



# Advances in Vaccine Manufacturing by Tofflon

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Tofflon Science and Technology Group Co., Ltd.

# Business Scope

Learn From Medical Science; Contribute to Medical Equipment

## Machine

### Tofflon Pharma

DS	DP	API	OSD	DPP
Bio/CGT	Injection	API	OSD	Packaging
CES/SUB/SSB Purification & Filtration Bio-solution Prep. Freeze & Thaw Inactivation Cell Processing Station Cryopreservation Syst.	Solution Prep. Filling Syst. (Vial/Ampoule/BFS/PFS) Freeze Drying Barrier Syst.	Synthesis Drying Syst. Fermentation Herbal	Weighing Granulating Drying Mixing	Inspection Labeling Cartoning Palletizing



## Engineering

MNGT.

Clean  
Room

Service

Eng.

CD, BD, DD  
Project MNGT.  
Validation MNGT.  
Automation

HVAC  
Water Sys.  
Clean Room Constr.



**Smart Factory**  
(Tech. + Auto. + Data)

## Consumables

Consumables

Packaging

SU Bags  
Culture Media  
Resins  
Filters & Membrane

COC/COP Vial

Drug Manufacturing Science

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# Experts in Biopharmaceutical Company

30 Years Expertise

USD 600 Million Revenue  
(FY 2021)

50 Countries & Regions  
Installations

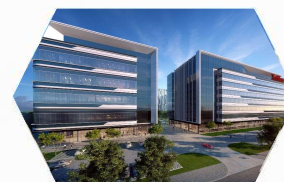
Since  
1993

6 Global JV and Tech  
Partners

- Kyowac(Japan)
- Top(Japan)
- Airex(Japan)
- Omca(Italy)
- Itema(Italy)
- Praxair(USA)

