



**Tofflon**

# Tofflon Best Practice for Human Vaccine

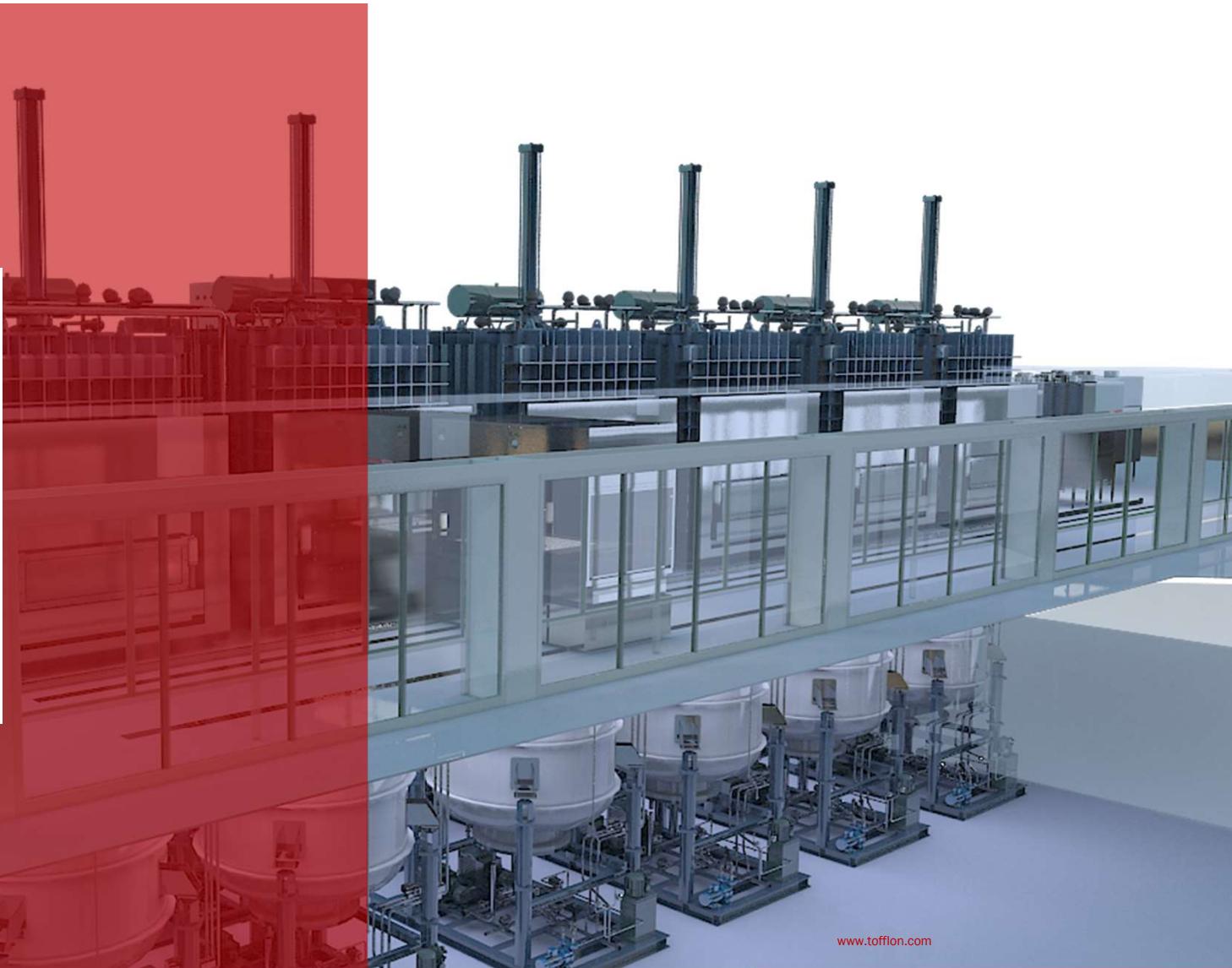
**EXPERTISE IN PHARMACEUTICAL INDUSTRY**

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[www.tofflon.com](http://www.tofflon.com)



## About Tofflon



[www.tofflon.com](http://www.tofflon.com)

