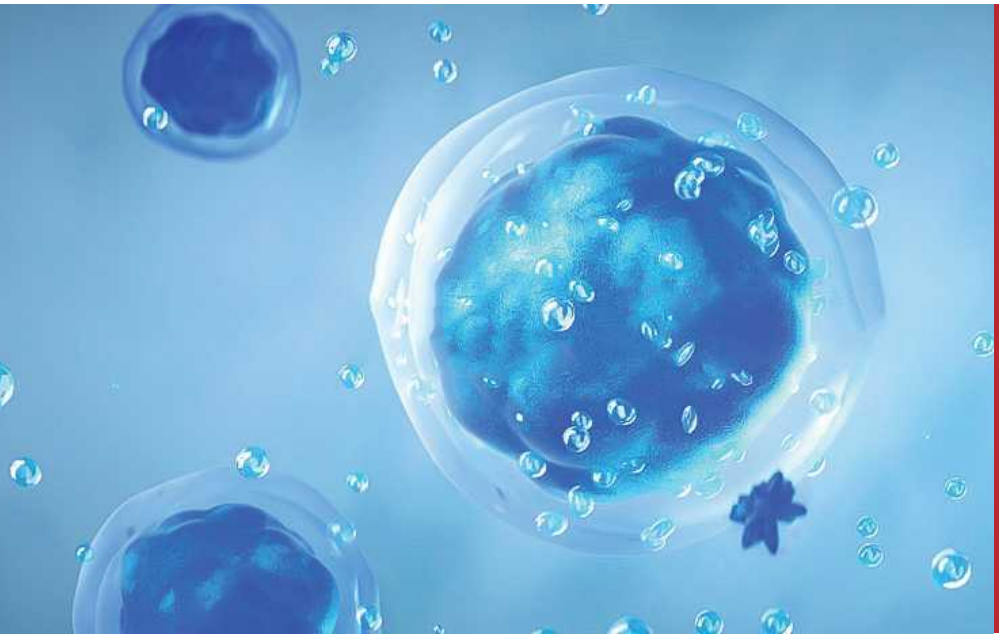
Tofflon



Biomedical transformation
platform solution provider

EXPERTISE IN BIO-PHARMACEUTICAL

Expertise in Bio-pharmaceutical

RANDOM FACTS ABOUT US

30+

30 years refrigeration experience
30 years of experience in pharmaceutical machine design

2,000+

2,000 patented technologies
200 software Copyrights

2,800+

Serving more than 2,800 pharmaceutical companies worldwide

12,000

More than 12000 sets of equipment and systems worldwide

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Founded
1993

2000
Establish Shanghai KYOWAC.
Tofflon brand enters the international market.

Establish Tofflon Airex.
2005

2011
Tofflon is listed.
Establish Tofflon TOP.
Establish the European R & D Center.

Establish Tofflon Packaging Company.
Establish Tofflon Intelligence.
Establish Medical Equipment Company.
2015

2020
Strengthen the three major strategies.
Strengthen the industrial layout.

The new model of (M+E+C)^{AI}.
The mainstream brand in the global market.
Future

Founded in 1993 and listed on GEM in 2011, Tofflon (stock code 300171), headquartered in Shanghai, is a total solution provider of process services and consumables, core equipment and engineering for global pharmaceutical companies.Adhering to the core value of "Heavenly rewarding diligence" and the mission of "professional technology serving biopharmaceuticals", and with the development strategy of "systematisation, internationalisation and digitalisation", Tofflon has been continuously developing its products and services to meet the needs of the global pharmaceutical industry.We will continue to move forward with the development strategy of "systematisation, internationalisation and digitalisation".

Tofflon has four core business divisions: Bioprocess Division, Formulation Equipment Division, Engineering Division, and Food Engineering Division.So far, there are 26 domestic holding subsidiaries such as Tofflon Life Sciences and Tofflon Dewei, 13 overseas holding subsidiaries, a total of 8 basic manufacturing bases at home and abroad, and 3 global R&D centres in China, the United States, and Germany. Tofflon continues to strengthen the research of drug manufacturing science and pharmaceutical machine science manufacturing, and is committed to building "a next-generation platform for drug manufacturing to provide a platform for research and development, pilot and We are committed to building a "next-generation drug manufacturing platform" to provide professional solutions for R&D, pilot and commercial production, and to facilitate rapid R&D and large-scale commercial production of drugs.

Bioprocess Business Division

- CGT Solutions
- Biological Products Solutions
- Synthetic Biology Solutions
- API Solutions

Pharmaceutical Preparation Equipment Business Division

- Sterile Drug Preparation Solutions
- Solid Dosage Formulations Solutions
- Inspection & Packaging Solutions

Engineering Business Division

- Intelligent & Informational Solutions
- Modular Pharmaceutical ProductionFacility Solutions
- Pharmaceutical Water & Air Conditioning System Solutions
- M + E Integrated Delivery Solution for Pharmaceutical Facilities

Food Engineering Business Division

- Liquid Food Solutions
- Sterile Food Solutions
- Food Pretreatment Solutions

Life Sciences



Tofflon Technology Group Co., Ltd. (SZ: 300171) was established in 1993. It is an integrated pharmaceutical equipment service provider that provides pharmaceutical processes, core equipment, and system engineering solutions to global pharmaceutical companies. Its products are used in injections, solid preparations, chemical raw materials, bioengineering, traditional Chinese medicine, medicine, food and other fields.

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, single-use 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 single-use 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.

Guidelines for Somatic Cell Clinical Research (Trial)

Somatic cell preparation

- For somatic cell preparations used in clinical research, their preparation should follow the relevant basic principles and requirements of the Good Manufacturing Practice (GMP), with a relatively stable production process and controllable quality.
- The functional areas in the preparation workshop/laboratory are reasonably set up, and the cleanliness of each functional area meets the needs of the preparation process. The cleanliness needs to be tested by a qualified testing agency and/or the environmental monitoring of the clean area to meet the relevant requirements of GMP.

