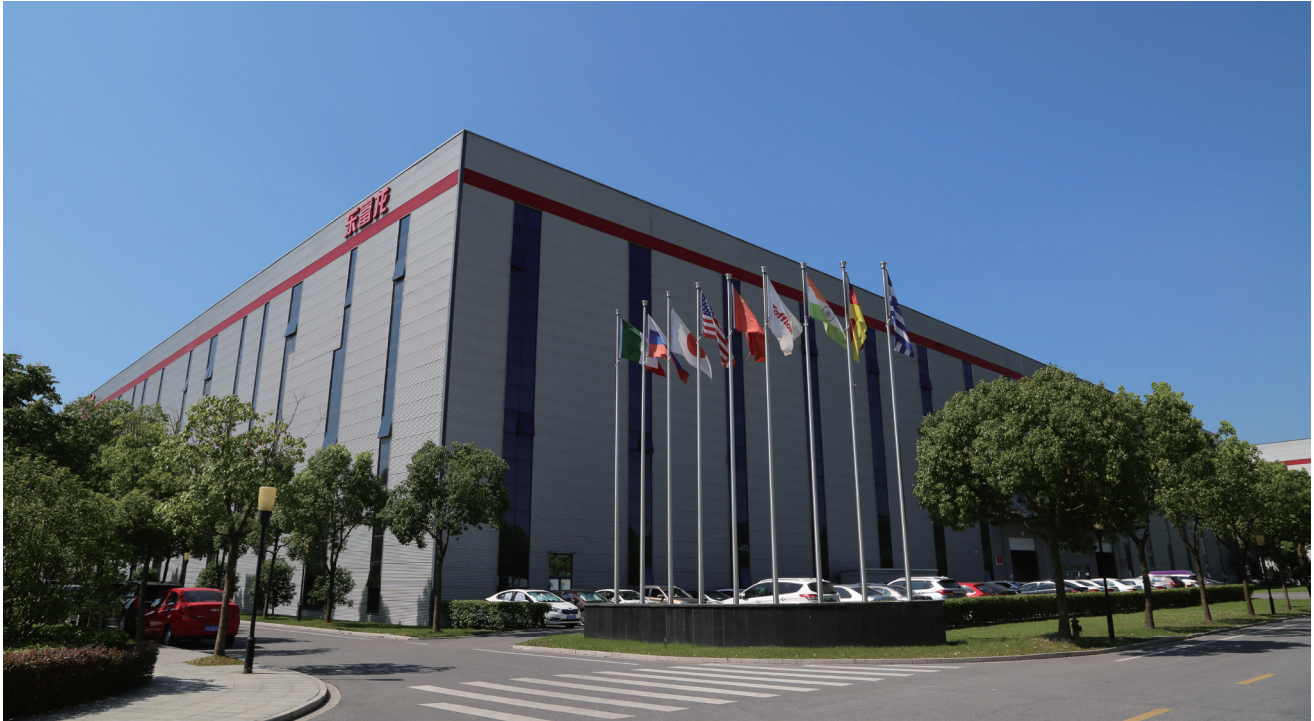


Tofflon



Disposable Bioreactor System

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.

Disposable Bioreactor System

The single-use bioreactor has the advantages of modularization, one-stop scheme and mixing tank design of bioreactor platform. Designed specifically for scalability and stability, the SUB bioreactor system provides the performance and flexibility needed to move from process development to large-scale biopharmaceutical production. The SUB bioreactor system can be operated in batch culture, feed culture, and perfusion modes.

■ Product Application

- ✔ Selectivity - according to customer needs to choose the bottom magnetic stirring, magnetic stirring center axis, mechanical oblique stirring and other forms.
- ✔ Ease of use -- the reactor adopts the front door form and (optional lifting device), easy to quickly install the biological reaction bag, shorten the operation time.
- ✔ Scalability -- Easy to expand, optional optical or disposable pH/DO electrodes, online cell density sensors, etc.
- ✔ Intelligence -- in line with relevant GMP requirements and standards, the key training parameters for precise control and data recording, can be connected with the company's EMS management system.