**[www.tofflon.com](http://www.tofflon.com)**

28

45

1400

2500

10000

28 years manufacturing experience in pharmaceutical industry

Products are distributed in more than 45 countries and regions around the world

1326 patented technologies  
111 software Copyrights

It serves more than 2500 pharmaceutical companies worldwide

More than 10,000 sets of equipment and systems around the world

**Years of Experience**

**Countries & Regions**

**Intellectual property**

**Pharmaceutical Customers**

**Equipment & Systems Installation Worldwide**

# Tofflon Vision

What We Learn Today and Tomorrow in

The Science of Drug Manufacturing and  
Process Equipment Manufacturing

For the Future of

Smart Pharma Factory Building

### Drug Development

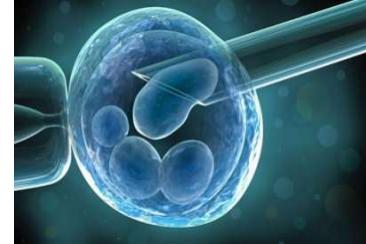
Small  
Molecules



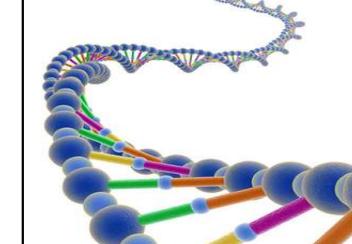
Large Molecules



Stem Cell

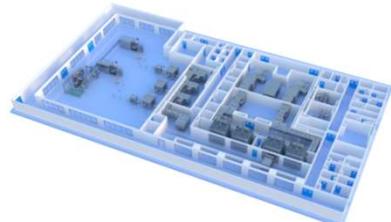


Tissue  
Regeneration

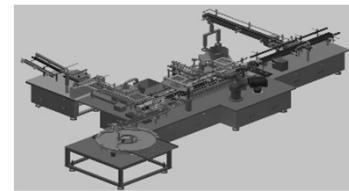


### Drug Manufacturing

Large-scale Mfg (Generics)



Flexible Mfg (Biotech/Biopharma)

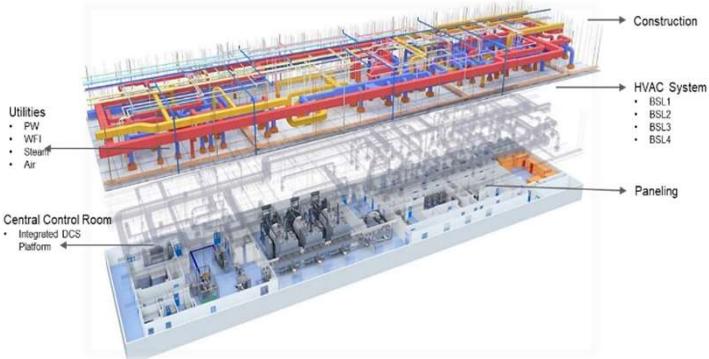


Cell Therapy Mfg



# Tofflon's Integrated Solution for Biosimilar

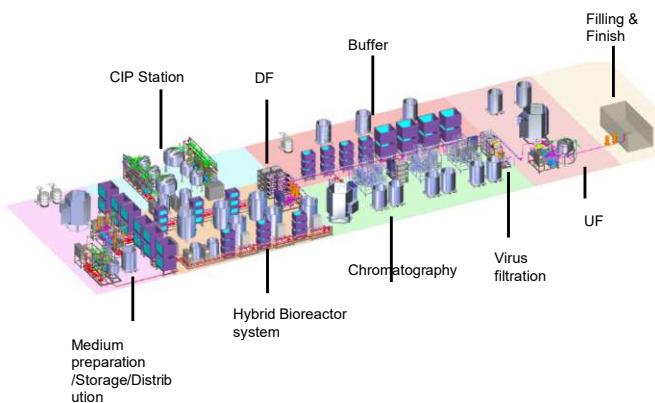
## Engineering



- ✓ Concept Design
- ✓ Basic Design
- ✓ Detailed Design
- ✓ Process Design
- ✓ Cleanroom/HAVC
- ✓ Project Management

EPC

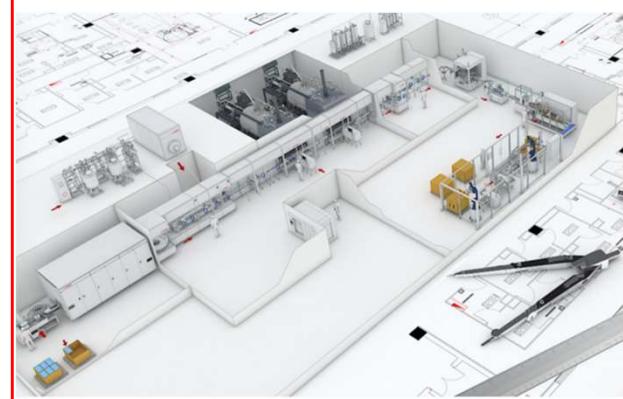
## DS



- ✓ Bioreactor(SS/SUB)
- ✓ Chromatography System
- ✓ Filtration(DF/TFF/HF/VF)
- ✓ Medium/Buffer Preparation
- ✓ CIP/SIP Skid
- ✓ Freeze & Thaw
- ✓ Inactivation System

