Tofflon

TCell-Pro
Single-use Cell Processor

EXPERISE IN BIO-PHARMACEUTICAL

Tofflon
Life Science Co.,Ltd.

Founded in 1993, Tofflon Science and Technology Group Co., Ltd. (SZ:300171) is a comprehensive pharmaceutical equipment and service provider that provides the global pharmaceutical enterprises with overall solutions for pharmaceutical technology, core equipment and system engineering, whose products are applied in injectates, solid preparations, chemical APIs, bioengineering, traditional Chinese medicine, medicine, food and other fields.

Tofflon's Life Sciences Co.,Ltd. focuses on the research and development of front-end technologies in the biopharmaceutical and medical industries, and provides the one-stop services integrating equipment system, devices and consumables (including bio-reagents, resin, filters, disposable bags and holder):

- In the field of cell therapy, we provide the overall solutions for the preparation and production of immune cell pipeline, stem cell pipeline, tumor cell vaccines, etc.
- In the field of gene therapy, we provide the overall solutions for the research & development and industrialization of nucleic acid drugs (mRNA/DNA) and viral vector drugs.
- In the field of biological sample bank, we perform the research and development of automatic sample storage management system to provide the overall solutions for cell seed and tissue sample.
- In the field of consumables, we have formed a complete consumable scheme in 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.
- In the field of disinfection, we are committed to clean room disinfection, surface and external disinfection, infection control, terminal disinfection and multi-drug resistant microorganism disinfection, providing an overall solution for environmental disinfection.

Relying on Tofflon Group's mature design, manufacturing, engineering construction and after-sales service capabilities all around the world, Tofflon Life Sciences Division can serve the biopharmaceutical industry more quickly and professionally.

Single-use Cell Processor

Single-use cell processor (SUC) is a fully sealed, automatic cell treatment system, which can adapt to the cGMP requirements in the clean room environment above class C, be used for R&D and production for the cell production purposes, improve the development process of cell production purposes, and provide the one-time solutions for research and development of cell production purposes. The whole system consists of TCell-Pro equipment, disposable consumables and specialized process software.

- TCell-Pro employs axial density gradient centrifugation controls the flow rate and direction of the test solution by the specialized gas path control mode and the pipeline steering device to provide automatic processing of cell production.
- Three types of disposable consumables, with each corresponding to a well designed process flow.
- Five sets of cell preparation process software.

Features of SUC

- Fully closed and automatic system.
- The disposable sealing technology adopted to provide a sterile production environment for cells and greatly reduce the risk of contamination.
- Lower the personnel participation and reduce batch errors.
- Save cell treatment time and reduce environmental investment cost.
- The equipment software system is consistent with the regulatory requirements of 21CFR Part 11.
- Three-level authority management compliant with cGMP specifications.

SUC platform

TCell-Pro equipment

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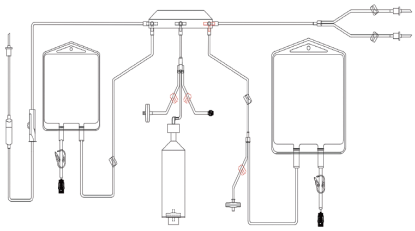

Disposable consumables

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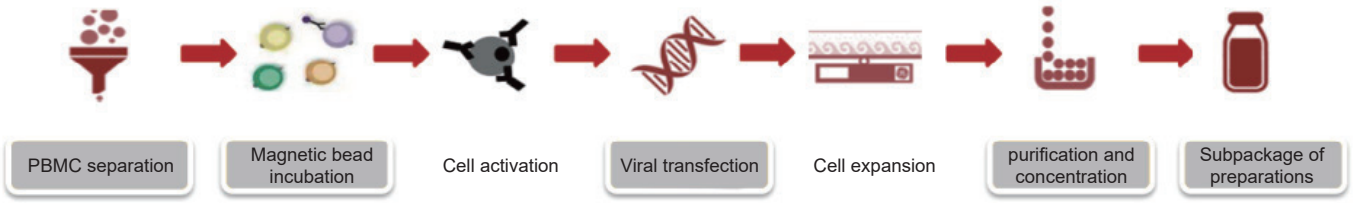
Process software

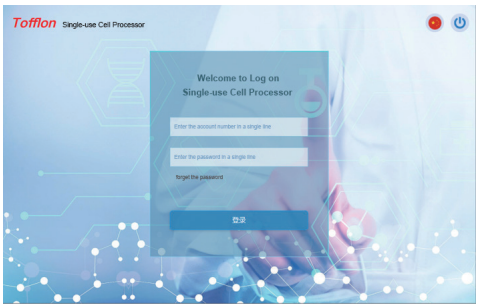
Features of TCell-Pro

- Process software: mononuclear cell isolation, magnetic bead incubation, viral vector transfection, purification and concentration, dilution and subpackage.
- High cell harvest rate and high cell viability.
- Complete and traceable data, compliant with cGMP specifications.
- Precise control of speed, volume and other parameters in the process.
- Real-time monitoring of pressure, temperature, etc. in the process.
- Simplified and user-friendly HMI.
- Specialized process software that is suitable for different application scenarios.

