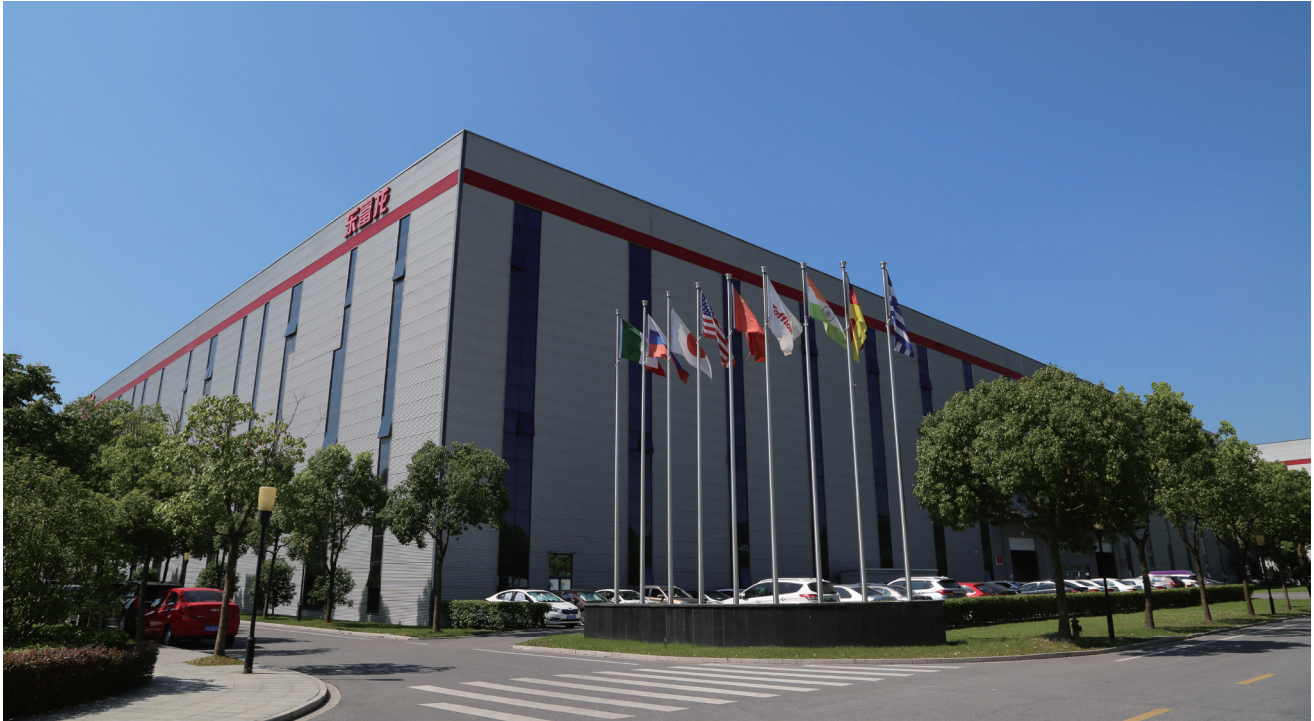


Tofflon



**SuBed-C
Single-use Fixed Bed
Bioreactor**

Tofflon Life Science Co.,Ltd.



Founded in 1993, Tofflon Science and Technology Group Co., Ltd. (SZ:300171) is a pioneering Chinese enterprise in the field of biotechnology, with a rich history of 30 years. With annual sales reaching 5.4 billion RMB in 2022 and a global workforce of 5,500 employees, Tofflon has established over 50 offices worldwide, embodying a globalized business and team.

Tofflon Life Sciences Co., Ltd., the flagship subsidiary within the group, plays a pivotal role in their portfolio. It focuses on the research and development of cutting-edge technologies in the biopharmaceutical and life science industries. As a strategic division Tofflon life science provides one-stop solutions and services that integrate bioprocessing equipment, core consumables like sterile bags, culture media, resins to further enquire and professionally.