Bioengineering

## DP



- ✓ Formulation Preparation
- ✓ Washing/Sterilization/Capping
- ✓ Filling(Vial/PFS)
- ✓ Isolator/cRABS/oRABS
- ✓ ALS(RBR/AGV)
- ✓ Lyophilization
- ✓ Auto Inspection/Packaging

Fill&Finish

## Consumables Application Segment

### Single Use Bag

- Cell Culture
- Medium/Buffer Preparation
- Freeze & Thaw
- Aseptic Transfer/Harvest
- Bulk Filling



### Biological reagent

- Medium(HEK293,CHO/Stem Cell)
- Cryoprotectant(DMSO)
- Recombinant Trypsin Solution
- BenzoNuclease



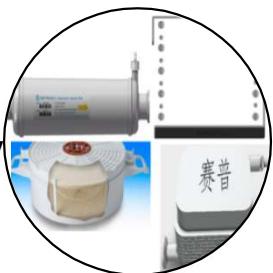
### Slurry

- Purose- Agarose
- Rigose -Agarose
- Pudex-Sephadex Gel
- Finedex- Agarose&Sephadex



### Filter/Membrane

- Sterility Filtration
- Ultrafiltration Membrane
- Virus Remove Filtration
- Depth Filtration
- Membrane Chromatography



## Tofflon Innovative Solutions

- ❖ **Process Scale-up and Technology Transfer**
- ❖ **Advanced Drug Manufacturing**
- ❖ **Next Generation Drug Manufacturing**  
**(Continuous Mfg. & Smart Mfg.)**



# Tofflon Innovations For Vaccine Manufacturing



# Machine

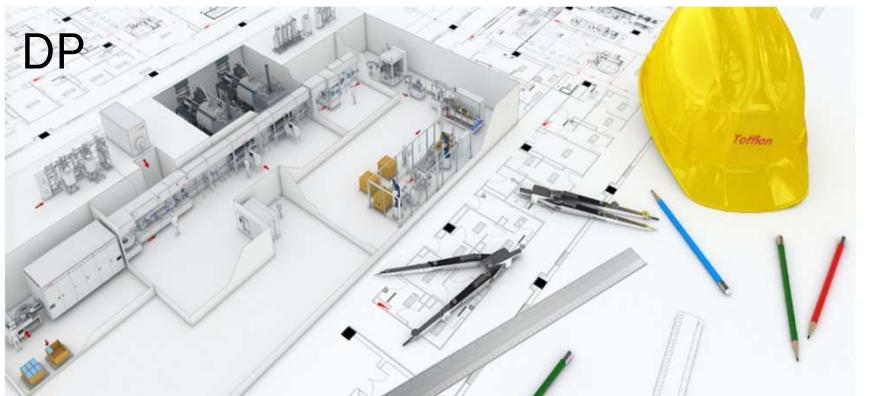
+

# Engineering

DS



DP



DE



## Product overview

### Seed treatment



CO2 incubator



Automated liquid nitrogen storage System



Cell processing full-station system



Cell expending system

### DS (upstream)



SS. bioreactor      SU. bioreactor



SS. Bio-Solution preparation system      SU. mixer



CIP station      SU. bin



Flexible mixer

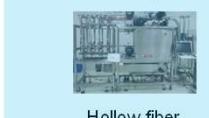
### DS (downstream)



Depth filtration system



Tangential flow filtration system



Hollow fiber filtration system



Chromatography system



Column and packing station



Slurry tank



Lab chromatography system

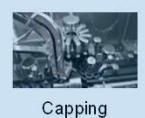


TFF system

### DP



Solution preparation system



Capping



Filling line (Vials/Ampoule/BFS/PFS)



