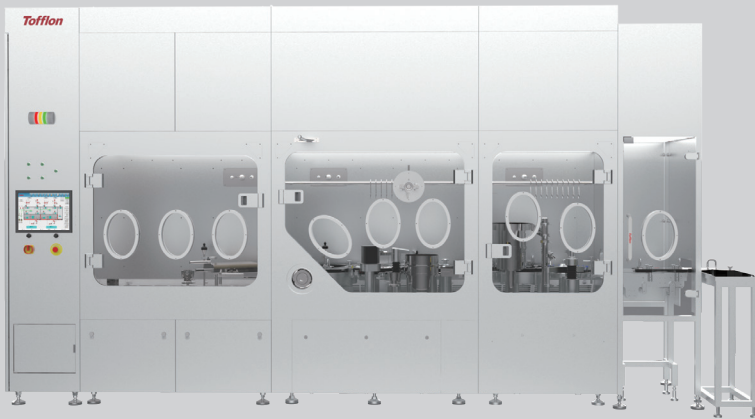
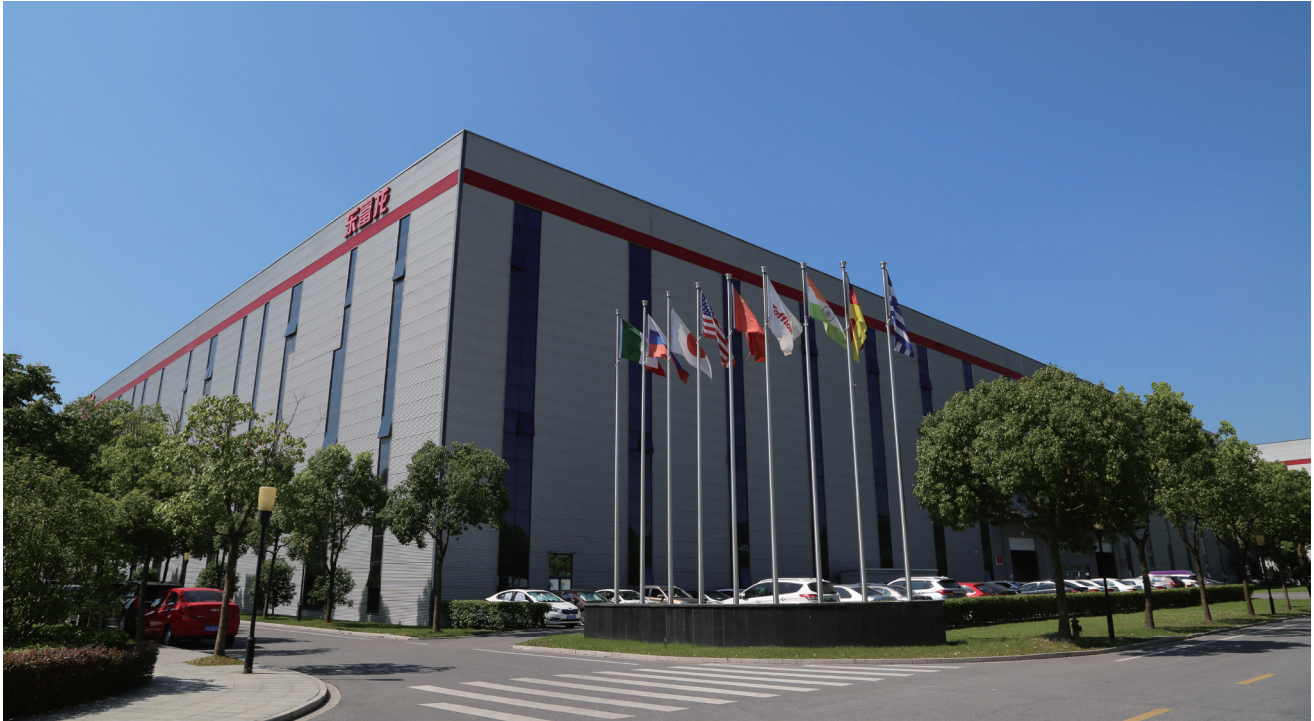


Tofflon



**MiniKUFill Automatic Filling
System**

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.

