

**PHARMACEUTICAL SERVICES**  
**YOUR VACCINE PRODUCTION PARTNER**



**VACCINE PROJECT KEY STEPS**

Concept design



Basic/Detailed engineering construction project (EPC/EPCM)



URS development



Risk assessment



QA system implementation

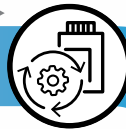
Commissioning & qualification



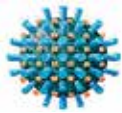
Inspection support



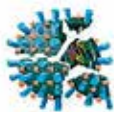
Process validation



**CLASSIFICATION OF VACCINES**



Whole virus



Split virus



Subunit (surface antigen)



Live attenuated



Bacteria

• **VIRAL**

• **BACTERIAL**



**Attenuated** ("Live")

**Inactivated** ("Killed")

- Complete
- Fraction

Generally to preserve the life of the antigen  
 Generally when liquid solution has low stability



**INJECTABLE VACCINE PRODUCTION PROCESS FLOW**

Production & Purification of Antigen



**LYOPHILIZATION**

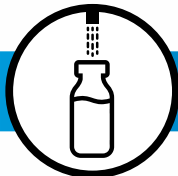


Washing

Depyrogenation



Capping



Filling



Formulation & Blending



External washing



Inspection



Secondary Packaging





## VACCINE PRODUCTION SERVICES



### Engineering

- BSL areas with negative differential pressures
- BIBO filters
- CIP/SIP
- Biowaste systems
- Disinfection systems
- Isolator / RABS integration



### Construction

- Special construction for critical environments with containment requirements
- Project Management
  - Construction Site Supervision
  - Procurement
  - Start-up



### Consultancy

- Vaccine Project business plan development/support
- GAP assessment (Process & Facilities)
- New Annex 1 fully compliance (CCS, RA ...)
- QA system implementation



### Commissioning & Qualification Validation

- Project C&Q
- Cleanroom qualification (GMP & ISO 14644)
- Laminar flow booths, isolators and RABs qualification
- Thermal qualification (depyrogenation, lyophilization and sterilization)
- Biodecontamination validation

## **OTHER TELSTAR PRODUCTS & SERVICES:**

- **Process Equipment**
- **Complete line Solutions**
- **Lyophilization and Sterilization process optimization/development Services**
- **Calibration Services**
- **Customer Service (including Equipment upgrade, retrofit & refurbishment)**



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