Chapter-13
Pharmacology & Toxicology

D.Pharma 2nd Year Notes

Chapter- 13

Biologicals

Definition, types and indications of biological agents with examples.

Video Class Dekhne Ke Liye QR scan Kare

Biologicals:

- Biologicals, also known as biologics, refer to medical products derived from living organisms or their derivatives.
- Biologicals, are those class of medicines which are grown and then purified from large-scale cell cultures of bacteria or yeast, or plant or animal cells.
- Biologicals are a diverse group of medicines which includes vaccines, growth factors, immune modulators, monoclonal antibodies, as well as products derived from human blood and plasma.
- What distinguishes biologicals from other medicines is that these are generally proteins purified from living culture systems or from blood, whereas other medicines are considered as 'small molecules' and are either made synthetically or purified from plants.
- This can include proteins, vaccines, gene therapies, and monoclonal antibodies, among others. Biologics are used to treat a wide range of diseases, including cancer, autoimmune disorders, and infectious diseases.
- They differ from traditional small-molecule drugs in their complexity and the manner in which they act on the body.

Sources Of Biologicals

- Mammalian cell cultue
- Humans
- Avian cell culture
- Mice
- Transgenics
- Insect cell culture

Steps Involved In Production:

1. **Develop Host:** A host cell is developed by isolating the DNA sequence that codes for the desired protein,
2. **Establish a Cell Bank:** A cell bank is then established using elaborate cell screening and selection process

3. **Protein Production System:** The "engineered" cells are then cultured on a large scale under growth conditions to optimize cellular production
4. **Purification:** Fractions containing the desired protein are harvested and isolated, and the undesired proteins and impurities are separate
5. **Analysis:** Protein molecules are analyzed for uniformity in terms of structure, character, and potency;
6. **Formulation:** Therapeutic protein is then formulated

Types of Biologicals:

There are several different types of biologicals, including:

1. **Proteins:** Examples include insulin for diabetes and erythropoietin for anemia.
2. **Vaccines:** These are used to prevent the spread of infectious diseases.
3. **Gene therapies:** These involve the introduction of a functional gene into a patient's cells to treat genetic disorders.
4. **Monoclonal antibodies:** These are laboratory-made molecules that mimic the immune system's ability to fight off harmful substances.
5. **Cell therapies:** These involve the transplantation of living cells into a patient's body to treat diseases or conditions.
6. **Toxoids:** These are toxins that have been made harmless and used as vaccines against certain bacterial diseases.
7. **Fusion proteins:** These are made by combining two different proteins to treat diseases such as arthritis and cancer.
8. **Recombinant DNA products:** These are produced using genetic engineering techniques and used to treat a range of conditions, including hemophilia and growth hormone deficiencies.

Indications of biological agents with examples:

Here are some indications for biological agents along with examples:

1. **Cancer:**
   - Monoclonal antibodies such as trastuzumab (Herceptin) are used to treat breast cancer.
   - Cell therapies such as chimeric antigen receptor T cell (CAR-T) therapy are used to treat certain types of blood cancers.
2. **Autoimmune disorders:**
   - Monoclonal antibodies such as adalimumab (Humira) are used to treat rheumatoid arthritis.
   - Fusion proteins such as etanercept (Enbrel) are used to treat psoriatic arthritis and ankylosing spondylitis.
3. **Infectious diseases:**
   - Vaccines such as HPV vaccine and influenza vaccine are used to prevent the spread of the respective diseases.
   - Monoclonal antibodies such as infliximab (Remicade) are used to treat viral infections such as hepatitis B and C.
4. **Hormonal deficiencies:**
   - Recombinant DNA products such as human growth hormone (HGH) are used to treat growth hormone deficiency.
   - Insulin is used to treat diabetes.
5. **Genetic disorders:**
   - Gene therapies such as lentiviral vector gene therapy are used to treat severe combined immunodeficiency.
   - Stem cell transplantation is used to treat genetic blood disorders such as sickle cell anemia.
6. **Neurological disorders:**
   - Monoclonal antibodies such as ocrelizumab (Ocrevus) are used to treat multiple sclerosis.
7. **Inflammatory disorders:**

- Fusion proteins such as infliximab (Remicade) are used to treat inflammatory bowel diseases such as Crohn's disease and ulcerative colitis.

8. **Allergic conditions:**

- Monoclonal antibodies such as omalizumab (Xolair) are used to treat severe asthma and allergic rhinitis.