



EPC Services by TOFFLON

The turnkey solution
of pharmaceutical engineering



Tofflon Introduction



Founded in 1993

Headquartered in Shanghai
8 modern manufacturing bases in China
Over 800,000 m2 of professional
production workshop

Listed in 2011

GEM Listing Stock Code: 300171
Over 6,000 professionals

\$910 million sales

Nearly 2,000 customers worldwide
10,000+ equipment delivered to date



Minhang, Shanghai
Headquarter
100,000 m2



Minhang, Shanghai
Assembly workshop
50,000 m2



Minhang, Shanghai
OSD Equipment
5,000 m2



Jinshan, Shanghai
Pressure vessel
120,000 m2



Fengxian, Shanghai
Machining, sheet metal
20,000 m2



Hangzhou
Life science center
200,000 m2



Dongtai
Manufacturing center
300 Acre, 280,000 m2



Chengdu
COP Container center
10,000 m2

Overseas Branches & Joint venture



Italy/Germany R&D Center



Russia branch



United States branch



India Branch



Singapore Biotech Center



Verification
2006



Control System
2008



Liquid nitrogen
freeze dryer
2010



Water system
2013



Freeze dryer
2004



Isolator
2011



Formulation
system
2012



Autoclave
2013



Electropolishing
2013
www.tofflon.com



Chinese
medicine
2016



Customers



Small Molecule

Brand Drugs



Generic



Large Molecule

mAbs、ADC



Vaccine



Insulin



Plasma



Cell Gene Therapy



Scientifically pharma machinery serve for pharma manufacturing science

Machinery

API

Bio-DS

CES/SU/SS
Purification
Freeze & thaw
SU fill
Inactivation

API

Crystalization
Drying
Compound
Fermentation
Chinese
medicine

Primary Packaging

Injection

Preparation
Filling
(vial/ampoul
/BFS/PFS)
Lyo
Barrier

OSD

Weiging
Granulation
Drying
Mixing
Transfer
WIPSIP

Secondary Packaging

Inspection & Packing

Inspection
Leakage detection
Labling
Carton/palletizae
Code
Packing



Engineering

Management

FS/CD/BD/DD/3D
CQV
Automation
Consultant

Construction

HVAC Equipment
CU Equipment
Cleanroom Installation
MEP Installation



Consumables

Consumables

Bags
Media
Resin
Filter

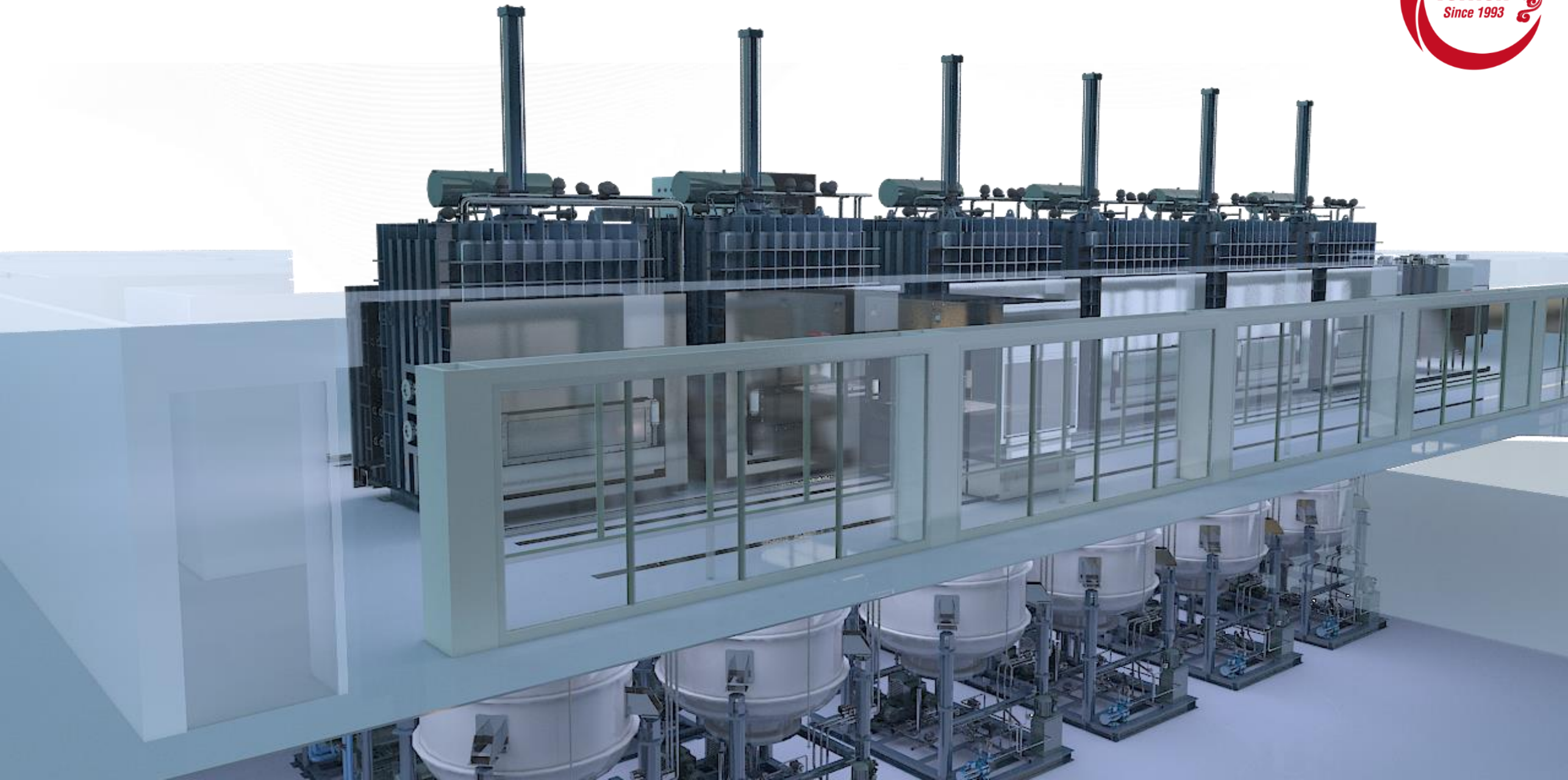
Container

COP Vial Container
COP PFS Container

EPCM

Empowering pharma industry by smart machine manufacturing

Equipment Total Solution



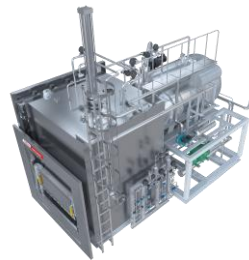
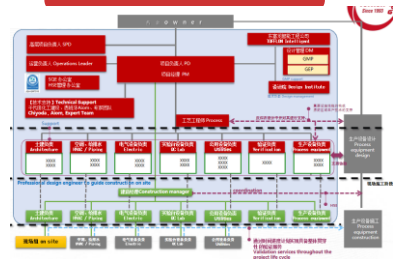
Large Molecule Drugs



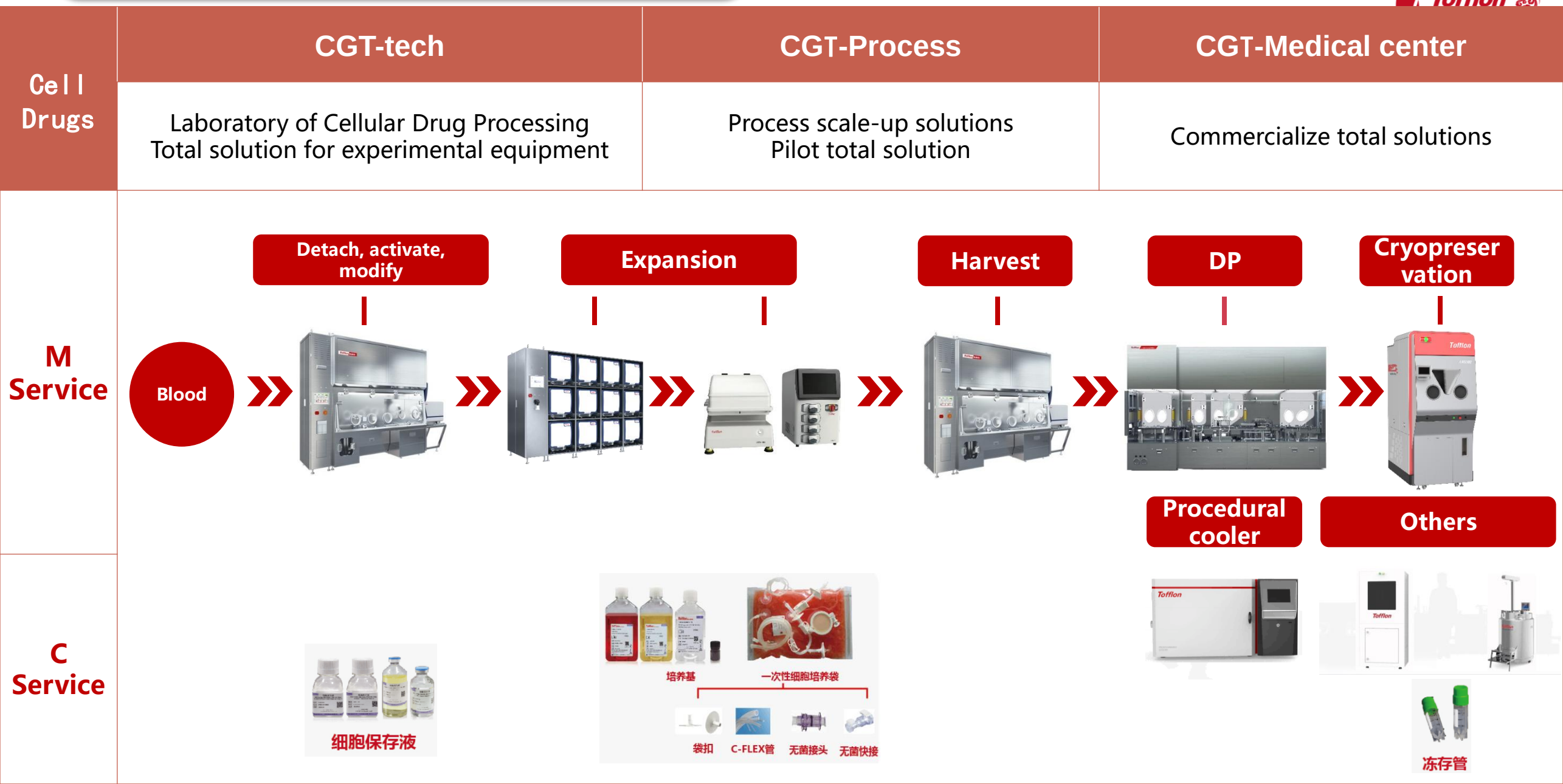
Large Molecule	Biotech	BioProcess	BioPharma
	Bioengineering Laboratory Total solution for experimental equipment	Process scale-up solutions Customized equipment development Pilot-commercialized total solution	Single-use technology/stainless steel technology Total solutions for large-scale manufacturing
DC Service	Seed store Inoculation Cell Culture Harvest Purification Viral filtration Concentration Bulk store Automatic LN storage CES Bioreactor Depth filter Chromatography column & system Nano-filtration Ultra filtration Freeze-thaw system Solution Preparation SS SU Hollow fiber Chromatography system Lab scale chrom system (Hi-Pure) Manual chrom column Auto chrom column Inactivation		
DS Service	Cell store Media CES bag Aseptic connector SUB bag Media Aseptic connector & filter	Resin Fixture	Membrane Freeze bag Bag buckle C-flex tube

Large Molecule Drugs



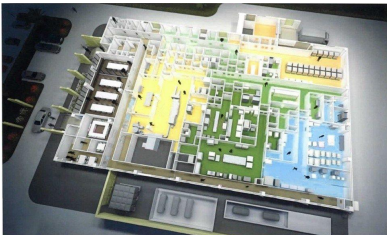
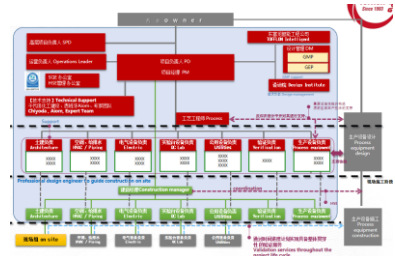
	Biotech	BioProcess	BioPharma	
Macromolecular	Bioengineering Laboratory Total solution for experimental equipment	Process scale-up solutions Customized equipment development Pilot-commercialized total solution	Single-use technology/stainless steel technology Total solutions for large-scale manufacturing	
DP Service	DS > DP > Lyo > Inspection > Packaging			
				
DE Service	Design/BIM > Equipment > Construction > PM			
		 		

Cell & Gene Therapy Drugs



Small Molecule Drugs



Small molecule	Pharmatech	Pharma Process	Pharma
M Service	Injection Process Laboratory Solid dosage process laboratory Total solution for experimental equipment	Process scale-up solutions Development of customized equipment for complex formulations Pilot-commercialized total solution	Injections/solid dosages Total solutions for large-scale manufacturing Flexible manufacturing overall solution
	Synthesis > 3-in-1/lyophilized > Crushing/packing     	Compound > DP > Lyo > Inspection > Packaging      Weighing > Granulation/drying > Mixing > Transfer > Packaging     	Design/BIM > Equipment > Construction > PM     

EPC Total Solution



The turnkey solution of Pharmaceutical engineering

E

Concept Design
Basic Design
Detailed Design
BIM Design
Validation



P

HVAC
Pure Water System
WFI System
Pure Steam System



C

Electromechanical
installation
Clean pipes
Project Management



The turnkey solution



Content of Services



Project Management

1

- General management from engineering to construction.
- Project Controls on Schedule/Cost
- Quality Assurance & Control
- Interface management and coordination
- Permitting organization management
- Change Management

Engineering

2

- CD/BD/DD deliverables
- 3D Model Design
- Engineering reviews
- Value Engineering
- Technical Inquiry, clarification and TBE for procurement
- Vendor drawing review & approval
- Engineering support during construction

Procurement Service

3

- Vendor list preparation
- Procurement for utilities equipment and services as Scope
- Post-PO activities such as expediting, logistics coordination, site materials control vendor site service coordination
- Procurement Reporting PSR & ESR

Permitting

4

- Lead and organize permitting of project in scope
- Timely report permitting progress
- Coordinate Client attend meeting and pay fee timely to ensure schedule
- Support Client to achieve milestone against schedule

Construction & HSE Management

5

- Constructability Review
- Evaluation to Contractor
- Construction Management
- Construction progress tracking
- Project handover
- HSE management

Advantages



The turnkey solution Advantage

1

High quality

2

Short duration

3

High efficiency

4

Low energy

5

Cost control

Why Tofflon



Engineering

Special understanding of engineering from 28 years of equipment manufacturing

- Constructability study during design
- Thorough value engineering study
- Acquire abundant process equipment information

Procurement

Supplier & Manufacturing

- Strategy sourcing to guarantee supply and cost advantage
- Key equipment manufacturing
- Professional procurement supervision and management system

Engineering



EPC

Total solution service

Construction

Management

- Responsible, target-oriented project management by a single contact person
- Lean project structure/organization
- Strategic support through the entire project life cycle

Management

Construction

- 20 years of pharmaceutical industries mechanical installation experience
- Quick project execution
- Schedule and cost management

Engineering Divison



AXIOM

There are more than 80 people in various majors

Cases throughout Europe, North America, South America and other places; EU GMP correspondence



Spain

中国
China

日本
Japan

- Feasibility study
- Master plan
- conceptual design
- Basic design
- Construction drawing design
- BIM design
- Validation consultation
- Project management
- Cost management
- Mechatronic management
- Civil management
- Quality control
- Security management

Tofflon 东富龙

Tofflon Smart Engineering Co.