MiniKUFill AUTOMATIC FILLING SYSTEM

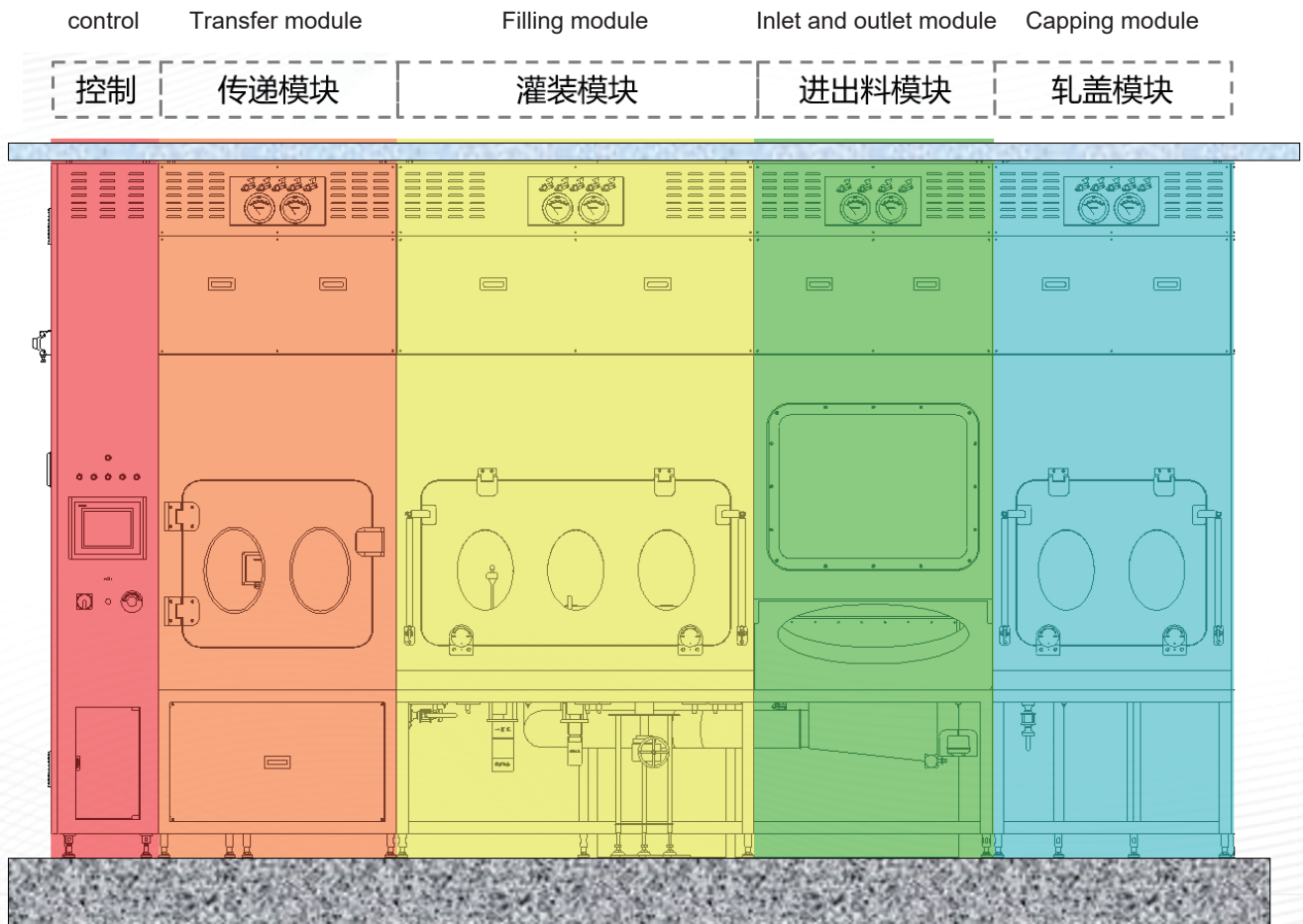


The MiniKUFill automatic filling system is designed for the production and application of gene therapy, viral vectors, antibodies, vaccines and other final preparations. The MiniKUFill system is an innovative manufacturing model designed to provide maximum flexibility and convenience for small-scale drug manufacturing in the laboratory, clinical and small pilot scale. The MiniKUFill system relies on the production environment created by its isolator and can be placed in a Class C or D cleanroom setting. The whole system structure is compact, modular design, simple public engineering requirements, filling machine/capping machine/-freeze drying machine and other equipment supporting isolators can be combined according to different needs.