■ Technical characteristics

- ✔ High efficiency jacket heat transfer efficiency: honeycomb jacket close contact with cell liquid, high heat transfer efficiency
- ✔ Pipeline management system: baffle design, top bracket
- ✔ High precision control instrument: gas mass flow control, peristaltic pump, weighing unit, on-line monitoring electrode, external temperature control unit
- ✔ Independent research and development program: Siemens PLC+ PC development software
- ✔ Hardware and software automation: external instrument signal integration into the automatic control system, remote start and stop and control
- ✔ Process development and scale-up services: Based on experience in stainless steel and scale-up design for single production



Functional parameter

- ✔ Meet the 5:1 culture volume
- ✔ The speed range can be adjusted, the control accuracy is $\pm 1\text{rpm}$
- ✔ pH electrode: Control range 2~12 control accuracy ± 0.05
- ✔ DO electrode: Control range 0%~200% control accuracy $\pm 3\%$
- ✔ Weighing control accuracy $\pm 3\%$, display accuracy $\pm 0.1\text{kg}$
- ✔ Temperature control accuracy ± 0.2 , display accuracy ± 0.1

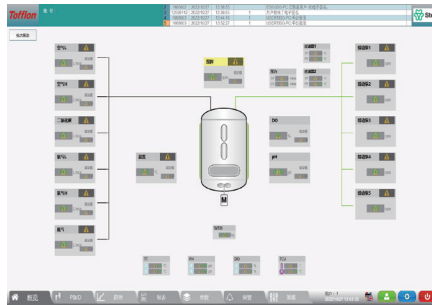
Application field

- ✔ The field of antibody drugs, such as: Monoclonal antibody, double antibody, ADC and other antibody drug development and production
- ✔ Vaccine field, such as: adenovirus novel coronavirus vaccine, influenza vaccine and other drug development and production
- ✔ Recombinant protein field, such as: recombinant human interferon, recombinant human insulin drug development and production
- ✔ Cell therapy/gene therapy fields, e.g., development and production of viral vectors