GMP Appendix - Cell Therapy Products

Chapter Four: Plant, Facilities and Equipment

- Article 11 [Closed System] It is advisable to use a closed system or equipment for the production operation of cell products; the cleanliness level of the environment where the closed system or equipment is placed can be appropriately reduced.

Chapter Seven: Production Management

- Article 33 [Sterile Process Simulation] The sterile process simulation test for cell products, gene modification vectors directly used in the production of cell products, or other initial biological materials should at least meet the following requirements:
  (1) For aseptic production operations using a non-closed system, the sterile process simulation test should include all exposed processes of manual operations;
  (2) For aseptic production operations using a closed system, the sterile process simulation test should focus on the steps related to the connection with the closed system; if there are aseptic production operations that are not simulated, a risk assessment should be conducted, and the rationality of not simulating should be explained in writing.
- Article 36 [Prevention and Control of Contamination and Cross-Contamination in Production] Measures should be taken during the production process of cell products to prevent contamination and cross-contamination as much as possible and control quality risks, such as:
  (2) When using a non-closed system or equipment for production, different varieties of cell products should not be produced simultaneously in the same production area, and different batches of the same variety of cell products should not be produced simultaneously in the same production operation room;
  (6) When using a closed system for cell culture, different batches of products can be cultured and stored simultaneously in the same production operation room or the same incubator, but effective measures should be taken to avoid confusion. When using a non-closed system for cell culture, physical isolation (such as using a honeycomb incubator) should be carried out for different batches of products in the incubator or independent incubators in different production operation rooms should be used. A certain cleanliness should be maintained in the incubator and it can be disinfected or sterilize.
- Article 40 [Single-use Consumables] Single-use materials should be used as much as possible for sterile consumables that come into direct contact with cell products.

Chapter Nine: Product Traceability System

- Article 47 [Product Traceability System] Enterprises should establish a product identification and traceability system to ensure that during the entire process of donor material transportation, reception, and product production and use, products from different donors will not be confused or erroneous, to ensure the matching between donor materials or cells and patients, and to enable traceability.
  This system should preferably use a validated computerized system, which should be able to achieve two-way traceability of the product from the donor to the patient or from the patient to the donor, including the entire process from the receipt, transportation, production, inspection and release of donor materials to the transportation and use of the finished product.

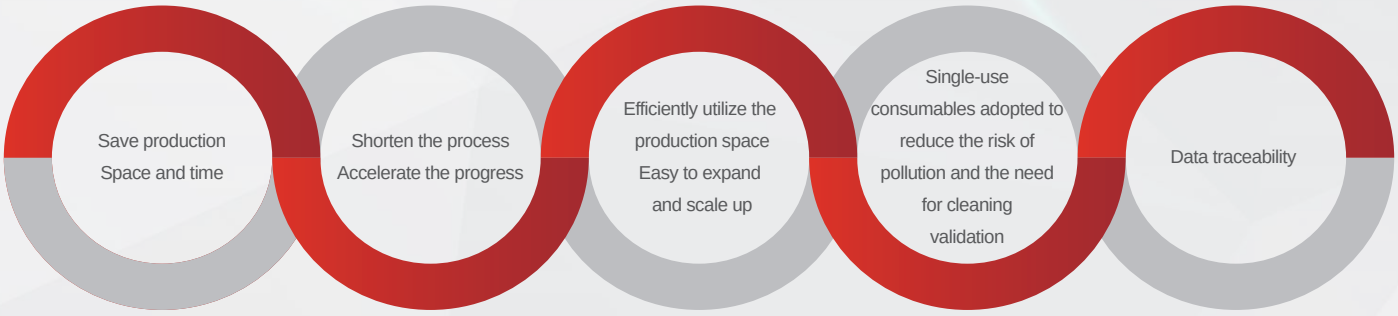
Comparison between intelligent cell preparation system and traditional B+A

Item	GMP Cell Preparation Station	B+A production model
Operation method	Closed system equipment, personnel do not directly contact key operating areas	Open system, personnel directly contact key operating areas
Cell preparation process mode	Customized integrated design according to customer proces	Open clean room, individually equipped with key cell preparation equipment
Background Environment requirements	C/D level (lower construction, operation and maintenance costs)	Class B (significant construction, operation and maintenance costs)
O&M Costs	C/D-level: rooms and equipment operating costs	Class B rooms: high energy consumption, repeated wiping, wearing, maintenance costs and consumables costs
Clean room area	The overall workroom and supporting auxiliary function rooms are smaller	Clean room partitions are complex and require a large area
Work uniforms	Single-layer work clothes, one-time changing.	Mask wrapping and double-layer work clothes are less comfortable
Batch/productchange cleaning method	Automatic VHP sterilization without the need for manual on-site supervision.	Room fumigation + manual wiping with disinfectant
Cleaning time	Automatic site clearance in 2 hours, which can achieve site clearance and sterilization between batches to prevent cross-contamination.	Regular fumigation and cleaning, wiping and cleaning between batches, high risk of cross contamination
Protection level	Complete isolation, high protection level	Open system, low protection level, prone to cross contamination