- In the realm of cell therapy, we offer complete solutions for the preparation and production of immune cell pipelines, stem cell pipelines, tumor cell vaccines, and more.
- For gene therapy, we provide overall solutions for the research, development, and industrialization of nucleic acid drugs (mRNA/DNA) and viral vector drugs.
- In the field of biological sample banking, we conduct research and development of automatic sample storage management systems to provide comprehensive solutions for cell seed and tissue samples.
- In the consumables sector, we have developed a complete range of products including disposable bags (culture bags, mixing bags, storage bags), bio-reagents (culture media, cryoprotectants, Ficoll, growth factors), resin (GFC, AC, AEX, CEX, HIC, MMC), filtration (microfiltration, deep filtration, TFF, cassette), and hard packaging materials.
- We also focus on disinfection, offering comprehensive solutions for clean room disinfection, surface and external disinfection, infection control, terminal disinfection, and multi-drug resistant microorganism disinfection, ensuring effective environmental disinfection.

Leveraging Tofflon Group's extensive expertise in design, manufacturing, engineering construction, and after-sales service worldwide, Tofflon Life Sciences Division is committed to serving the biopharmaceutical industry with enhanced speed and professionalism.

Single-use Fixed Bed Bioreactor

Single-use Fixed Bed Bioreactor (SuBed-C) is an automatic, single-use, fixed-bed bioreactor that provides an excellent growth environment for adherent cells. It is a fully integrated high-density cell culture bioreactor, which combines the advantages of one-time technology and cascaded culture mode to optimize the upstream and downstream process flow.

This product is used in biopharmaceutical vaccine production, cell therapy and gene therapy. Especially when it comes to the preparation of adeno-associated virus (AAV), lentivirus (LV), adenovirus (Adeno), oncolytic virus (oncolytic) and other viral vectors and exosomes, the device can achieve perfect assistance.

Process Introduction

- ✔ Contains the controller PLC, stirring motor, electrical connection and the bottom assembly of the heating wall
- ✔ Bioreactor docking platform with weighing unit
- ✔ Includes a liquid inlet preheating module
- ✔ Contains the intermediate components of the gas management module
- ✔ Includes a top assembly with multiple sets of pumps, probe connectors, probe transmitters, electrical connectors, emergency stop buttons, and touch panel
- ✔ An external TCU for bioreactor temperature control



Technical Features

- ✔ Fully automated, reducing the preparation time and realizing the rapid deployment of the entire device
- ✔ For the traditional cultivation process, the one-time technology is conducive to the process exploration of the research and development end, providing trial and error space, saving time and cost, and realizing the rapid rollout of the production line
- ✔ Equipment covers an area of 2 m², can express 500 m² culture area, equivalent to 200 40-layer cell factories (2.5 m² / piece)
- ✔ The oxygen exchange technology of cascaded flow culture was used to achieve high density cell culture and improve the equipment KLa
- ✔ Real-time monitoring and accurate control of gas, temperature, peristaltic pump working strategy, DO, pH, pressure, speed and other parameters, as well as basic formula program management
- ✔ The external TCU water bath controls the temperature through PID, and has a good heat exchange structure design to ensure the stability of the fixed bed culture environment temperature
- ✔ During the culture process, the medium is circulated along special lines to achieve low shear force (see consumables for details).
- ✔ Low density inoculation can be achieved

■ Process Flow



- **Seed recovery steps used**

The amount of use is about 6, this step is mainly to revive the seed cells, passing 1-2 generations to restore their biological activity.

- **Initial expansion use of seeds**

The dosage is about 12, and this step aims to further expand the quantity of seed cells.