Inspection



RABS / ISOLATOR



Labeling



Cartonning



Case Packer



Rubber Cleaning

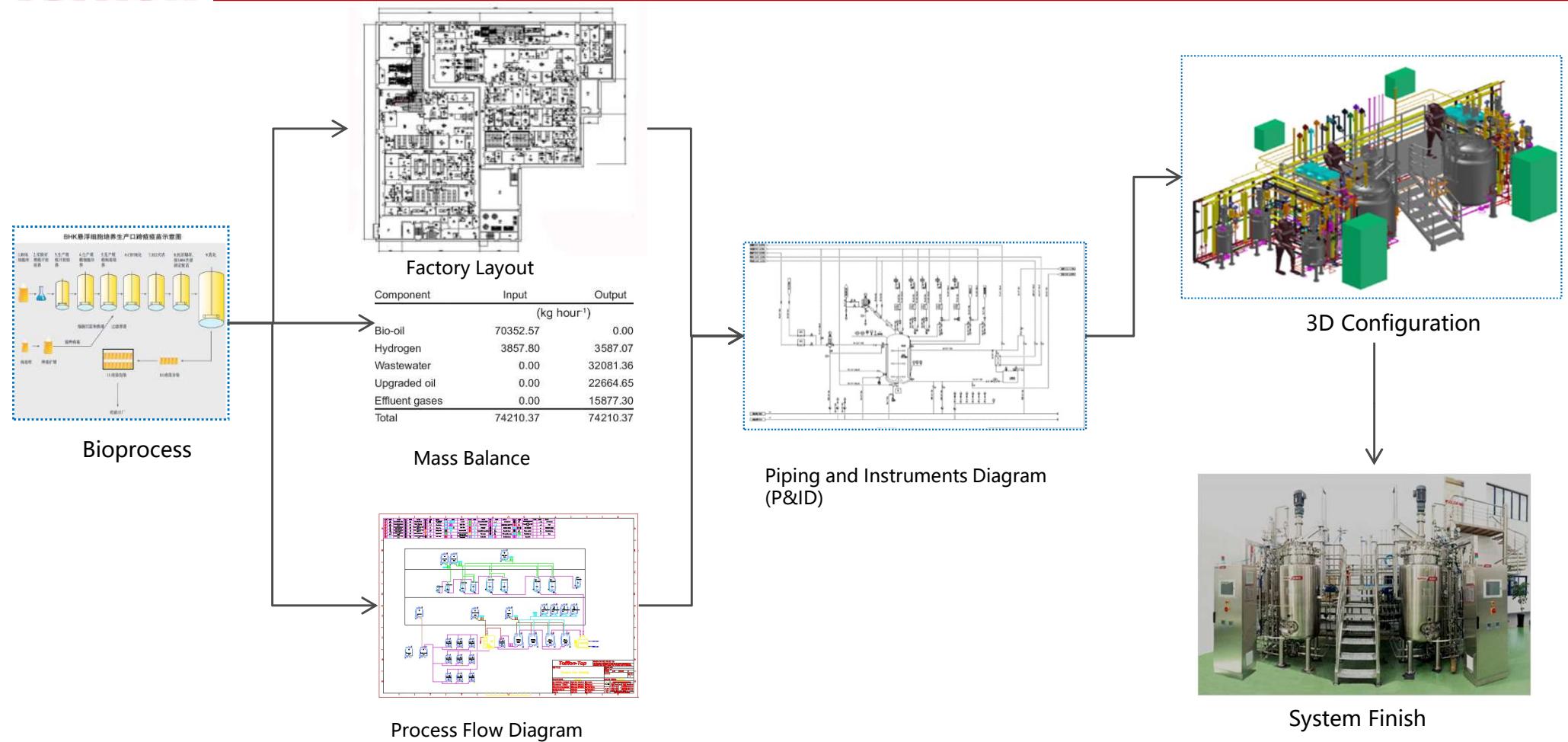


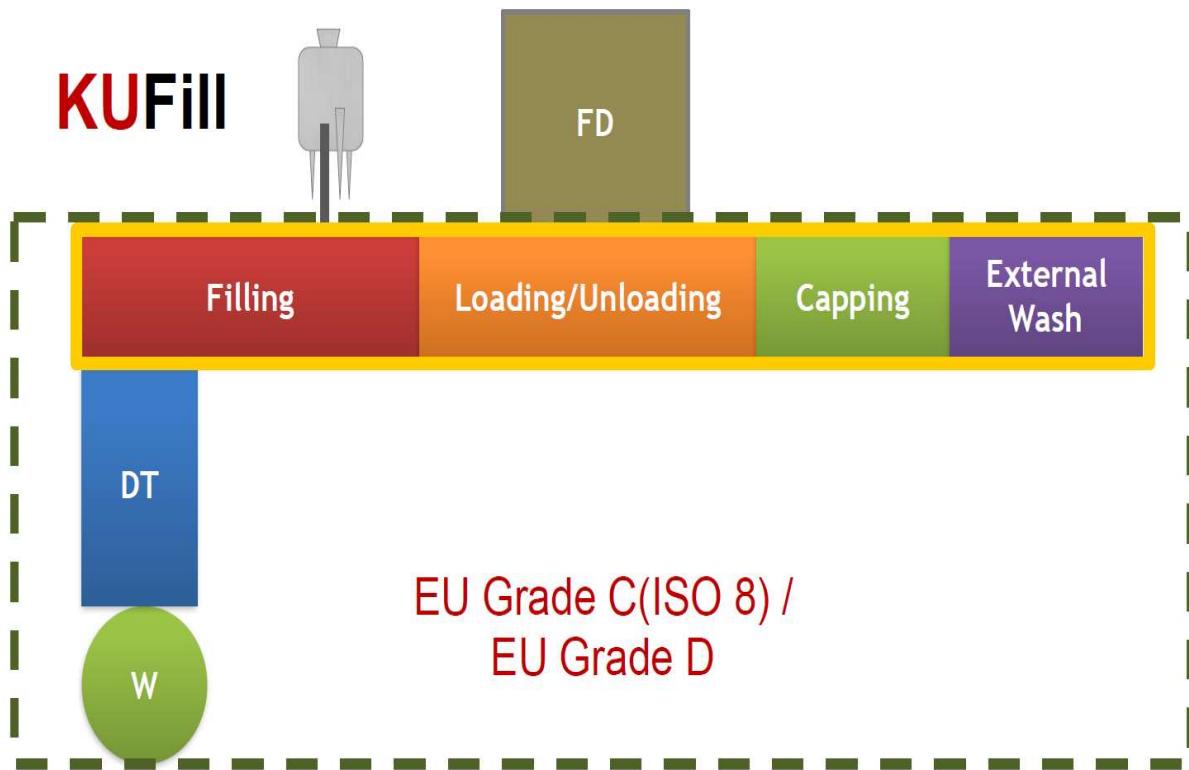
RBR / AGV



Lyophilizer

## Integrated Solution



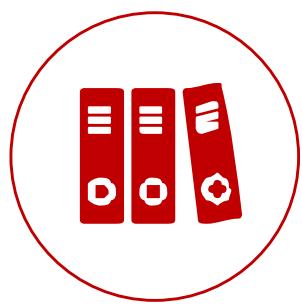


- Freeze Dryer
- Row-by-Row
- Isolator
- Auto Solution Preparation Systems (ASPS)
- Filling Line (Washer, Tunnel, Filler, Capper, External Washer)
- DCS

## □ What Advantages KUFill Is Offering

- cGMP Compliance
- Modular Building Interfaces
- Automation and Isolation
- Systems Integration
- Modular Equipment
- Expandable Factory
- More New Technologies
- Integrated Project Management
- Added Value Technical Support and Service