Advantages of intelligent cell preparation system

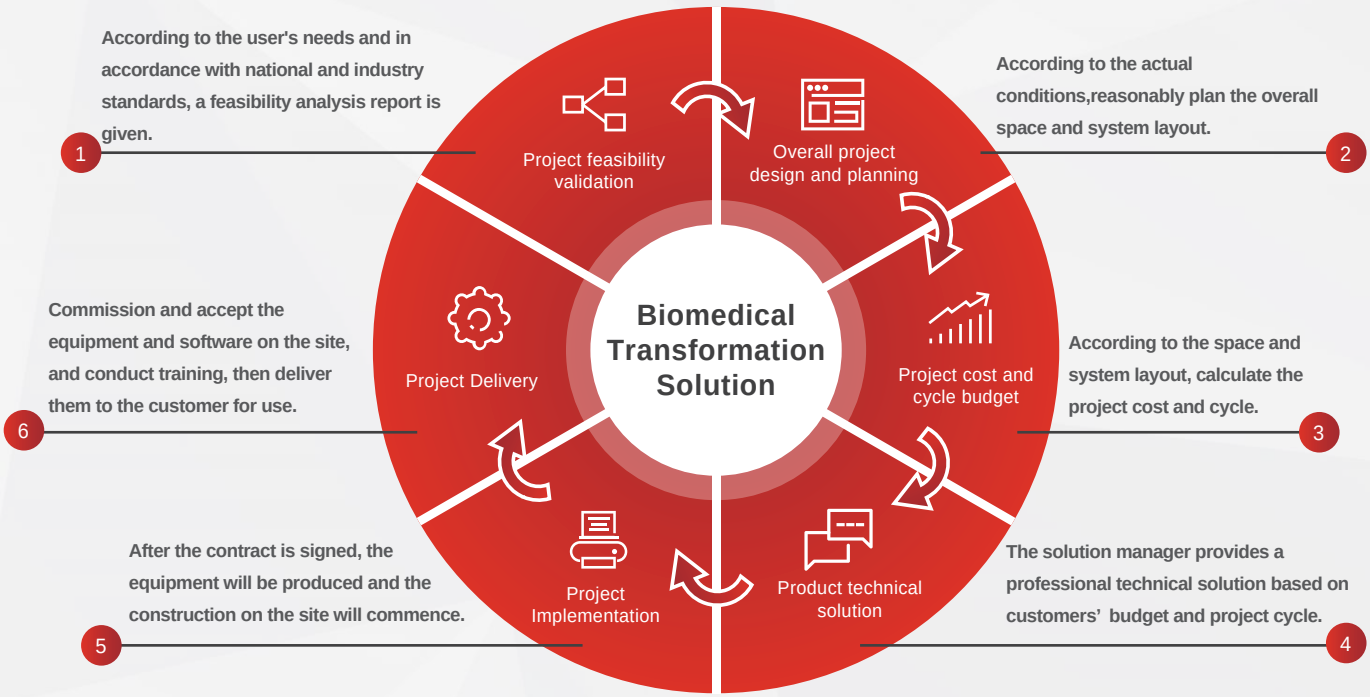




Biomedical transformation platform solution formulation process

According to the different process routes of users, solutions that meet meet customers' needs are formulated. It can realize the management of the entire process from blood collection, in vitro preparation, inspection and release, frozen transportation, and reinfusion.



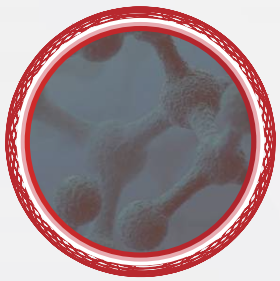
Project implementation plan



Total solution

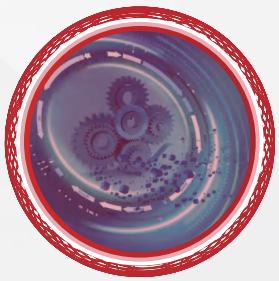
With years of technical precipitation and continuous innovation, Tofflon has accumulated excellent technical capabilities. We have mature large-scale production experience and can provide customers with efficient and stable production guarantees. Our technical team has comprehensive and flexible technical capabilities to meet your diverse needs and provide you with customized solutions.

In the field of GMP production services, Tofflon always adheres to a rigorous attitude to provide customers with one-stop services from clinical research to clinical transformation. Our GMP production services follow a strict quality management system to ensure the safety, effectiveness, and reliability of products. Through our professional services, we help customers successfully achieve the industrialization of scientific research results.



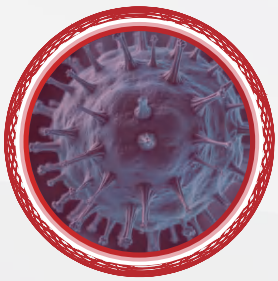
Cell Therapy Solution

- Stem Cell
- Immune Cell
- Tissue-specific Cell
- Mesenchymal Stem Cell（MSC）
- Induced Pluripotent Stem Cell（iPSC）
- Hematopoietic Stem Cell



Plasmid Platform Solution

- Plasmid DNA
- Minicircle DNA
- mRNA Plasmid



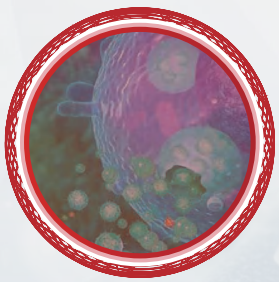
Virus Platform Solution

- Adeno-associated Virus（AAV）
- Lentivirus
- Adenovirus



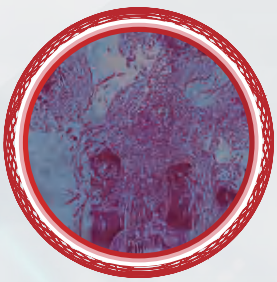
Vaccine Solution

- Chick Embryo
- Mammalian Cell
- Insect Cell
- Yeast Cell



Exosome Solution

- Immune Cell
- Stem Cell
- Tumor Cell
- Kidney Cell
- Plant Cell



Sample Library Solution

- Blood
- Tissue
- Cell
- DNA

Cell Therapy Solutions

Tofflon

Tofflon provides key process equipment for the cell therapy process flow, involving steps such as cell activation, transfection, culture, washing and concentration, formulation and dispensing, programmed cooling, cryogenic storage, and resuscitation. It includes space-closed systems and disposable processing systems to meet the needs of users for different types of cell processes.

