNA technologies. As a result, HIV infection posed a major risk to haemophilia patients who received human blood clotting factors: According to most estimates, 60 to 80 percent of haemophilia patients who were exposed to factor VIII concentrates between 1979 and 1984 are HIV seropositive using the Western blot assay. More than 659 people with haemophilia had AIDS as of May 1988.

Since blood clotting factors are created by the human liver, the known sequence of Factor IX RNA was utilised to search for the gene coding for Factor IX in a library of DNA discovered in the human liver: A novel oligonucleotide was generated and tagged that was homologous to Factor IX mRNA. A human liver double-stranded cDNA library was screened using the resulting probe complete two-stranded DNA sequences. The full COOH-terminal coding sequence of the eleventh codon and the whole 3'-untranslated region were found in cDNA.

Plasmids encoding the Factor IX gene, as well as plasmids harbouring a gene that codes for methotrexate resistance, were transfected into Chinese hamster ovary cells. The insertion of DNA into a eukaryotic cell is known as transfection. Transfected DNA is not normally integrated into the cell's genome, and hence is not usually passed on to later generations *via* cell division, unlike the comparable process of transformation in bacteria. As a result, in order to achieve a "stable" transfection, a gene that offers a large survival benefit must also be transfected, causing the few cells that did integrate the transfected DNA into their genomes to multiply as cells that did not integrate the DNA are killed. "Growth in increasing doses of methotrexate" enhanced the survival of stably transfected cells while reducing the survival of other cells in this investigation. Stably transfected Chinese hamster ovary cells produced significant amounts of Factor IX, which was demonstrated to have significant coagulant capabilities, though to a smaller extent than Factor IX produced from human blood.

Recombinant DNA techniques have also been employed to create transgenic farm animals that can produce pharmaceutical products for use in humans. For instance, pigs that produce human hemoglobin have been created. While blood from such pigs could not be employed directly for transfusion to humans, the hemoglobin could be refined and employed to manufacture a blood substitute.