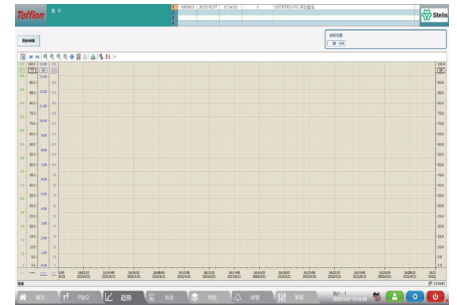
Software control system



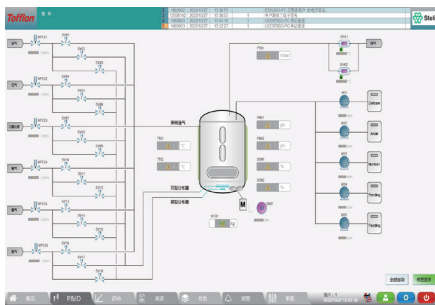
Login interface



Overview interface



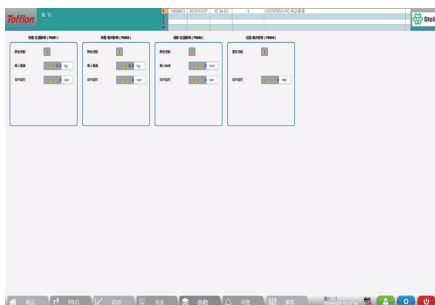
Curve interface



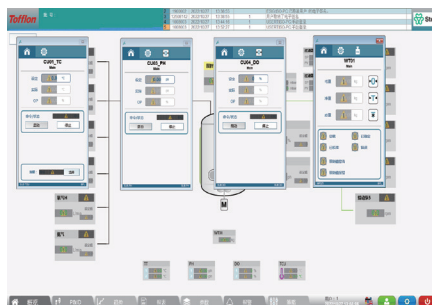
P&ID interface

Alarm interface

Log interface

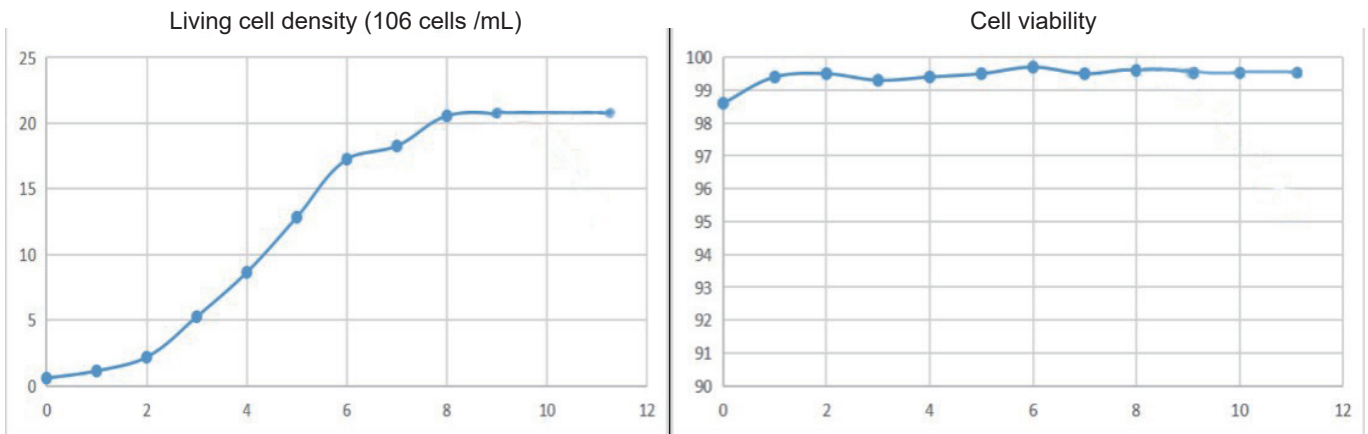


Parameter interface



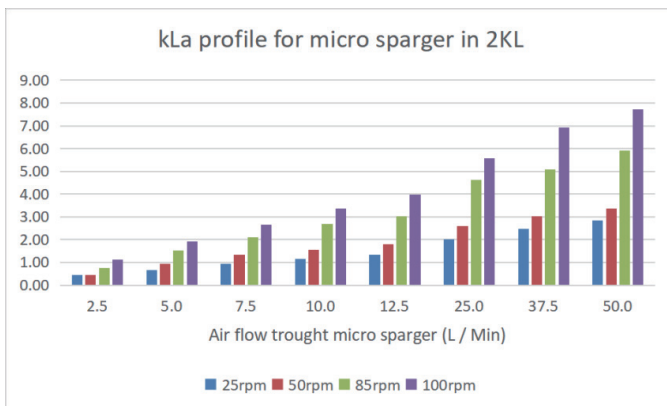
Functional interface

Cell experiment

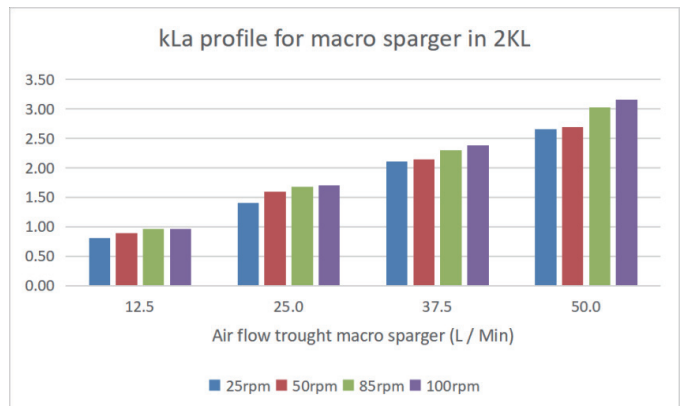


The culture cycle was 12 days: 1-8 days, the density of living cells reached the highest 2×10^7 cells /mL, cell viability 99.5%