Immune cell therapy space closed process solution

1 Apheresis

2 Cell Isolation, Activation, Transfection

3 Cell Expansion and Culture

4 Harvesting, Washing, Concentrating



GMP Cell Preparation Isolator



Honeycomb Incubation System



GMP Cell Preparation Isolator

5 Filling

6 Programmed Cooling

7 Liquid Nitrogen Cryogenic Storage

8 Clinical Transfusion of Cell Preparations



Cell Thawing System（Bag） & Cell Thawing System（Cryovial）



Automated Cryogenic Biological Sample Storage System(LNS 102 series)& (Cellbank series)



Programmable Cooler & Programmable Cooler (Non-liquid nitrogen)



Cell Subpackage System

Immune cell therapy single-use process solution

1 Apheresis

2 Cell Separation, Activation, Transfection

3 Cell Expansion and Culture

4 Harvesting, Washing, Concentrating





TCell-Pro Single-use Cell Processing System



Single-use Bioreactor Rocker



TCell-Pro Single-use Cell Processing System & TCell-Max High-Throughput Cell Processing System

8 Clinical Transfusion of Cell Preparations

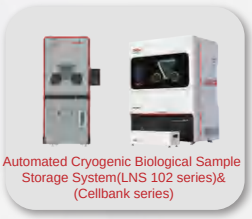
7 Liquid Nitrogen Cryogenic Storage

6 Programmed Cooling

5 Filling



Cell Thawing System（Bag） & Cell Thawing System（Cryovial）



Automated Cryogenic Biological Sample Storage System(LNS 102 series)& (Cellbank series)



Programmable Cooler & Programmable Cooler (Non-liquid nitrogen)



Cell Subpackage System

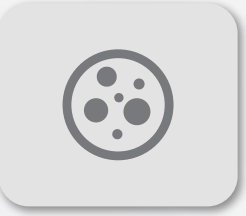
iPSC-derived NK cell product preparation process solution

1 HiPSC Cell Bank

2 Cell Inoculation, SCF and Other Factors

3 Cultured and Differentiated Hematopoietic Progenitor Cells

4 Change Cell Medium and Add 1L15 and Other Factors





GMP Cell Preparation Isolator



Honeycomb Incubation System



GMP Cell Preparation Isolator

9 Product Return

8 Cell Cryopreservation

7 Controlled Rate Freezing

6 Wash Concentration

5 NK Cell Expansion



Cell Thawing System（Bag） & Cell Thawing System（Cryovial）



Automated Cryogenic Biological Sample Storage System(LNS 102 series)& (Cellbank series)



Programmable Cooler & Programmable Cooler (Non-liquid nitrogen)



GMP Cell Preparation Isolator



Honeycomb Incubation System & BRG Series Bioreactor

MSC cell drug preparation process solution



Solution Features

- Standardized, in line with GMP production requirements and FDA 21 CFR PART 11 production record and quality control requirements;
- Fully enclosed, all operations are carried out in a closed space in each link, and it is no longer required to operate in the B+A clean area. It can be completed only in the general C-level clean area, reducing the requirements for the hardware of the operating site and thereby reducing the operating and construction costs;
- Realize the simultaneous cultivation of multiple batches, make efficient use of space, and the production of different batches of cell products of the same variety can be carried out simultaneously in different production operation rooms in the same production area;
- The whole process is electronically and informatically managed, which is convenient for management and standardized production.

Plasmid Platform Solution

Tofflon

Tofflon can provide the core process equipment for plasmid production, covering the entire process from seed amplification, culture, concentration, filtration, and dispensing. It offers diverse solutions according to the production requirements of plasmids for different viral vectors.

Integrated solution for plasmid preparation and production platform

1 Seed Amplification
2 Fermenter Culture
3 Cell Harvesting
4 Alkali Lysis Neutralization
5 Clarification


BRG Series Bioreactor


Single-use Fermentation Reactor System


Single-use Mixing System


Alkali Lysis Neutralization Module


Clarification System

10 Filling
9 Sterilization Filtration
8 Ultrafiltration
7 Purification
6 Plasmid Purification and Concentration


Cell Subpackage System


Sterilization Filtration System


Laboratory Ultrafiltration System


Chromatographic System


Laboratory Ultrafiltration System

Solution Features

- Compliance, in line with GMP regulatory requirements and FDA 21 CFR PART 11 production record and quality control requirements;
- Overall solution, an overall solution for the entire process, with standardized design to reduce docking errors;
- Flexibility, it can provide multiple options such as SS and SU to meet the needs of different public works;
- Informatization, it can provide a global SCADA system to realize the fully informational management of the plasmid production process.

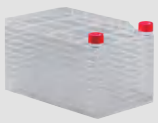
Virus Platform Solution

Tofflon

Tofflon can provide the core process equipment for lentivirus production, covering the entire process from seed culture, clarification, ultrafiltration concentration, virus removal, and sub-packaging. According to different viral vectors, diversified solutions can be provided.

Lentivirus process solution

1. Seed Culture
2. Cell Culture, Transfection, Viral Packaging, Cell Lysis, Nuclease Digestion
3. Clarification
4. Ultrafiltration Concentration



Ten-layer Cell Factory



Single-use Bed-Cell mini Bioreactor System



Clarification System



Laboratory Ultrafiltration System

5. Chromatography
6. Ultrafiltration Concentration
7. Sterilization Filtration
8. Filling



Cell Subpackage System



Sterilization Filtration System



Laboratory Ultrafiltration System



Chromatographic System

Solution Features

- Compatible with multi-line vaccine bulk solution production process solutions;
- Can achieve a fully closed pipeline connection throughout the process to reduce risks;
- Covers the entire process from R&D to commercial production;
- Meets the requirements of GMP regulations and the production record and quality control requirements of FDA 21 CFR PART 11.

Vaccine Solution

Tofflon

Tofflon can provide the core process equipment for vaccine production, covering the entire process from plasmid linearization, chromatography, ultrafiltration, IVT, sterilizing filtration, and sub-packaging, to achieve the automated and modular production of the entire vaccine production line.

mRNA vaccine process solution

1 Plasmid Linearization

2 Composite Mode Chromatography

3 Ultrafiltration Concentration

4 IVT



Single-use Bioreactor Rocker



Chromatographic System



Laboratory Ultrafiltration System



Single-use Bioreactor Rocker

9 Filling

8 LNP Preparation

7 Sterilization Filtration

6 Ultrafiltration Concentration Change

5 Chromatography



Cell Subpackage System



LNP-060L Nano Drug Preparation System



Sterilization Filtration System



Laboratory Ultrafiltration System



Chromatographic System

Solution Features

- Optional single-machine combined and integrated solutions for different scenarios, with full automatic control, beautiful design, and compact structure;
- The one-stop solution concept reduces operational errors by personnel;
- The all-disposable hardware platform reduces the early hardware cost investment, reduces the cleaning and verification time, improves the production capacity of the multi-product co-production workshop, and increases the flexibility of the platform;
- The automated platform strengthens data management and data integrity.

