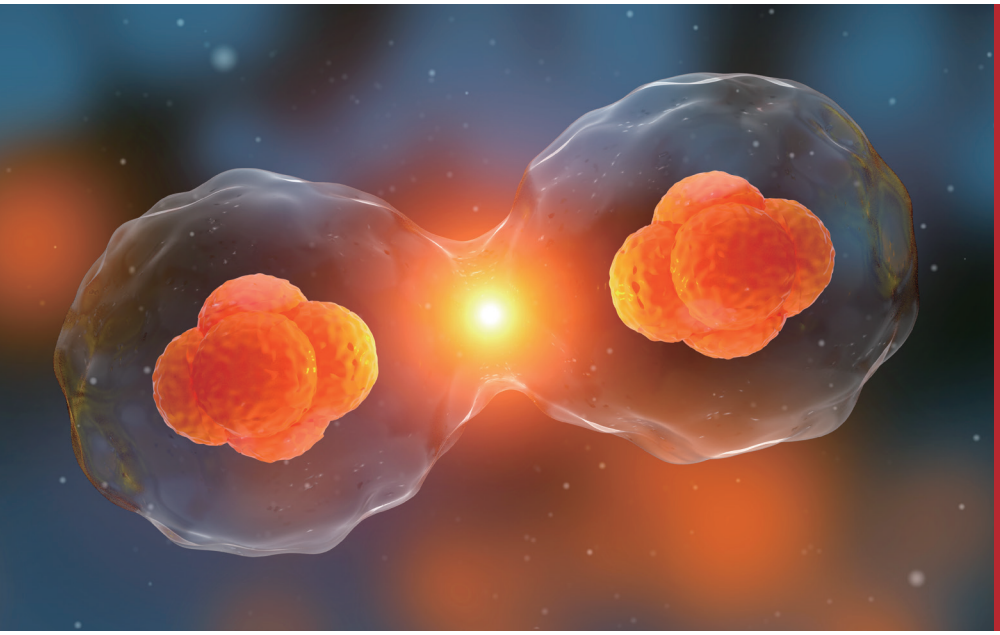
Tofflon



Holistic Approach of Cell Therapy

EXPERTISE IN BIO-PHARMACEUTICAL

CONTENTS

scope of APPLICATION

Cell therapy

P4 **Application fields**

P6 **Company introduction**

P7 **Equipment and Technology**

- **P8** — GMP Cell Therapy Isolator
- **P9** — BEEHIVE culture system
- **P10** — SUC single-use cell treatment system
- **P11** — SUR single-use biological swinger
- **P12** — Single-use tank
- **P13** — Culture media
- **P14** — Disposable culture bag
- **P15** — MiniKUFill full-automatic filling system
- **P16** — Cell subpackage system
- **P17** — Programmable cooler
- **P18** — Full-automatic liquid nitrogen storage system
- **P19** — Small capacity automation LN storage system
- **P20** — Biological sample bank information management system
- **P21** — Resuscitation instrument

P22 **Project management**

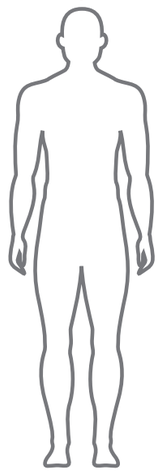
P23 **Verification support**

P24 **Automatic control system**

P25 **Project cases**

Holistic Approach of Cell Therapy Platform

Blood sampling



Cell isolation & transfection



Cell preparation station - GMP grade



TCell-Pro

Cell Expansion



Honeycomb culture system



SUR



Glass bioreactor

Harvest, Elution & Concentration



Cell preparation station - GMP grade



TCell-Pro

Cell recovery



Thawing instrument



Cryopreservation



Manual LN reservoir



Automatic LN reservoir



Mini Automatic LN reservoir

Programmable cooling

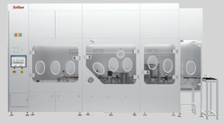


Programmable controller

Fill / Dosage



Manual filling isolator



Automated - MiniKUFill



TCell-Pro



Cell dosage system

Tofflon
Life Science Division



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 Division focuses on the research and development of front-end technologies in the pharmaceutical and medical industries, and provides the one-stop services integrating instruments, equipment and consumables (including consumables, reagents, fillers, filters and packaging materials).