■ Product application

- ✓ Lentivirus (LV) vector, adeno-associated virus (AAV) preparation production.
- ✓ General-purpose cell preparation.
- ✓ mRNA preparation production.
- ✓ It is suitable for batch multi-variety, multi-specification production of CDMO company and other cell/gene therapy, antibody, vaccine small/pilot or clinical phase I/II production

MiniKUFill CORE SYSTEM



MiniKUFill schematic diagram

System characteristics

- ✓ The automatic filling design of gene therapy viral vector/cell therapy product preparation can meet the flexible production of various packaging materials.
- ✓ According to the use needs of research and development personnel, the degree of automation is relatively high, easy to operate, easy to maintain, simple public engineering requirements.
- ✓ It can meet the regulatory requirements of GMP and FDCP. It can meet aseptic and/or toxic production requirements.
- ✓ It can meet the requirements of various varieties and provide a powerful pilot test platform to help customers deepen process research, process amplification, process optimization and verification.
- ✓ Highly modular and ReadyEngineered; It has a smaller footprint.
- ✓ Short delivery cycle, to achieve faster products to market. Equipment costs are lower.

MiniKUFill MODULAR DESIGN



Temporary storage

The temporary storage can satisfy the VHP sterilization, disassembly, turning and feeding of the outer packaging surface of the rinsed Xillin bottle



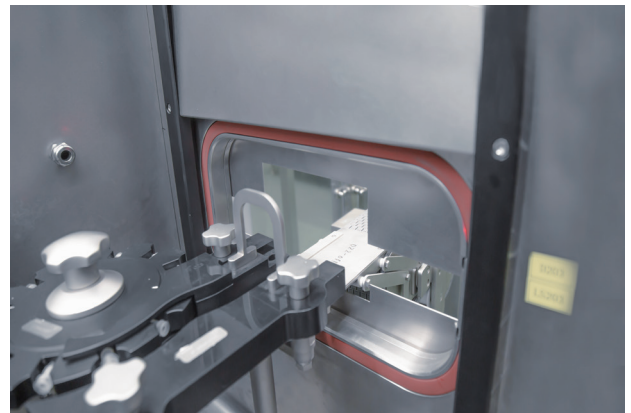
Filling plug

Filling and tamping compartment, automatic filling and tamping operation of preparations



Capping

Cover rolling, automatic cover rolling operation after filling and plugging



Discharge

After the automatic capping is completed, materials are collected and stored through the discharge port

MiniKUFill MODULAR DESIGN

Celine bottle production line

Bulk cillin bottle

RTU Nest Box Cillin Bottle

RTU Tray Cillin Bottle

Modular design

The MiniKUFill system has evolved into a variety of platforms and solutions based on the characteristics of each drug. Among them, Xilin Bottle platform adopts highly standardized and modular design, which can realize the common production of conventional Xilin bottle water needle and lyophilized products. Combo platform, by adopting flexible and customized design, can realize the collinear production of various dosage forms such as xilin bottles, pre-filling needles and card bottles.

Flexible production line

RTU Nest Box Cillin Bottle

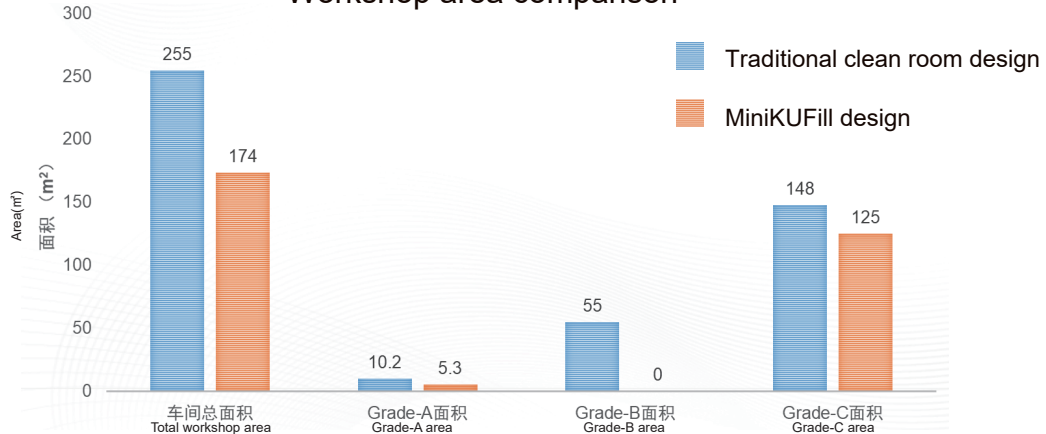
RTU nest box card type bottle

RTU nest box pre-filling needle

Customized design

Product advantage

Workshop area comparison



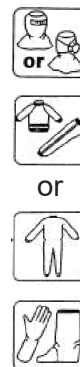
* Reduced plant construction and future operating costs