Grade B engineering design qualification in chemical, petrochemical and pharmaceutical industry

Engineering & CQV: 100+ people

Digitalization & automation: 60+ people

20+ Registered Engineer in Process, Architecture, Structure, Plumbing and Electricity

Top domestic expert resources



Tofflon 东富龙

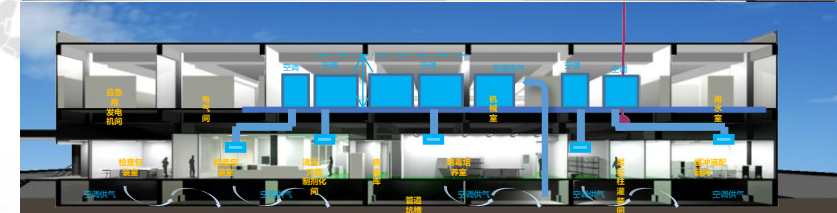
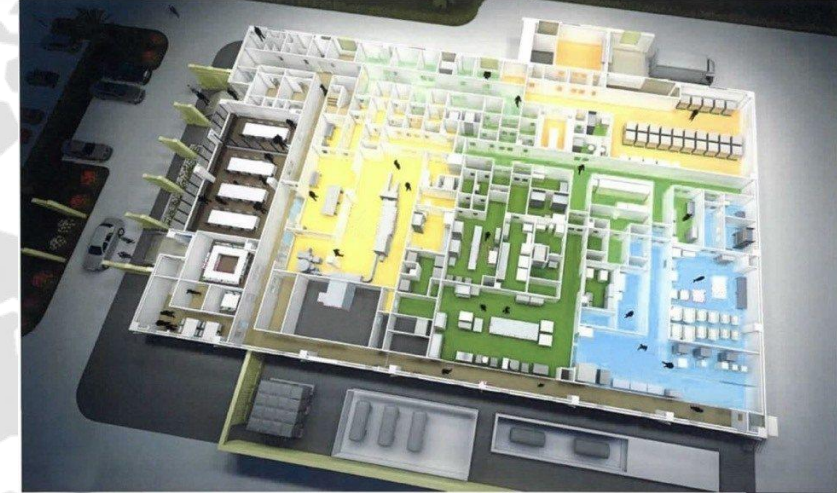
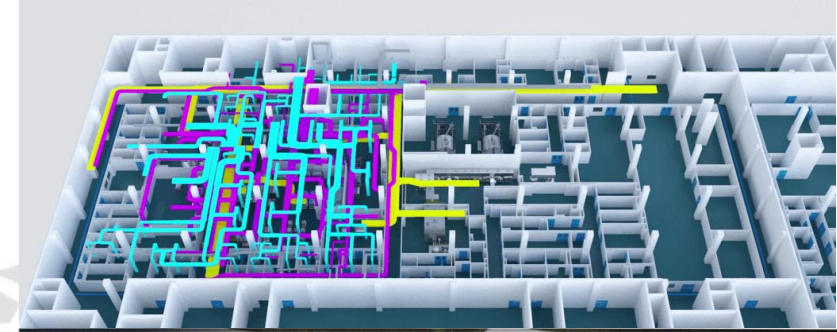
Tofflon Dehui Installation Co.

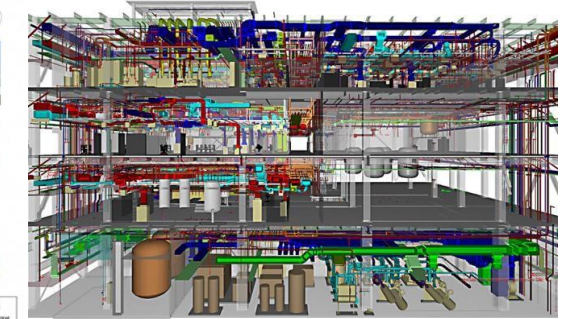
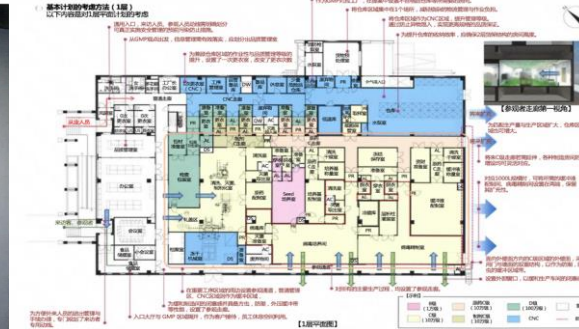
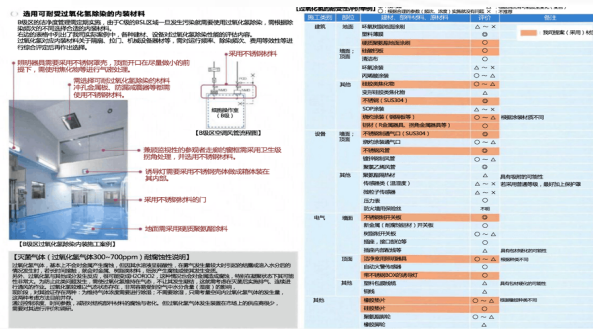
Project execution: 240+ people

Water & HVAC equipment: 60+ people

Expertise in cleanroom & MEP installation cases

100M\$+ sales per year





Process Package Design

- Process description
- Mass balance
- PFD
- Recommended layout
- Equipment list
- Process schedule
- Automation strategy

Conceptual Design

- Room Layout
- Clean Classification
- Material & Personnel Flows
- Utility Consumption
- HVAC Zoning
- Process Schedule
- Price Estimate
- Project URS

Basic Design

- P&ID U&ID
- Fixed room layout
- Equipment Specification
- Piping Study
- Design Report

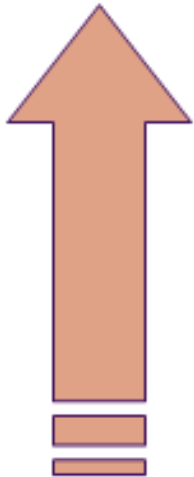
Detailed Design

- IFC drawing
- Material specification
- 3D Model
- ISO drawing
- Material Requisition
- Vendor Print

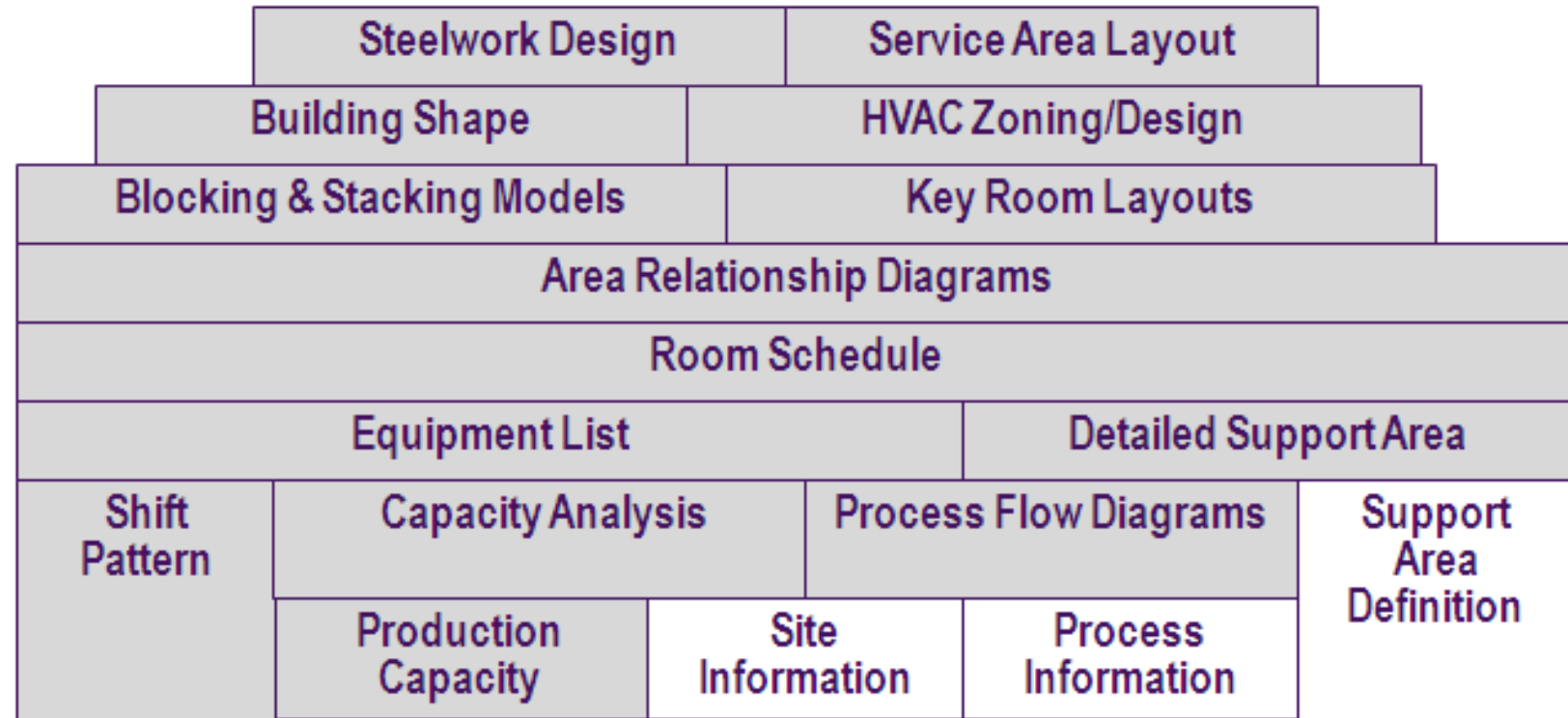
Conceptual Design



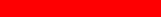
DERIVED
DESIGN
INFORMATION



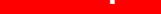
CORE DATA



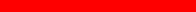
Process Design



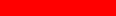
Mass balance



Process Optimize



Shift & Debottleneck



PFD
P&ID

N-3 Shake Flask

N-2 Rocking Motion

N-1 Stirred Tank Reactor

Production Bioreactor

2 Stage Depth Filtration

Protein A Affinity chromatography

Low pH Virus Inactivation

Protein A Affinity chromatography

Ion exchange chromatography

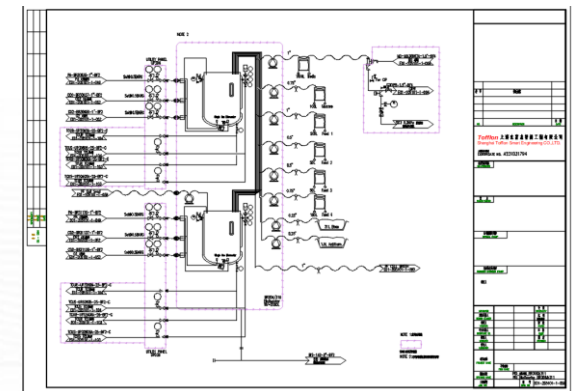
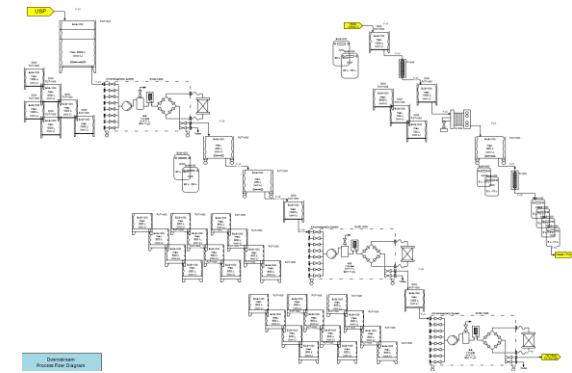
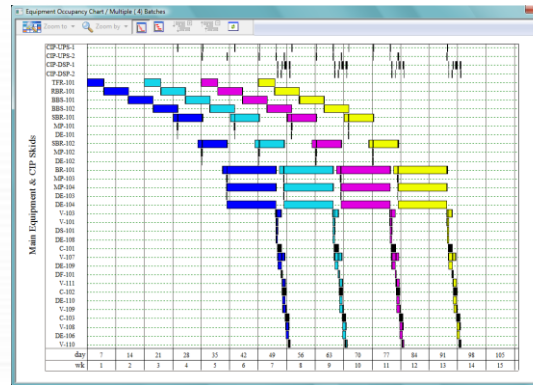
Nano filtration

Final UF | DF

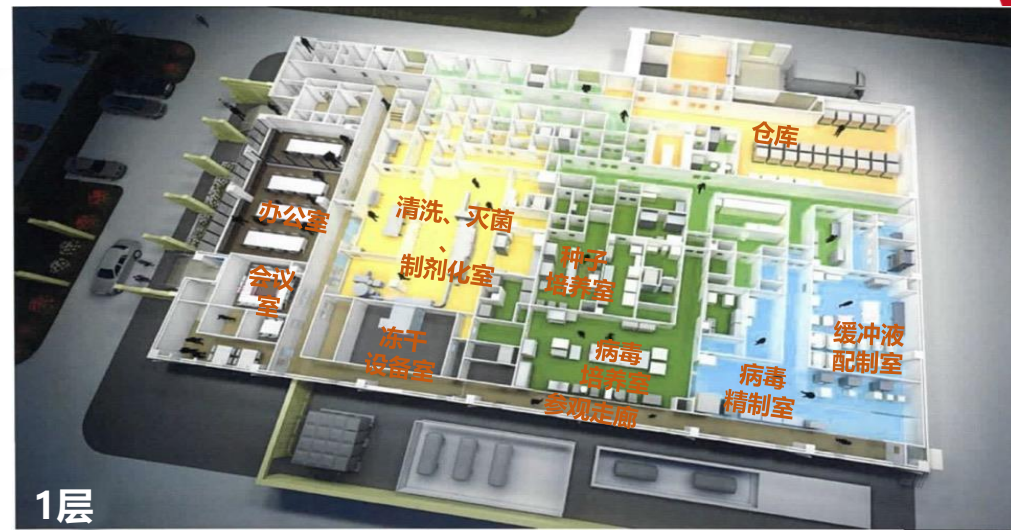
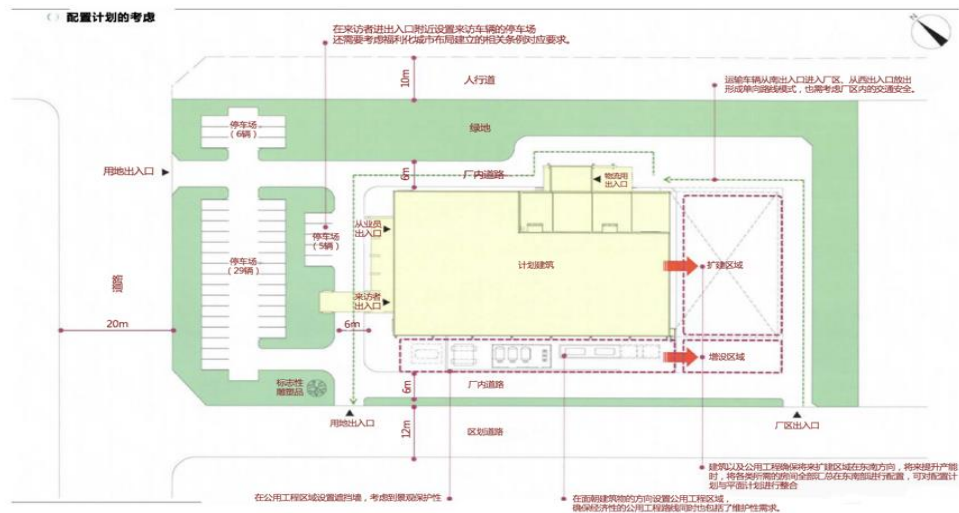
Bulk fill and finish

