Current mode of protein vaccination production

Step 1: Generation of the antigen/ recombinant protein derived from the pathogen in bacterial or yeast cell cultures.

Step 2: Release antigen from the cells and purification from growth media

Step 3: Purification of the recombinant proteins by chromatography

Step 4: Addition of an adjuvants (substrate that non- specifically increases the immune response), stabilizers (increase shelf life) preservatives (allow multi-dose vials to be used safely)

Step 5: combining all components of the vaccines and uniformly mixing in a single vessel, filling the vaccines into single vials or syringes, sealing and labelling. Some vaccines are freeze dried and reconstituted at the time of administration.

Prophylactic Vaccines: Sub-Unit Vaccines

- Use components of a pathogen (surface protein)
- Safe and highly characterized vaccines
- Examples: Hepatitis B, HPV

Benefits

1. Chances of adverse reactions to the vaccine are lower
2. Purified protein(s) as an immunogen that ensures that the preparation is stable and safe, is precisely defined chemically
3. Free of extraneous proteins and nucleic acids that may initiate undesirable side effects

Risks

1. Likely take several additional doses, or booster shots, to maintain a person's immunity.
2. High cost of protein purification. Isolated protein or carbohydrate antigen may differ in its conformation.

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<u>Prophylactic Vaccines: Hepatitis B (HEPLISAV-B®)</u>

- Protects against infection by all forms of the hepatitis B virus
- Prevents the development of HBV-related liver cancer.
- Combination of hepatitis B surface antigen (HBsAg) with a proprietary Toll-like Receptor 9 agonist to enhance the immune response [Hepatitis B Vaccine (Recombinant), Adjuvanted]
- Intramuscular injection, 2 doses.