* Class C workshop usage scenario



More simplified procedures for changing clothes



* Class B workshop usage scenario

MiniKUFill MATCHING CAPACITY DESIGN

Freeze-drying machine specifications	2R/4R Celine bottle quantity	25VPM Filling time	50VPM Filling time	6R/8R Celine bottle quantity	25VPM Filling time	50VPM Filling time
Lyo-0.5	2000	80min	40min	1000	40min	20min
Lyo-1	4000	160min	80min	2000	80min	40min
Lyo-2	8000	320min	160min	4000	160min	80min

Capacity Table 1: lyophilized products

Type of packing material	Bottle shape	Nest version specification	Capacity (per hour)	
			PFS 1000M	PFS 1000M
Prefilling needle	0.5mL	160	1000	2400
	1mL Slender	160	1000	2400
	1mL Slender	100	900	2100
	1mL	100	900	2100
	2.25mL	100	810	1600
	3mL	100	760	1500
	5mL	64	670	1200
	10mL	42	360	840
	20mL	30	220	520
Cassette bottle	3mL	100	600	1200
Celine bottle	2R	120	1000	2200
	4R	120	850	1870
	6R	48	420	930
	8R	48	300	800
	10R	48	300	800
	15R	24	150	400
	20R	24	150	400
	25R	24	100	300
	30R	24	100	300

Capacity Table 2: Water needle products (RTU cladding)

MiniKUFill ASEPTIC TRANSFER PROCESS

■ Delivery of outsourcing materials

RTU packaging material:

There are two forms of RTU packaging materials on the market at present: one is Rtu-ready to Use (nest box) type packaging, and the other is Rtu-ready to Use (tray) type packaging. The two forms of packaging can be unpacked by manual/automatic/semi-automatic unpacking machine.

Bulk cillin bottle

For the need to clean and sterilize the bottle, can be processed through the matching bottle washing machine and tunnel oven.

■ Transfer of liquid medicine

Disposable Technology +RTP/SART Connection:

Disposable technology is widely used for products with high accessory value, such as monoclonal antibody and ADC. Disposable liquid bags are used for aseptic assembly with the peristaltic pump of filling machine through RTP or SART interface after liquid mixing is completed.

Mobile tank +RTP connection:

It is suitable for small batch products, such as small molecule antitumor drugs, etc., after the liquid mixing is completed, it is transferred to the filling machine through the movable aseptic receiving tank, and is assembled aseptically through the aseptic connector +RTP.

Fixed pipe connection:

For large batch products, the liquid is connected to the buffer tank in the isolator through a hard tube after completion.

■ Aseptic transfer of rubber plug and aluminum cap

For small batch:

In the case of a small batch, the RTU packaging material is placed in the isolator before production, the outer surface of the packaging bag is sterilized by VHP, and the bag is removed manually during production.

For large quantities:

RTU (Ready to Use)+RTP

When the product batch is large, the RTP port reserved for rubber plug/aluminum cap transfer is connected with the RTP bucket equipped with rubber plug/aluminum cap for aseptic transfer of rubber plug/aluminum cap.

RTS (Ready to Sterilize)+RTP

In the case of a large batch of products, the RTP port reserved by the equipment is used for the transfer of rubber plug/aluminum cover. After the packaging material is sterilized, the RTP port is connected with the packaging material for the aseptic transfer of rubber plug/aluminum cover.