- In the field of cell therapy, it provides the overall solutions for the preparation and production of immune cells, stem cells, tumor cell vaccines, etc.;
- In the field of gene therapy, it provides 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, it performs the research and development of automatic sample storage management system to provide the overall solutions for cell and tissue sample banks;
- In the field of consumables, we have formed a complete consumable scheme in disposable bags (reaction bags/dispensing bags/storage bags), reagents (culture media/cryoprotectants), fillers, filtration (microfiltration/deep filtration/ultrafiltration/nanofiltration), and hard packaging materials;
- In the field of disinfection, it is committed to air and surface disinfection, infection control, terminal disinfection and multi-drug resistant bacteria disinfection, providing an overall solution for environmental disinfection.

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

Key System&Technology



GMP CELL THERAPY ISOLATOR

- Level C+A integrated platform, providing complete sealing and isolation. Higher compliance with the regulations, greatly reducing the requirements of background environment level
- Integrated H2O2 sterilization, quick sterilization within 2 hours without load, reaching the 6log sterilization effect. Integrated online environmental monitoring device, sterile environment verifiable
- All key data parameters are recorded and exported to a conclusive report. Customizable design, with the equipment more consistent with the cell technology
- Meet the needs of multi-variety co-linear production, improve the work efficiency and save the plant space
- The equipment can provide cell separation, extraction, activation, sampling, culture, fluid change, observation, collection, etc.





BEEHIVE CULTURE SYSTEM

- Modular and easy to expand, the incubator can increase synchronously with the subsequent capacity expansion, and it can realize data sharing management with the isolator
- Wireless communication of real-time data, with three-level authority requirements, and supporting the query and report export functions
- The design of BEEHIVE incubator is in line with the standards for YY1621-2018 medical carbon dioxide incubator, and the culture effect is better than that of ordinary incubator
- The RTP form is used to provide the quick sterile docking between the incubator and the isolator; the docking time is about 40 seconds to 1 minute, and no additional sterilization is required; the internal environment of the incubator is Level A sterile environment
- Independent control units, which do not affect each other and it can be identified by scanning the code to avoid the risk of confusion and error

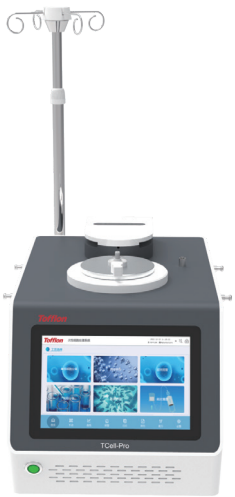




SUC SINGLE-USE CELL TREATMENT SYSTEM

- Suitable for most cell treatment applications
- Applicable to PBMC separation, washing and concentration, dilution and subpackage, virus transduction, magnetic bead incubation, etc.
- The single-use technology adopted to provide a sterile production environment for cells and greatly reduce the risk of pollution
- It can provide real-time monitoring and accurate control of parameters such as speed, temperature, pressure and volume during the treatment
- Select different software packages according to different treatment requirements and comply with the cGMP requirements
- It can open the relevant communication protocols to connect with SCADA systems of all companies







SUR SINGLE-USE BIOLOGICAL SWINGER

- Closed system, avoiding open operation
- The disposable cell biological bag ensures flexible switching between products and avoids the risk of cross contamination
- Wave mixing, providing better gas exchange and low shear force
- Applicable to scale-up culture process and parallel culture process
- Various sensors, software customization and disposable cell bag customization can be selected as required
- Replaceable tray and upper cover, forming different specifications of equipment; The modular design of the control box makes it convenient to match with the accessories as required.

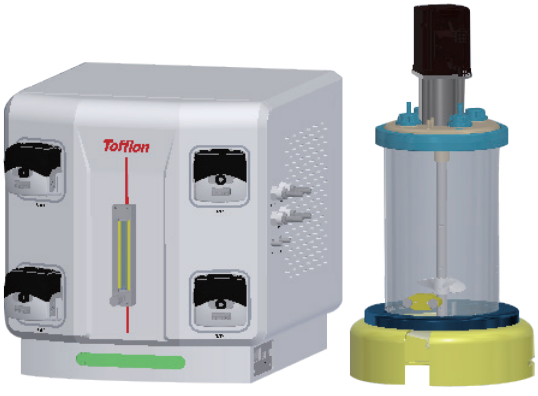
Model	Working volume
CES-10L	0.2-5L
CES-25L	2-10L
CES-50L	5-35L