Mass Balance of 2000 L Scale-Upstream					
Equipment	InletStream	Volume	ProductFlow	OutletStream	Volume
LN2 Storage Tank			WCB vial		
CO ₂ Incubator (N-6)	Seed medium	30 ml	30 ml. / 125 ml. Flask	Sterile sample	1 ml
	MTX		37°C, 5% CO ₂	Waste	5 ml
	CO ₂				
		5 days			
CO ₂ Incubator (N-6)	Seed medium	100 ml	120 ml. / 500 ml. Flask	Sterile sample	1 ml
	MTX		37°C, 5% CO ₂	Waste	20 ml
	CO ₂				
		3 days			
CO ₂ Incubator (N-4)	Seed medium	400 ml	500 ml. / 2000 ml. Flask	Sterile sample	1 ml
	MTX		37°C, 5% CO ₂	Waste	100 ml
	CO ₂				
		3 days			
CO ₂ Incubator (N-3)	Seed medium	2000 ml	800 ml.-3 / 3000 ml. Flask -3	Sterile sample	1 ml
	MTX		37°C, 5% CO ₂	Waste	200 ml
	CO ₂				
		3 days			
WAVE BR (N-2)	Seed medium	8 L	10 L (25L) WAVE 25	Sterile sample	5 ml
	Feed medium	15 L	37°C, 5% CO ₂	Waste	400 ml
	Air	0.2 L min	Final volume 25 L		
	CO ₂	0.2 L min			
		5 days			
BR 600 (N-1)	Seed medium	100 L	120 L (400L) / SUB 500	Sterile sample	10 ml
	Feed medium	290 L	37°C	Waste	20 L
	Air-1	10 L min			
	O ₂ -1	10 L min	Final volume 400 L		
	CO ₂	10 L min			
	Air-2	20 L min			
	O ₂ -2	25 L min			
	N ₂	?			
		5 days			
BR 2000 (N)	Seed medium	1300 L	2000 L SUB 2000	Sterile sample	60 ml
	Feed medium-1	350 L	37°C	Sample	500 ml
	Feed medium-2	35 L			
	Base	50 L			
	Glucose	50 L			
	Anti&am	5 L			
	Air	20 L min			
	O ₂	20 L min			
	CO ₂	10 L min			
	Air-2	50 L min			
	O ₂ -2	50 L min			

Steps					Protein A	
Step	Description	Volume (CV)	Volume (L)	Flow rate(cm/h)	Time(h)	
CIP 1	Buffer 1	2	64	200	0.2	Max Load capacity 50 g/L Resin
CIP 2	Buffer 1	1.3	40	50	0.4	Load rate 45 g/L Resin
Equilibration	Buffer 2	7	223	100	2	Load Cycles 2
Load	Load Sample	39.3	1250	200	3.9	Column Height 20 cm
Wash 1	Buffer 2	7	223	100	0.7	Column Diameter 45 cm
Wash 2	Buffer 3	6	64	200	0.2	Column Volume 12 L
Elution	Buffer 4	7	223	100	0.2	Column Capacity Utilization / Max 90%
Neutralization	Buffer 2	2	64	200	0.2	Max linear flow rate 300 cm/hr
CIP 1	Buffer 1	6	64	200	0.3	Max volumetric flow 477 L/hr
CIP 2	Buffer 1	1.3	40	50	0.5	Elution Collection 3 CV
Storage	Buffer 5	3	95	200	0.3	Step yield 95%
System CIP	Buffer 6		500			198 L
				Process time :	13.9	2.7 kg
						14.2 g/L
Steps					Protein A	
Step	Description	Volume (CV)	Volume (L)	Flow rate(cm/h)	Time(h)	
CIP 1	Buffer 1	2	113	200	0.2	Max Load capacity 50 g/L Resin
CIP 2	Buffer 1	1.3	71	10	0.5	Load rate 45 g/L Resin
Equilibration	Buffer 2	7	396	100	2	Load Cycles 2
Load	Load Sample	22.1	1250	200	2.2	Column Height 20 cm
Wash 1	Buffer 2	7	396	200	0.7	Column Diameter 60 cm
Wash 2	Buffer 3	2	113	200	0.2	Column Volume 12 L
Wash 3	Buffer 4	396	396	100	0.5	Column Capacity Utilization / Max 90%
Neutralization	Buffer 2	2	113	200	0.2	Max linear flow rate 300 cm/hr
CIP 1	Buffer 1	2	113	200	0.2	Max volumetric flow 845 L/hr
CIP 2	Buffer 1	1.3	71	10	0.3	Elution Collection 3 CV
Storage	Buffer 5	3	170	200	0.3	Step yield 95%
System CIP	Buffer 6		500			139 L
				Process time :	16.5	2.7 kg
						10.9 g/L

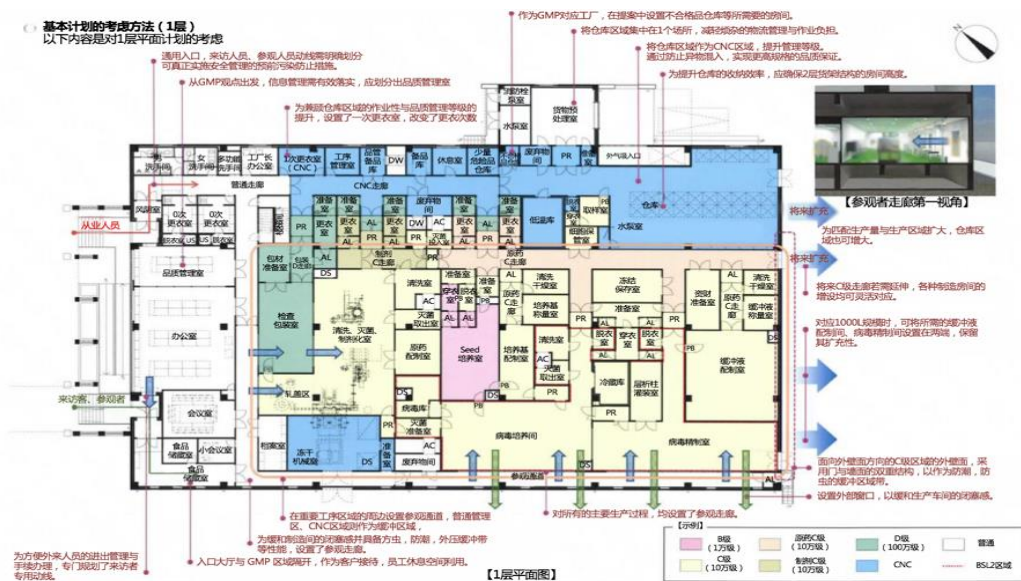


Layout Design



○ **基本计划的考虑方法（1层）**
以下内容是对1层平面计划的考虑

以下内容是对1层平面计划的考虑



- 选用可耐受过氧化氢除染的内装材料

B级区的洁净度管理需定期实施, 由于C级的BSL区域一旦发生污染就需要使用过氧化氢除染, 需根据除染剂的不同选择合适的内容材料。右边的表格中列出了我收集到的案例中, 各种建材、设备对过氧化氢除染性能的评估内容。过氧化氢对应内作材料关于阻隔、拉门、机械设器器材等, 需对运行频率、除染频次、费用等效性等进行综合评价后再作出选择。



【灭菌气体（过氧化氢气体300~700ppm）耐腐蚀性说明】

过氧化氢气体,基本上不会对金属产生腐蚀性,但因其水溶液具有强酸性,在露点温度量较大时形成的结晶或流入水分中发生反应,若长时间接触,就会对金属、塑料等材料,造成严重腐蚀或使其性质变化。另外,过氧化氢与其他物质发生反应,很可能造成 H_2O_2 和 O_2 ,这两种情况也会对金属造成腐蚀,特别是在超临界状态下,危险性更大。因此上述原因发生,常需把过氧化氢气体装在气态,不通过直接接触,这就需要在灭菌室或灭菌釜内,进行循环的气体。过氧化氢气体以 O_2 形式存在,非常容易出现裂解到 O_2 和 H_2O 中(湿度)的分解。同时发现,对材料存在两种:为维持 O_2 浓度需要受到控制;不需要控制,只靠微量空间内过氧化氢气体的变化量。这两种考虑方法都有利有弊。另外,过氧化氢气体对塑料材料,特别是对结构内部材料的腐蚀与老化。但过氧化氢气体发生装置在市场上的供应尚很少,因此,过氧化氢气体和 O_2 的混合,是过氧化氢气体发生装置在市场上的供应尚很少。

附录A 工程材料性能及选用指南					附录B 工程材料性能及选用指南	
施工类别		部位	材料、配件材料、原材料	评价	备注	
建筑	地面	环氧砂浆地面涂料	① 环氧砂浆地面涂料	△ ~ ×	环氧砂浆 (采用) 材料	
			塑料薄膜	○		
			环氧砂浆地面涂料	○		
	墙面、 顶面	乳胶漆	乳胶漆	○		
			乳胶漆	○		
			乳胶漆	○		
	其他	环氧砂浆	环氧砂浆	△ ~ ×		
			环氧砂浆	○ ~ △		
			环氧砂浆	○ ~ △		
			环氧砂浆	○ ~ △		
			环氧砂浆	○ ~ △		
设备	墙面、 顶面	环氧砂浆	环氧砂浆 (钢板板等)	○ ~ △	环氧砂浆材料不同	
			铝材 (R金属膜、铝角金属膜等)	○		
			不锈钢排气口 (SU5304)	○		
	其他	环氧砂浆	环氧砂浆	△ ~ ×		
			环氧砂浆	○ ~ △		
			环氧砂浆	○ ~ △		
	电气	墙面	环氧砂浆	环氧砂浆	△ ~ ×	具有吸湿的可能性 若采用普通等级, 最好加上保护层
				环氧砂浆	○ ~ △	
				环氧砂浆	○ ~ △	
		其他	环氧砂浆	环氧砂浆	△ ~ ×	具有吸湿的可能性 若采用普通等级, 最好加上保护层
				环氧砂浆	○ ~ △	
环氧砂浆				○ ~ △		
其他	地面	环氧砂浆	环氧砂浆	△ ~ ×	具有吸湿的可能性 若采用普通等级, 最好加上保护层	
			环氧砂浆	○ ~ △		
			环氧砂浆	○ ~ △		
	其他	环氧砂浆	环氧砂浆	△ ~ ×	具有吸湿的可能性 若采用普通等级, 最好加上保护层	
			环氧砂浆	○ ~ △		
			环氧砂浆	○ ~ △		
	电气	墙面	环氧砂浆	环氧砂浆	△ ~ ×	具有吸湿的可能性 若采用普通等级, 最好加上保护层
				环氧砂浆	○ ~ △	
				环氧砂浆	○ ~ △	
		其他	环氧砂浆	环氧砂浆	△ ~ ×	具有吸湿的可能性 若采用普通等级, 最好加上保护层
				环氧砂浆	○ ~ △	
环氧砂浆				○ ~ △		
电气	墙面	环氧砂浆	环氧砂浆	△ ~ ×	具有吸湿的可能性 若采用普通等级, 最好加上保护层	
			环氧砂浆	○ ~ △		
			环氧砂浆	○ ~ △		
	其他	环氧砂浆	环氧砂浆	△ ~ ×	具有吸湿的可能性 若采用普通等级, 最好加上保护层	
			环氧砂浆	○ ~ △		
			环氧砂浆	○ ~ △		
电气	墙面	环氧砂浆	环氧砂浆	△ ~ ×	具有吸湿的可能性 若采用普通等级, 最好加上保护层	
			环氧砂浆	○ ~ △		
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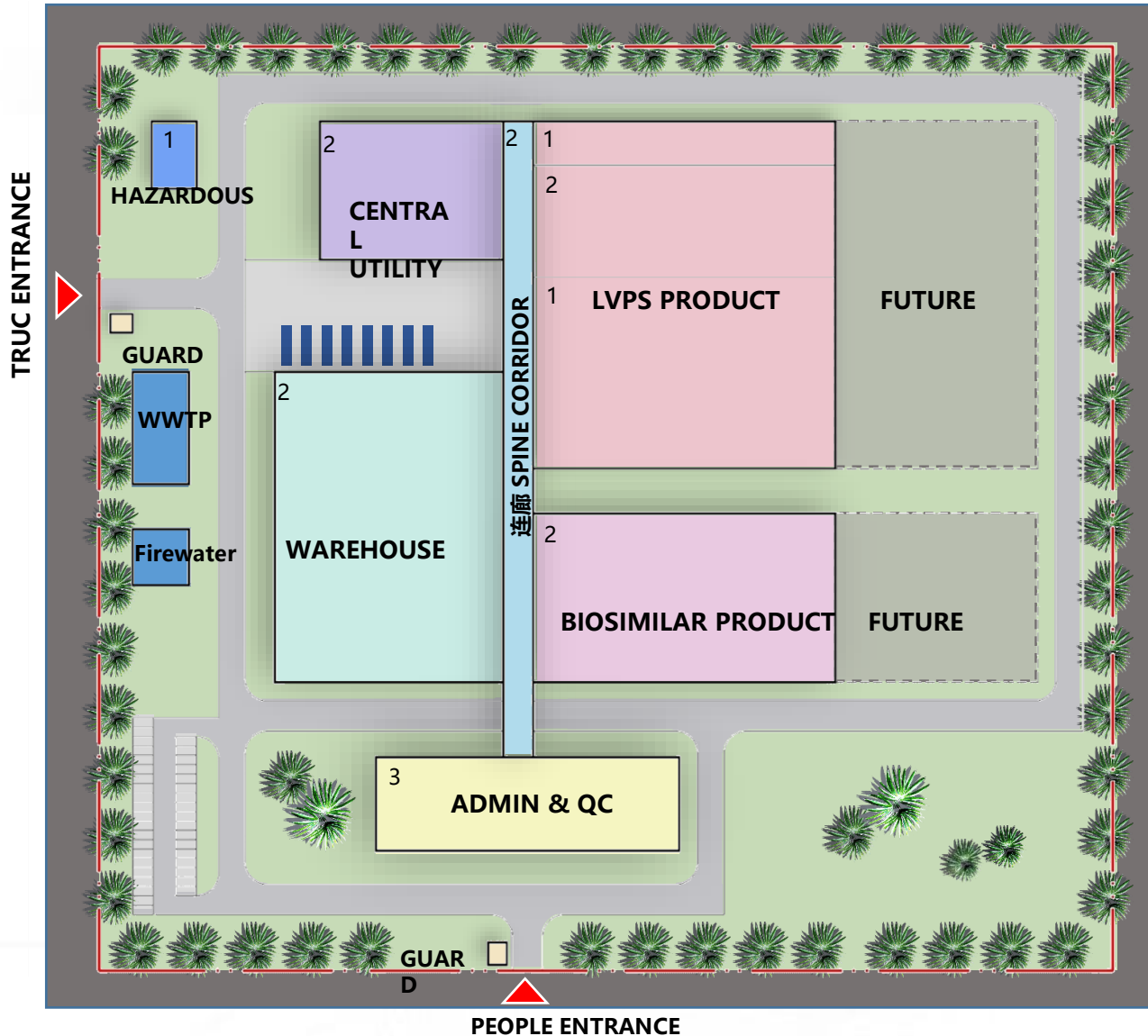
Exterior Design



