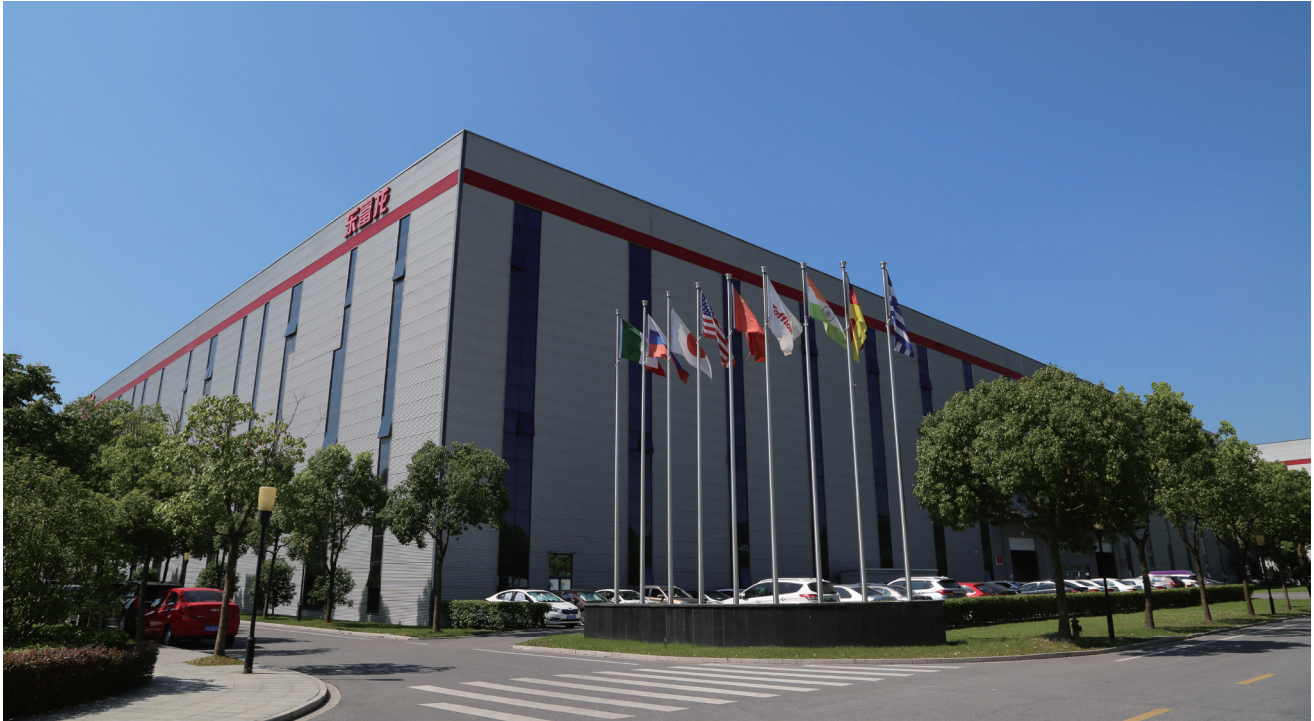


Tofflon



**Cell Subpackage
System**

Tofflon Life Science Co.,Ltd.

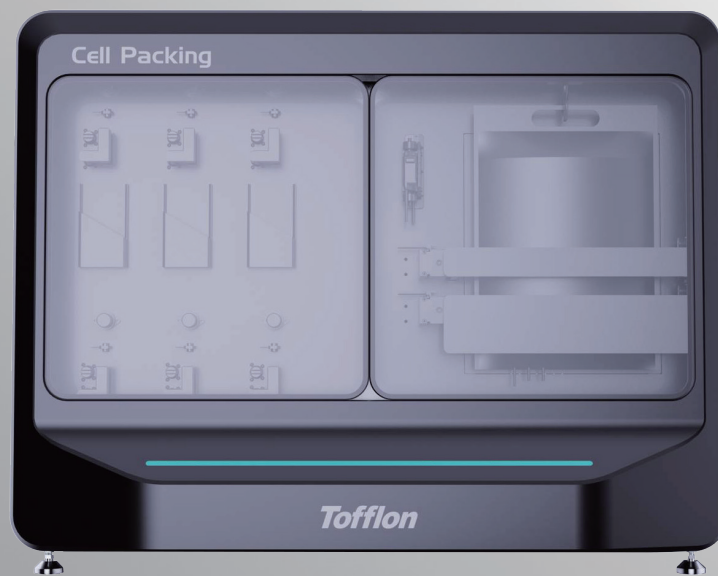


Founded in 1993, Tofflon Science and Technology Group Co., Ltd. (SZ:300171) is a pioneering Chinese enterprise in the field of biotechnology, with a rich history of 30 years. With annual sales reaching 5.4 billion RMB in 2022 and a global workforce of 5,500 employees, Tofflon has established over 50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



Cell Subpackage System

The cell subpackage system (CSS) employs disposable bags and tubings to complete a high-flux, accurate, fast and reliable closed fully-automatic sterile subpackage. This system is composed of stock solution mixing unit, semiconductor temperature control unit and multi-station subpackage unit, which can be customized according to the actual process requirements of the customers.