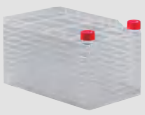
Exosome Solution

Tofflon

Tofflon can provide the core process equipment for exosome production, covering the entire process from cell culture, separation and purification, filling / freeze-drying, and provide customers with an overall solution from pilot-scale to commercialization.

Exosome 3D process solution

1 Seed Culture » 2 Cell Culture » 3 Clarification » 4 Ultrafiltration Concentration



Ten-layer Cell Factory



Single-use Bed-Cell mini Bioreactor System



Clarification System



Laboratory Ultrafiltration System

8 Lyophilized Exosomes « 7 Filling « 6 Sterilization Filtration « 5 Chromatography



0.2㎡ Desktop Freeze-drying Machine & Experimental Freeze-drying Machine



MiniKUFill Automatic Filling System



Sterilization Filtration System



Chromatographic system

Solution Features

- The sheet-like carriers are closely packed inside the reactor, creating an efficient 3D cell culture environment and significantly improving production efficiency;
- The innovative waterfall flow and circulation culture mode enables the continuous harvest of exosome supernatant, greatly increasing production capacity;
- The uniquely designed filler microsphere structure has a processing capacity that is hundreds of times that of the traditional gel filtration process, while maintaining excellent purity and high flow rate;
- It fully complies with GMP production standards and the production record and quality control requirements of FDA 21 CFR PART 11 to ensure the reliability of product quality.

Biobank Solution

Tofflon

Tofflon provides key process equipment for the steps involved in the sample storage process, including programmed cooling, cold chain transportation, low-temperature storage, and sample recovery. It is equipped with an information management system for the biobank to provide users with a new intelligent storage model.

Biobank Solution

1. Controlled Rate Freezing
2. Cold Chain Transport
3. Fully Automatic Ultra-low Temperature Storage
4. Fully Automatic Cryogenic Storage
5. Sample Resuscitation



Cell Thawing System（Bag） & Cell Thawing System（Cryovial）



Portable Biological Sample Transfer Container



Modular Automated Cryogenic Biological Sample Storage System

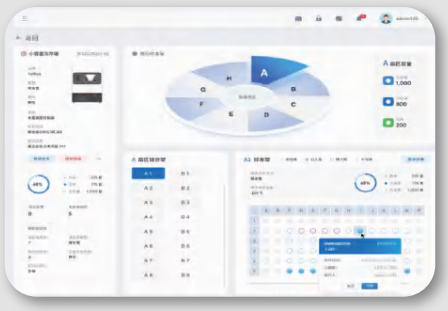


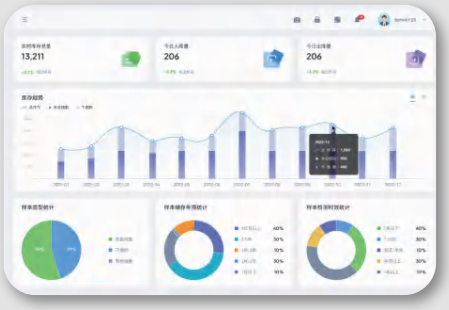
Automated Cryogenic Biological Sample Storage System(LNS 102 series)& (Cellbank series)



Cell Thawing System（Bag） & Cell Thawing System（Cryovial）

The sample library management software, as a carrier that connects storage devices, operations, and monitoring, provides a complete information service chain for the sample library business process.





PC





Mobile terminal

Solution Features

- Standardized procedural control to reduce the influence of human factors;
- Cold chain protection throughout the storage process to reduce the impact of repeated freezing and thawing on cell quality;
- Automated storage to achieve automatic and precise access to the whole box/single item;
- Equipment Internet of Things for real-time remote viewing of sample and equipment information;
- The whole process is electronically and informatically managed for easy management and standardized operation.

Space closed system



GMP Cell Preparation Isolator



Honeycomb Incubation System



MiniKUFill Fully Automatic Filling System



Cell Therapy Drug Filling Isolator

Single-use closed system



TCell-Pro Single-use Cell Processing System



TCell-MAX High-Throughput Cell Processing System



Single-use Bioreactor Rocker



Cell Subpackage System



Single-use Bed-Cell mini Bioreactor System

Biobank



Programmable Cooler



Programmable Cooler（Non-liquid nitrogen）



Automated Cryogenic Biological Sample Storage System(LNS 102 series)



Cell Thawing System（Bag）



Cell Thawing System（Cryovial）

Consumables



Single-use Bag



Culture Media



Resins



Filters & Cassette

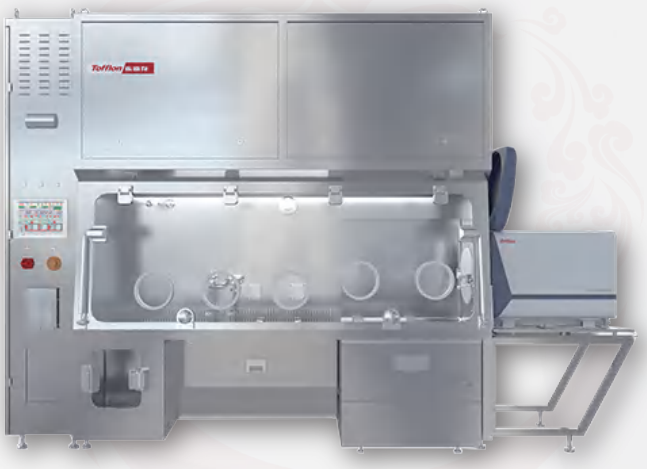


COP Vial

GMP Cell Preparation Isolator

According to the customer process, the key equipment required for cell preparation is configured in the Class A working environment, such as centrifuge, shaker, RTP incubator, metal bath, microscope, etc., which meets the ergonomic design and is easy to operate.