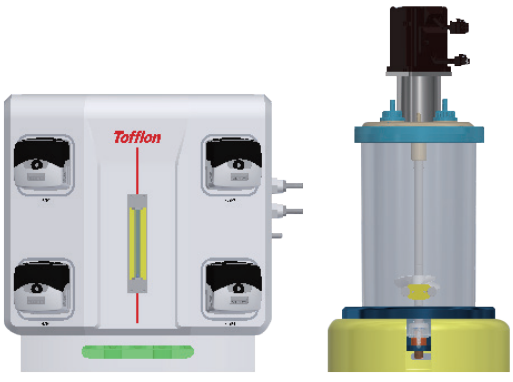




SINGLE-USE CELL CULTURE TANK

- The single-use tank is mainly used for small bioreactors for laboratory process development and exploration. This reactor can be pre-irradiated and sterilized, and it can be put into use only by connecting the corresponding pipeline
- Compared with the conventional glass tanks, it saves the cost of sterilization equipment required for the use of glass tanks, does not require any sterilization, and is simple, fast and efficient
- Meanwhile, it is single-use, there is no risk of cross infection of batches or risk of test or production failure due to unclean sterilization; it is the first choice for the laboratory or pharmaceutical companies to develop the early process.





CELL CULTURE MEDIA

Tofflon Life Sciences Division has a biological reagent business department that carries out the research & development and production of biological reagents (culture media), focuses on the life science research and biotechnology industry, is committed to building a comprehensive supply platform for the research & development and production of domestic biological reagents that integrates the research &development and innovation of key reagents, application transformation, as well as industrial production and sales, provides full line support for the development and production of key reagents for life science research and biotechnology, and furnishes the overall localization solutions for key reagents. In the field of cell and gene therapy, it provides the overall solutions for key reagents such as serum-free culture media for culture, cytokine for induction and stimulation, and cryopreservation solution for cell and gene therapy technology (CAR-T/TCR-T/NK and other immune cell and stem cell therapy technologies).

HEK293 chemical composition limited culture media	T cell serum-free culture media	NK cell serum-free culture media kit
● HEK293 CDM15 ● HEK293 CDM26	● MCM CulLymT -SFM 10	● MCM CulLymNK -KIT01 ● MCM CulLymNK -KIT02
Mesenchymal stem cell serum-free m culture media	**Cell preservation solution**	**Recombinant trypsin digestion solution (1×)**
● MCM CulMsc -SFM 30	● MCP CryoSpr-MD HPC(B) ● MCP CryoSpr-DHQ 05 (B) ● MCP CryoSpr-DHQ 10(A) ● MCP CryoSpr-DHQ 10(B)	● PDE RecTrypsin-LQ01 ● PDE RecTrypsin-DP01



DISPOSABLE CULTURE BAGS

- Disposable cell culture bag
- Disposable freeze-thaw bag
- Disposable stirring bag
- Disposable 2D liquid storage bag
- Disposable 3D liquid storage bag
- Disposable biological reaction bag





