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Biopharming: The Next Frontier in Pharmaceutical Production

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Introduction:

Biopharming is a method of producing recombinant proteins such as pharmaceutical substances for treatment or prevention of human disease or biomaterials for therapeutic purpose by use of genetically engineered animals or transgenic animals. Transgenic livestock that produce recombinant proteins in their milk can provide an economic and safe system for production of valuable proteins for medical use. Thousands of years of animal breeding have yielded domesticated varieties of cows, sheep, and goats that produce prodigious volumes of milk. Dairy cows, for example, have a yearly milk output of about 10,000 liters, making it possible for a single lactating cow to produce tens of kilograms of therapeutic proteins. Relatively small herds of a few hundred lactating transgenic cows or goats can produce several hundred kilograms of purified protein per year.

The term ***pharming*** was coined to convey the idea that milk from transgenic farm ("pharm") animals can be a source of authentic human protein drugs or pharmaceuticals.

Main Requirements for Biopharming:

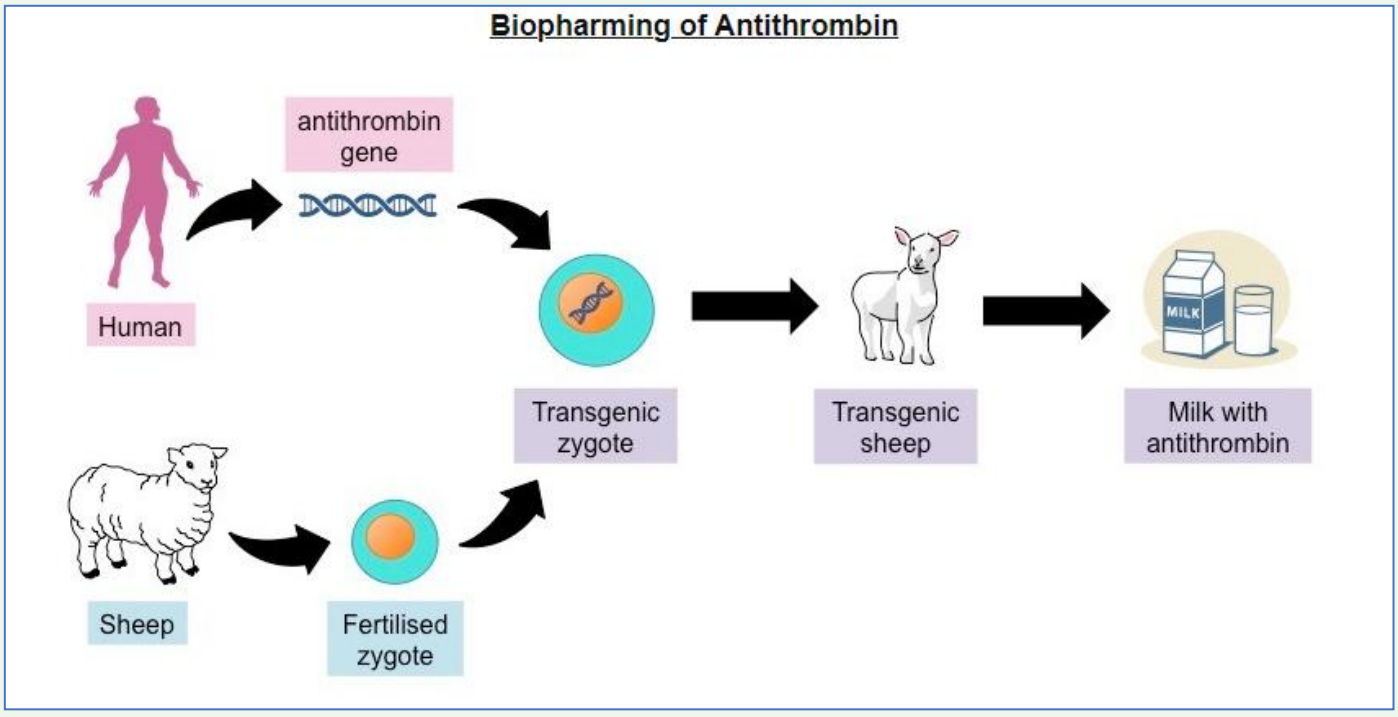
- Insertion of target genes into hosts (animals) that would not normally express those genes
- The desired compound can potentially be expressed in a form that is routinely harvested (e.g. milk, eggs etc)

Milk is a renewable, secreted body fluid that is produced in substantial quantities and can be collected frequently without harm to the animal. A novel drug protein that is confined to the mammary gland and secreted into milk should have no side effects on the normal physiological processes of transgenic animal and should undergo post-translational modifications that, atleast, match closely those in humans. Finally, purification of a protein from milk, which contains only a small number of different proteins, should be relatively straight forward.

Necessity For Biopharming:

i) For decades simple recombinant proteins, such as insulin and human growth hormone, have been produced in genetically engineered bacteria and yeast. But more complex proteins, such as blood clotting factors and monoclonal antibodies, cannot be produced in this manner because they have complex folding patterns and require the addition of sugar molecules to become biologically active. Only mammalian cells are capable of performing these sophisticated modifications.

ii) Although some complex therapeutic proteins can be manufactured in mammalian cell culture (e.g., Chinese hamster ovary cells), producing these substances in transgenic farm animals offers some advantages. Lactating female cows and goats can be induced to secrete the recombinant protein into their milk, from which it is readily purified. Examples of therapeutic proteins produced in the milk of farm animals include blood clotting factors, fibrinogen, and alpha-1-antitrypsin.



Challenges:

- **Unregulated Gene Expression:** The main technical challenge involved in animal biopharming is to ensure that the transgene coding for a therapeutic protein or vaccine is expressed only in the animal's milk and not in other tissues.

  Approach: Combine the gene for a therapeutic protein with a piece of regulatory DNA called a "promoter," which controls expression of the gene. This construct is then inserted into fertilized eggs from the production species, so that all progeny of the founder animal inherits it. Although the transgene exists in every cell of the animal's body, the promoter activates it only in the cells of the mammary gland, so that the pharmaceutical protein is secreted along with other milk proteins.

- **Time Taken for Expression:** The main drawback of biopharming in cattle is that it takes nearly three years from the transfer of a transgene into a single-cell embryo to the production of the protein in the milk of an adult female animal. For goats, the time interval between creation of a transgenic embryo and production of pharmaceuticals in the lactating adult is 16 to 18 months.
- **Biosafety Concerns:** The production of pharmaceuticals in the milk of transgenic farm animals has raised some biosafety concerns. First, because the expression of a transgene can be unpredictable, there is the risk that the protein product could "leak" from the mammary gland and enter the animal's blood circulation to cause harmful systemic effects. Another concern is that male animals produced through gene transfer, or unused transgenic females, could be slaughtered for food. In that case, meat contaminated with potentially harmful pharmaceuticals might enter the human food supply.

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