This system is mainly used in the subpackage of allogeneic cell products such as UCAR-T, CAR-NK and mRNA vaccines , and also applicable in other field of pharmaceutical and medical industries.

Product Specifications

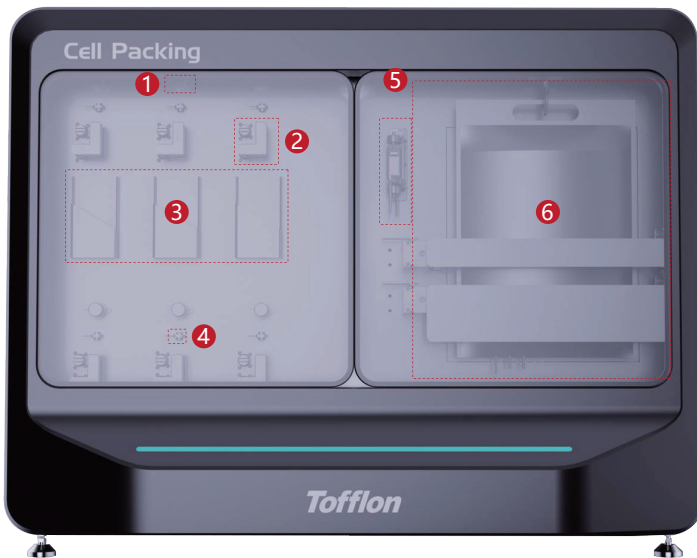
- ✓ Standard specifications: 6 stations, 10 stations, 20 stations (which can be customized according to the customer requirements) subpackage in 6-300 bags can be provided through pipeline connection or liquid diverter.



Features of Cell Subpackage System

- ✓ Subpackage size: Subpackage volume 20mL~500mL.
- ✓ Information management: Whole-process information management of data reading and recording.
- ✓ Modular integration: It can meet the customization requirements of different customers.
- ✓ Automatic control: Fully closed automation, avoiding cross contamination and reducing risks.
- ✓ Data integrity: It complies with the regulatory requirements, and the data of the subpackage process is recorded and traceable.