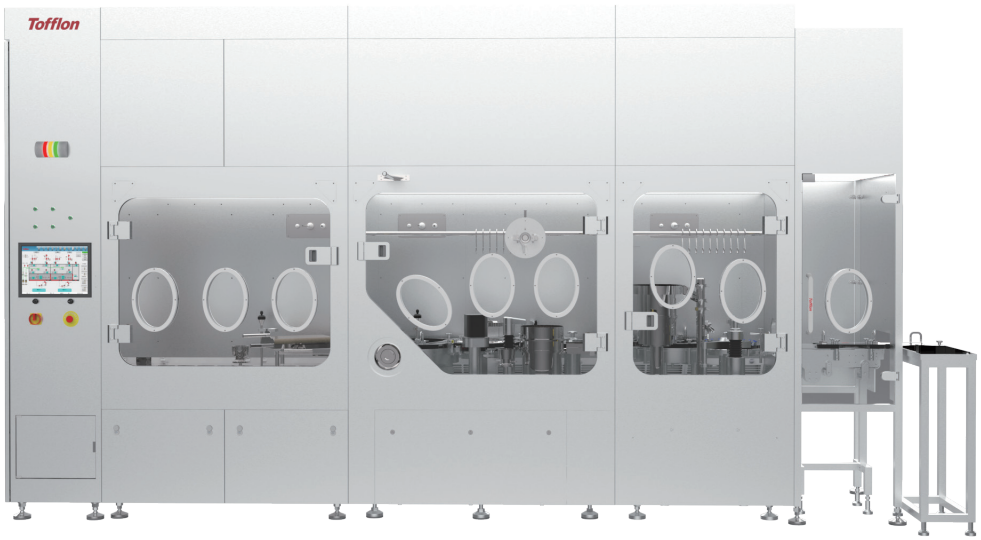






MiniKUFill AUTOMATIC FILLING SYSTEM

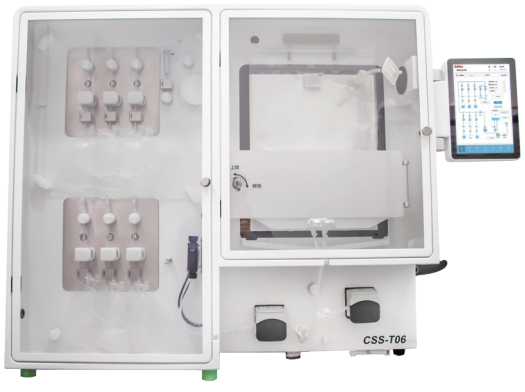
- The automatic filling design for virus carrier for gene therapy/preparations for cell therapy can adapt to the flexible production of multiple packaging products
- According to the use needs of research & development personnel, the degree of automation is relatively high, it is easy to operate and maintain, and the requirements for public works are low
- It can meet the regulatory requirements of GMP and US FDAcGMP; It can meet the requirements of sterile and/or toxic production
- It can meet the requirements of various tests, provide a pilot test platform, and help complete the deepening of process research, process scale-up, process optimization and verification
- Highly modular, realizing ReadyEngineered; Smaller footprint area
- Short delivery cycle, realizing faster product launch; Lower equipment cost





CELL SUBPACKAGE SYSTEM

- Subpackage specifications: Supporting single-use subpackage consumables to meet different cell subpackage needs;
- High subpackaging accuracy: The subpackage volume can be accurate to +/-2%, and the quality of subpackage of cell preparations is highly consistent;
- Automatic control: The transitioning of the subpackage process from manual filling to automation can improve the efficiency, reduce the human error and reduce the cost, avoiding direct contact between personnel and immune cells and greatly reducing the risk of microbial contamination;
- Data integrity: It meets the compliance requirements of electronic signature and authority classification; the data of the subpackage process are recorded and traceable;
- Informatization management: The code scanning gun reads the QR code or barcode to record the relevant data; by printing the QR code label, the product name, batch number, date, operator ID, subpackage weight and other information of each bag of cell fluid can be synchronously recorded.







PROGRAMMABLE COOLER

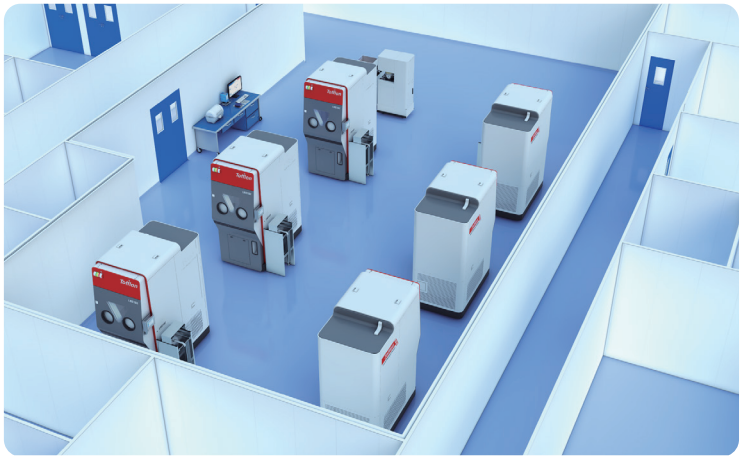
- High repeatability of sample cooling process
- Dual solenoid valves, one for standby and one in operation, to ensure the sample cooling safety
- The communication port can be opened to meet the needs of the users when configuring SCADA and other data acquisition systems
- It can be accessed to the sample information management system (BIS) of Tofflon to realize the complete recording and tracing of sample information
- Compatible with code scanning gun and other quick identification and input peripherals to quickly create the cooling process
- It meets FDA 21CFR Part 11 authority and audit tracking requirements