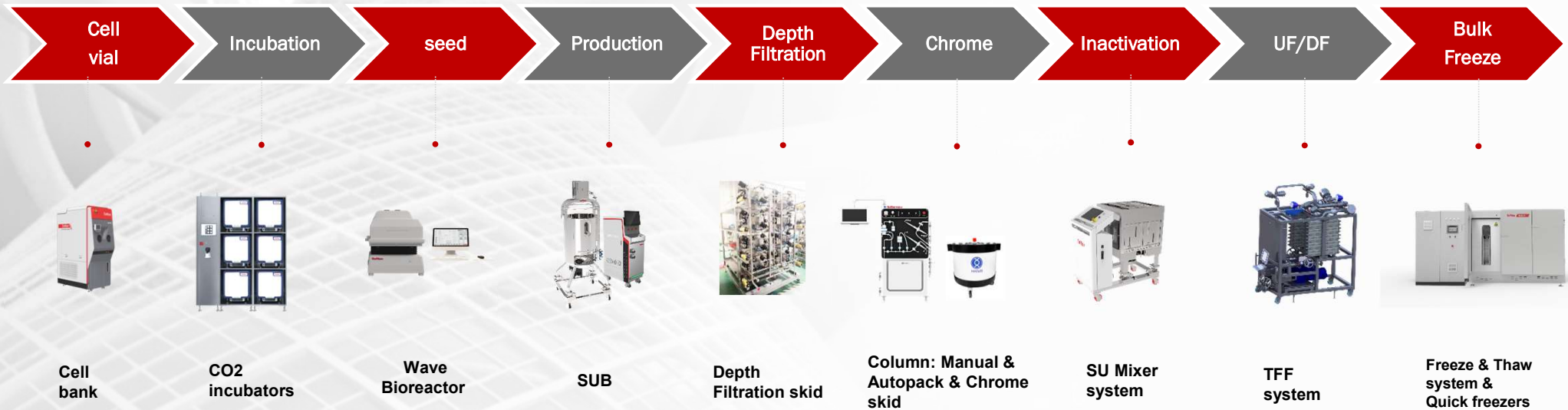
5000 Employees

Serving **over 2800**  
pharmaceutical companies  
worldwide



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# DS-Hybrid



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# DS-SS

Cell  
vial

Incubation

seed

Production

Depth  
Filtration

Chrome

Inactivation

UF/DF

Bulk  
Freeze



Cell  
bank



CO2  
incubators



Glass  
Bioreactor



SS Bioreactor /  
Fermenter



Depth  
Filtration  
skid



Column:  
Manual &  
Autopack  
& chrome Skid



Vessel  
system



TFF  
system



Freeze & Thaw  
system &  
Quick freezers

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# Advanced Injectables

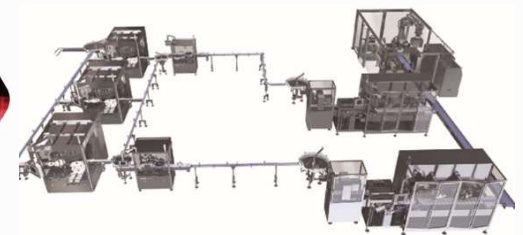
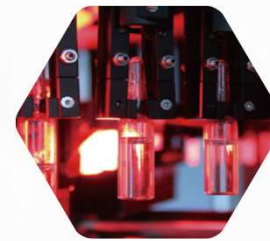
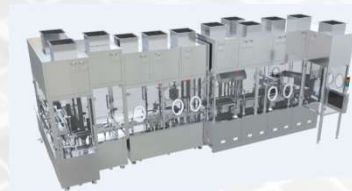
Compounding

Filling

Lyophilization

Inspection & Detection

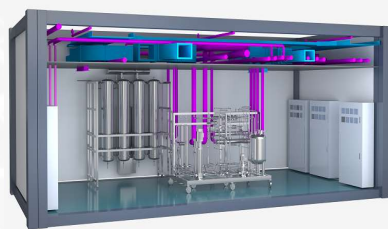
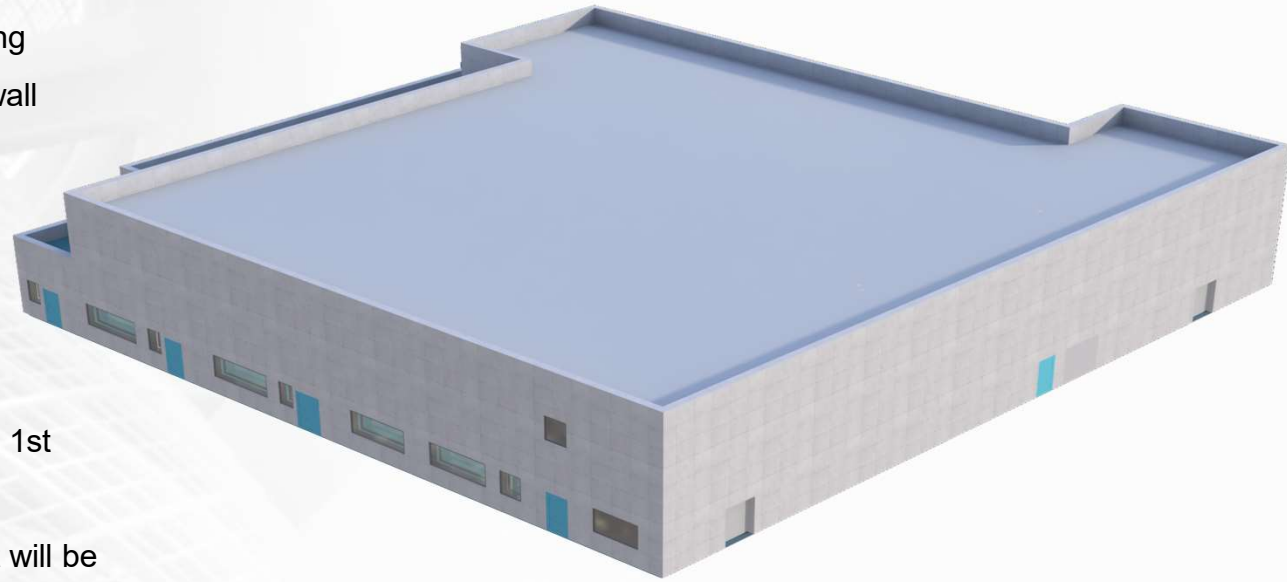
Secondary Packaging



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# Modular Factory

1. Steel frame transformed to Module Manufacturing Workshop for pre-assembly, floor & part of the wall installed simultaneously
2. Main duct, firewater piping installation.
3. Piping, cable tray installation
4. Roof installation (onsite installation space to be reserved)
5. HVAC room (2nd floor) installation (in sync with 1st floor)
6. Before Factory Acceptance Test, key equipment will be pre-assembled, pre-engineered, pre-qualified in the modules.
7. Each module will be shipped by trucks after disassembling



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# Single use Fixed bed Bioreactor