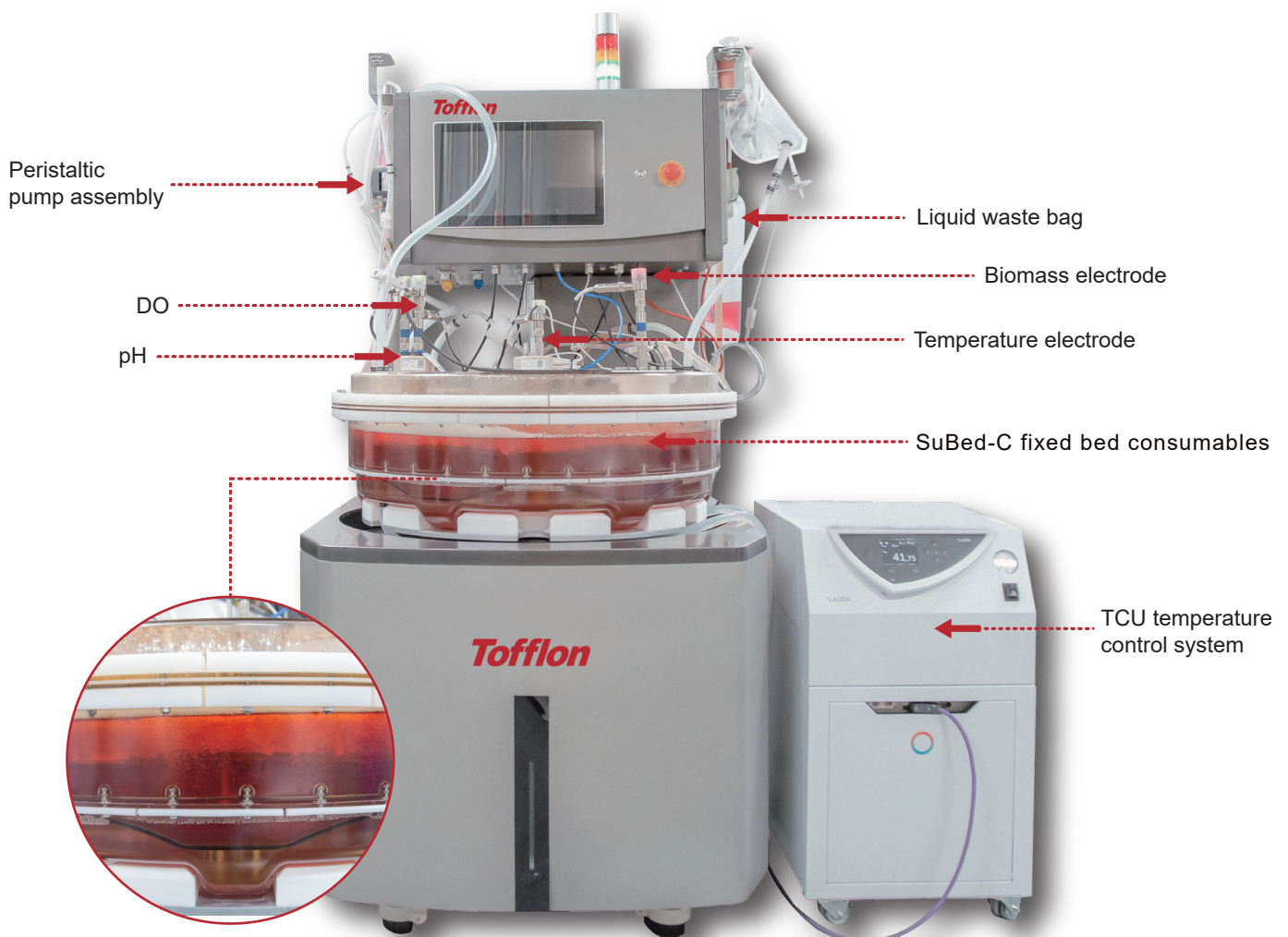
- **Massive amplification and transfection after vaccination**

Vector selection was carried out according to the desired amount of cells. The amount of vector loading was performed, and the type and dosage of transfection medium were selected according to the type of AAV produced.

- **Acquisition of target products**

It involves aseptic filtration, chromatography, ultrafiltration concentration, subpacking and filling.