AC-LINE SYSTEM

- -130 ° C full cold chain guarantee, seamless automatic docking with external low temperature carrier, and the ability to maintain low temperature for a long time under unexpected conditions and troubleshooting
- Automatic sorting, automatic identification, automatic recording of key step data, suitable for scale access or frequent access
- Information system docking, and direct and remote linkage between BIS and equipment, providing grid management of cash order and query
- Data collection; all monitoring data of the equipment can be integrated, displayed and exported in BIS
- Compliance; authority and data traceability meet FDA 21CFR Part 11, and storage and cold chain temperature meet various standards and specifications







SMALL CAPACITY AUTOMATION LN STORAGE SYSTEM

- Large flux and high efficiency: It is most suitable for the application scenarios of cell bank with large storage quantity and small access quantity in a single batch
- There is no repeated freeze-thaw and full cold chain guarantee is provided, and the complete sample temperature history data including key steps can be queried and traced through sample ID
- Applicable to SBS plate rack and standard square plate rack, with low requirements for cryogenic vials
- The software meets the regulatory requirements of FDA 21CFR Part 11 Authority and audit tracking, etc., and it can provide remote maintenance, alarm and information push
- The supporting sample information system BIS can manage the data of manual tanks, refrigerators and automatic storage equipment on the same platform

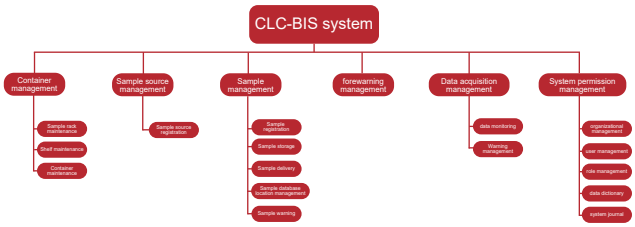




CLC-BIS

For the management in cell therapy, the system includes six modules: Container management, sample source management, early warning management, sample management, data collection, system and authority management. The system covers business processes from "sample source registration, sample information registration, sample storage" and other functions. Other functions, such as equipment operating temperature, sample status and other data information collection and monitoring, authority control, are supplemented to ensure the safety of samples and system operation in a multi-dimensional manner.

Function module schematic:





Value of information system construction in cell therapy

- Drive the standardization of operation process and management refinement of cell sample bank in production, unified management of resources, and standardization of data coding
- Provide strong support for building a high-quality and high-standard cell sample bank, and solve it in a timely manner in case of any abnormal problem discovered during the real-time monitoring
- Platform-based resource data management, building a complete information service chain from data acquisition, storage, processing, mining to open sharing
- It can provide the complete temperature history data and traceability information for each key operation step and temperature of the specific subpackaged cells in the cell bank
- Convenient operation and improved operation efficiency through equipment docking
- Whole-process paperless operation, quick tracking and positioning of antibody cell sample query



RESUSCITATION INSTRUMENT

- It simplifies the sterilization requirements and improves the convenience of use.
- The process parameters can be optimized and solidified.
- The process repeatability and consistency are improved.
- Compliance: It meets FDA 21CFR Part 11
- Informatization: The data can be recorded and traced