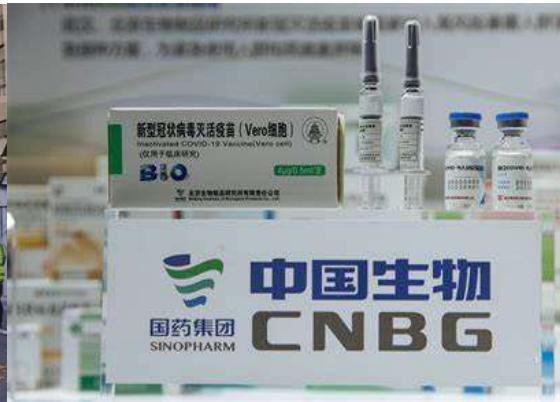




## COVID-19 Case Study

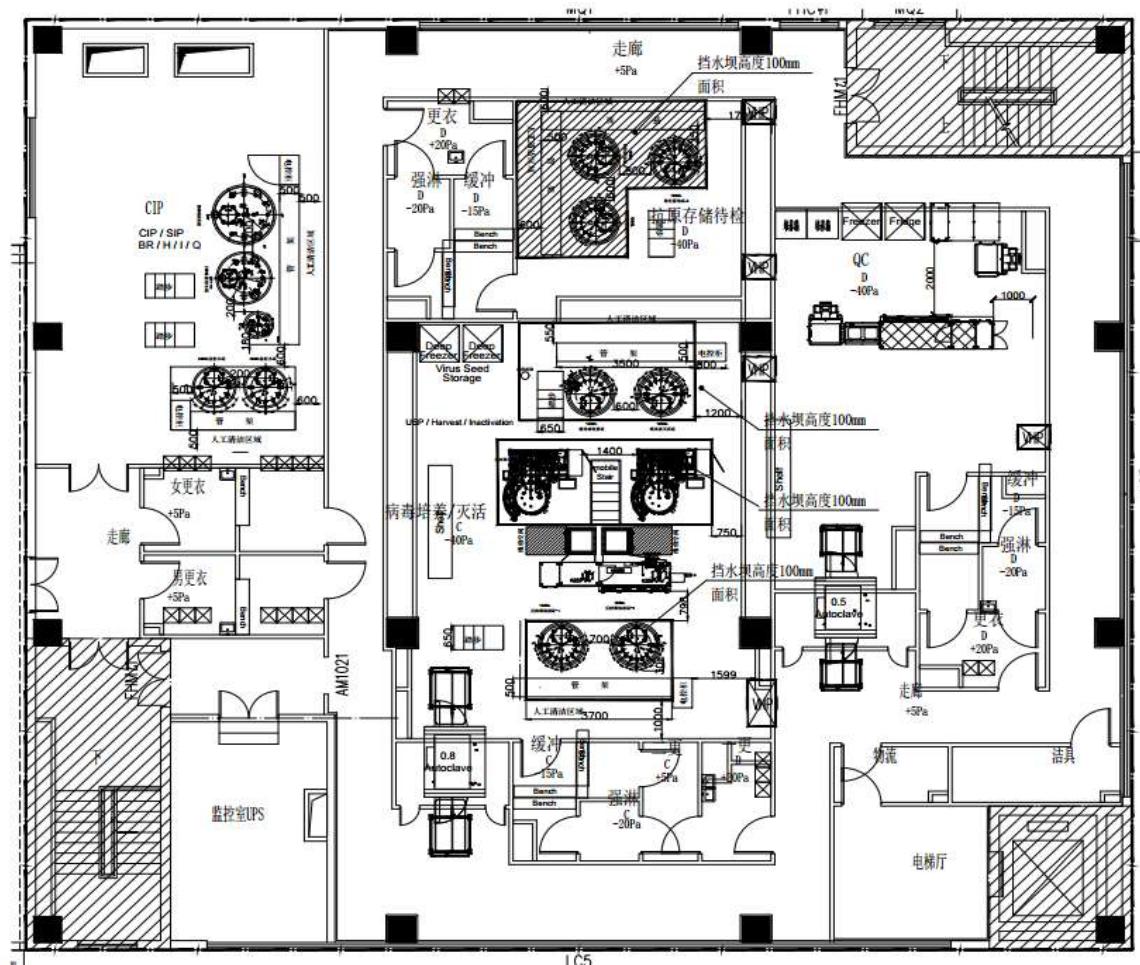


Phase I	Phase II	Phase III	Phase IV
<b>104</b> Vessels	<b>144</b> Vessels	<b>120</b> Vessels	<b>84</b> Vessels
<b>2020/2/10</b> Project Setup	<b>2020/10/15</b> Project Setup	<b>2021/4/30</b> Project Setup	<b>2021/4/30</b> Project Setup
<b>2020/3/15</b> Delivery	<b>2020/12/5</b> Delivery	<b>2021/5/14</b> Delivery	<b>2021/5/15</b> Delivery
<b>2020/4/15</b> SAT Finished	<b>2021/1/20</b> SAT Finished	<b>2021/6/15</b> SAT Finished	<b>2021/7/10</b> SAT Finished



### Detailed Scope:

Equipment	Capacity
Cell tank	300L
Solution preparation tank	1000L
Solution preparation tank	300L
Reactor storage tank 1	1000L
Reactor storage tank 2	1000L
Virus inactivation tank 1	1000L
Virus inactivation tank 2	1000L
Storage tank 1	1000L
Storage tank 2	1000L
Storage tank 3	1000L
Concentration tank	1000L
Concentration storage tank 1	300L
Concentration storage tank 2	300L
WFI Tank	1000L
Alkaline solution tank	1000L
WFI Tank	2000L
Alkaline solution tank	3000L
Warm water tank	200L
Customized isolator System	
Beehive Incubators	



**Customer: CNBG, China  
Cell line Vero ,1.2B Does/year(Total)**

**Project: Phase One**

**Tofflon's Scope**

- Total 104 tanks for medium and buffer preparation and storage
- Stainless steel bioreactors
- Virus inoculation isolator
- QC isolator
- Chromatography system
- Ultrafiltration system