List of Cell Subpackage System



Capacitive touch screen

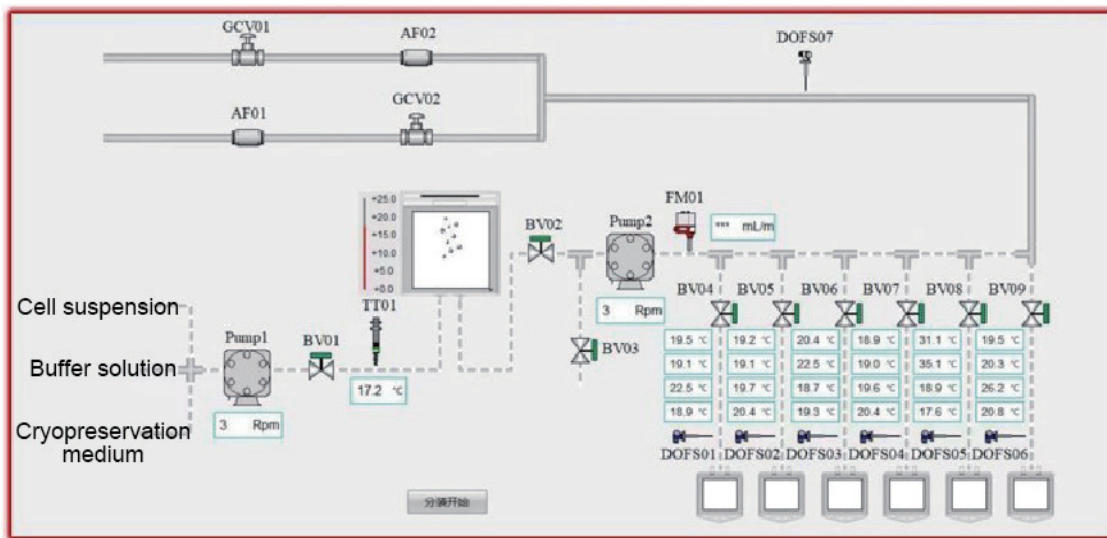
- ① Pinch valve

④ Optical fiber liquid level sensor
- ② Heat sealing device

⑤ Ultrasonic flow sensor
- ③ Subpackage unit

⑥ Mixing temperature control unit

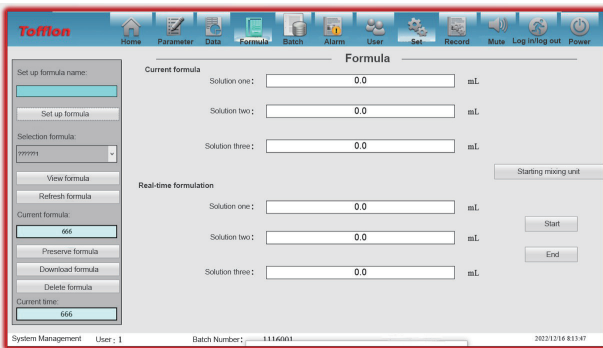
Technological Process



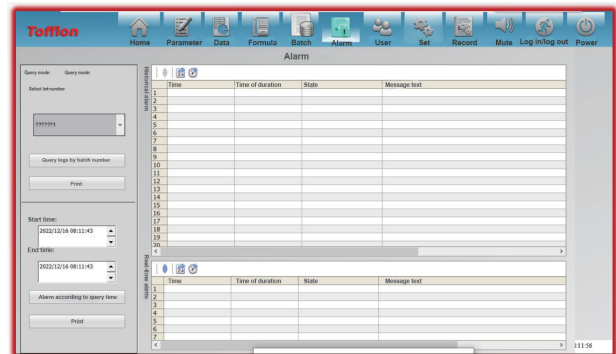
Technical Parameters

- ✓ Subpackage accuracy: The volume error within $\pm 2\%$.
- ✓ Temperature change: The temperature control error within $\pm 1^\circ\text{C}$.
- ✓ Solution homogeneity: The density deviation within $\pm 5\%$.
- ✓ Cell activity: Maintain the cell activity above 95% of initial cell solution.
- ✓ Residual air of product bag: The residual air in the final product bag is less than 2mL.

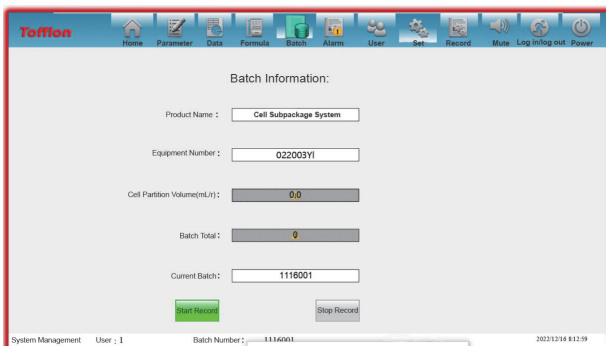
HMI



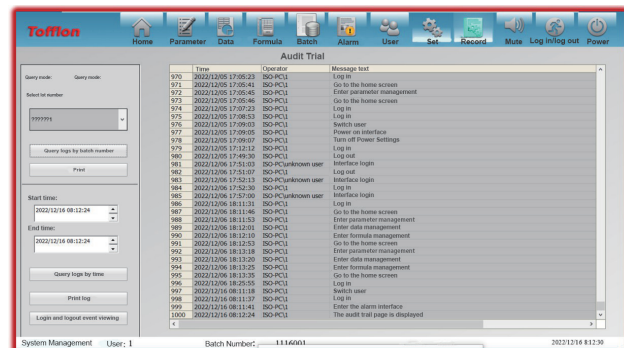
Formula management



Alarm information



Batch management



Operation record

Software Features

- ✓ It can provide the fully-automatic operation and complete data record, compliant with the regulatory requirements of FDA 21CFR Part 11.
- ✓ Data share between relevant equipment by SCADA after signing the relevant communication protocols.
- ✓ Simple operation interface and easy to operate.