Application scenarios of TCell-Pro



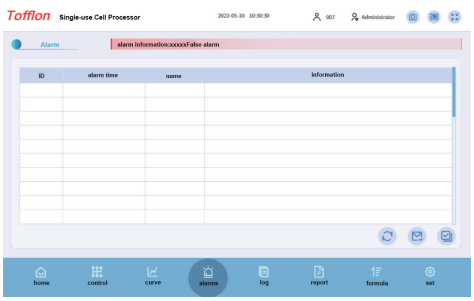
TCell-Pro software operation interface



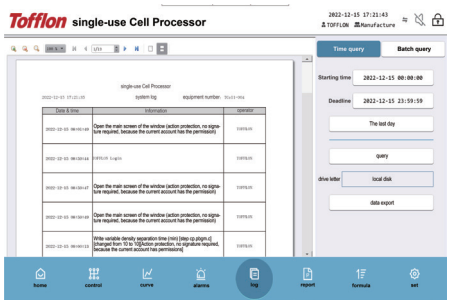
Login interface

Process interface

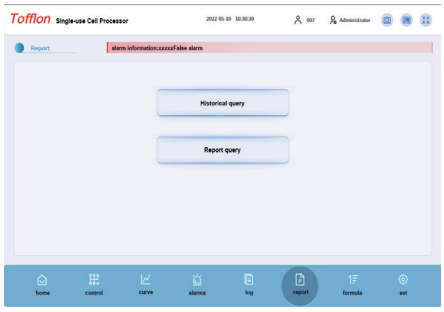
Curve interface



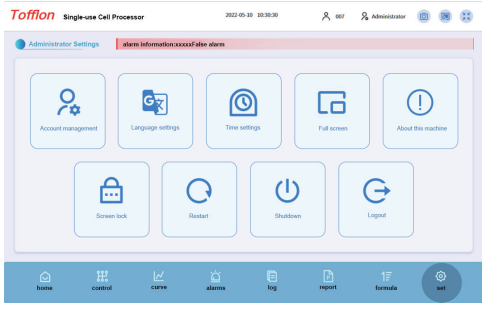
Alarm interface



Log interface



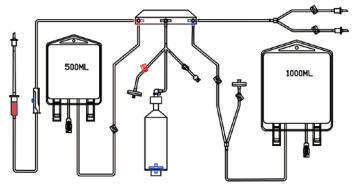
Report interface



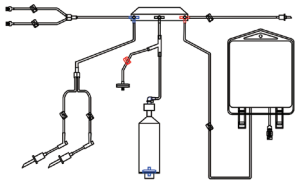
Setting interface

Parameter interface

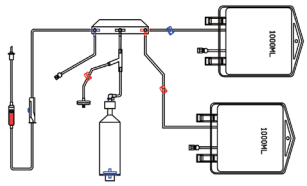
TCell-Pro consumables



TK-01



TK-02



TK-03

Consumables are sealed and sterilized by ETO

Different consumables match different processes

Process parameter

Process	Starting volume	Final collection volume	Working time	Remark
mononuclear cell isolation	30~120mL	45mL	70min	Cell harvest rate >55% Cell viability >95% Removal rate of red blood cells >99%
Magnetic bead incubation	20~880mL	8~500mL	0~80min	Harvest rate >80% Viability >95%
Viral transfaction	20~880mL	20~500mL	0~100min	The transfaction efficiency is equivalent to the manual mode Cell viability >95%
Purification and concentration	20~1,200mL	20~500mL	0~60min	Cell harvest rate >80% Cell viability >95%
Dilution and subpackage	0~220mL	Subpackage as required	0~30min	Volume accuracy ±0.5 mL Cell concentration difference <10%