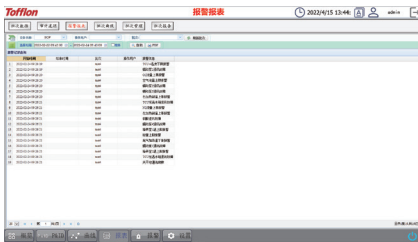
■ Products and Components Display



Software Feature

- ✔ Provides highly automated integrated equipment operation data recording in compliance with 21CFR Part11 regulations
- ✔ Alarm Settings will be performed according to user requirements
- ✔ Comply with pharmaceutical GMP standards to implement four-level authority management

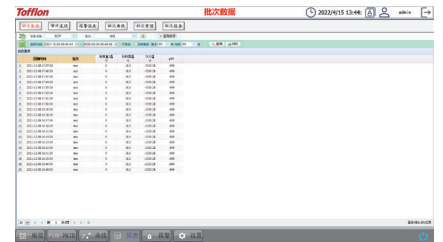
Software Control System



Alarm interface



Curve interface



Batch interface

Tofflon 批号: 2023 02 27 293 1 培养时间: 0 3 49 M

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批次启动

空气 A 0.40 L/min

氧气 A 0.05 L/min

二氧化碳 A 0.00 L/min

氮气 A 0.20 L/min

培养室温度 37.05 °C

尾气加热温度 65.1 °C

补料室温度 23.3 °C

加热毯温度1 25.1 °C

加热毯温度2 24.5 °C

TCU温度 41.51 °C

压力1 1.0 mbar

压力2 182.8 mbar

pH 7.12

DO 41.5 %

生物量 0.0 pF/cm

ST1 0 RPM

ST2 0 RPM

ST3 0 RPM

ST4 0 RPM

ST5 0 RPM

ST6 0 RPM

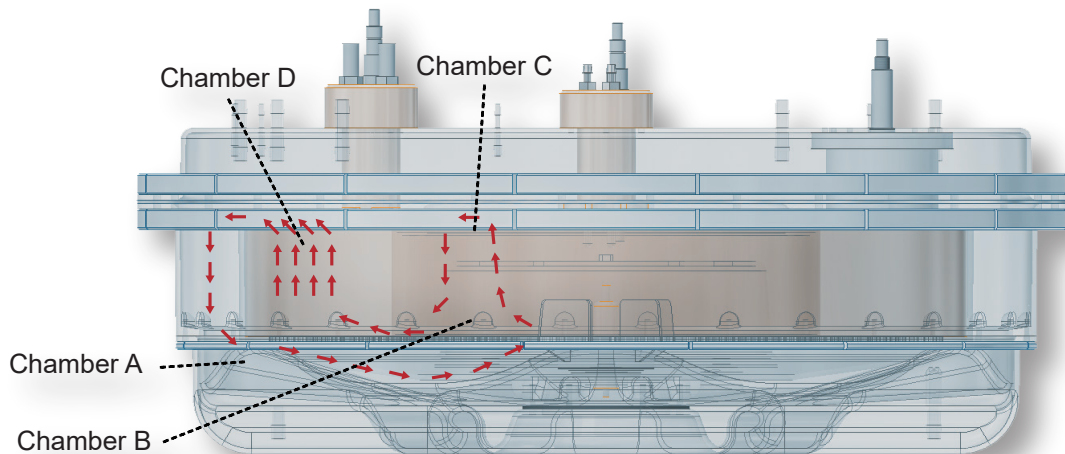
ST7 0 RPM

称重: 83.4 kg | 转速: 231 RPM | 台秤: 0.011 kg

SuBed-C

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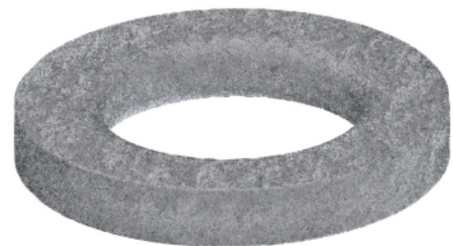
■ Similar Waterfall Flow Cultivation Method