KLA test



Liquid level 2000L (full load), micro-bubble ventilation KLA



Liquid level 2000L (full load), large bubble ventilation KLA

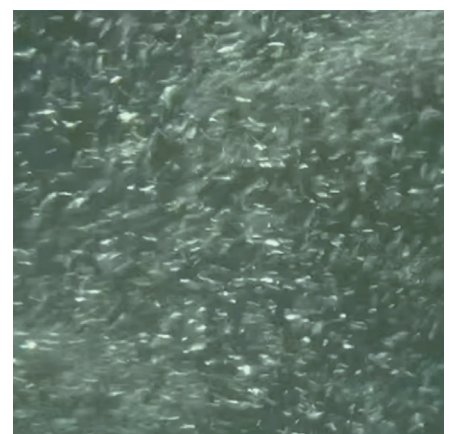
Mixing speed rpm and bubble distribution test



80rpm Liquid level 2000L(full load)
Top bubble distribution



105rpm Liquid level 2000L(full load)
Top bubble distribution



Liquid level 2000L(full load)
Bottom bubble distribution

Supporting consumables

Disposable bioreaction kits are designed for upstream applications in cell therapy, antibody drug seed expansion, and vaccine production. The agitator system was originally developed for immersion mixing applications, providing both excellent stability and excellent mixing and aeration performance.

Product specifications: 50 l / 200 l / 500 l / 1000 l / 2000 l (customizable)

Product characteristics

- ✔ Portable to use: Single-use technology eliminates the need for cleaning and thus avoids the risk of cross-contamination.
- ✔ Stability: Made from multiple layers of transparent film, it provides high mechanical strength against tearing while also providing biological inertia against fluid contact.
- ✔ Customizable: Disposable biological reaction bags can be customized according to customer requirements of connectors, tubes and special accessories.
- ✔ Stirring device, ventilation chassis device: to achieve rapid mixing and oxygen dissolution effect
- ✔ A variety of connectors, sensors, or filters are available for different functions to support various upstream and downstream requirements of buffers, media, products and intermediates, and other process fluids.



Product information

Single-use Bioreactor Bag					
Equipment model	SUB50L	SUB200L	SUB500L	SUB1000L	SUB2000L
Maximum working volume	50L	200L	500L	1000L	2000L
Minimum working volume	10L	40L	100L	200L	400L
Agitator diameter	205mm	205mm	255mm	305mm	405mm
Stirring rate	0-360rpm	0-360rpm	0-250rpm	0-140rpm	0-115rpm
Perfusion line	●	●	●	●	●
Disposable electrode	●	●	●	●	●

