Vaccine Manufacturing Platform With Covid19 Vaccine Case Study
Company Profile
Company Introduction

**Founded in 1993**
- Headquartered in Shanghai
- Over 100,000 m² of professional production workshop

**Listed in 2011**
- GEM Listing Stock Code: 300171
- Over 2,000 professionals

**Globalization**
- China’s leading pharmaceutical equipment industry
- International market share ranked top

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Business Scope

Tofflon Pharma

Injectable
- Lyophilized product
- Liquid product
- Infusion
- Eye drop

API
- Freeze drying
- Chemical synthesis
- Fermentation
- Herbal extraction

Bio-E
- Solution preparation
- Bio-fermentation
- Separation & purification
- Waste treatment system

OSD
- Capsule
- Solids
- Tablet
- Material transportation

Smart
- Automation
- Information
- Intelligence

EPCM
- HVAC
- Maintenance
- Electronic systems
- Inspection & control

Tofflon Medical

Precision Medical
- Gene diagnosis
- Cell
- Immunotherapy

Medical Manufacturing Science

Turn-key Solution

Pharmaceutical Equipment

Life Science

Equipment Supplier to Solution provider

Smart Factory Technology + Automation + Dataflow
Tofflon For Vaccine Platform
Vaccine Manufacturing Platform

Viral Vaccine Process

1. Cell Expansion
   - Flask
   - Cell factories
   - Xpansion system
   - Cell

2. Virus Proliferation
   - BSE
   - Isolator
   - SUB

3. Downstream
   - Chromatography
   - TFF
   - Filtration

4. Inactivation
   - Incubators

5. Storage
   - Freeze & Thaw systems
   - Blast freezers

6. Fill and finish
   - Solution preparation system
   - RAB system
   - Filling line
   - Cartoning

Manufacturing Area

- AHU Designing
- Airlocks and partitioning of area
- Pressure zoning
- Area Classification
- Containment
- Process flow
- Waste management
Upstream Capabilities

- Cell Bank & Isolators
- Wave Bioreactor
- Incubator System
- SUB
- Bioreactors
- Vessel System

Upstream Solutions
Downstream Capabilities

Chromatography column & Systems

TFF Systems

Hollow Fiber systems

ILC, ILD, Integrated Systems

Freeze & Thaw systems

Vessel systems
Bioinactivation & Decontamination capabilities

- BSL3/BSL4 manufacturing area
- Sterile time: 2 Hr for the passbox 6 logarithmic reduction killing effects of microorganism
- Efficient decomposition system to shorten the ventilation time to reduce H2O2 content to less than 1 ppm
- Robotic VHP
- Efficient heat energy utilization
- The inactivation effect is the same as that of steam sterilization at 121.1 °C for 30 minutes
- Continuous operation
- Scada platform controlling and data acquisition
- Economic compared to batch
Injectable Capabilities

- Automatic Formulation System
- Automatic Vial/Ampoule Filling Line
- Stopper/Cap Washer
- Air Handling Unit
- Clean Room
- Automatic Packaging System
- Intelligent Inspection Machine
- Barrier System
- Capping Machine
- Freeze Dryer
- Auto Loading System

Washing & Drying  Rubber Cleaning  Filling  Capping  Inspection  Packaging
In production for virus inoculation, virus distribution, harvesting fluid handling, in QC for QC purpose viz virus sterility inspection, mycoplasma inspection, titer and other experiments.

Isolator designed with incubator cart to transfer material from isolator to incubator through RPT port.

Considered sterility requirements and toxicity protection requirements for isolator.

The internal dimensions of the isolator chamber are reasonably customized according to the different equipment, which are involved in different process.

Separate air supply and separate air exhaust for isolator to ensure that isolator has no effect on the control of the differential pressure in the laboratory.

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**Case study 1:** Beijing National Institute of Biological Sciences

**Product:** Inactivated Virus vaccine

**Problem statement:**
Closed and contained operation for handling of virus.
Case study 2: Jilin Jinsheng Pharmaceutical Co., Ltd. China

EPC
- Construction
- Blast proof area
- Partitioning
- HVAC
- EMS, BMS

Process
- Upstream Equipment
- Downstream equipment
- Tank systems
- CIPSIP system
- Piping & Integration
- Automation
Thank You

Q&A