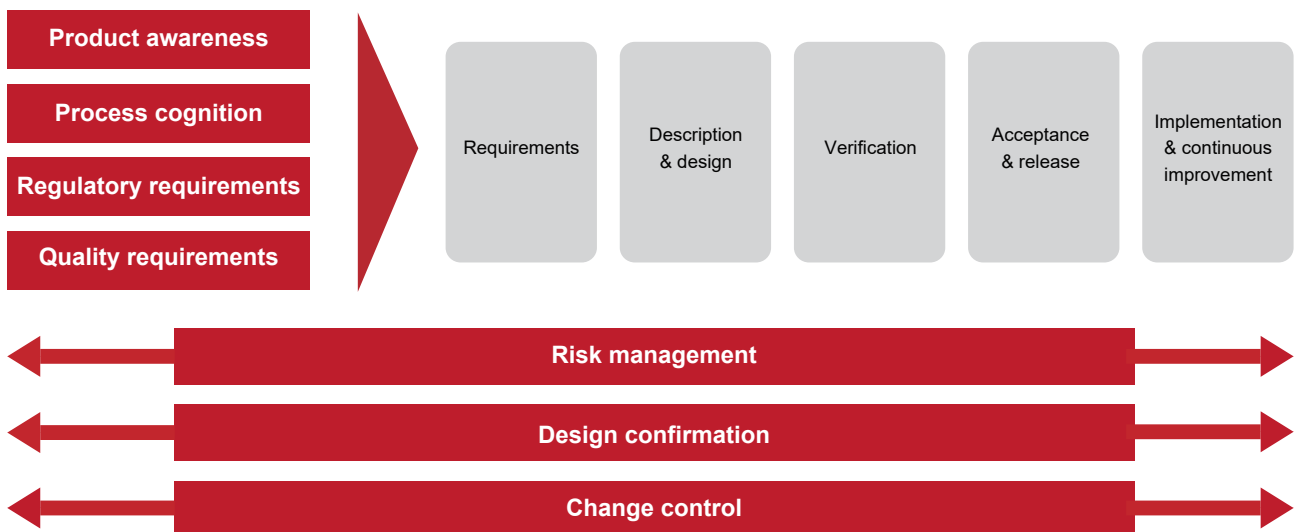
Project Management

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.



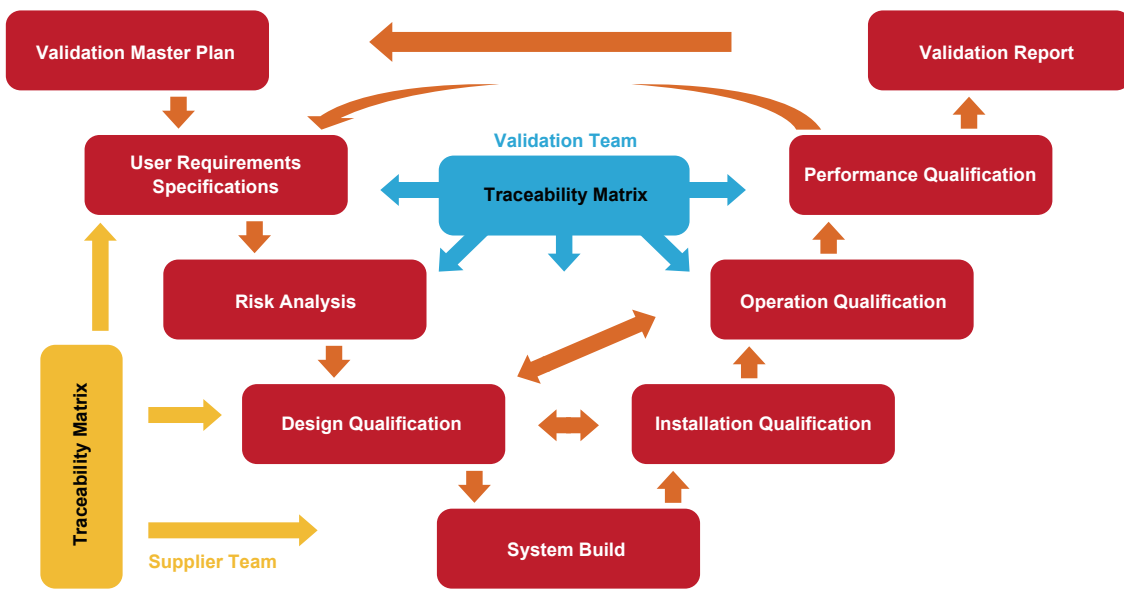
- ✔ Reliable quality
- ✔ Short cycle
- ✔ Focus on cost

Good Engineering Practice - GEP



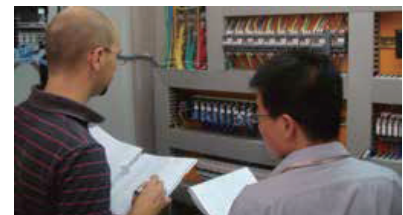


Validation Support



Verification Document System

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





Tofflon Tofflon Science and Technology Group Co.,Ltd.

Address: No.1509,Duhui Road,Shanghai,China 201108

Tel: +86 21 6490 1123 / 6490 6201

Fax: +86 21 6490 5148 / 6490 6202

E-mail: lifescience.info@tofflon.com

www.tofflon.com