Provide full asepsis guarantee for cell preparation process operation, and realize cell separation, extraction, activation, sampling, culture, liquid exchange, observation, collection, etc., on the system equipment, combined with our self-developed cellular drug GMP management system, To provide a practical, GMP compliant and ergonomic cell drug manufacturing equipment for mass production of cell therapy drugs. GMP cell drug preparation station is also suitable for clinical trials of cell therapy products.



Comply with:

- **China Drug GMP Specifications**
- **Guiding Principles of Cell Therapy Product Research Institute and Evaluation Technology (Trial)**
- **EU ATMP Frontier Drug GMP Guideline**
- **FDA Sterile Drug Production Guideline**



Cell centrifugation



Environmental monitoring



Cell observation



RTP valve



Honeycomb Incubation System



RTP incubator



Transit trolley

Product Features

- Modular, high flexibility, easy to expand, to meet the needs of large-scale cell culture production.
- According to the requirements of cell preparation process, the data information sharing and management of the whole station and honeycomb culture system can be realized.
- It can realize data wireless communication (WIFI), and can still do data maintenance after separation, which is easy to data management and tracking.
- It has the requirement of three-level permission setting, and meets the relevant requirements of FDA electronic records and electronic signatures.
- The system supports data report query and report export.
- With the total air pressure monitoring function, to prevent the pressure is too low to cause insufficient air supply.
- Cell culture management of different samples (i.e., multiple batches) at the same time can be achieved, completely isolating the risk of cross-contamination between different samples.
- To provide a high assurance of aseptic cell culture environment, the gas entering the incubator is filtered in two stages, one stage in the control line of the honeycomb culture system and the other stage inside the incubator.
- Each incubator has an independent control unit, the control of adjacent incubators in the hive will not affect each other, and the culture of different cell types can be realized in the incubator of different nest positions of the same honeycomb culture system at the research end.
- The honeycomb is equipped with a code scanning function to identify the box number and batch number of the incubator, avoiding the risk of confusion or error during cell preparation.

TCell-Pro Single-use Cell Processing System

Single-use cell processing system 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.

Product Features

- 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.

Specification

Process	Starting volume	Final collection	Remark
Mononuclear cell isolation	30~120mL	45mL	Cell harvest rate >55% Cell viability >95% Removal rate of red blood cells >99%
Magnetic bead incubation	30~880mL	8~500mL	Harvest rate＞80% Viabilitu＞95%
Viral transfaction	30~880mL	20~500mL	The transduction efficiency is comparable to manual Cell viability > 95%
Purification and concentration	30~880mL	20~500mL	Cell recovery rate > 80% Cell viability > 95%
Dilution and subpackage	0~220mL	Maximum 5 bags	First bag volume and last bag Accuracy ±2mL, ±1mL in the middle Cell concentration difference < 10%

Single-use Bioreactor Rocker

Single-use Bioreactor Rocker (SUR) is designed for cell therapy specially. The system provides good mixing and ventilation through rocking technology. The system ensures a sterile environment and reduces the risk of contamination through disposable biological bags.
As a general-purpose cell culture and fermentation technology platform, the system provides reliable and accurate performance throughout the research, process development and production environment. Batch culture mode or perfusion culture mode can be used to obtain more cells and higher expression quantity, which is convenient for cell amplification culture.



Product Features

- Suitable for almost all the cell culture applications.
- Suitable for different culture strategy, like batch culture, fed-batch culture and perfusion culture.
- Suitable for suspension culture, flake carrier culture and micro carrier culture.
- The disposable bio-reaction bag is a enclosed system that could minimize the risk of cell contamination.
- Process monitoring: The key culture parameters (Swing speed, Angle, Temperature, DO, pH, perfusion rate, CO_2 concentration, weight, pressure, etc.) could be precisely controlled by PID and tracked.
- Two monitoring model applicable, CO_2 concentration control model suitable for basic disposable bag, and pH/DO control model suitable for pH/DO applied disposable bag.
- Suitable for use in a regulatory environment and complies with requirements and standards of cGMP.
- Optional parts like pH/DO sensor module.
- The optional remote monitoring of culture situation within the equipment can be monitored in real time through the mobile phone, message and E-mail, and the real-time alarm information and parameter information can also be checked.

Specification

Item	Parameter		
Tray (replaceable)	10L	25L	50L
Culture bag volume	10L	20L	50L
Culture volume	200mL-5L	200mL-10L	2L-25L
temperature control range	room temperature+3~40℃		
Temperature control accuracy	±0.2		
Swivel speed control range	1-42rpm		
Swing angle control range	1°-12°		

Cell Subpackage System

The Cell packaging System (CSS) uses a process combined with single-use consumables to achieve high-throughput, accurate, fast, and reliable closed, fully automated aseptic packaging. The system is composed of stock liquid mixing unit, temperature control unit and multi-station sub-assembly unit, which can be customized according to the actual process requirements of customers.

The system can be widely used in pharmaceutical and medical industries, and has a wide application prospect in the packaging production of cells, viruses, vaccines and other products.



Product Feature

- Packaging specifications: volume ranges from 2 mL to 150 mL
- Information management: The whole process of data reading and recording is managed informatization.
- Modular integration: It can meet the customized sub-packaging process requirements of different customers.
- Automatic control: The sub-packaging process is fully enclosed and automated to avoid human contact and reduce risks.
- Data integrity:It complies with regulatory requirements, and the data of the sub-packaging process is recorded and traceable throughout the entire process.

Technical parameter

- Temperature control: The liquid in the liquid bag is intelligently controlled at 2 - 8℃.
- Cell solution homogeneity: The density deviation is within 10%.
- Cell viability: Maintain more than 95% of the initial cell viability.
- Air residue in the product bag: The air residue in the final product bag is less than 2 mL.