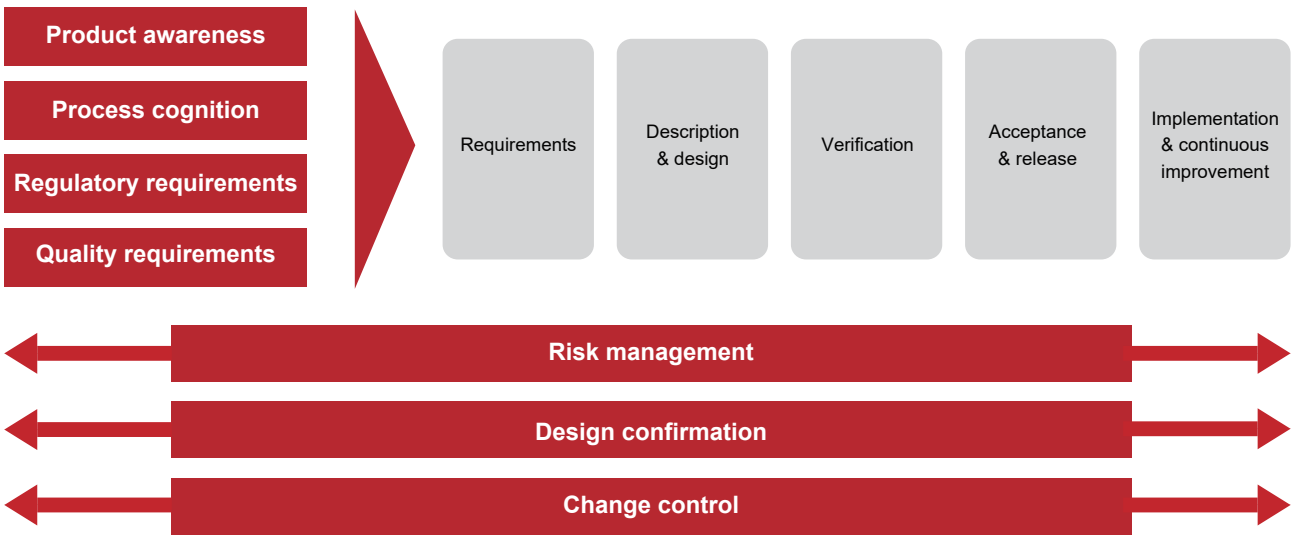
Project Management

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.



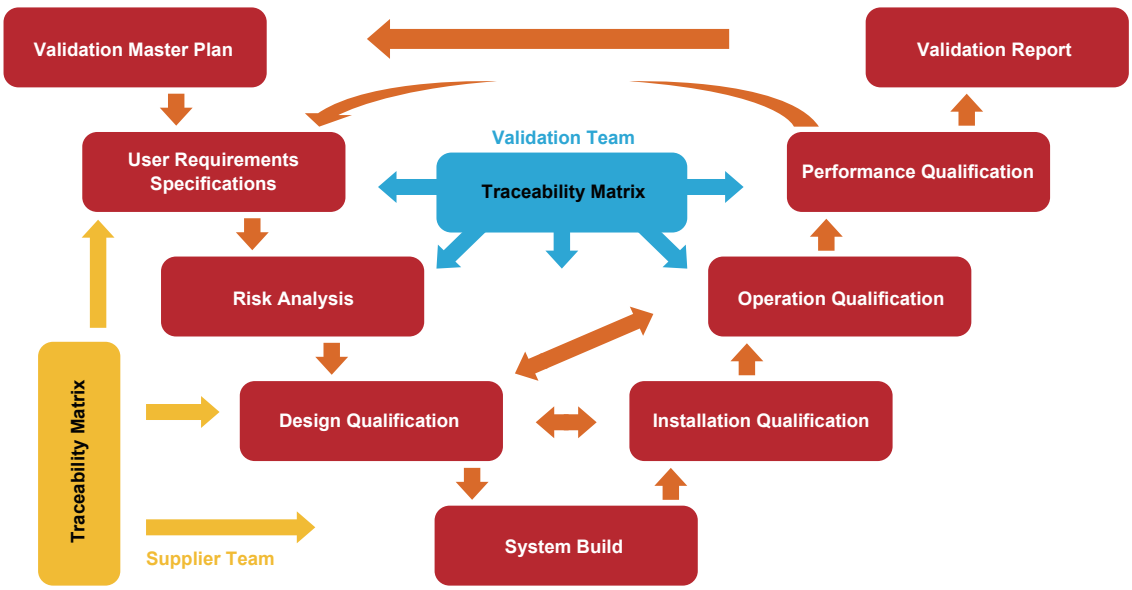
- Reliable quality
- Short cycle
- Focus on cost