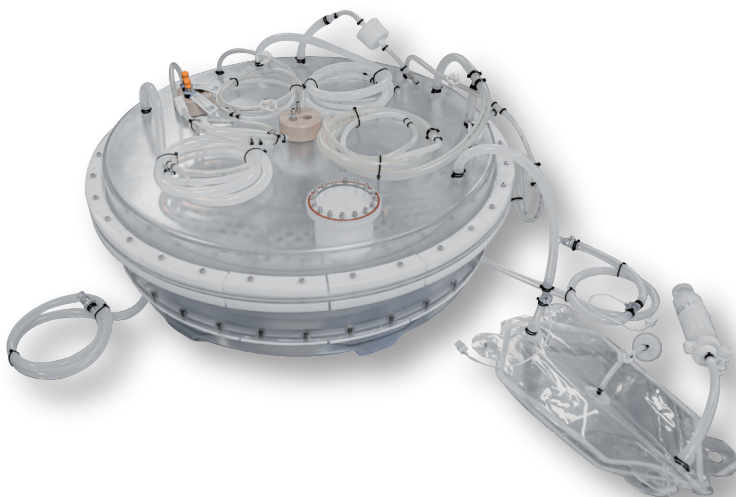
■ Consumables Introduction

SuBed-C fixed bed consumables include disposable pH electrode, disposable DO electrode, disposable biomass electrode, disposable temperature electrode, disposable pressure sensor, stirring device and pre-loaded special carrier; The carrier uses medical-grade PET fibers to provide cells with a growth area of up to 500 m². The oxygen transfer mode of cascades culture makes it have efficient KLa, and the magnetic coupling agitation provides thrust to achieve closed circulation of special paths, so as to achieve high-density cell culture, which has higher productivity per unit production space than the traditional tank stirring production equipment.

- ✓ Material: Medical grade PET fiber
- ✓ Performance: Its single-layer thickness is 0.44 mm, and the aperture is about 15 microns
- ✓ Surface area: 1200-1500cm²/g



PET



■ Consumables Specification Sheet

Bioreactor	Reactor diameter (mm)	Fixed bed height	Carrier volume	Reactor volume (L)	Surface area (m ²)	
					Low density LL	High density HL
SuBed-C mini	115	20	0.04	1	0.53	0.8
SuBed-C mini	115	40	0.08	1	1.06	1.6
SuBed-C mini	115	100	0.2	1	2.6	4
SuBed-C 500/100	870	20	5	70	66	100
SuBed-C 500/200	870	40	10	70	133	200
SuBed-C 500/500	870	100	25	70	333	500

■ System Configuration Table

Model			SuBed-C mini	SuBed-C 500	
System configuration	Dimension	Integrated system	550*380*560	1500*1000*1800	
	Weight	Integrated system	40kg	400kg	
	Instrument	pH		•	•
		DO		•	•
		Biomass probe		/	•
		Temperature probe		•	•
	Pump	Peristaltic pump		•	•
		External peristaltic pump (optional)		/	•
	Temperature control	TCU		/	•
		Electric heating		•	•
		weigh		•	•
		External platform scale		/	•



