

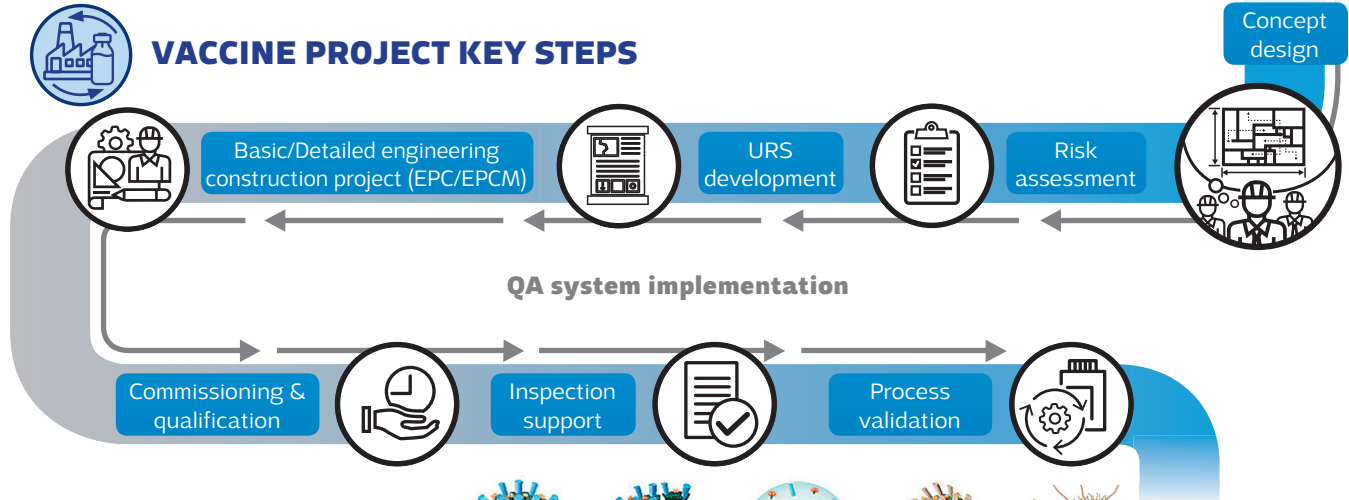


PHARMACEUTICAL SERVICES

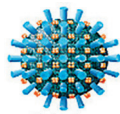
YOUR VACCINE PRODUCTION PARTNER



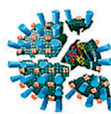
VACCINE PROJECT KEY STEPS



CLASSIFICATION OF VACCINES



Whole virus



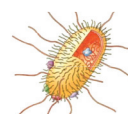
Split virus



Subunit
(surface antigen)



Live
attenuated



Bacteria

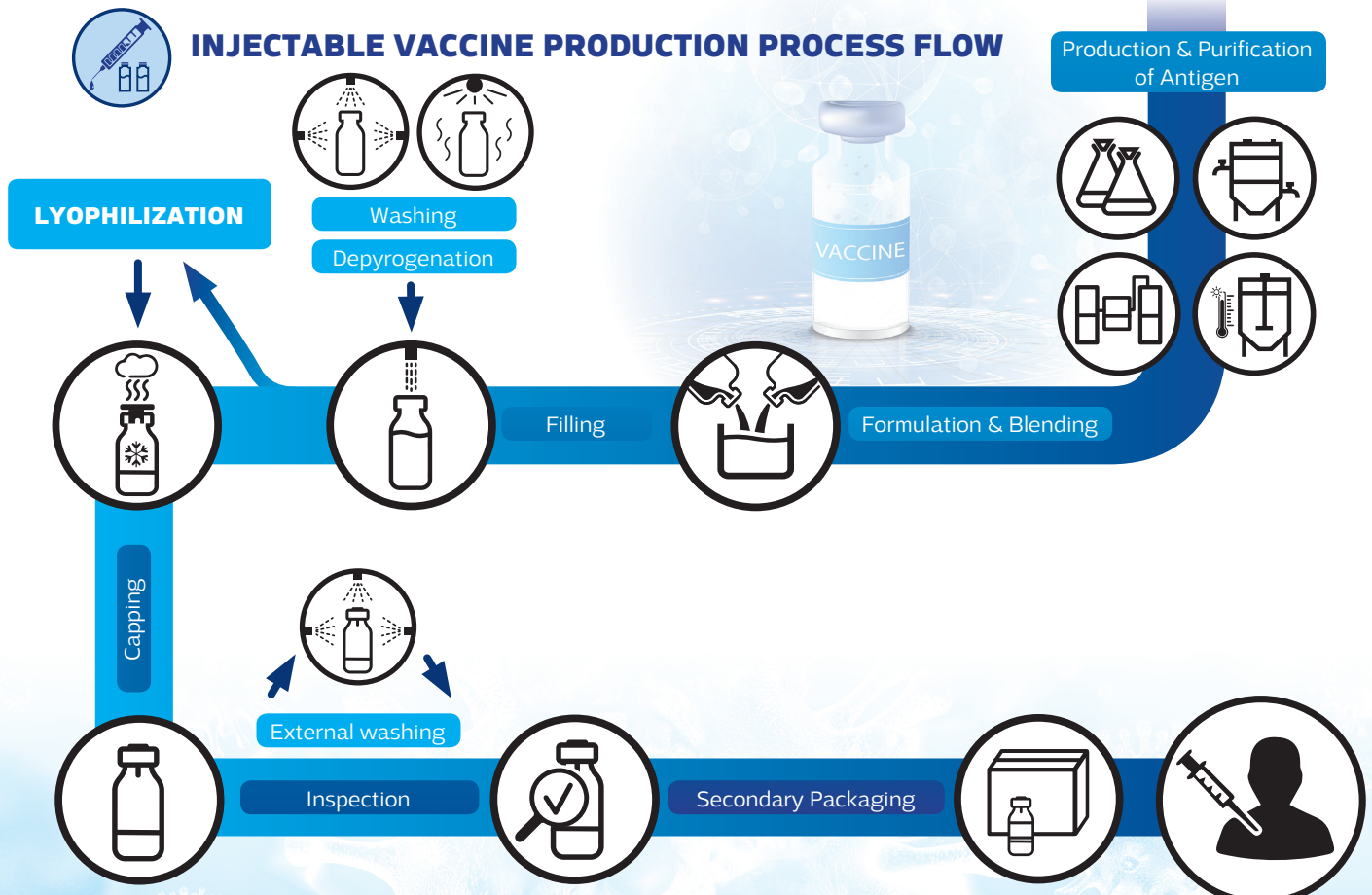
- VIRAL
- BACTERIAL

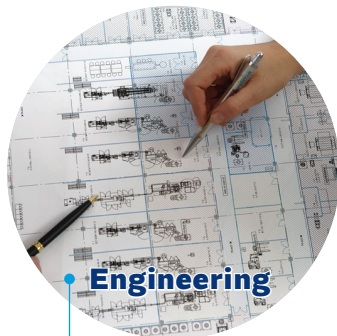
Attenuated ("Live")
Inactivated ("Killed")
• Complete
• Fraction

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



INJECTABLE VACCINE PRODUCTION PROCESS FLOW





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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