**Customer: CNBG, China**

**Project: Phase Two  
Coronavirus Vaccine (8 Lines)**

**Tofflon's Scope:**

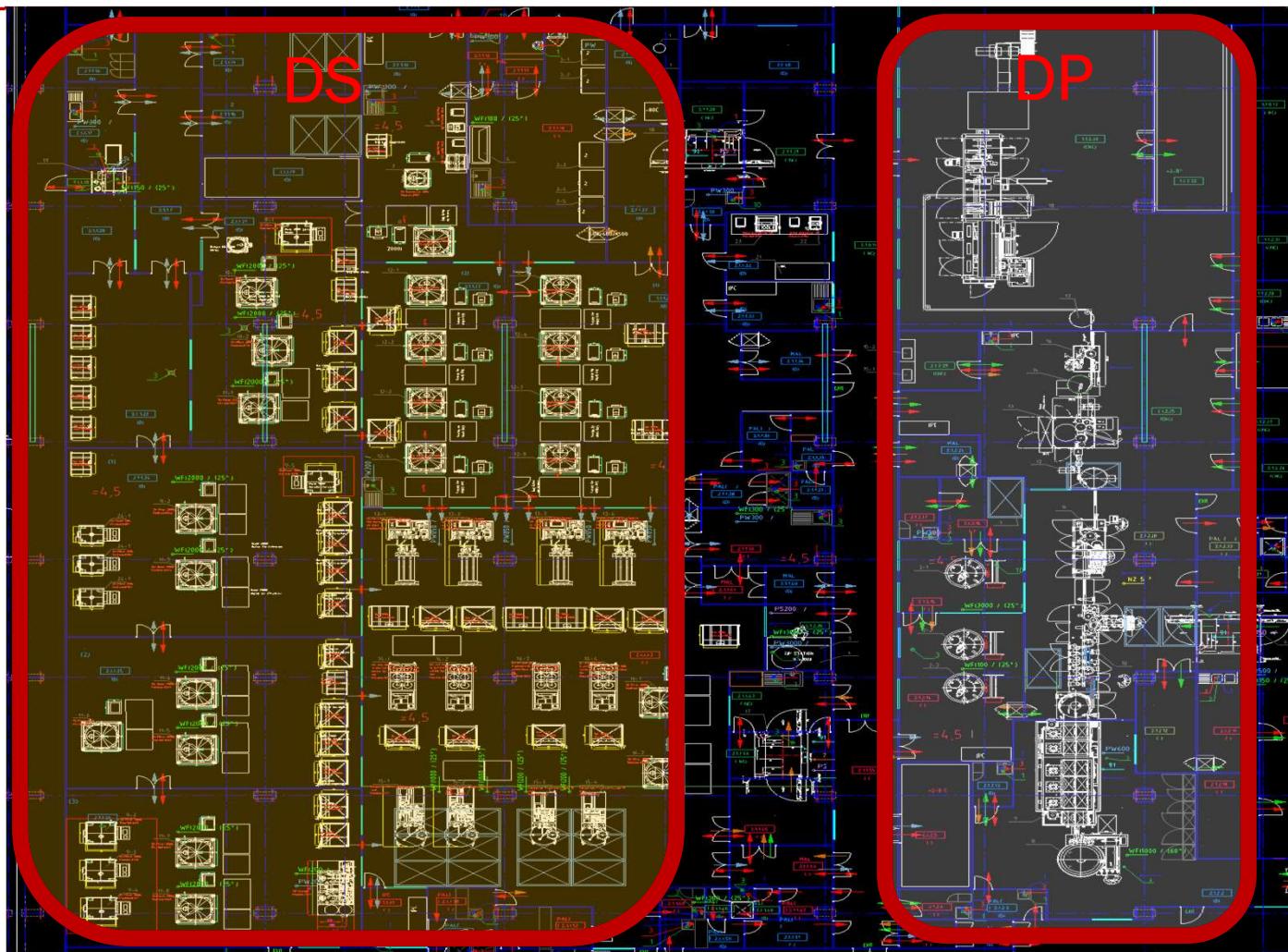
- 8-1000L\*2 Bioreactor storage tanks
- 8-1200L Virus harvest tanks
- 8-1200L Virus inactivation tanks
- 8-1200L\*2 storage tanks for liquid to be tested
- 2-1200L and 600L concentration storage tanks
- 2 sets of double-tank CIP
- 1000L\*7 medium preparation tanks

**Progress: In production**



**Strengths :**

- ◆ Turnkey project
- ◆ Integrated solution
- ◆ Multiply planform
- ◆ Disposable system
- ◆ Fast Delivery
- ◆ Flexible operation



**Customer : R-Pharm, Russia**

**Cell Vector :HEK-293,Ad5+Ad26,100M**

**Dose/year**

**Tofflon's Scope:**

- UPS process (Bioreactor + Medium)
- CES 100L 400+ sets
- SUB 2KL 20+ sets
- SUM for Medium & Buffer 50+ sets
- Bin 50+ sets
- DPS process (DF/TFF + Chroma)
- TFF 20sqm 40+ sets
- Chromatography System 50+ sets
- Auto Column ID 800 50+ sets
- CIP/SIP Skid 4+ sets
- Bio-killed System 3+ sets
- Freeze & Thaw for Bulk 100L 2+ sets
- Fill & Finish Line 5+sets