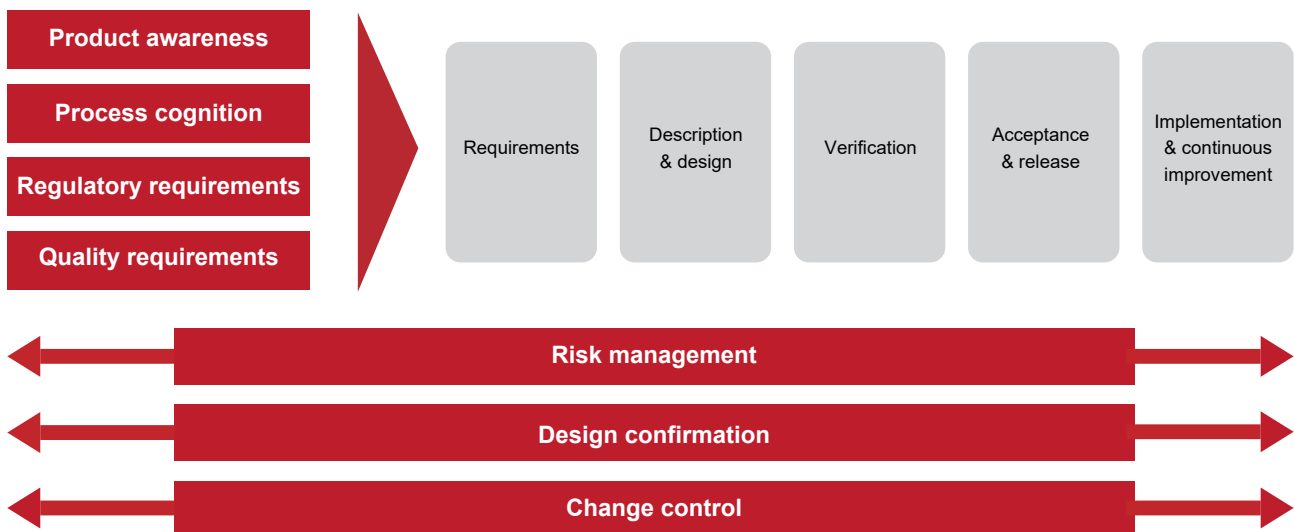
Project Management

Three main factors determine the success of the project. Our organizational mode has been making constant update and improvement to enable you to fully achieve these goals. Through cooperation with us, you can minimize the direct resources required to manage the selection, purchase, installation, startup and verification of new production equipment.

- ✔ Reliable quality
- ✔ Short cycle
- ✔ Focus on cost

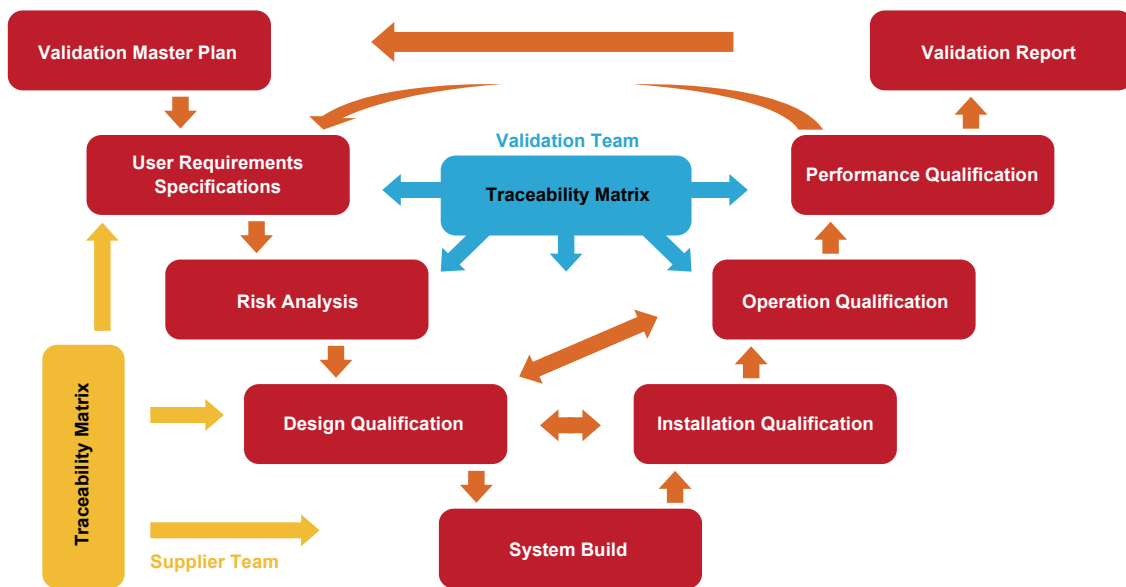


Good Engineering Practice - GEP



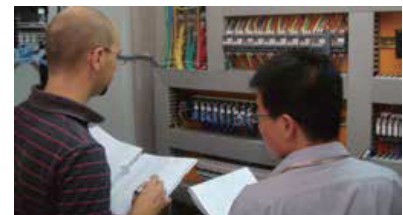


Validation Support



Verification Document System

- ✔ Complete document system
- ✔ Strict quality guarantee process
- ✔ Comply with cGMP confirmation scheme
- ✔ Ensure the stability and reliability of product quality





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