Interior Design



Plot Plan Design



Proposal Comparison & Analysis



楼层构成的考虑

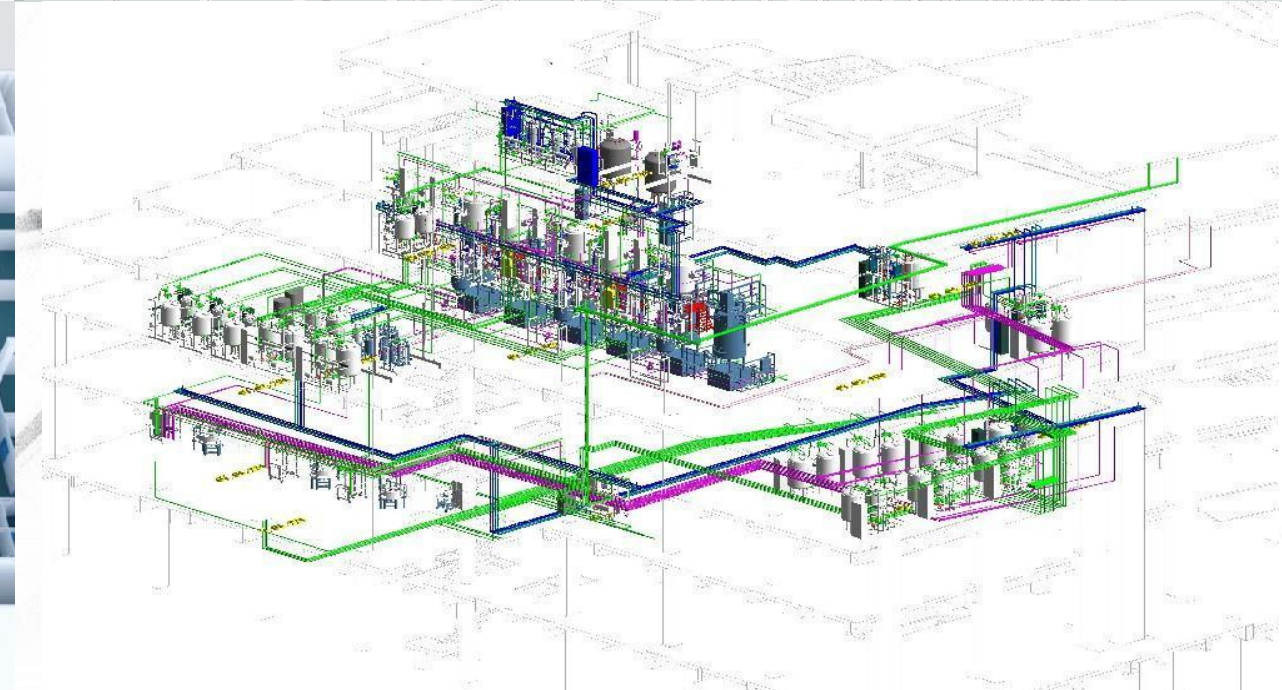
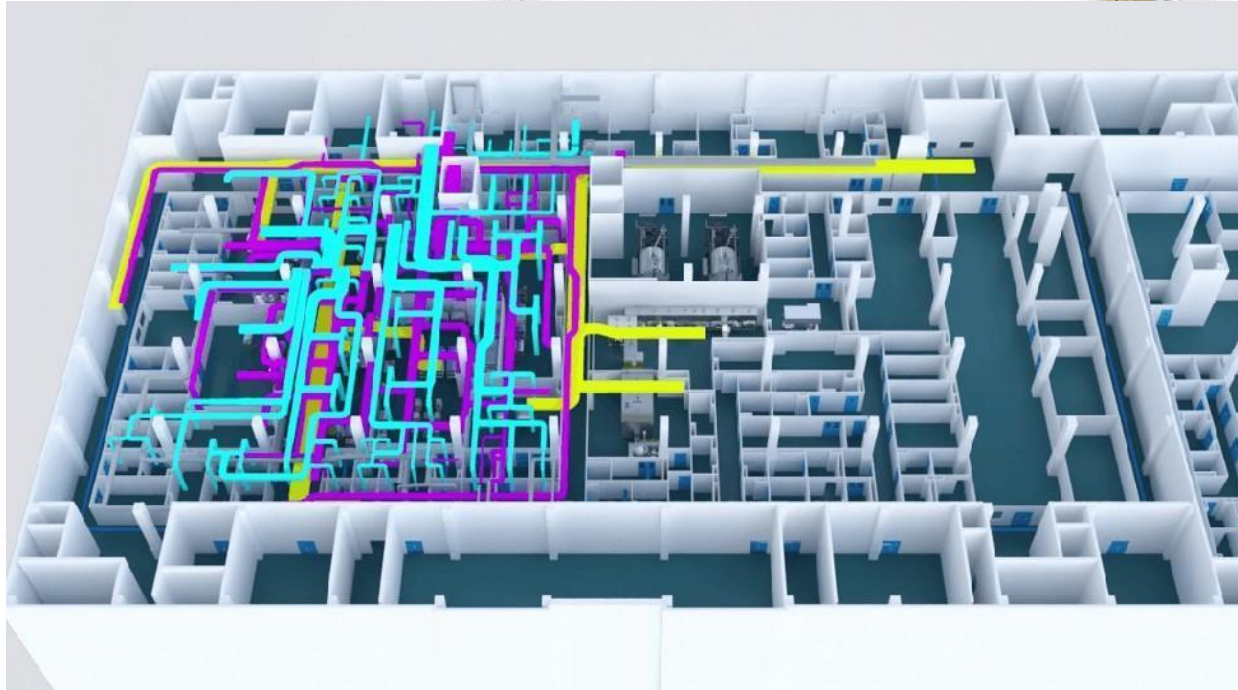
综合评价良好且可行的方案					
	案1 平房方案	案2 2层方案 全部性能集中在1层	案3 2层方案 质保分离方案	案4 2层方案 管理共用区域2层方案	案5 2层方案 制造区域2层方案
平面模块计划					
现场地皮的有效利用	△ 存在无法确保将来扩展用地的可能	○	◎ 建筑面积紧凑	◎ 可缩小建筑面积的方案	◎ 建筑面积紧凑
参观人员对应 (制剂化、原药区域)	◎ 参观通道在1层，访问性良好	◎ 参观通道在1层，访问性良好	◎ 参观通道在1层，访问性良好	◎ 参观通道在1层，访问性良好	△ 需具备能够至2层的升降机
物流作业	◎ 将全部功能集中在1层	◎ 将全部功能集中在1层	○	○	× 所有的原材料，需要垂直搬运，作业性差。
品质管理区域 配置	○ 通过对更衣、空调系统等的明确划分解决问题能够缩短取样动线	○ 通过对更衣、空调系统等的明确划分解决问题能够缩短取样动线	◎ 通过楼层进行明确划分	◎ 通过楼层明确划分	△ 通过对更衣、空调系统等的明确划分解决问题从生产区域开始的取样动线可缩短，但物流区域太远。
机械室平面布局	○ 机械室与制造区域在同一层，不需要楼板贯通，风管、管道线路会稍微变长一些。	◎ 风管、管道线路短	◎ 风管、管道线路短	◎ 风管、管道线路短	× 2层需要设置PS、DS，空间效率差，风管、管道的铺设量较其他更多。
办公管理与手续运营 从业人员通道	◎ 全部性能集中在1层	◎ 全部性能集中在1层	○ 除品质管理区域外，所有性能集中在1层	△ 管理区域在2层，来访者也可访问2层	○ 各种性能都需要在2个楼层一起构建，作业者，来访者都必须在上下层之间移动。

本提案重视对品质管理区域的独立性，单独提出此方案3。

楼层构成的考虑

BIM Design

BIM design checks for design errors and optimizes them.
Simulate the construction sequence and export the list of materials.



Digital Application



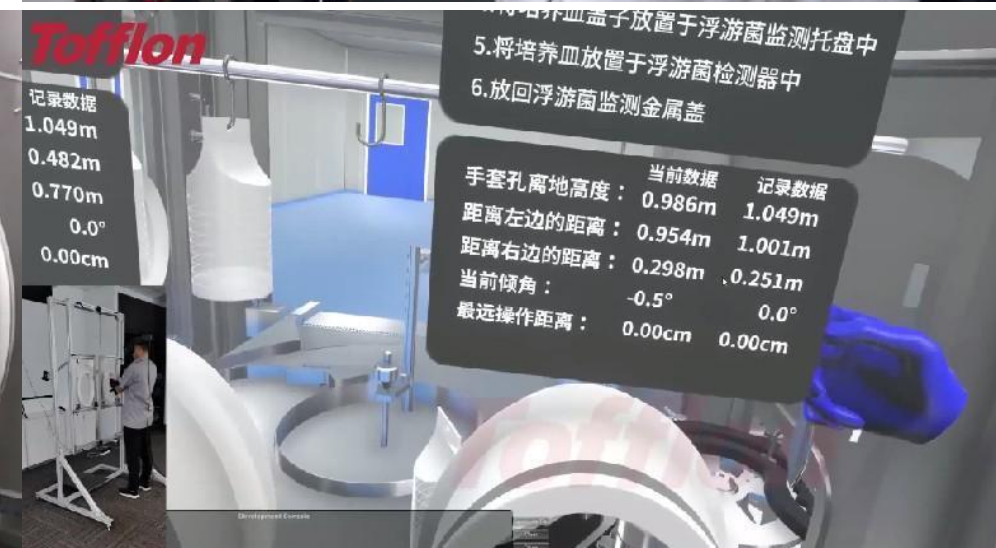
VR/AR Digital twin

Mock up

Training

AR maintenance

AR SOP guidance



Procurement management



Strategic Purchasing

Based on group requirements and the infrastructure, strategic purchasing group study the supplier sourcing and supplier evaluation.



Material Control

The Materials Scheduling team draws up a procurement plan based on the orders and compiles the exact project schedule.



Transport and Logistics

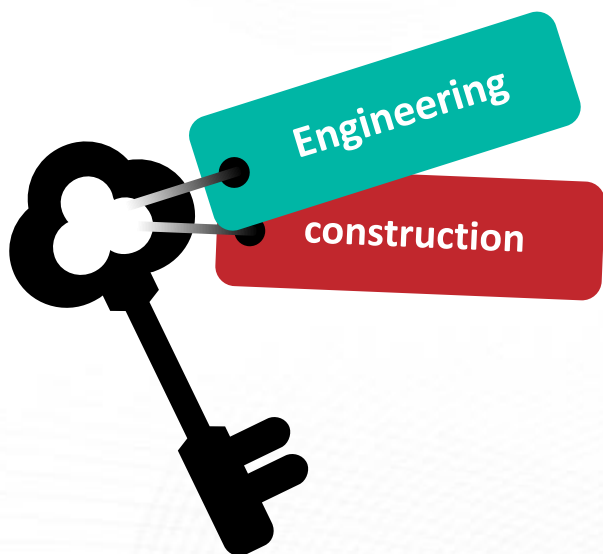
The tasks include handling receipt of incoming goods correct storage and shipping of outgoing goods with high efficiency.



Supplier Management

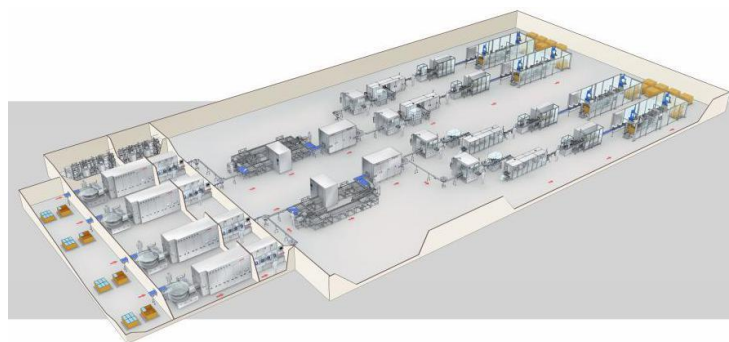
Based on purchasing strategy, supplier management team establish and develop supplier list, and update it according to our supplier evaluation standard.

Engineering construction



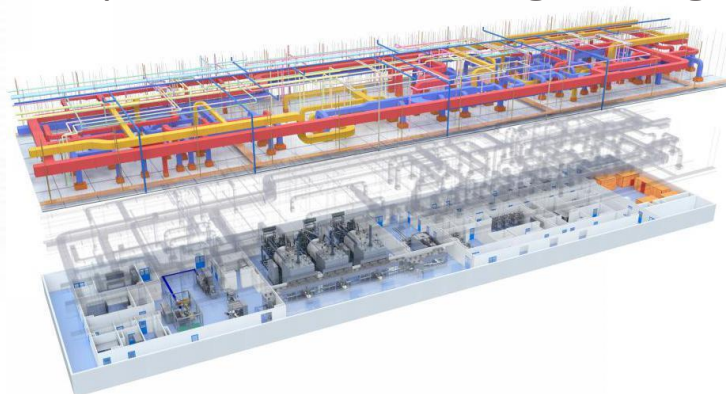
Equipment Installation

Injection, OSD, BIO-E, API equipments



Clean rooms & HVAC & construction

Overseas project management and global purchasing
Cooperation with local Engineering Institution



Construction Management



Technical disclosure

Design engineer on-site guidance



Cost management

The cost engineer is responsible for the budget and final accounts of the project



Schedule control

The PM team is responsible for project schedule management. Risk control



Contract management

CM to ensure project progress, cost, and control project financial risks

Construction Features



Construction Features



Key utility equipment



Water System

Tofflon cooperates with European AQUANOVA to provide high-end injection water, purified water, pure steam system and distribution system;

Intelligent distribution of water by crests

Automatic maintenance system

Automatic disinfection system



HVAC

The frame adopts high-strength non-cold bridge aluminum profile with a closed cavity structure.