## Project 3 – Adenovirus Vector COVID-19 Vaccine Project



## Project 4 – Recombined COVID-19 Vaccine Project

### Project Overview

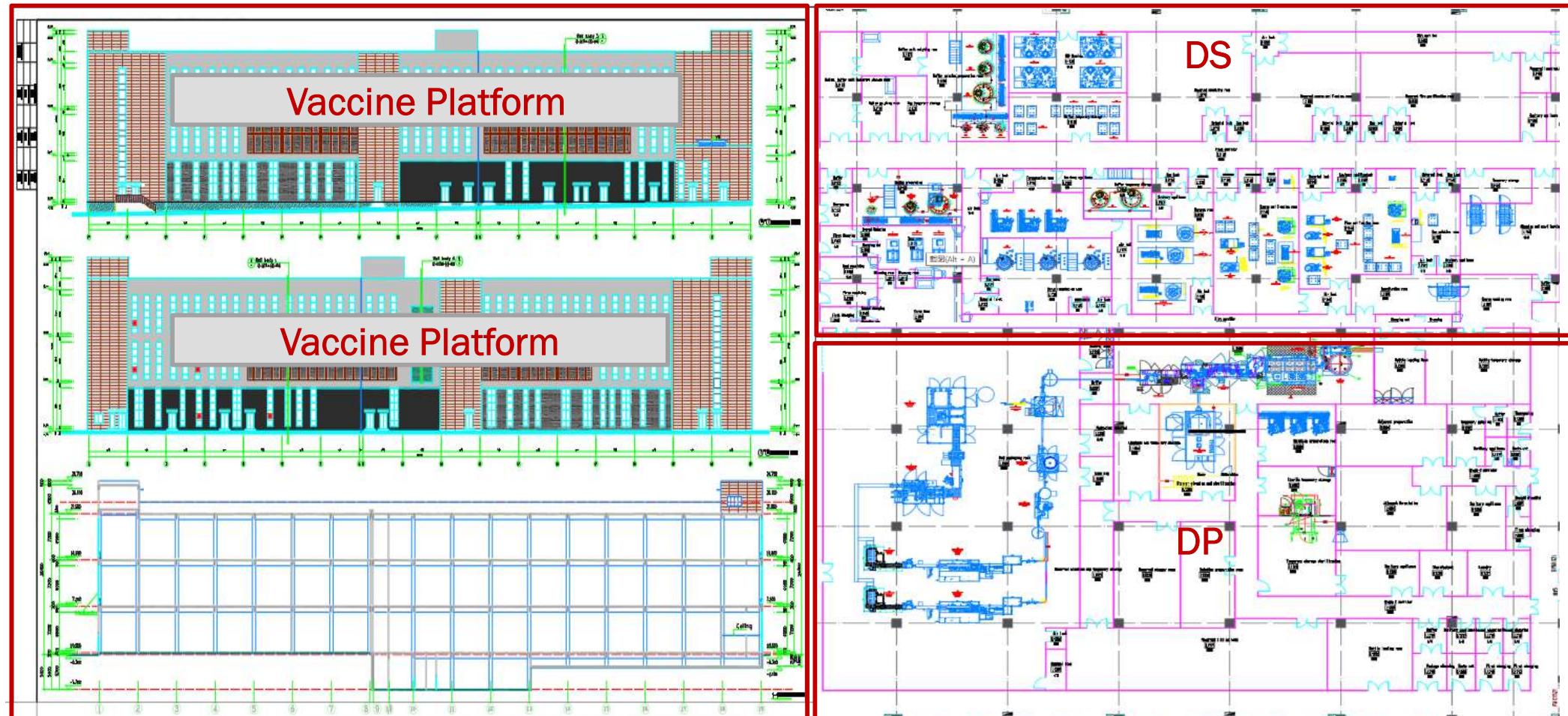
- Company : WestVac
- Product :Recombinant **COVID-19 Vaccine**
- Cell line: Insect Cell with Baculovirus
- Technology Routes : Recombinant Protein
- Output :Total **100M** doses/Year (liquid product packing with Vial )
- Facility: Chengdu China
- Harvest term **14** days/Batch
- Lead time **3** months



### Supply Scope

- UPS Process (Bioreactor + Medium)
- CES 50L 2+ sets
- SS Bioreactor 1KL\*3 sets
- Medium & Buffer Tanks 10+ sets
- Bin(Tank) 15+ sets
- DPS Process (DF/TFF + Chroma)
- TFF 5Sqm 2sets+TFF 100Sqm 1Set
- HB 128m<sup>2</sup> 1 set+76.8m<sup>2</sup> 1 set
- Chromatography System 2400LPH 3sets
- Auto Column ID 600 5+Set
- CIP/SIP Skid 1 Sets
- Bio-killed System1Sets
- Freeze& Thaw for Bulk 100L 1
- Fill&Finish Line 2 Sets

## Project 4 – Recombined COVID-19 Vaccine Project



## Project 4 – Recombined COVID-19 Vaccine Project

SS Bioreactor



Cell culture Zone

Preparation Tank



Medium Preparation Zone

### Ultra Filtration System



Filtration Zone

### Chromatography System



Purification Zone

Preparation System



Formulation Zone

Preparation System



Formulation Zone

## Bulk Vial Washing & Sterilization



Washing & Sterilization Zone

## Aseptic Filling



Aseptic Filling Zone

### Inspection and Leakage Detection



Inspection Zone

### Labeling & Cartoning Packing



Secondary Packing Zone

**Tofflon Vision:  
Smart Pharma Factory Builder**

**Warmly Welcome  
To Tofflon**

