

Biologicals

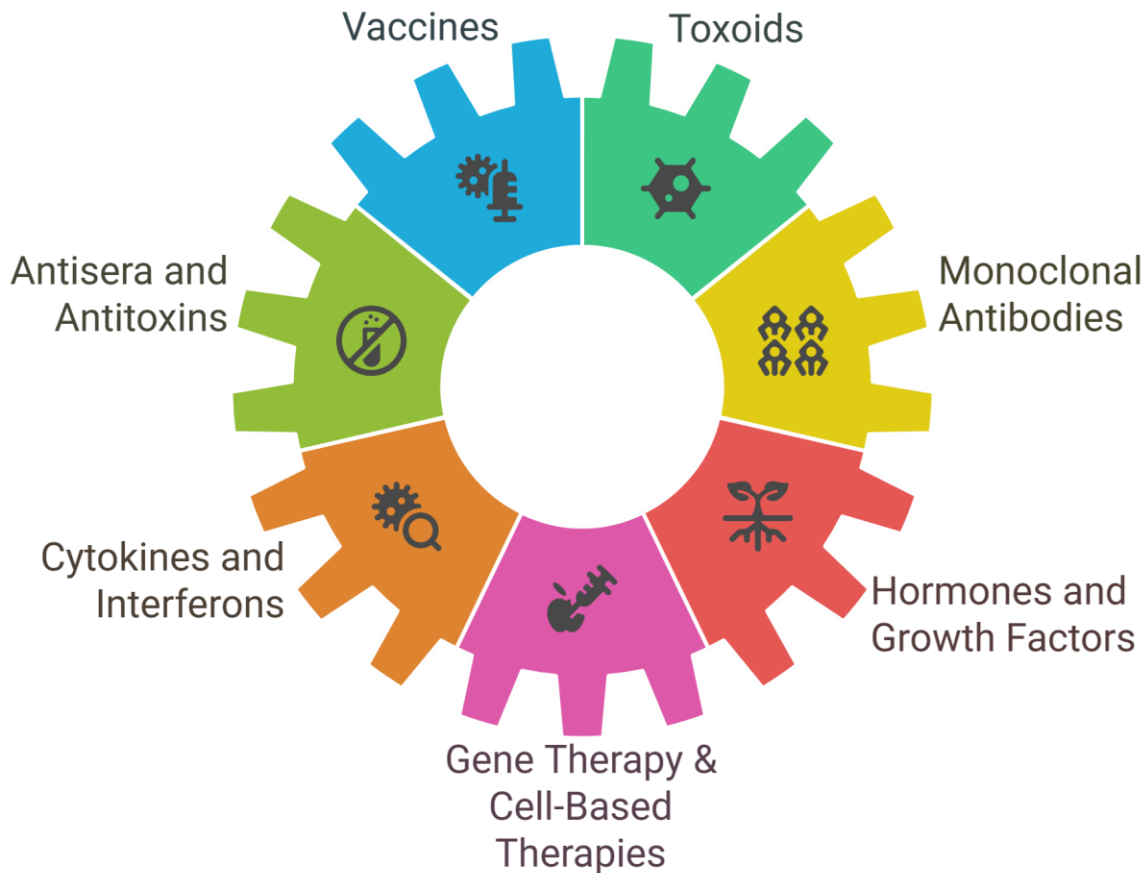
Biologicals: Definition & Types

Definition:

- **Biologicals (or biologic agents)** are therapeutic substances derived from **living organisms** (human, animal, or microbial sources) that are used to **prevent, diagnose, or treat diseases**.
- Unlike conventional drugs which are chemically synthesized, biologicals are **large, complex molecules or mixtures** that include proteins, nucleic acids, or living cells.

Types of Biological Agents:

Biologicals can be broadly categorized into the following:



1. Vaccines

- **Purpose:** Stimulate the immune system to develop immunity against specific infectious diseases.
- **Types:**
 - **Live attenuated vaccines** (weakened organisms) – e.g., MMR, BCG, oral polio
 - **Inactivated vaccines** (killed organisms) – e.g., Hepatitis A, rabies

- **Subunit/recombinant/conjugate** – e.g., Hepatitis B, HPV, Hib
- **mRNA vaccines** – e.g., COVID-19 mRNA vaccines (Pfizer, Moderna)

2. Toxoids

- **Purpose:** Inactivate bacterial toxins to prevent toxin-mediated disease.
- **Examples:**
 - Tetanus toxoid
 - Diphtheria toxoid

3. Antisera and Antitoxins

- **Purpose:** Provide **passive immunity** by giving preformed antibodies.
- **Examples:**
 - Anti-rabies serum (from equine or human sources)
 - Anti-tetanus serum
 - Anti-venom (snake, scorpion bites)

4. Monoclonal Antibodies (mAbs)

- **Purpose:** Target specific **antigens or receptors** in diseases like cancer, autoimmune disorders, and infections.
- **Types:**
 - **Murine (-omab):** Fully mouse-derived
 - **Chimeric (-ximab):** Mouse-human
 - **Humanized (-zumab):** Mostly human
 - **Fully human (-umab):** Entirely human
- **Examples:**
 - **Infliximab:** anti-TNF- α (used in rheumatoid arthritis, Crohn's)
 - **Trastuzumab:** HER2+ breast cancer
 - **Rituximab:** CD20+ B-cell lymphoma
 - **Adalimumab:** Fully human mAb for autoimmune diseases

5. Cytokines and Interferons

- **Purpose:** Regulate immune system or fight viruses/cancer.
- **Examples:**
 - **Interferon- α :** Used in hepatitis B/C, certain cancers

- **Interleukin-2 (IL-2):** Renal cancer, melanoma

6. Hormones and Growth Factors (biologically derived)

➤ Examples:

- **Insulin** (human recombinant)
- **Erythropoietin (EPO)** – anemia in CKD
- **Growth hormone (GH)** – growth disorders

7. Gene Therapy & Cell-Based Therapies

➤ **Advanced biologicals** using:

- **Genetically modified cells** (CAR-T cells for leukemia)
- **Gene editing tools** like CRISPR
- **Stem cell therapy** for tissue regeneration

Indications of Biological Agents

Biologicals are used in a wide range of conditions:

1. Infectious Diseases

- Prevention: Vaccines (e.g., measles, COVID-19)
- Post-exposure prophylaxis: Antisera (e.g., rabies, tetanus)

2. Autoimmune and Inflammatory Diseases

- Rheumatoid arthritis (e.g., Adalimumab, Etanercept)
- Psoriasis
- Inflammatory bowel disease (e.g., Infliximab)

3. Cancers

- Monoclonal antibodies (e.g., Trastuzumab, Rituximab)
- Immunotherapy (e.g., Nivolumab – checkpoint inhibitor)

4. Blood and Endocrine Disorders

- Anemia (Erythropoietin)
- Diabetes mellitus (recombinant insulin)
- Growth hormone deficiency

5. Organ Transplantation

- Immunosuppressive biologics (e.g., Basiliximab – IL-2 receptor blocker)

6. Rare Genetic Disorders

- Enzyme replacement therapy (e.g., Gaucher disease – Imiglucerase)



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