**SU\_Fixed bed –Mini Bioreactor**

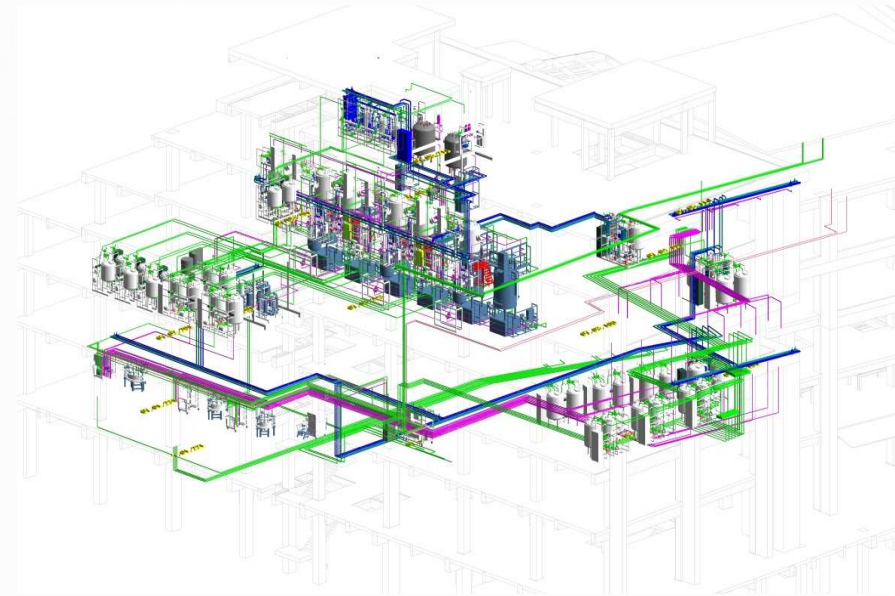


**SU\_Fixed bed –C- Bioreactor**

## Application

- Vaccine production MRC5 cell lines,
- Cell & Gene therapy
- Adeno-associated virus (AAV)
- lentivirus (LV)
- Adenovirus (Adeno),
- Oncolytic virus (oncolytic)

