Telstar

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

Commisioning & qualification

Inspection support

Process validation

CLASSIFICATION OF VACCINES

Whole virus | Split virus | Subunit (surface antigen) | Live attenuated | Bacteria

- **VIRAL**
- **BACTERIAL**

→ **Attenuated** ("Live") — Generally to preserve the life of the antigen

Inactivated ("Killed") — Generally when liquid solution has low stability

- **Complete**
- **Fraction**

INJECTABLE VACCINE PRODUCTION PROCESS FLOW

Production & Purification of Antigen

Formulation & Blending

Filling

Washing

Depyrogenation

LYOPHILIZATION

Capping

External washing

Inspection

Secondary Packaging

YOUR VACCINE PRODUCTION PARTNER

PHARMACEUTICAL SERVICES

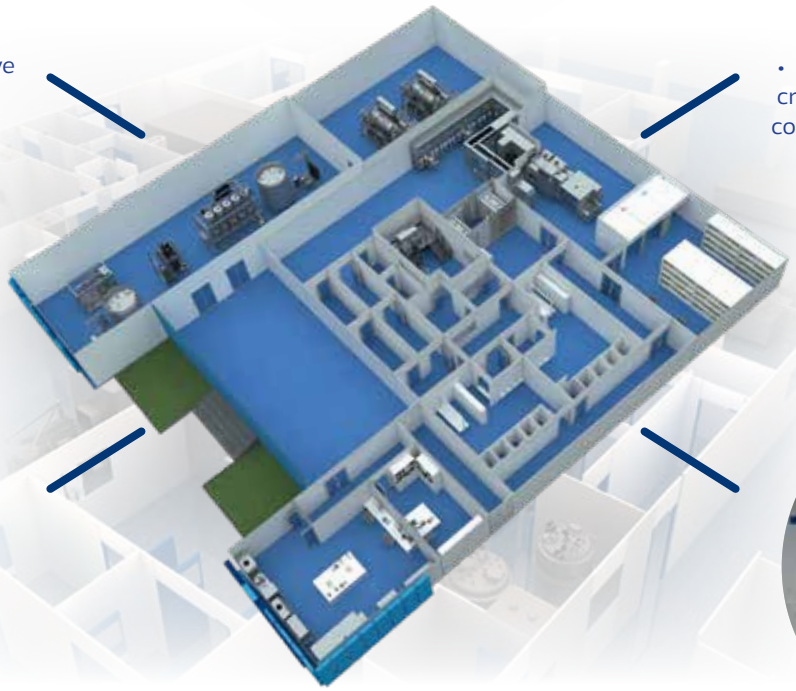
Engineering

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

VACCINE PRODUCTION SERVICES

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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