About Tofflon
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

**EPC**
- Concept Design
- Basic Design
- Detailed Design
- Process Design
- Cleanroom/HAVC
- Project Management

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

**Fill & Finish**
- Formulation Preparation
- Washing/Sterilization/Capping
- Filling (Vial/PFS)
- Isolator/cRABS/oRABS
- ALS (RBR/AGV)
- Lyophilization
- Auto Inspection/Packaging
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
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
- CIP station
- SU. bin
- Flexible mixer

DS (downstream)
- Depth filtration system
- Column and packing station
- Tangential flow filtration system
- Hollow fiber filtration system
- Lab chromatography system
- Slurry tank
- Chromatography system
- TFF system

DS (upstream)
- SS. bioreactor
- SU. bioreactor
- SS. Bio-Solution preparation system
- CIP station
- SU. bin
- Flexible mixer

DS (downstream)
- Depth filtration system
- Column and packing station
- Tangential flow filtration system
- Hollow fiber filtration system
- Lab chromatography system
- Slurry tank
- Chromatography system
- TFF system

DP
- Solution preparation system
- Capping
- Filling line (Vials/Ampoule/BFS/PFS)
- Inspection
- Solution preparation system
- Slurry tank
- Column and packing station
- Tangential flow filtration system
- Hollow fiber filtration system
- Lab chromatography system
- TFF system
- Capping
- Inspection
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- Inspection
- Solution preparation system
Integrated Solution

Bioprocess

Factory Layout

Mass Balance

Process Flow Diagram

Piping and Instruments Diagram (P&ID)

3D Configuration

System Finish
Integrated Solution

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

KUFill

EU Grade C (ISO 8) / EU Grade D
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
## Project 1 – Inactivated COVID-19 Vaccine Project

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

Project Setup: 2020/10/15
Delivery: 2020/12/5
SAT Finished: 2021/1/20
Detailed Scope:

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cell tank</td>
<td>300L</td>
</tr>
<tr>
<td>Solution preparation tank</td>
<td>1000L</td>
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<tr>
<td>Solution preparation tank</td>
<td>300L</td>
</tr>
<tr>
<td>Reactor storage tank 1</td>
<td>1000L</td>
</tr>
<tr>
<td>Reactor storage tank 2</td>
<td>1000L</td>
</tr>
<tr>
<td>Virus inactivation tank 1</td>
<td>1000L</td>
</tr>
<tr>
<td>Virus inactivation tank 2</td>
<td>1000L</td>
</tr>
<tr>
<td>Storage tank 1</td>
<td>1000L</td>
</tr>
<tr>
<td>Storage tank 2</td>
<td>1000L</td>
</tr>
<tr>
<td>Storage tank 3</td>
<td>1000L</td>
</tr>
<tr>
<td>Concentration tank</td>
<td>1000L</td>
</tr>
<tr>
<td>Concentration storage tank 1</td>
<td>300L</td>
</tr>
<tr>
<td>Concentration storage tank 2</td>
<td>300L</td>
</tr>
<tr>
<td>WFI Tank</td>
<td>1000L</td>
</tr>
<tr>
<td>Alkaline solution tank</td>
<td>1000L</td>
</tr>
<tr>
<td>WFI Tank</td>
<td>2000L</td>
</tr>
<tr>
<td>Alkaline solution tank</td>
<td>3000L</td>
</tr>
<tr>
<td>Warm water tank</td>
<td>200L</td>
</tr>
<tr>
<td>Customized isolator System</td>
<td></td>
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<tr>
<td>Beehive Incubators</td>
<td></td>
</tr>
</tbody>
</table>
Project 1 – Inactivated COVID-19 Vaccine Project

Customer: CNBG, China
Cell line Vero, 1.2B doses/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
Project 3 – Adenovirus Vector COVID-19 Vaccine Project

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 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 128m² 1 set+76.8m² 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

Preparation Tank

Cell culture Zone

Medium Preparation Zone
Preparation System

Formulation Zone
Bulk Vial Washing & Sterilization

Aseptic Filling

Washing & Sterilization Zone

Aseptic Filling Zone
Inspection and Leakage Detection

Labeling & Cartoning Packing

Inspection Zone

Secondary Packing Zone
Warmly Welcome
To Tofflon

Tofflon Vision:
Smart Pharma Factory Builder