# Large scale integrated SS project

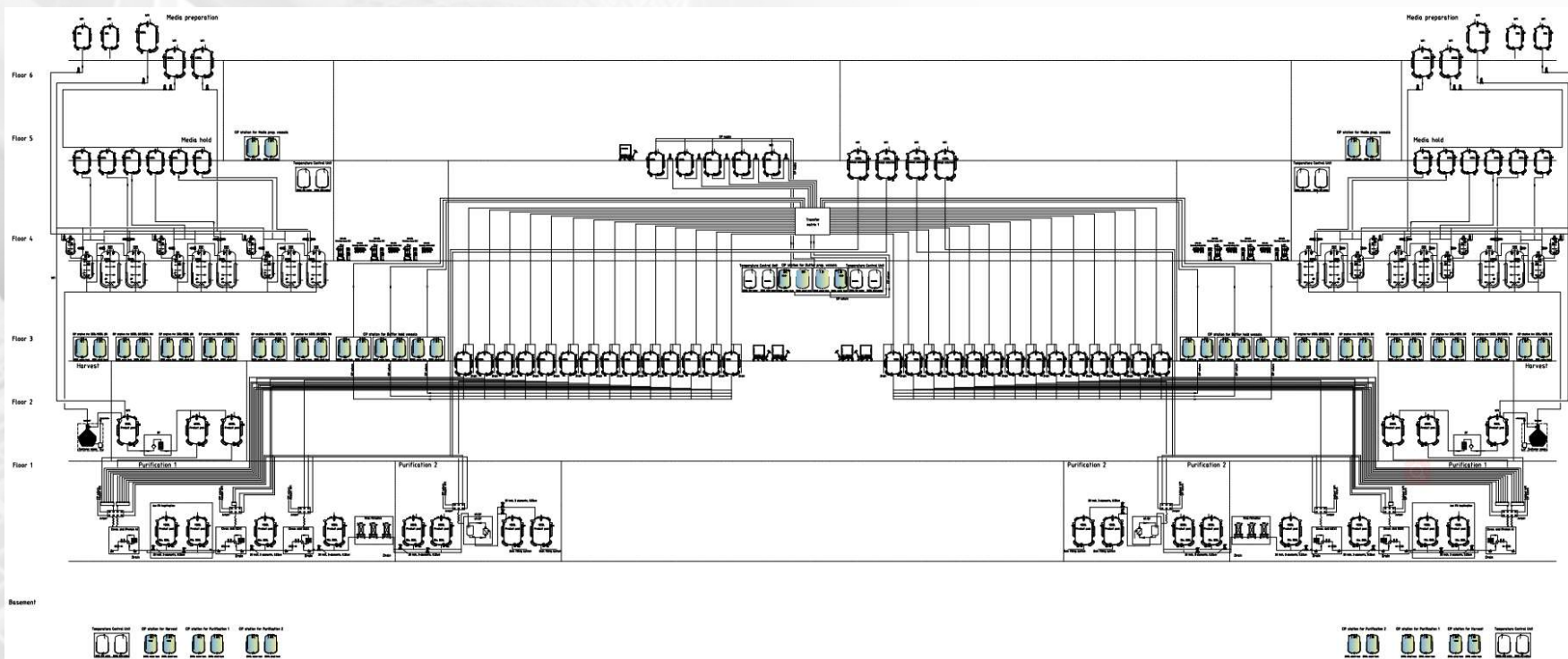


## Industry Challenges:

- Complicated process with many docking units and control strategy
- Higher Utility costing
- Integrated complex piping
- Flexibility

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# Large Scale Vaccine Manufacturing

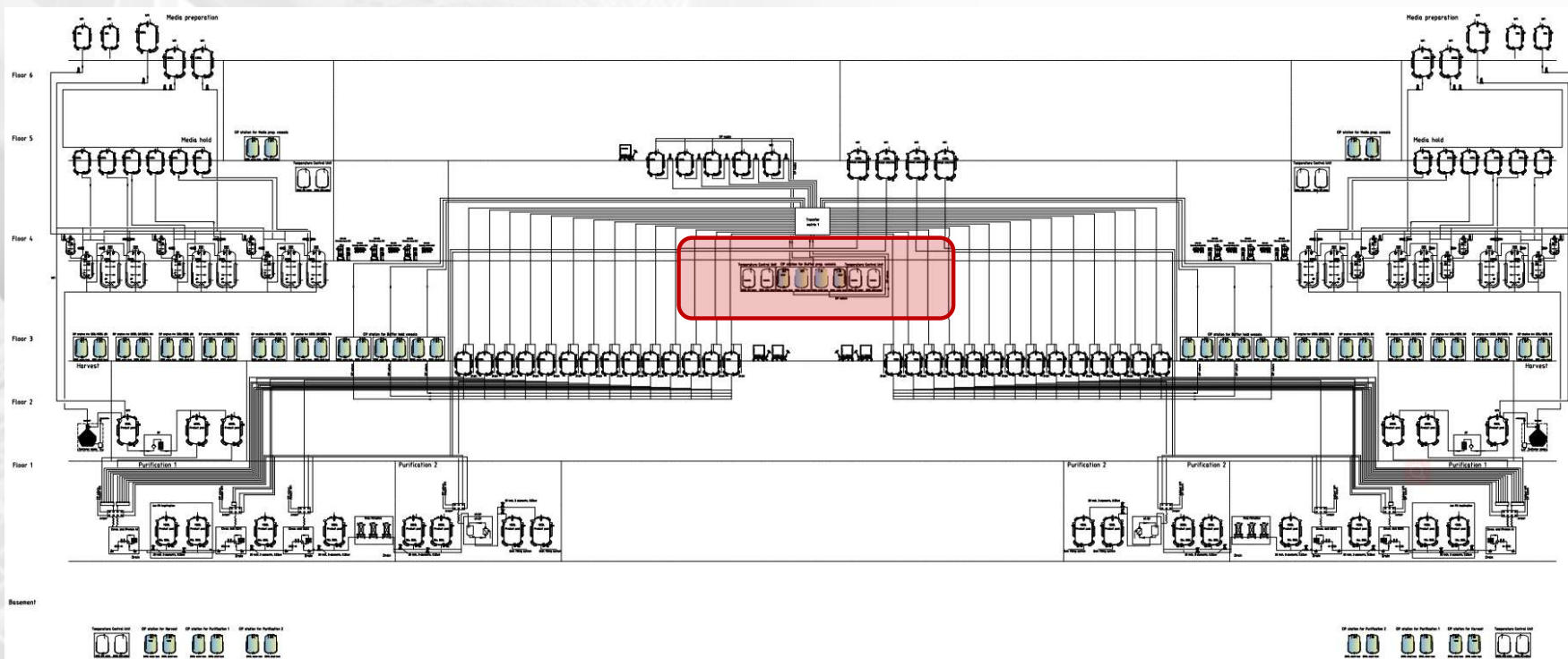


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# Approach 1 – Optimized TCU system