Specification

Item	Parameter
Product model	CSS-N20
Number of dispensing bags	20 bags
Subpack volume range	2~150mL
Size (L * W * H mm)	1175*520*880
Weight (kg)	100

Programmable Cooler

Programmed cooling instrument is a kind of high performance, safe and reliable refrigeration equipment with controllable temperature change rate. The programmed cooling system adopts the latest temperature control technology and liquid nitrogen dispersion technology to make the programmed cooling process uniform and stable, and can be widely used in light industry, agriculture, medicine, basic biological research and other fields.



Product Feature

- **Safety:** Door interlock control, double solenoid valve, one standby one, to ensure the safety of sample cooling.
- **Process repeatability:** The sample cooling process repeatability is high.
- **Data integrity:** Automatic output of complete cooling electronic report .
- **Expansibility:** The software can access the user HIS/LIMS.
- **Sterilization compatibility:** The internal chamber and shell of the whole machine support VHP sterilization.
- **Regulatory compliance:** The control software meets FDA 21CFR Part 11 authority and audit trail requirements.

Selection Parameter

Item	Parameter		
Product model	LNC180	LNC340	LNC520
Volume	18L	34L	52L
Maximum flux	2mL / 385bottles 50mL / 30bags 250/500mL / 10bags 750/1000mL N/A	2mL / 810bottles 50mL / 60bags 250/500mL / 20bags 750/1000mL 8bags	2mL / 1195bottles 50mL / 90bags 250/500mL / 40bags 750/1000mL 16bags
Refrigerating medium	Liquid nitrogen		
Temperature control range	+50℃~-180℃		
Temperature deviation	< 2℃		
Cooling rate	0.1~99℃/min		
Heating rate	0.1~10℃/min		
Cooling program	Default programs, user-defined programs		
Man-machine interface	10 inch color touch screen		
Optional configuration	All kinds of pipe racks, sweep gun, UPS		
Overall dimension	985×670×550mm	1140×640×550mm	1320×640×550mm
Weight	90kg	100kg	110kg
Rated power	2500w		

Automated Cryogenic Biological Sample Storage System

The deep and low temperature sample storage system can provide a continuously stable gas phase nitrogen storage environment below -150℃, automatic access control, and intelligent and information management of sample storage historical data.



LNS102



CellBank

Product Feature

- **Sample security:** Sample access throughout the cold chain -130℃ (minimum support -180℃) protection.
- **Consumable compatibility:** Support storage freeze-storage tube, freeze-storage box and freeze-storage bag.
- **Intelligent:** Single tube/box automatic sorting, automatic identification, key step data automatic recording and correlation.
- **Information system:** BIS (Biobank Information Management System) directly and remotely linked with equipment, to achieve access to orders, query network management, support HIS/LIMS.
- **Reliability:** Equipped with temperature, level monitoring and automatic replenishment systems to maintain a constant sample storage temperature.
- **Regulatory compliance:** The control software complies with FDA 21CFR Part11 rights management and audit trail requirements.

Specification

Item	Parameter	
Product model	LNS102	CellBank
Cryopreservation tube capacity	0.5mL：50094 1mL：40986 2mL：19494	0.5mL：8400 1mL：4900 2mL：4900
Frozen storage bag capacity	25mL：800 bags 50mL：360 bags	/
Storage temperature	≤-150℃（min. -180℃）	≤-150℃（min. -180℃）
Sorting temperature	≤-130℃（min. -180℃）	≤-130℃(min. -180℃)
Overall dimension	1950x1130x2500mm	1660x1216x2255mm
Overall weight	1200kg	1000kg
Standby power	200W	200w

Cell Thawing System

Designed for cell resuscitation in cryogenic cryopreservation bags, the cell resuscitation device is compatible with a variety of cryopreservation bag types (cell cryopreservation bag volume ranges from 10 mL to 1000 mL), and can quickly resuscitation cells from solid to liquid state without additional manual operation, while ensuring cell viability.



Product Features

- **Dry cell resuscitation:** metal bath to avoid experimental errors caused by external factors.
- **Precise temperature control:** Multiple temperature sensors, real-time temperature monitoring.
- **Uniform recovery process:** Dynamic recovery, cells are heated evenly.
- **Compliance with regulatory requirements:** The control software complies with FDA 21CFR Part11 Rights Management and audit Trail requirements.
- **Extensibility:** The software can access user HIS/LIMS.



Specification

Item	Parameter	
product type	Bag	Tubular
Control temperature range	Room temperature ~40℃	0~40℃
Sample volume	10~1000mL bags	0.8~1.5mL cryovial
Thawing recovery time	2~6min	3min
Temperature program	Default programs, user-defined programs	/
Man-machine interface	10.1 inch color touch screen	Color display
Overall size	420x420x200mm	200x162x162mm
Rated voltage	220V	220V

Typical case

A hospital in Sichuan




A hospital in Beijing




A hospital in Xiamen





A hospital in Guangdong




A CDMO company in Shanghai




A biological company in Hangzhou




A biological company in Nanjing




A research institute in Beijing






Service Model

Service Commitment

- We provide you with "7×24 hours" hotline service and "7×8 hours" technical support service.
- We will respond to the technical support, demands and complaint calls you put forward within 2 hours and handle them in a timely manner.
- There will be at least two return visits (including phone return visits and on-site return visits) every year to understand the product usage and continuously improve the product according to the usage suggestions.
- The after-sales service quality management team mainly tracks and investigates the quality of after-sales service, and assesses the after-sales service team in order to provide users with high-quality after-sales service.

Field Service

- Regularly conduct return visits to customers.
- For demands that cannot be handled by phone or remotely, after confirmation by both parties, arrive at the scene in a timely manner to handle the faults.