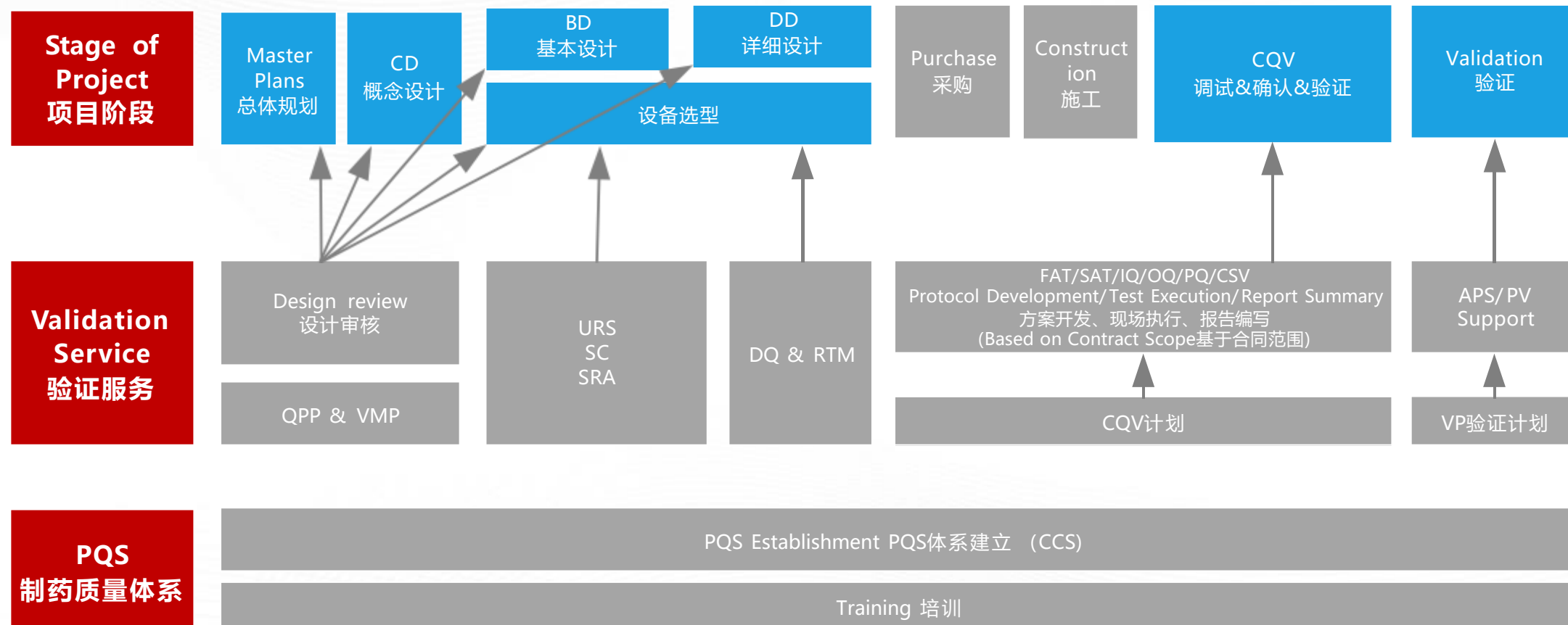
Eliminate all cold bridges. No condensation.

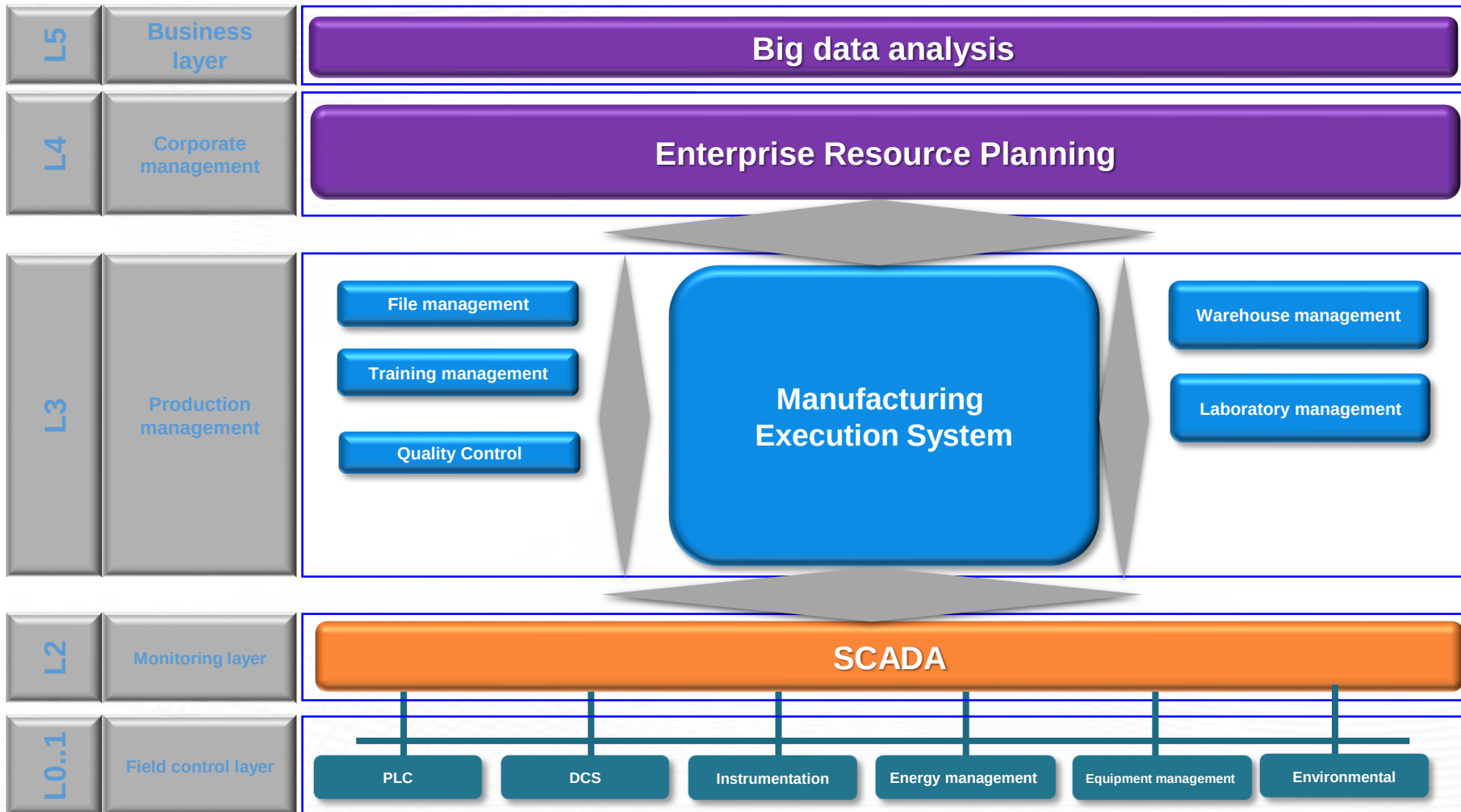
The high-strength aluminum alloy profile is the skeleton and adopts an externally mounted structure.

The wall plate and frame are connected by crimp external fastening, and the inner section of the chassis body has been eliminated for easier cleaning.

Comply with EU clean room air conditioning unit standards .









Tofflon Modular Factory

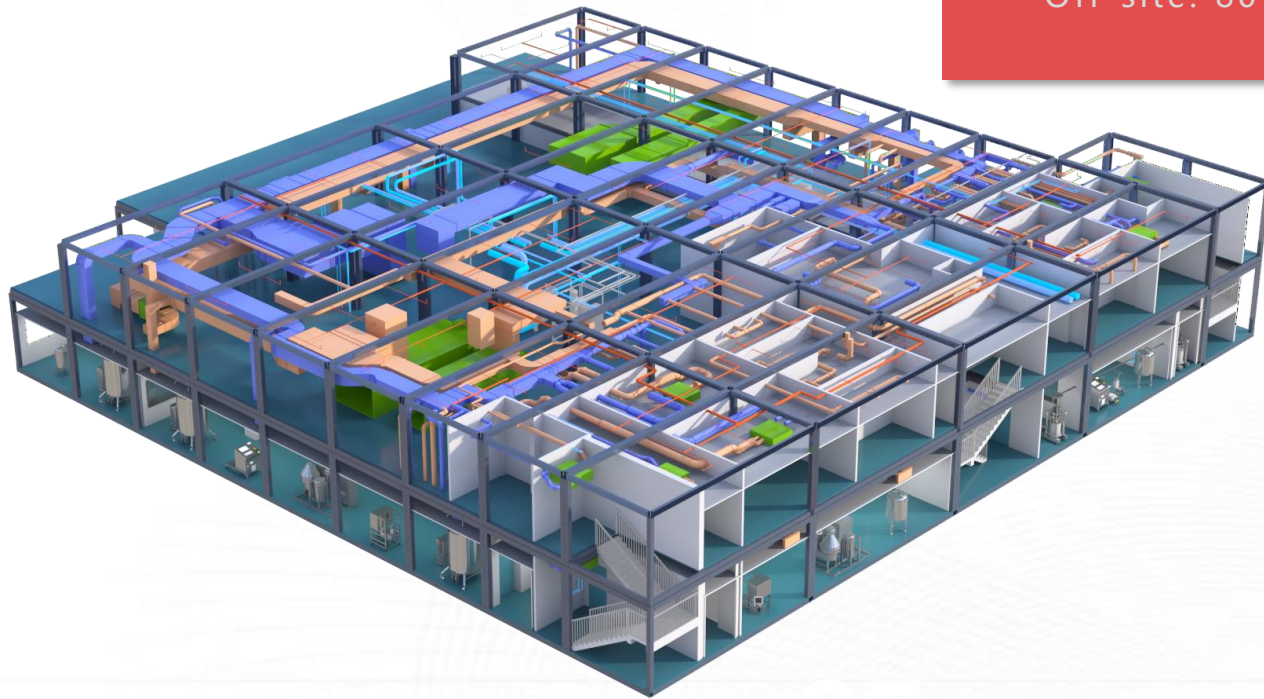
Brief Introduction



Tofflon Science and Technology Group Co., Ltd.

www.tofflon.com

What is Modular



80%

Off-site: 80%

10

Turn-key: 10 Month*

5%

Cost predictability:
5%

From Project to Product

Modular construction removes the 80% of the delivery of your project from the conditions on your final site. It includes all structural parts, building fixtures, clean room, HVAC, process equipment, utilities, power supply system, auto-control system etc. By Modular construction, we can deliver your project like an equipment.

*Take 4*2000L McAb as example.



Modular facilities

Suitable for greenfield project. The modular frame itself makes the building structure and no need for extra building shell. Including steel structure, building component, cleanroom installation, utilities, process equipment, piping, power supply and control system etc.

Modular Cleanrooms

Suitable for adapted into existing building shells. Prefabricated, autonomous cleanroom designs and technologies that includes cleanroom, utilities, process equipment, piping, power supply and control system etc.



Modular Facility Design Feature



Module size:

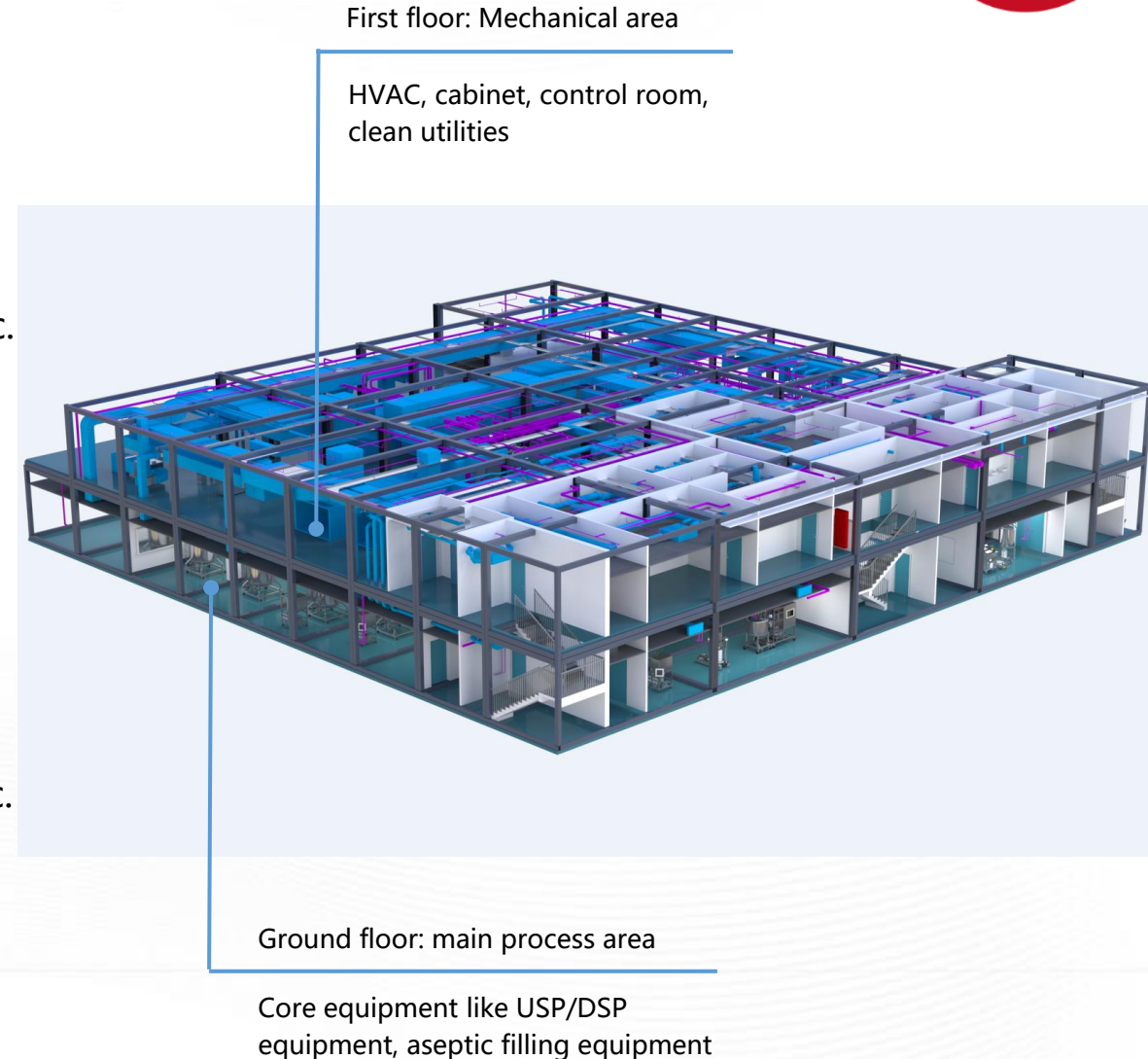
- Standard module size: 13.50m*4.50m*4.50m (L*W*H) ;
- Module size can be customized according to projects.