Contributes significantly reduction in operation cost

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## Approach 1 – Optimized TCU system

Jacket type		Total jacket water volume	Comments
Dimple		1,706L	Totally 43 sets of process vessels from 300L to 7,000L
Half coil		4,265L	
Guide plate		8,530L	

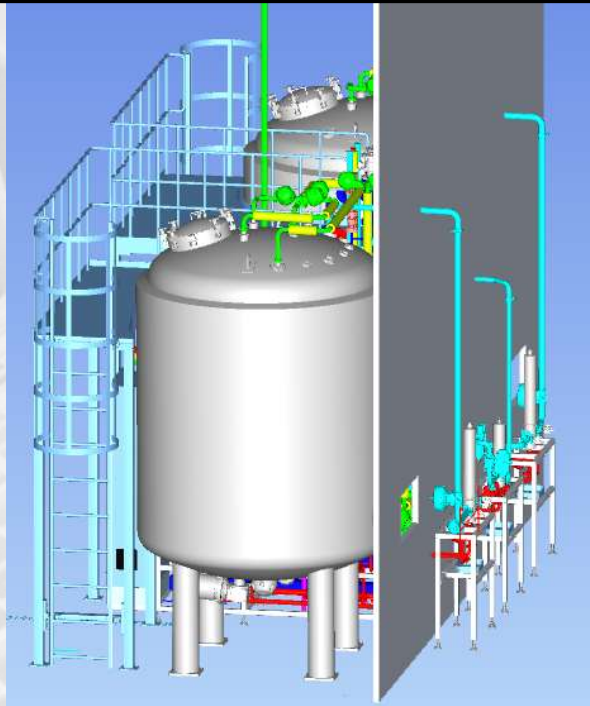
- Volume calculation
- Temperature range
- Loop pressure and flow rate



Centralize TCU system ensures minimal water waste

## Approach 2 – Optimization of Clean Room

Black area: CNC room    C Grade



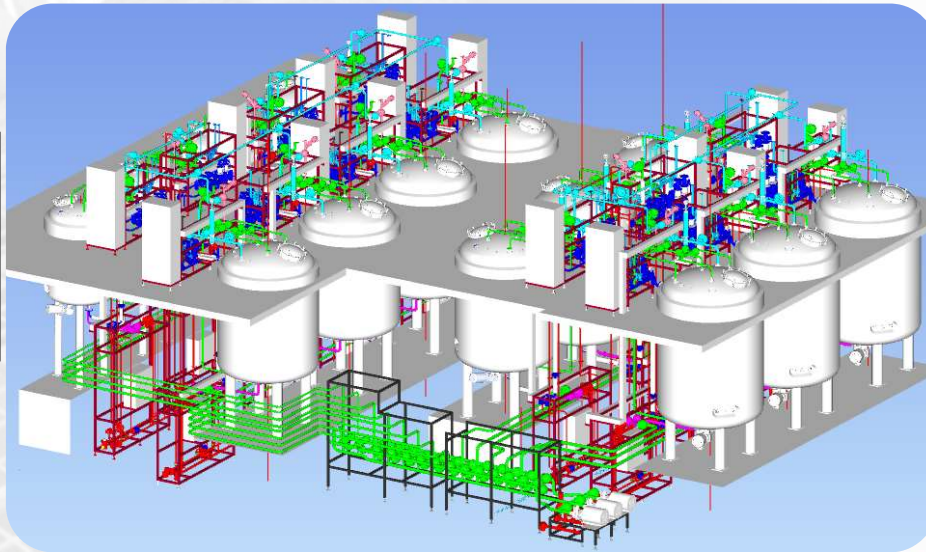
Reduce clean room area more than 30%

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## Approach 2 – Optimization of Clean Room

Black area

CNC room



Reduce clean room area more than 30%

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## Approach 3 – Modular Design and Installation