Service hotline

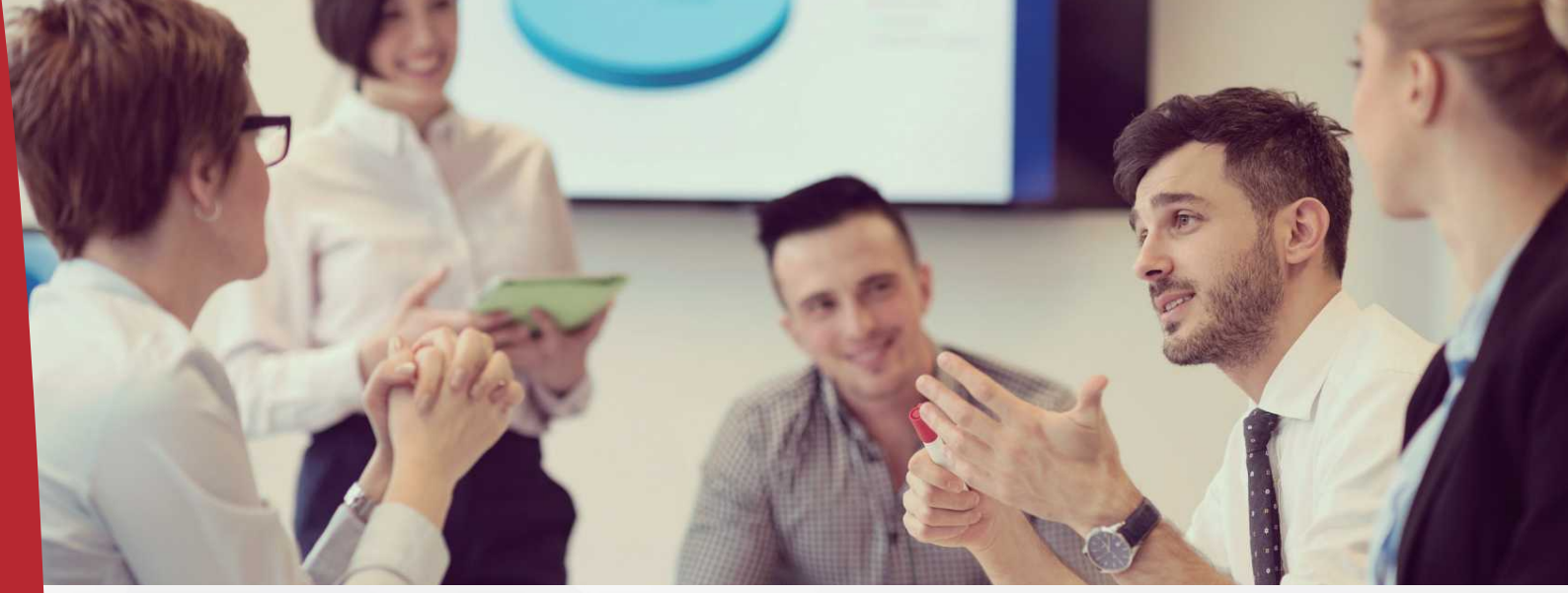
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The call center staff is responsible for answering the after-sales service hotline and proactively contacting customers.

After-sales service feedback platform

Customers register their needs and issues through the after-sales service feedback platform. Customer service staff will solve customer problems within the specified time according to requirements and actual conditions. Customers can view the progress of demand processing and confirm and evaluate the processing results.





Project Management

Three main factors determine the success of a project. Our organizational model is constantly being updated and improved 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 validation projects of new production equipment.



- **Reliable quality**
- **Short cycle**
- **Focus on costs**

Good Engineering Practice

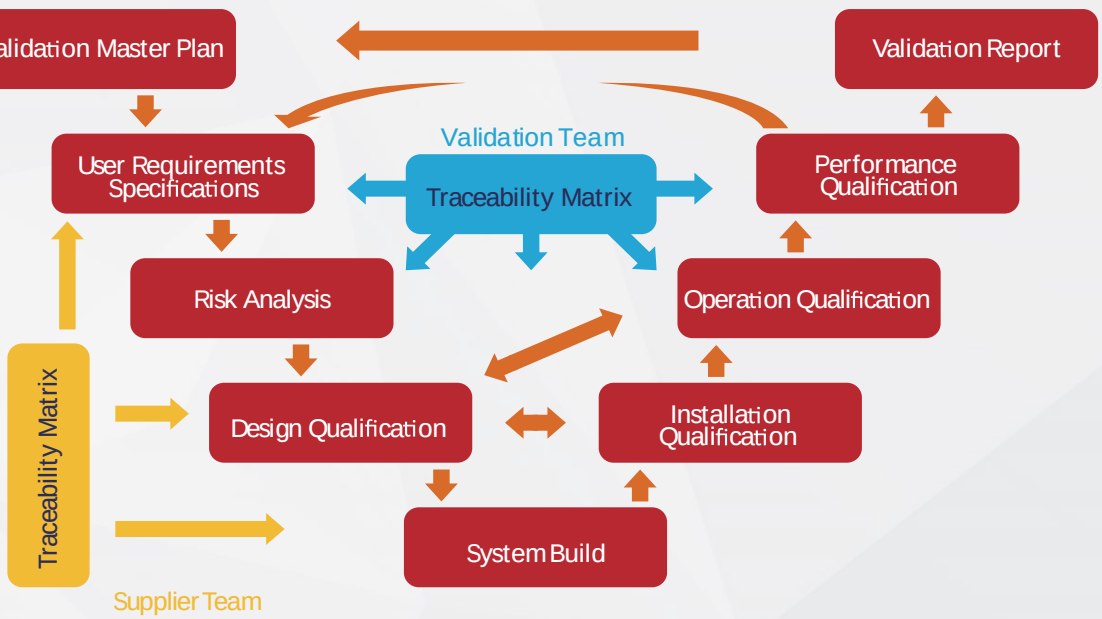
- Product cognition
- Process cognition
- Regulatory requirements
- Quality requirements

→ Demand → Description & Design → Validate → Accept & Release → Implement & continuous improvement

- Risk management
- Design validation
- Change control



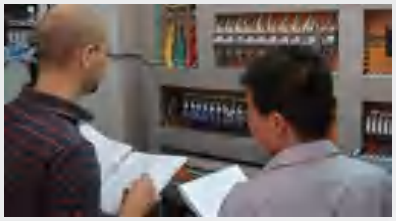
Validation Support



Verification document system

- Complete document system.
- Strict quality assurance process.
- In line with GMP validation protocol.
- Ensure the stable and reliable quality of products.







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