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DEPARTMENT OF BIOMEDICAL ENGINEERING

VII Semester

OBT357 BIOTECHNOLOGY IN HEALTH CARE

UNIT- 3 VACCINOLOGY

3.2 Conventional approaches to vaccine development

- Traditional vaccine development has historically relied on several established methods to induce immunity against infectious diseases. These approaches rely on manipulating pathogens (viruses or bacteria) or their components to stimulate an immune response without causing disease.

1. Live Attenuated Vaccines:

These vaccines use a weakened, or **attenuated**, form of the live virus or bacteria. The pathogen is made less virulent (disease-causing) through repeated culturing in a laboratory. The weakened pathogen still replicates in the body, which creates a strong and long-lasting immune response, often requiring only one or two doses. The immune response is very similar to what would be caused by a natural infection.

- **Examples:** Measles, mumps, rubella (MMR) vaccine, chickenpox vaccine, and the oral polio vaccine.

2. Killed (Inactivated) Vaccines

- These vaccines are made from a whole virus or bacteria that has been inactivated, or **killed**, using heat, chemicals, or radiation. The dead pathogen cannot replicate or cause disease, but its structure remains intact enough to be recognized by the immune system. Because the immune

response is weaker than with live vaccines, multiple doses or "boosters" are often required to maintain immunity.

- **Examples:** Inactivated polio vaccine (IPV), hepatitis A vaccine, and most flu shots.

3. Subunit Vaccines:

- These vaccines do not use the whole pathogen. Instead, they use a specific part of the pathogen, such as a protein, sugar, or a small piece of the virus's surface, that is highly effective at stimulating an immune response. They are very safe because they contain no live or killed virus parts that could cause disease.

- **Examples:** The hepatitis B vaccine (which uses a surface protein of the virus) and the HPV vaccine.

4. Toxoid Vaccines

- These vaccines are used to prevent diseases caused by bacteria that produce toxins (poisons). They are made from inactivated toxins, called **toxoids**. The toxoids are harmless but are still recognized by the immune system, which learns to neutralize the actual toxin if it encounters it later.

- **Examples:** Diphtheria and tetanus vaccines.

General Process of Conventional Vaccine Development:

1. **Pathogen Identification**: Identify the target pathogen and its immunogenic components (antigens).
2. **Antigen Preparation**: Attenuate, inactivate, or purify pathogen components using laboratory techniques (e.g., cell culture, chemical treatment, recombinant DNA).
3. **Preclinical Testing**: Test vaccine candidates in cell cultures and animal models to assess safety and immunogenicity.

4. **Clinical Trials**:
    - **Phase 1**: Small-scale trials to evaluate safety and dosage in humans.
    - **Phase 2**: Larger trials to assess immunogenicity and refine dosing.
    - **Phase 3**: Large-scale trials to confirm efficacy and monitor side effects in diverse populations.
5. **Regulatory Approval**: Submit data to regulatory bodies (e.g., FDA, EMA) for licensure.
6. **Manufacturing and Distribution**: Scale up production, ensure quality control, and distribute vaccines, often requiring cold-chain logistics.
7. **Post-Marketing Surveillance**: Monitor vaccine safety and effectiveness in real-world populations (Phase 4).

Limitations:

- Slow development process, less suited for rapidly emerging pathogens (e.g., pandemics).
- Some pathogens (e.g., HIV, malaria) are difficult to target due to complex biology or antigenic variation.
- Manufacturing can be costly and complex, especially for subunit and conjugate vaccines.

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