Good Engineering Practice - GEP





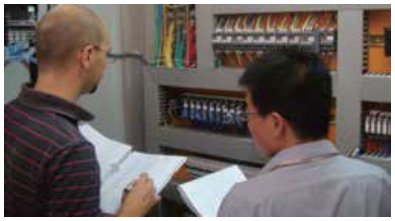
Validation Support



Verification Document System

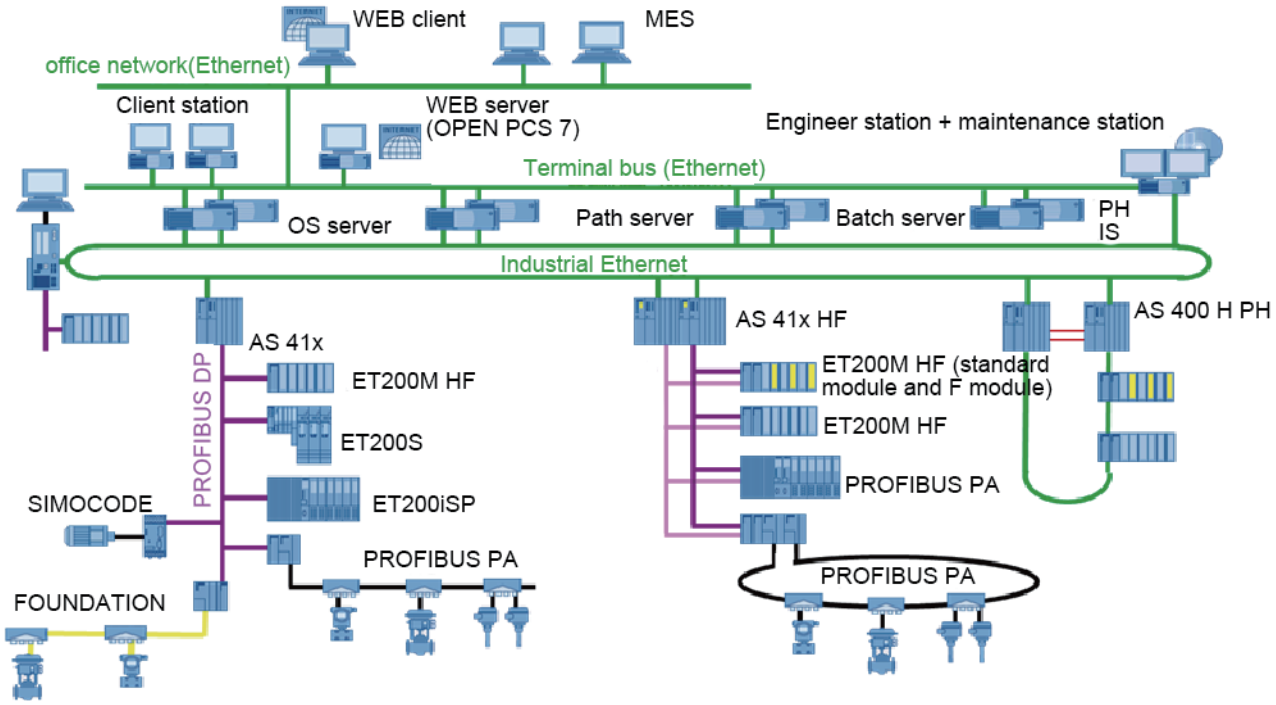
- Complete document system
- Strict quality guarantee process
- Comply with GMP confirmation scheme
- Ensure the stability and reliability of product quality



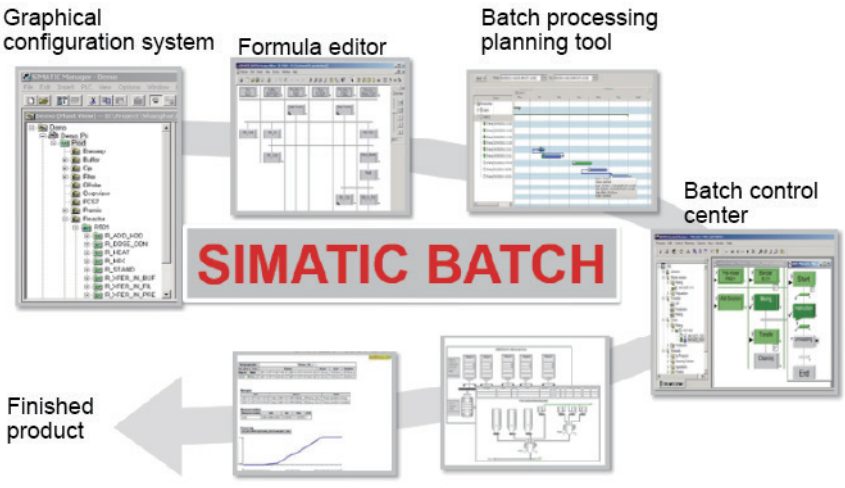


Automatic Control

The automation services from design, commissioning, FAT and SAT testing and computer system GMP verification are provided.



- Integrated system architecture
- Flexible expansion based on the project size
- Generate the project overview based on site structure
- Alarm information is transmitted layer by layer
- Advanced process library APL
- Independent operation panel
- Advanced interlocking function
- Visual sequence control view
- Centralized authority management assignment
- Seamless integration of batch processing system BATCH
- The batch processing system complies with S88 hierarchy



Tofflon

Project Case

CAR-T Real picture of project case





Stem cell project case shot





202302



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