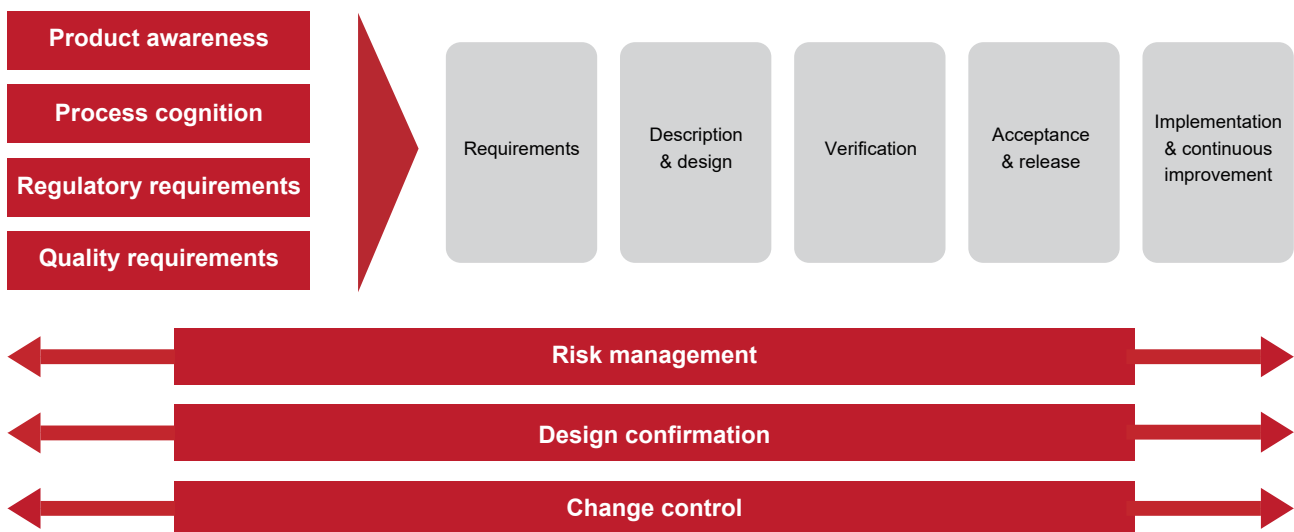
Project Management

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.



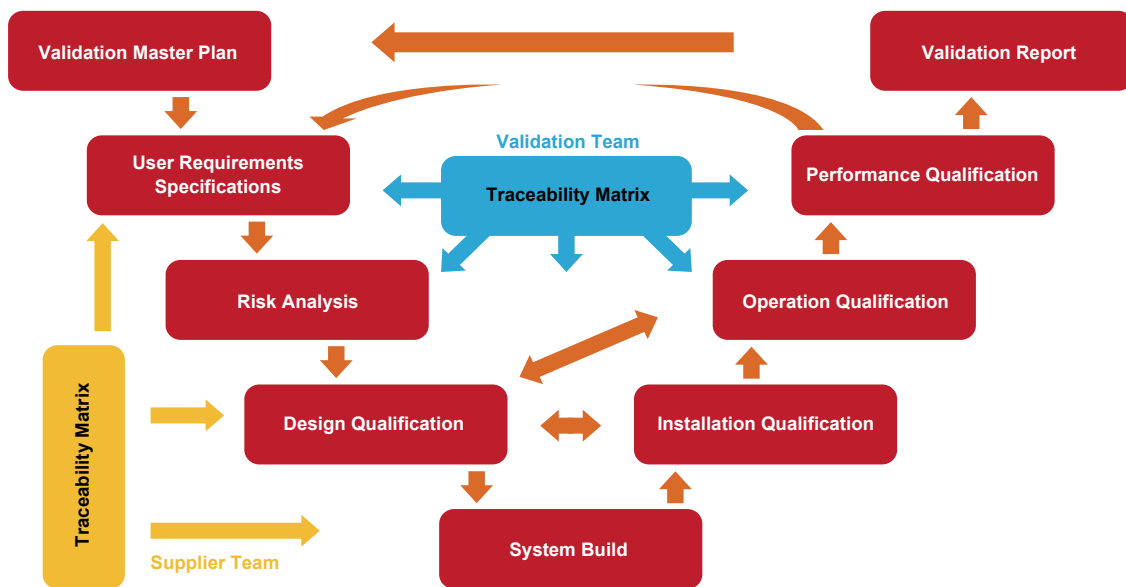
- ✔ Reliable quality
- ✔ Short cycle
- ✔ Focus on cost

Good Engineering Practice - GEP



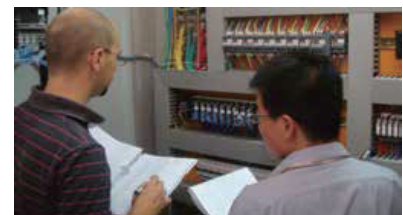


Validation Support



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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