Equipment parameters

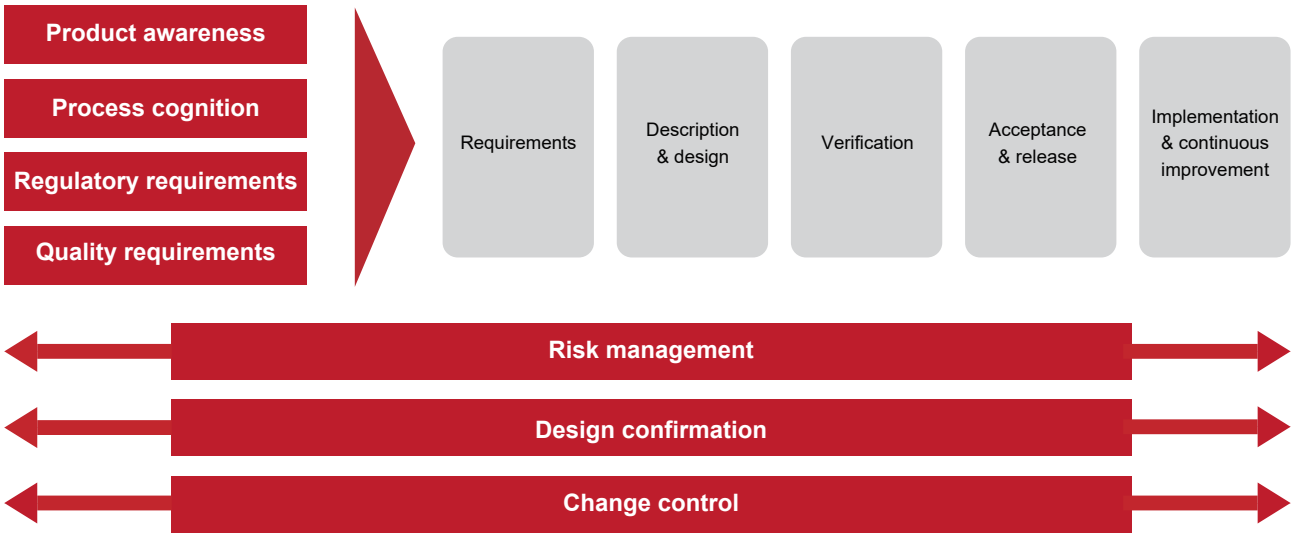
TCell-Pro parameters	
Maximum speed	6,000rpm
Maximum relative centrifugal force	1,200g
Maximum processing capacity of single time	220mL
Noise level	＜70dB(A)
Display dimension	10.1inch
Operating system	Linux
Power supply	AC220V±10%, 50Hz±1
Weight	20kg
Size	570*350*350 mm

Project Management

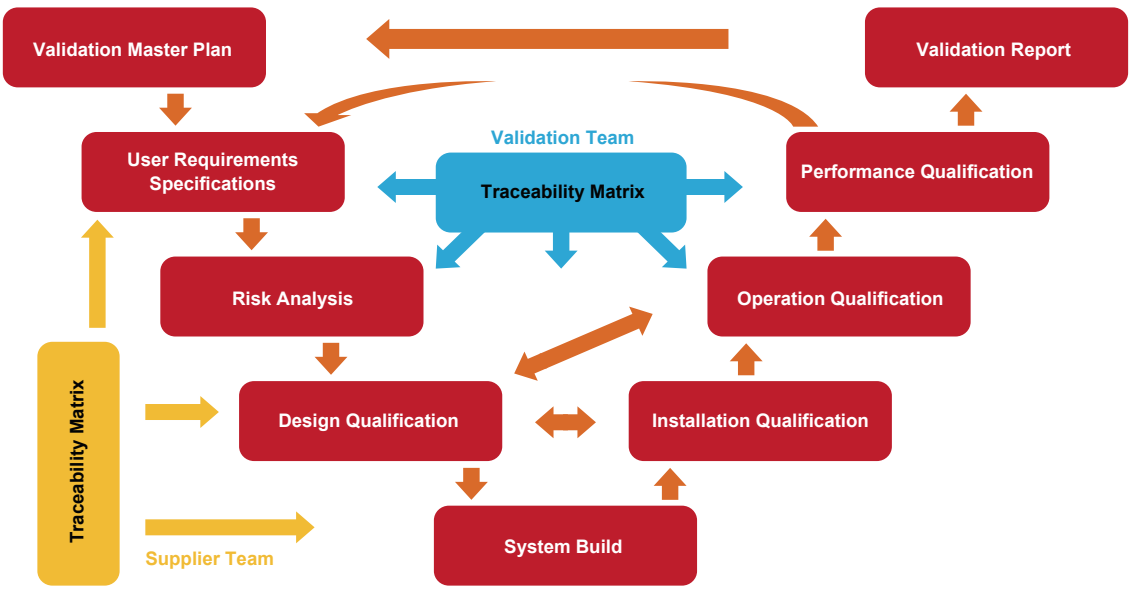
Three main factors determine the success of the project. Our organizational mode has been making constant update and improvement to enable you to fully achieve these goals. Through cooperation with us, you can minimize the direct resources required to manage the selection, purchase, installation, startup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

- Reliable quality
- Short cycle
- Focus on cost

Good Engineering Practice - GEP

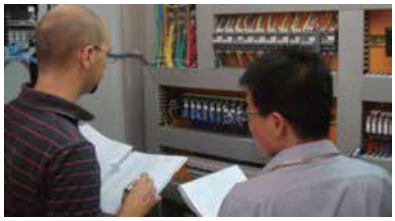


Validation Support



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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