Modular including:

- Core equipment, including bioreactor, chromatography, UF, filling, etc.
- Steel structure: including beam, column, installation fixtures, etc.;
- Cleanroom: including clean board, floor, windows, doors, etc.;
- HVAC system: including AHU, exhaust fan, ducts, turret, valves, etc.;
- Fire protection: including hydrants, extinguisher, fire alarm, sprinkler, etc.;
- Piping system: including clean utility, black utility, piping, valves, etc. ;
- Electrical: including power supply, lightning, socket, etc.;
- Telecommute: including entrance guard, interlock, network, CCTV, etc. ;
- Control system : including BMS/EMS etc., SCADA system as option;
- Furniture: including wardrobe, bench, etc.;

Service scope:

- Engineering, procurement, fabrication, construction turn-key solution ;



Modular Cleanroom design features



Module size:

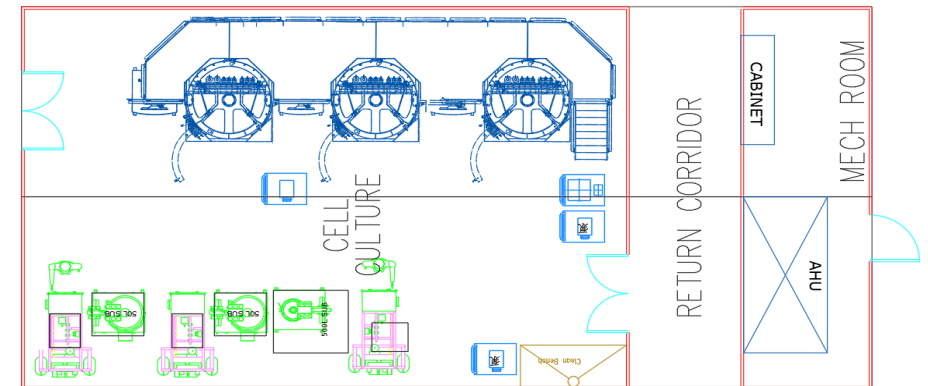
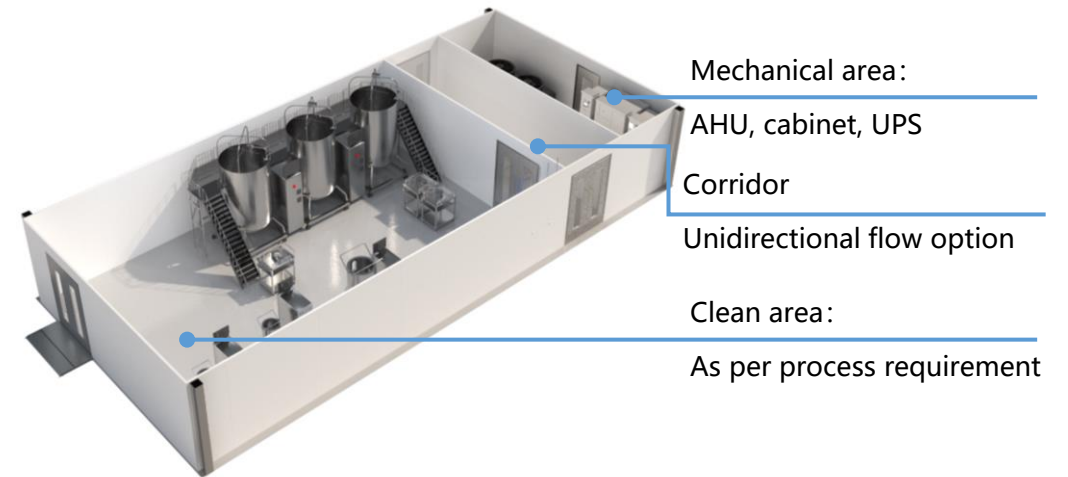
- Standard module: 12m*4m*3.5m (L*W*H) ;
- Module size can be customized according to projects.

Modular including:

- Core equipment, including bioreactor, chromatography, UF, filling, etc.
- Cleanroom: including clean board, floor, windows, doors, etc.;
- HVAC system: including AHU, exhaust fan, ducts, turret, valves, etc.;
- Fire protection: including hydrants, extinguisher, fire alarm, sprinkler, e ;
- Piping system: including clean utility, black utility, piping, valves, etc.;
- Electrical: including power supply, lightning, socket, etc.;
- Telecommute: including entrance guard, interlock, network, CCTV, etc.;
- Control system : including BMS/EMS etc., SCADA system as option;
- Furniture: including wardrobe, bench, etc.;

Service scope:

- Engineering, procurement, fabrication, construction turn-key solution;
- Pre-engineering, pre-commissioning, pre-qualification, pre-validation;
- Commissioning, qualification, verification (DQ/IQ/OQ) and training;



Tofflon Modular Concept - F⁵ Factory



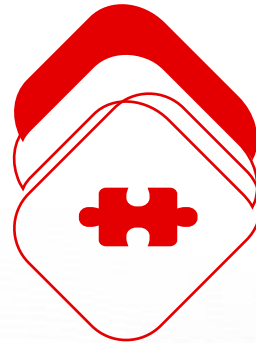
Flexible

- 1) **Suitable for multipurpose product platform** . With closed process equipment and ballroom concept.
- 2) **Customized equipment design** for modular project, fit into the modular precisely, and avoid site re-assembly.
- 3) **Relocatable**. easy for dis-assembly and re-assembly.
- 4) **Adaptable for scale-up and scale-out**, with little interfering for running facilities



Flawless

- 1) **High precision 3D model** design with BIM and E3D.
- 2) Machining accuracy guaranteed by **well trained in-house workers** and workshop **quality control system**.
- 3) **High level of FAT**, with **equipment commissioning** in factory.



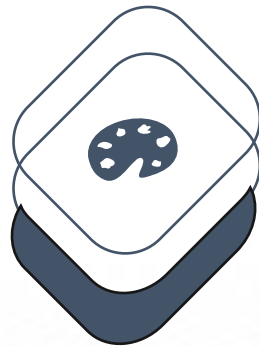
Future Production

- 1) High degree of **automation and digitization**, integrated SCADA & DCS control system.
- 2) **Continuous process concept**, with perfusion, continuous inactivation and purification equipment.



Fast-track

- 1) Schedule accelerated to **30-50%**.
- 2) **Overlapping** construction procedure, on-site civil foundation and off-site pre-assembly simultaneously.
- 3) **Pre-qualification and validation** off-site can reduce on-site qualification and validation time.



Firm

- 1) **Firm budget & cost**, minimize COs and reworks.
- 2) **Value engineering** concept, balance initial investment and long-term running cost.
- 3) **Firm project management**, sole contact point.



Comparison with stick-built facilities



Features	Modular Cleanroom	Modular Facility	Traditional
Quick Construction	✓ Off-site manufacturing & pre-qualification, quick fabrication on-site	✓ Civil, steel structure, cleanroom constructed in parallel	✗ Civil, steel structure, clean room constructed in sequence.
Movability	✓ Using air bearing to move modular unit	✓ Can be disassembled and moved by crane	✗ Not available
Scale up & out	✓ No interfering existing facilities when scale up/out	✓ No interfering existing facilities when scale up/out	✗ Need re-verification
Schedule (CD to OQ)	✓ 5-6 Months (not including building shell)	✓ 8-14 Months	✗ 16-24 Months
FAT	✓ Can be tested in factory, any problems solved off site	✓ Can be tested in factory, any problems solved off site	✗ Not available until mechanical completion
Pre-qualification	✓ Qualification can be done in factory	✓ Qualification can be done in factory	✗ Not available until mechanical completion

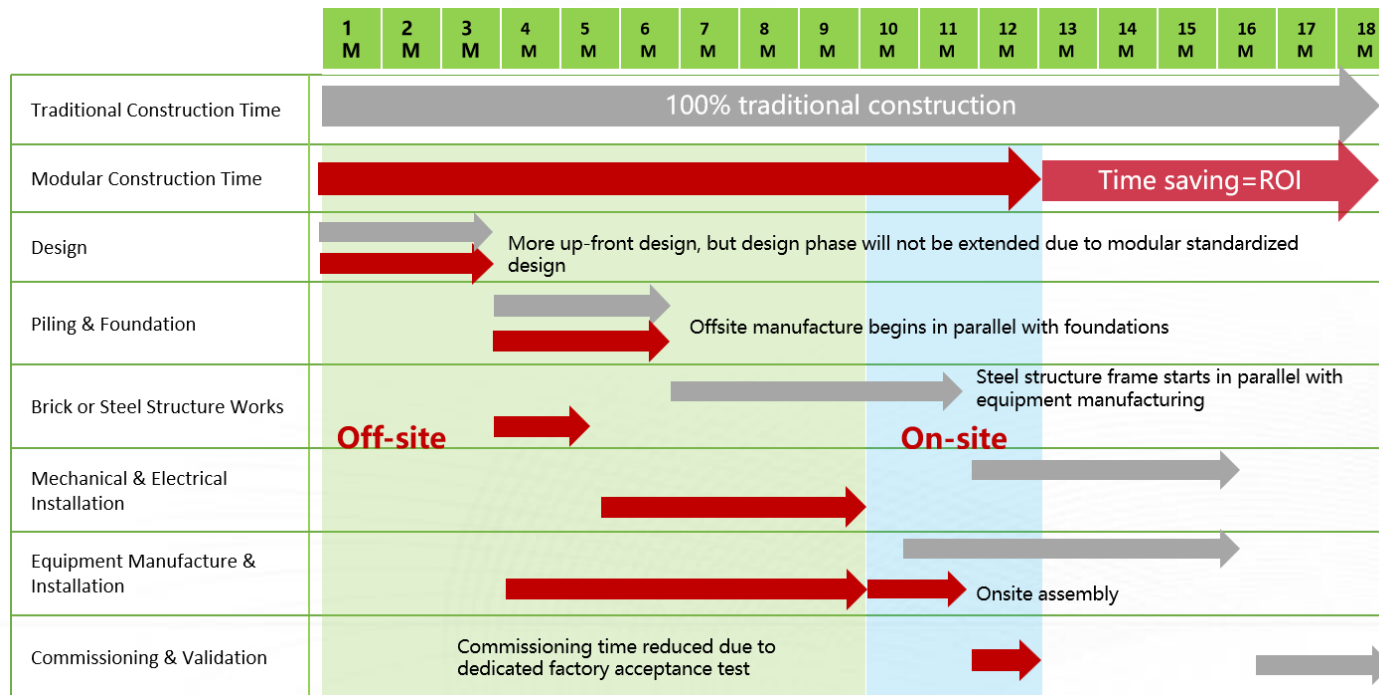
Schedule Comparison



Moving construction offsite and into a controlled factory environment reduces programme times by up to 50 percent.

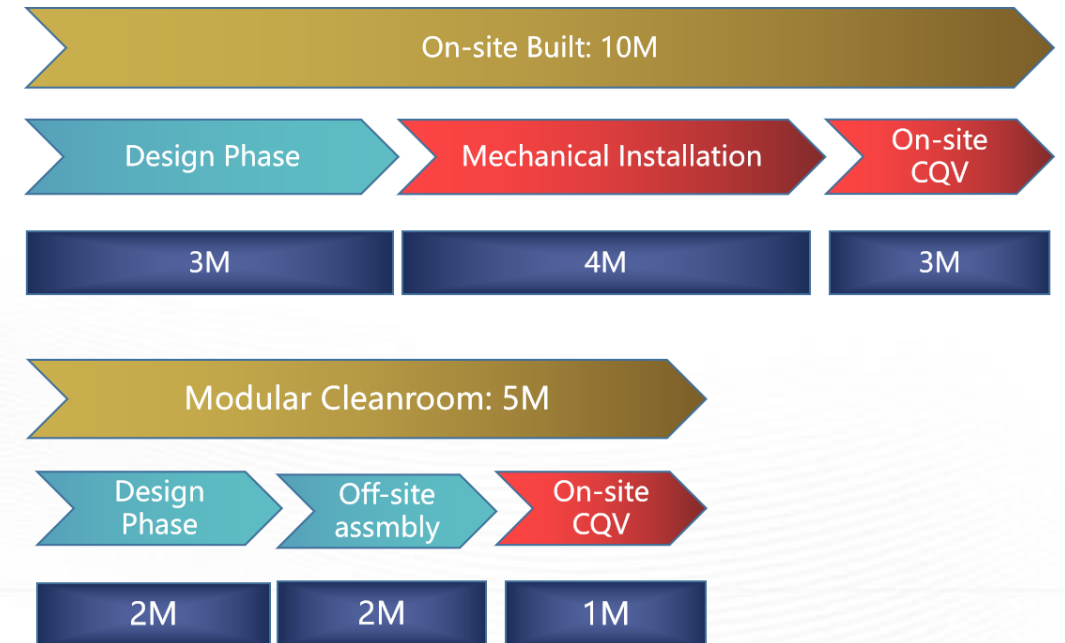
Stick-built facility construction: > 18 months

Modular facility construction: < 12 months

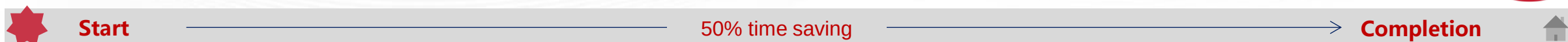


On-site fit out works: > 10 months

Modular cleanroom: ~5 months



Implementation Procedure



Feasibility Study

1. Decide modular option
2. Decide process/URS
3. Code, risk, feasibility analysis
4. Proposal comparison
5. Budget & economical analysis

Engineering Design

2. Process calculations
3. 3D Design
4. IFC drawings extract from 3D model
5. Manufacture drawing
6. Government

Workshop Assembly

1. Steel Frame manufacture & pre-assembly
2. Clean room & Mechanical Installation
3. Equipment Installation
4. FAT
5. Disassembly for transportation

Transportation

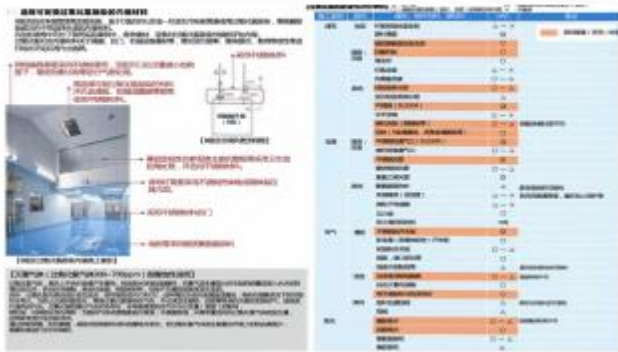
1. Land transportation: Lowboy truck
2. Sea transportation: Bulk carrier
3. Air transportation: as required

Onsite Construction

1. Civil foundation & UG works preparation
2. Module lifting and reassembly
3. Facade and roofing
4. Construction Management

Handover

1. Utilities and clean room commissioning
2. Process equipment commissioning
3. Qualification and verification



Process Design

- Process description
- Mass balance
- PFD
- Production layout study
- Equipment list
- Production scheduling study
- Automation strategy

Conceptual Design

- Module unit size
- Room Layout
- Cleanliness classification
- Material & Personnel Flows
- Utility Consumption
- HVAC Zoning
- Production Schedule
- Cost estimation
- Project URS

Basic Design

- P&ID
- U&ID
- Equipment specification
- Layout development
- MEP design
- Electrical design
- Piping Study
- Design Report
- Transportation study

Detailed Design

- IFC drawing
- 3D Model
- Material specification
- ISO drawing
- Material Requisition
- Vendor Print

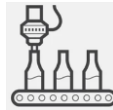
Modular Considerations & Strategies



Modular Structure

- Structural calculations
- Connections & joints
- Transportation plan
- Foundation design
- Insulation & waterproofing

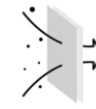
- ✓ Design partner TJAD & ECADI
- ✓ Mature technique from modular civil & datacenter application
- ✓ Rich experience experts



Process Equipment

- Equipment integration
- Overweight, oversize equipment
- Equipment crossing modules
- Equipment flexibility
- Equipment fasten & transportation

- ✓ Customized control system
- ✓ Adaptive designed equipment
- ✓ SU system and intensified system



Cleanroom & MEP

- Layout consideration
- EPC turn-key abilities
- Energy saving & cost saving

- ✓ Delicate design based on our understanding of the equipment
- ✓ 30 yrs cleanroom installation experience
- ✓ Innovative design of HVAC system
- ✓ Global partners Axiom