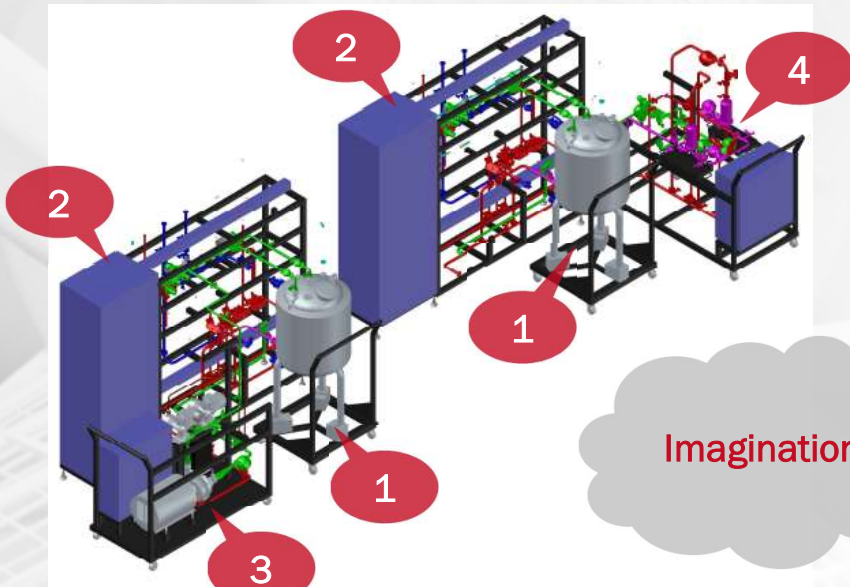
Modular Design

Modular Manufacturing

Modular Installation

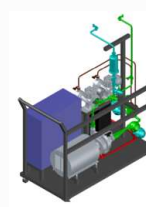


# Approach 3 – Modular Design and Installation



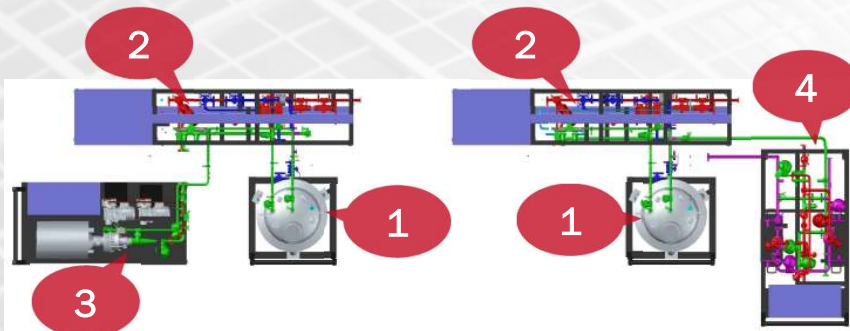
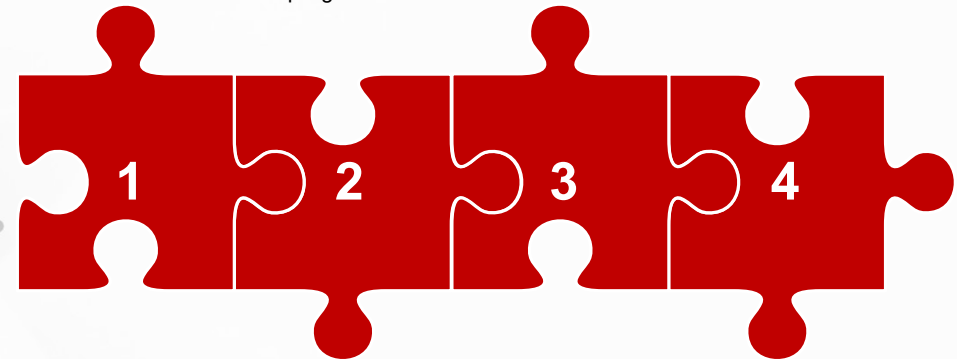
## Moveable vessel

- Jacketed vessel with insulation
- Vent filter
- Magnetic agitator
- Flush bottom valve
- Load cell
- TT/PT/CT/PH
- Sampling valve



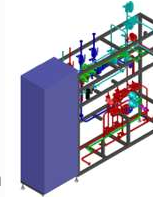
## CIP skid

- Circulation pump
- Air filter
- Alkali/Acid dosing
- Conductivity meter
- Sampling
- Control box



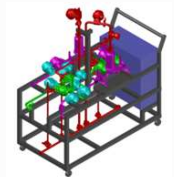
## Function skid

- Temperature control through jacket
- Sterilization for vessel
- Utilities docking
- Drain line connection
- Control cabinet



## Filtration skid

- Filtration for liquid
- CIP/SIP is available (need to connect with CIP skid and vessel)
- Control box



**Design  
Consulting**



**Project  
Management**



**3D  
Animation**



**Engineering  
Implement**



**Training &  
Validation**



**Information &  
Automation**

**Thank You For  
Your Kind Attention**