Note: ● Represents optional scheme



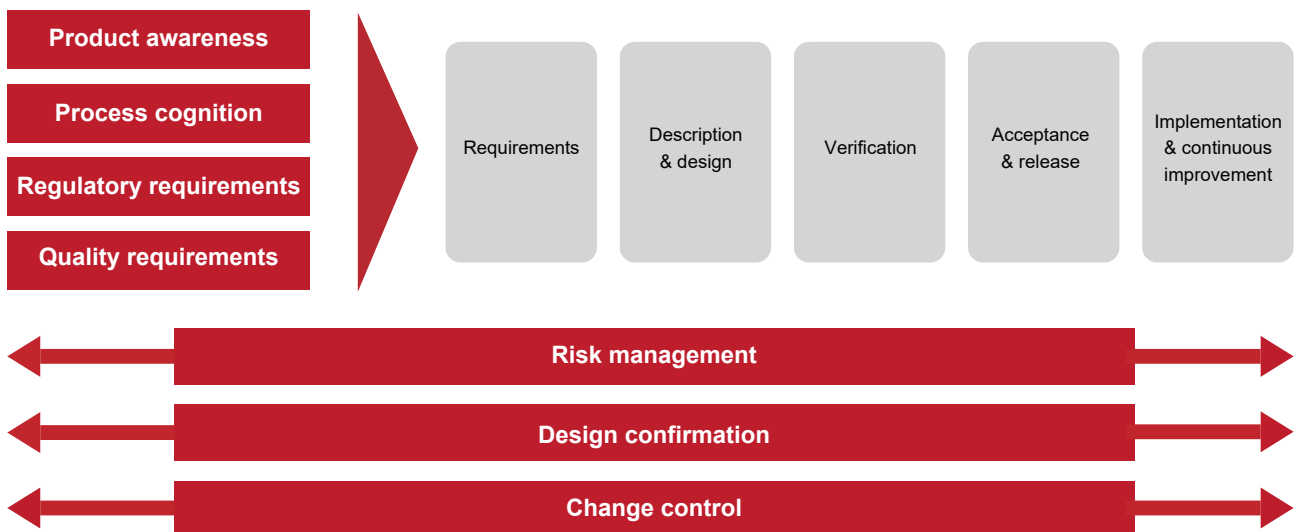
Project Management

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.



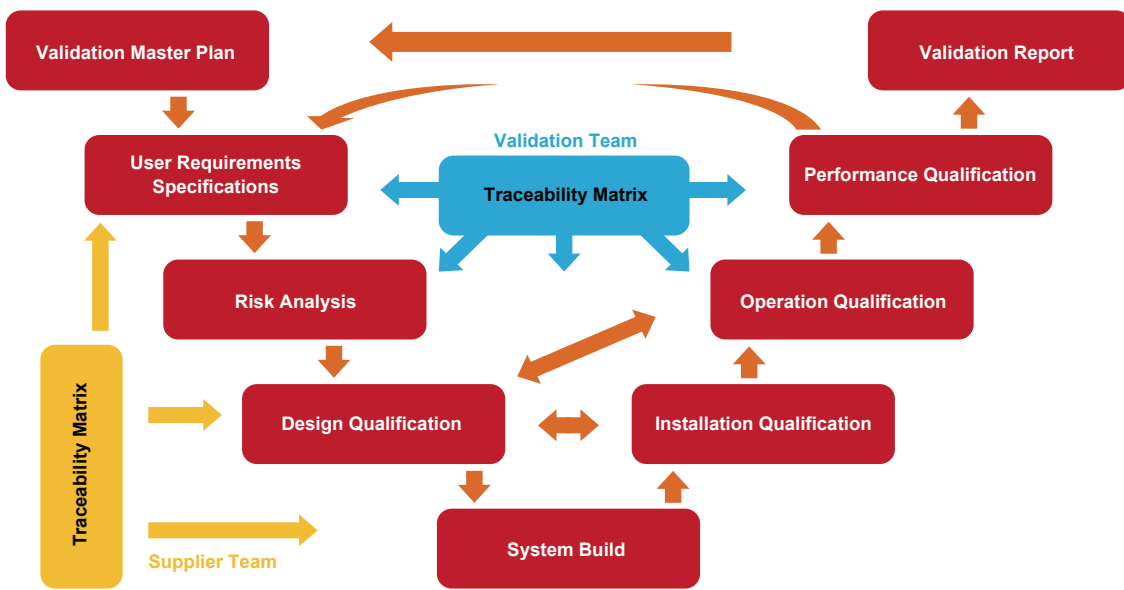
- ✔ Reliable quality
- ✔ Short cycle
- ✔ Focus on cost

Good Engineering Practice - GEP



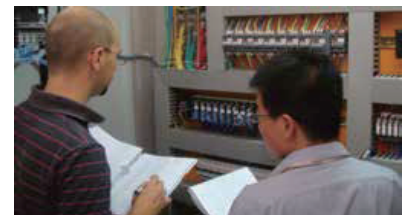


Validation Support



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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