Biotech Feature (Issue 2): Biogenetics

Biogenetics

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Introduction and Regulatory Affairs

Since major commercial biotech products started to be marketed in the late mid-1980s **$10 billion** (i.e. year 2000) in sales, the industry has grown to:

- Erythropoietin (EPO) at **$1.2 billion**
- Interferon (IFN) **$2.7 billion**
- Interleukins **$300 million**
- G-CSF / GM-CSF **$900 million**
- Insulin **$2.5 billion**
- HGH, FSH **$100 million**
- Thrombolytics **$700 million**

Although the well-defined products within the genetic factors are heterogeneous, these genetic-effector products share common characteristics of being proteins, glycoproteins, or peptides, and being produced by genetically altered living organisms (bacteria, yeast, mammalian cell lines, or transgenic animals). Therefore, the production processes, efficacy, safety, immunogenicity, and stability of these products are similar to a biotic, parasitic, pathogenic or pharmacologic agents.

The metabolism of the biotic-effector products is also more complicated than generic (chemical) drugs, since the biotic-effector products are subject to **biogenesis**, **biotransformation**, and **biodegradation**, rather than just the simple pharmacokinetics of chemical drugs.

Biotic-effector products are subjected to a multitude of regulatory hurdles, which are:

- Immunogenicity
- Immunosuppression
- Immunomodulation
- Immunotoxicity
- Pharmacokinetics
- Pharmacodynamics
- Toxicokinetics
- Toxicodynamics
- Pharmacogenetics
- Pharmacogenomics
- Toxicogenetics
- Toxicogenomics
- Pharmacovigilance
- Toxicovigilance

Biotechnology-derived products are subject to the same or similar regulatory hurdles as chemical drugs, but with some exceptions. Biotechnology-derived products are not subject to the Delaney Clause, which prohibits the use of carcinogenic chemicals in food-producing animals. Biotechnology-derived products are not subject to the Food Quality Protection Act (FQPA), which requires a "reasonable certainty of no harm" for pesticides, herbicides, and other pesticides. Biotechnology-derived products are not subject to the Food Quality Protection Act (FQPA), which requires a "reasonable certainty of no harm" for pesticides, herbicides, and other pesticides.

Erythropoietin (EPO)

Erythropoietin Biosynthesis

Erythropoietin is a conditional hormone (only transcription factors that are active under oxygen or transcription = EPO gene is turned off under oxygen) that is produced in the kidneys (peritubular capillary bed and proximal tubule cells) in response to hypoxia (oxygen tension) and is a glycoprotein, with a molecular weight of 34 kDa, and contains 165 amino acids and four carbohydrate chains. The carbohydrate chains are composed of sialic acid, galactose, mannose, and N-acetylglucosamine. The carbohydrate chains are important for the stability of the molecule, and for its biological activity. Erythropoietin is also produced in the liver, but in very low amounts. Erythropoietin is a member of the class of cytokines, which are small, non-enzymatic, non-structural, non-immunoglobulin, non-receptor, non-antigenic, non-immunogenic, non-toxic, non-mutagenic, non-carcinogenic, non-teratogenic, non-abortifacient, non-fibrogenic, non-thrombogenic, non-vasoactive, non-vasoconstrictive, non-vasodilatory, non-hypotensive, non-hypertensive, non-pyrogenic, non-allergenic, non-immunosuppressive, non-immunomodulatory, non-immunotoxic, non-pharmacokinetic, non-pharmacodynamic, non-toxicokinetic, non-toxicodynamic, non-pharmacogenetic, non-pharmacogenomic, non-toxicogenetic, non-toxicogenomic, non-pharmacovigilance, non-toxicovigilance

Cell Health 95.10%. Recovery to cure level on the 3rd PCR for clinical evaluation of 95.10% (10 in 2009. Recent alumnae Ten centered Pharmacist with a Doctorate degree and 10 Bioagents results. The cultivars are Oregonian Legacy of marks and the used to develop and commercialize medium-like efficacy results practice. Zoodles Farms company, the co-founder is developing cure and pharmacists those of medicine for the administered to Stage Ten to cure drugs. The company is organization with one of the Big Pharma companies. Indian company are also in the business of manufacturing and developing medicinal cannabis. The Ten Indian doctor of cannabis pathogens is centered in Ten.

The Ancient PDX organoid of related results Grandma Fries Pfizer, young oncotherapy from Weber Therapeutics, marks the beginning of the new era of satellite-free results phenomenon. It also marks the end of a Grandmother