Equipment integration strategy

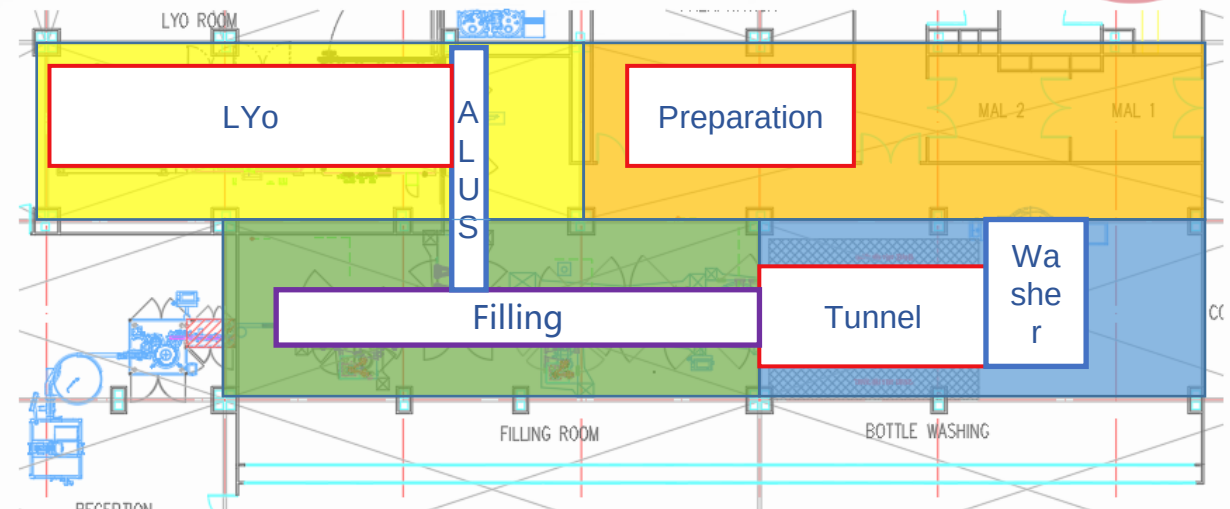


➤ Equipment Customization

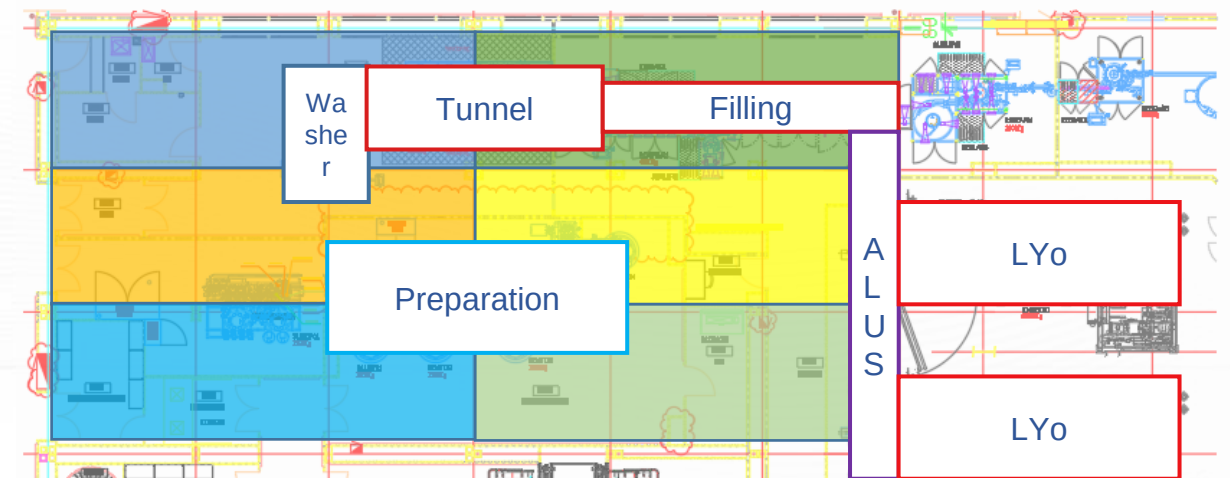
- ✓ Reducing connections between modules;
- ✓ Proper design to segregate filling line;
- ✓ Sectional design of tunnel to reduce size;
- ✓ Flexible design of Lyo chamber & condensor to reduce height and weight, making it available to fit in the module;
- ✓ Customized Isolator & BIBO design to reduce height;
- ✓ ALUS pro without pushing system to reduce spaces and increasing flexibility;
- ✓ Customized centralized control system & cabinet;

➤ Layout solutions

- ✓ Adjustment of modules to allow process layout more reasonable;
- ✓ Customized capper & stopper treatment machine for high-speed filling lines (located on 2nd floor)



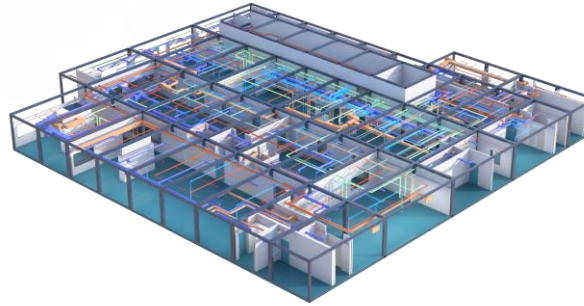
Vs.



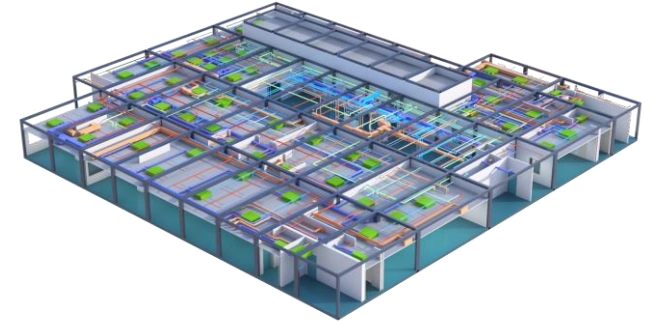
Brief Picture of Modular Delivery



Steel frame fabricate



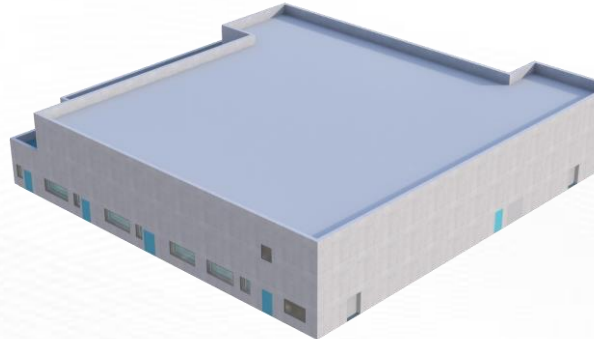
Piping & ducts installation



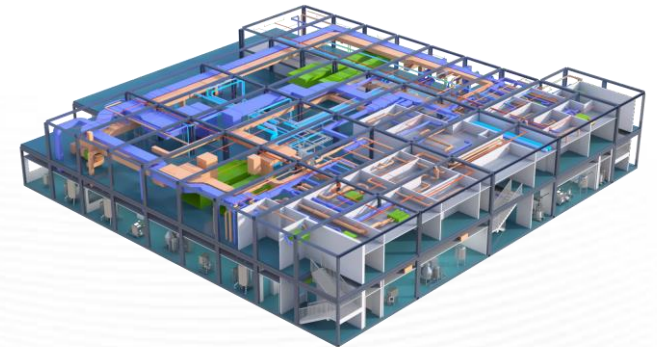
Clean room installation



Packing and shipping



Factory acceptance test



Equipment installation

Brief Picture of Modular Delivery



Civil foundation



Module lifting



Hook-up



CQV



Roof & Facades

Connection details



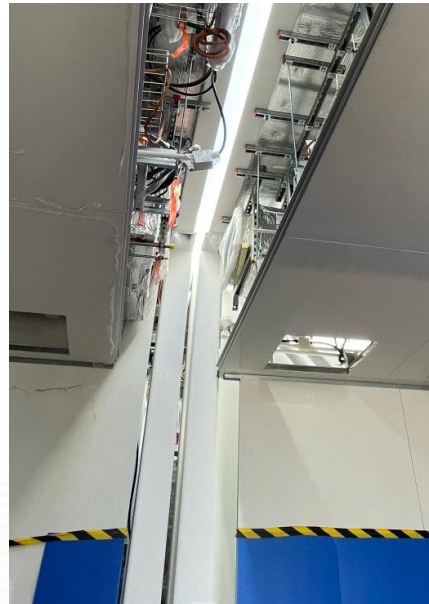
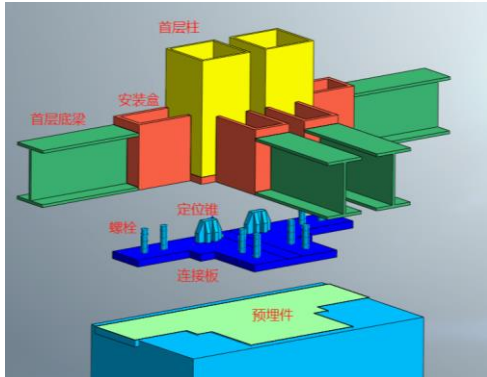
Structure
connection

Floor
connection

Cleanboard
connection

Duct & pipe
connection

Cable
connection





EPC Track Record

UAE Vaccine F/F Facility

- **Main Equipment:**

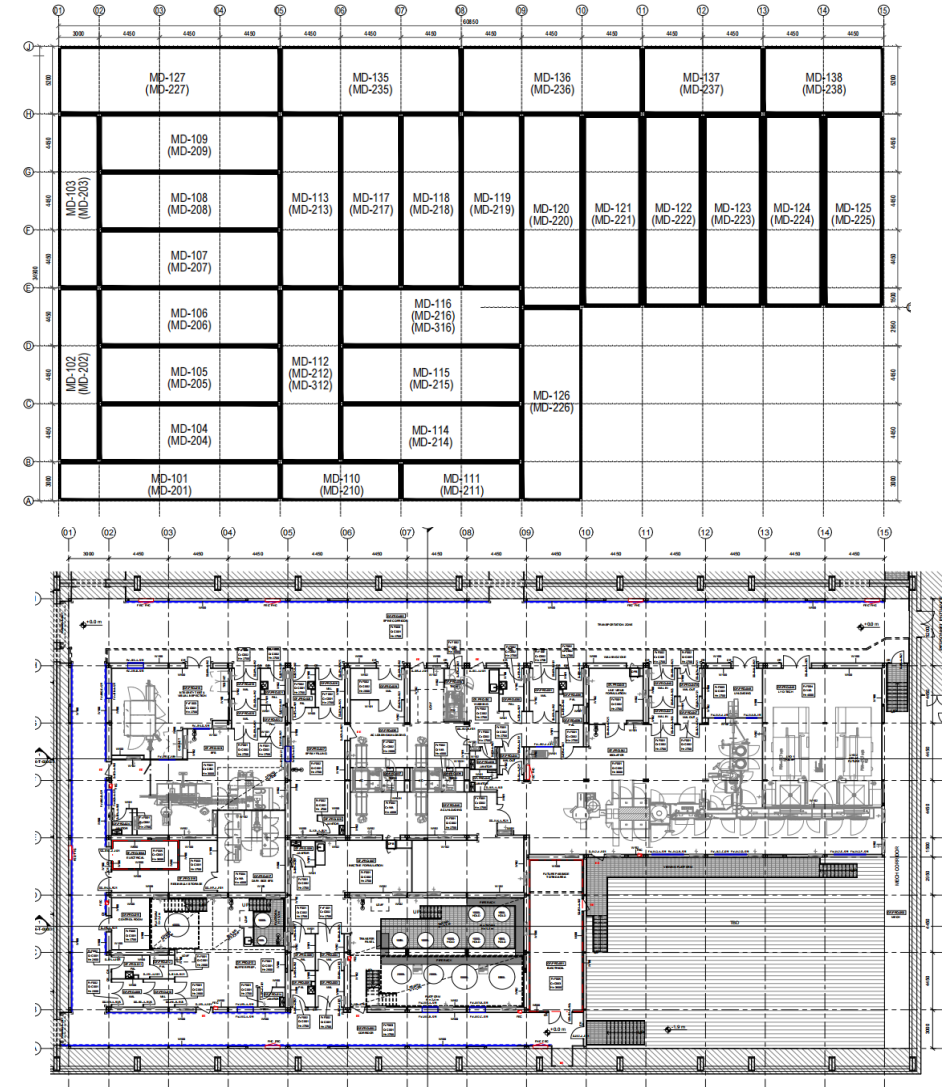
- 300vpm vial liquid/lyo filling line with isolator;
- 1800 uits/hr BFS filling line, 50~500mL;
- Formulation and preparation vessel system;

- **Facility Information:**

- Building footprint: 1800 m²;
- Total area: 3600 m²; 64 module units
- 1st floor area: 1800 m², 30 module units;
- 2nd floor area: 1800 m², 34 module units;

- **Project Considerations:**

- Core clean area in modular approach; less complex area (eg. secondary packaging, QC lab, animal house) in traditional approach;
- Box-in-box type modular facility, exterior building shell easy to build;
- Fast-track delivery: building shell and interior modular facility work in parallel. Whole project delivers in 12 months.



15kg OSD PODs, OBE5

Design Concept: Smaller area, faster construction

Capacity: 15-30kg per batch or sub-lot

- **1. Area classification:**

- Separate modules set for pedestrian flow, pretreatment, granulation and forming to avoid cross contamination
- Comply with GMP production requirements, Grade D clean area
- Integral modular installation of equipment and plant

- **Total dimensions:** 20 x 11.4 x 4.2 m

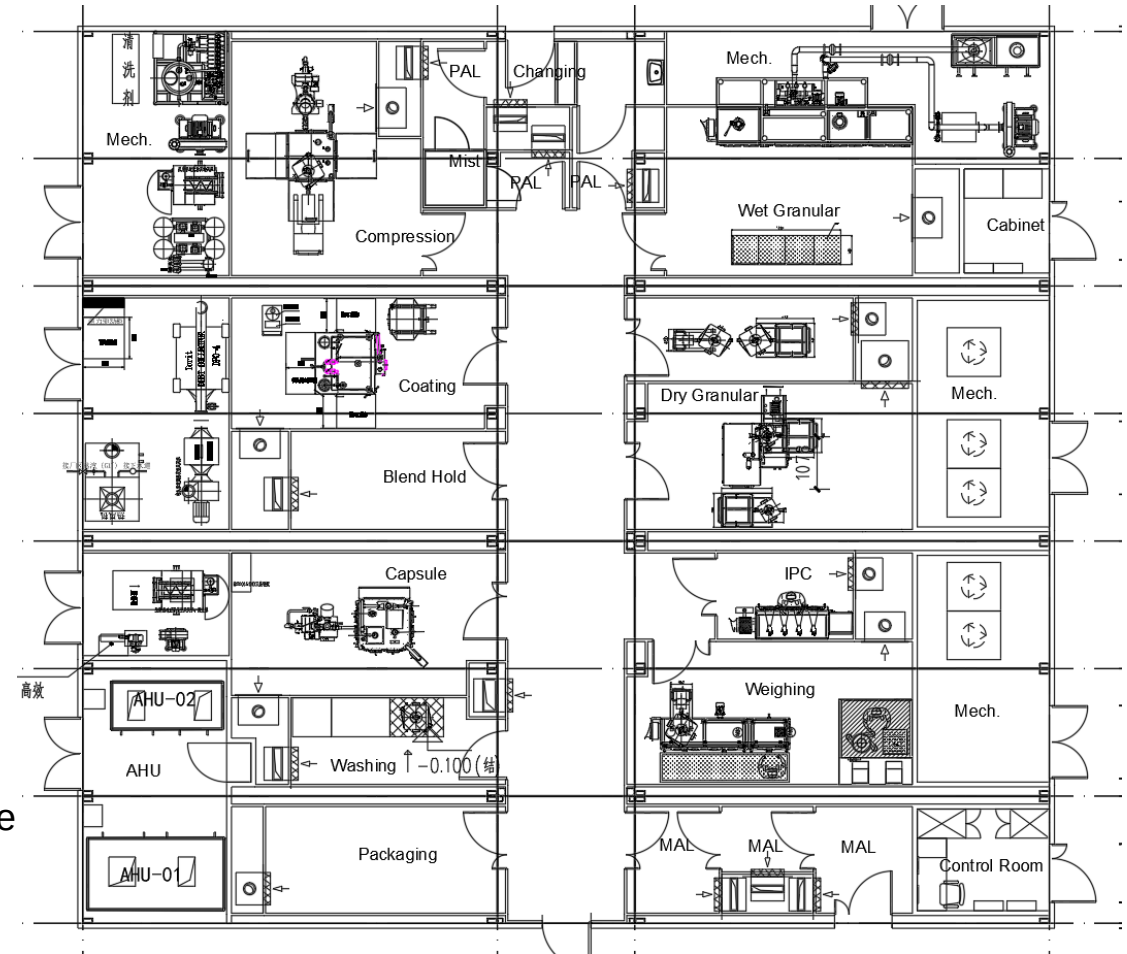
- **2. Equipment:**

- Pretreatment: weighing and sampling isolator
- Granulation: Wet granulation + Fluid bed dryer and Dry granulation
- Forming module: Tablet press, Coating machine and Capsule machine

- **3. Mechanical: HVAC, Mechanical service, power cabinet**

- **4. Containment Strategy:**

- Key process equipped with isolator;
- Key process area (weighing, granulation, compression, capsule) equipped with BIBO;
- Exhaust fan equipped with BIBO.





Lonza New DP Line Project

CMO DP Project- China GMP, WHO



Project Introduction
Investment: 40M ¥
Location: Guangzhou
Scope: EPCM
Area: 3,000m²
Duration: 240 Days



Equipment Supply Scope: Compounding, capping, inspection, labeling, packaging, compounding, CIP

Engineering Supply Scope: Procurement, equipment installation, cleanroom, MEP, CQV, MES



Egypt VBC Flu Vaccine Project

CMO DP Project- EU GMP, WHO



Project Introduction
Investment: 20M \$
Location: Egypt
Scope: EPCM
Area: 3,000m²



Equipment Supply Scope: Egg processing, Incubator, centrifuge, buffer & media preparation, purification, CIP, filling, inspection, packaging
Engineering Supply Scope: Procurement, equipment installation, cleanroom, MEP, CQV, MES



ADC drug EPC Project

ADC Drugs-GMP



Project Introduction
Investment: 80M ¥
Location: Liaoning
Scope: EPCM
Area: 24,000m²
Duration: 300 Days



Pharmaceutical
water system



HVAC system



Equipment Supply Scope: Washer, tunnel, filling, Lyo, ALUS, inspection, leakage detection, secondary packaging, CU
Engineering Supply Scope: Design management, procurement, equipment installation, cleanroom, MEP, CQV, MES



Guangzhou Ruibo mRNA Cov-19 Vaccine Aseptic Filling

Project Introduction:
Investment: 50M ¥
Location: Hangzhou
Scope: EPCM
Area: 5,000m²



Equipment Supply Scope: Washer, tunnel, filling machine, O-Rabs, automatic stopper & capper transfer, solution preparation

Engineering Supply Scope: CD/BD/DD, procurement, equipment installation, cleanroom, MEP, CQV, MES



Furen Hetero Onco Therapeutics Project

Anti-tumor product-GMP



Project Introduction
Investment: 50M ¥
Location: Henan
Scope: EPCM
Area: 3,000m²



Equipment Supply Scope: Washer, tunnel, filling, Lyo, RBR, Isolator, CU

Engineering Supply Scope: Design management, procurement, equipment installation, cleanroom, MEP, CQV, MES



Chengdu Westvac Biopharma Cov-19 vaccine project



Recombinant Cov-19 Vaccine - GMP

Project Introduction:
Investment: 400M ¥
Location: Chengdu
Scope: GC, EPCM
Area: 15,000m²



Equipment Supply Scope: CES, SS bioreactors, solution preparation tanks, UF/DF, chrom system & column, washer, tunnel, filling, isolator

Engineering Supply Scope: Design management, procurement, equipment installation, cleanroom, MEP, CQV, MES



Yunnan Walvax HPV Project



HPV Project-WHO PQ

Project Introduction
Investment: 200M ¥
Location: Yuxi, Yunnan
Scope: EPCM
Area: 15,000m²



Equipment Supply Scope: Bioreactor, buffer & media preparation, purification, CIP

Engineering Supply Scope: Design management, procurement, equipment installation, cleanroom, MEP, CQV, MES

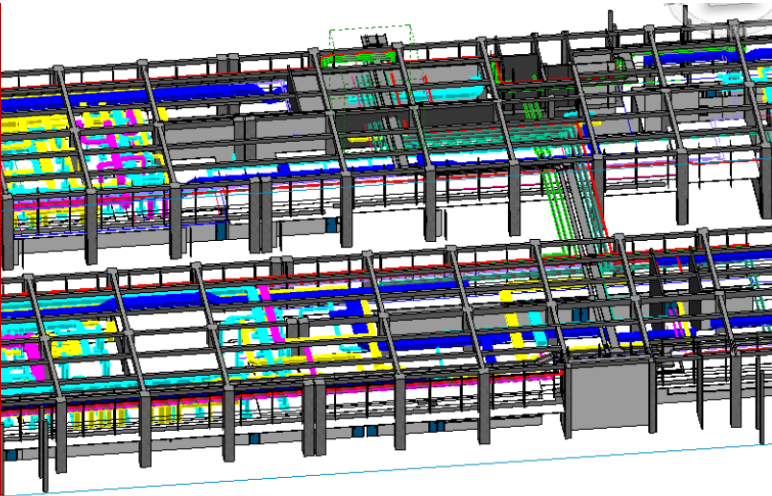


SHP Casino ADV vaccine project

ADV Cov-19 vaccine Project



Project Introduction:
Investment: 120M ¥
Location: Shanghai
Scope: EPCM
Area: 34,000m²
Duration: 80 Days



Equipment Supply Scope: N/A

Engineering Supply Scope: Design management, procurement, equipment installation, cleanroom, MEP, CQV, MES

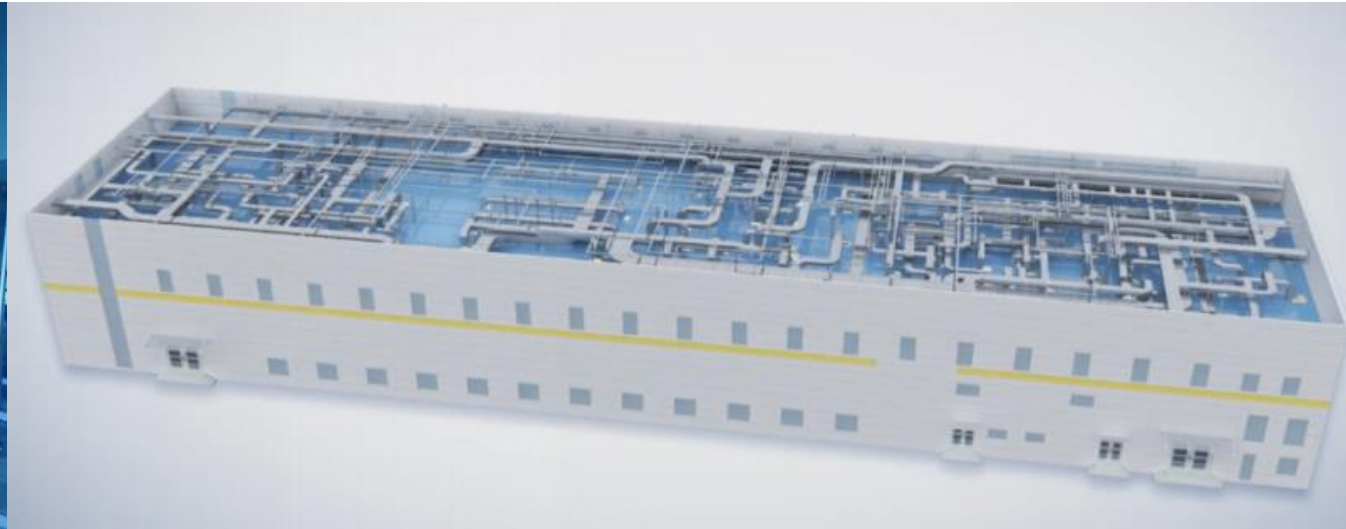


Boya Blood Product Project

Blood Product



Project Introduction:
Investment: 120M ¥
Location: Jiangxi
Scope: EPCM
Area: 12,000m²



Equipment Supply Scope: N/A

Engineering Supply Scope: Design management, procurement, equipment installation, cleanroom, MEP, CQV, MES



Junhemeng Bio-Pharma

Recombinant Growth Factor

Project Introduction:
Investment: 90M ¥
Location: Hangzhou
Scope: EPCM
Area: 5,000m²



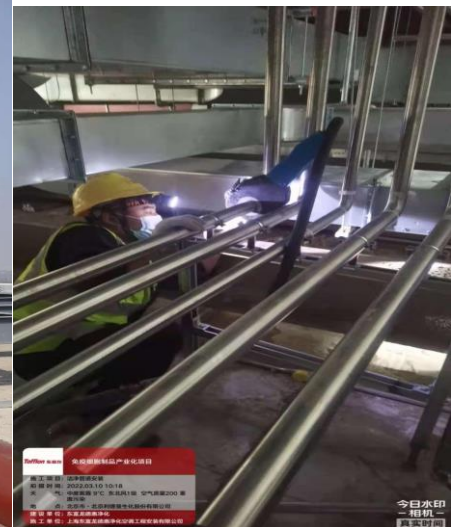
Equipment Supply Scope: Bioreactor, buffer & media preparation, chromatography column & skid, CIP, PFS filling, secondary packaging, CU
Engineering Supply Scope: CD/BD/DD, procurement, equipment installation, cleanroom, MEP, CQV, MES



Yongtai Bio-pharma

Car T/NK CGT Project GMP

Project Introduction:
Investment: 90M ¥
Location: Beijing
Scope: EPCM
Area: 16,000m²



Equipment Supply Scope: Cell culture station, Isolator

Engineering Supply Scope: CD/BD/DD, procurement, equipment installation, cleanroom, MEP, CQV, MES



Sichuan University National Research Center

Cell therapy & CART-GMP
CART - GMP

Project Introduction:
Investment: 50M ¥
Location: Sichuan
Scope: EPCM
Area: 4,000m²



Equipment Supply Scope: Cell culture station, Isolator, Aseptic filling

Engineering Supply Scope: CD/BD/DD, procurement, equipment installation, cleanroom, MEP, CQV, MES



Covid-19 vaccine Project in Uzbekistan

Cov-19 Vaccine - GMP

Project Introduction:
Investment: 50M ¥
Location: Uzbekistan
Scope: EPCM
Area: 2,200m²

Официально запущен проект генерального подряда Tofflon & Discover,
Желаем проекту между Tofflon и Центром Передовых Технологий Республики Узбекистан Полного Успеха

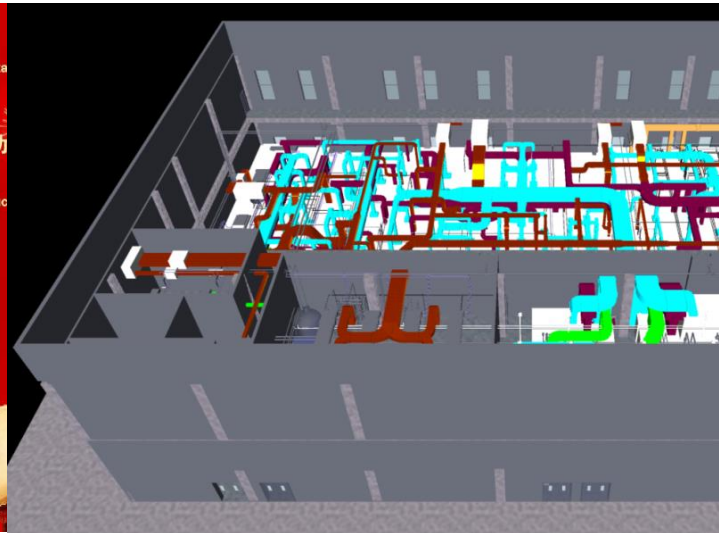
东富龙&Discover总承包项目正式启动

预祝东富龙与乌兹别克斯坦共和国先进技术中心合作项目取得圆满成功

Tofflon & Discover General Contracting Project officially launched,
wish project between Tofflon and Center of Advanced Technologies of Republic of Uzbekistan a Complete Success

Церемония начала
开工典礼
Commencement ceremony

DISCOVER INVEST CENTER FOR ADVANCED TECHNOLOGIES Tofflon 东富龙



Equipment Supply Scope: CES, Single use bioreactor, UF/DF, autoclave, purification, PFS filling, Rabs

Engineering Supply Scope: Design management, procurement, equipment installation, cleanroom, MEP, CQV, MES



SPH - Sudan Pharmaceutical project

OSD product - GMP



Project Introduction:
Investment: 20M ¥
Location: Sudan
Scope: EPCM
Area: 1,500m²
Duration: 100Days



Equipment Supply Scope: N/A

Engineering Supply Scope: Design management, procurement, equipment installation, cleanroom, MEP, CQV, MES



Jiangsu Hengrui Pharmaceutical Co., Ltd

Monoclonal antibody project



Project Introduction:
Investment: 30M ¥
Location: Jiangsu
Scope: EPCM
Area: 1,500m²
Duration: 120Days



Equipment Supply Scope: Bioreactor, CES, Bin, solution preparation, purification

Engineering Supply Scope: Design management, procurement, equipment installation, cleanroom, MEP, CQV, MES



Chiatai Tianqing Pharmaceutical Co., Ltd

OSD project



正大天晴
CHIATAI TIANQING

Project Introduction:
Investment: 150M ¥
Location: Nanjing
Scope: EPCM
Area: 8,000m²



Equipment Supply Scope: OSD Equipment

Engineering Supply Scope: Design management, procurement, equipment installation, cleanroom, MEP, CQV, MES



Luye Pharmaceutical Co., Ltd

Lyo lipidosome project



Project Introduction:
Investment: 100M ¥
Location: Yantai
Scope: EPCM
Area: 8,000m²



Equipment Supply Scope: Filling, Lyo, Isolator

Engineering Supply Scope: Design management, procurement, equipment installation, cleanroom, MEP, CQV, MES

All For Customers