



Isolator Technology



Add : No.1 xinkang Road,Yutan Town,Ningxiang,Changsha,China

P.C : 410600

Tel : (86) 731-87938222 87938255

Fax : (86) 731-879338201

Web: www.truking.cn



Any technical renewal will not inform.
We reserve the final explanation right for the catalogue.
Picture for reference only,subject to our available products.
October 2015 edition



COMPANY INTRODUCTION

TRUKING TECHNOLOGY LIMITED(hereafter referred to as TRUKING) was founded in 2002, located in National Grade Ningxiang economic and technology development zone. It is mainly specialized in research, manufacturing, sale and service of pharmaceutical machinery, such as ampoule compact line, vial compact line, oral liquid bottle compact line, Infusion glass bottle compact line , Non-PVC IV infusion soft bag line, solution preparation system, Freeze Dryer integrated system, auto inspection machine, auto inspection & leak detection machine, leak testing machine, rubber(cap) washing machine etc. TRUKING was officially listing in GEM of Shenzhen Stock Exchange on Jan.21,2014, stock name: TRUKING TECHNOLOGY LIMITED, stock code:300358.

Technology and quality of TRUKING is in leading position in China. Products of TRUKING covered all over the country, it supplied equipment to more than 1000 biological and chemical pharmaceutical enterprises such as Sinopharm, Harbin Pharmaceutical, China National Biotec Group, North China Pharmaceutical Group etc. and is replacing imported products. TRUKING had exported to more than 20 countries and areas such as Japan, India, Russia, Mexico and so on.

During these ten years, TRUKING won dozens of National and Provincial honorary titles such as "National May 1st Labor Certificate", "Hunan Province Excellent private -owned enterprise", etc. and numerous praise and prize from City and County government. Enterprise culture of TRUKING is "To be respected person, to make respected products, to run respected enterprise." , operation principle is "to be unique, or to be the first" , enterprise spirit is "Because of persistence, we are superexcellent!" TRUKING plans to be the first class global pharmaceutical machinery enterprise in 2025.

CONTENT

Application Fields of Isolator Technology	01
Protection Isolation System for High Potent API	02
Micro Negative Pressure Down-Flow Booth	03
Sterile Isolation System	04
Isolation System for Sterile Filling & Lyophilizing Line	05
Isolator for High Potent Solid Dosages Forms Drugs	06
Auxiliary Transferring System/ Testing Fittings	07
Our Services	08
Project Conceptual Design (CD)	09
Examples of Isolators Integrated With Process Equipment	10
Validation Flow Chart	11
Typical Customer	12

Application Fields of Isolator Technology



Development, manufacturing and testing of highly potent or toxic chemical or biological drugs.

- ▶ To protect the operator from hazardous material ,For example: high sensitive products (penicillin), contraceptive products, hormone, anticancer, radiopharmaceuticals, poison microorganism, spore bacterium or causative agent operation— Health
- ▶ To protect the environment from non-controlling spread of highly potent and toxic materials—Safety

Manufacturing and Testing of Sterile Drug Products

- ▶ Protect drug product from cross-contamination or external environmental influence — Sterile Assurance
- ▶ Supporting of Aseptic process filling line
- ▶ Sterile unit operation
- ▶ Sterility test in QC lab

Protection Isolation System for High Potent API

Combine with process, GMP and EHS requirement; systematic integration of highly potent powder processing system; isolators can be integrated with ANFD (filter and drier), miller and sifter, dry vacuum transfer system, filling machine and CIP/SIP process incorporated to satisfy the entire containment operation requirement.

Mainly for weighing, compounding, finished products packaging, sampling operation of toxic or high sensitive API drugs; besides the protection of operators, product and the operational environment can also be protected. We have provided isolator for OEL=0.1ug/m3 drug product and certified by the international third party successfully.

Common features of protection isolators

- ▶ Main body is fabricated of SS 316L and tempered glass
- ▶ Negative cabinet with pressure monitoring system
- ▶ Suitable ergonomics gloves size, amounts, type and location arrangement
- ▶ RTP port
- ▶ Cleaning and drainage port
- ▶ Safety-change air supply and exhaust HEPA filters
- ▶ Illumination level: 500-700Lux

Option

- ▶ Integrated with ANFD (filter and drier), vacuum drying after pressure filtration or suction filtration, sifting and sub-filling, etc of API process.
- ▶ Combined with CIP/SIP process
- ▶ Temperature and RH control
- ▶ Oxygen content control/monitoring
- ▶ Nitrogen displacement



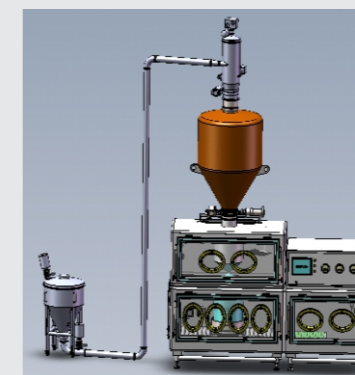
Compounding isolator



Sampling isolator



Weighing & filling isolator

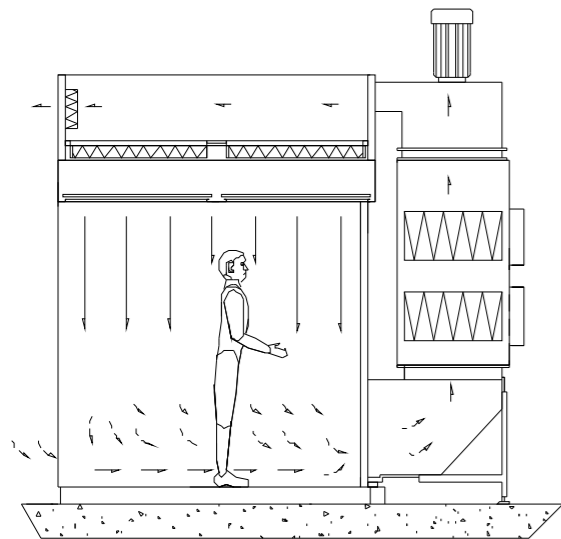


Integration isolation system with filtration, drying, weighing and filling process

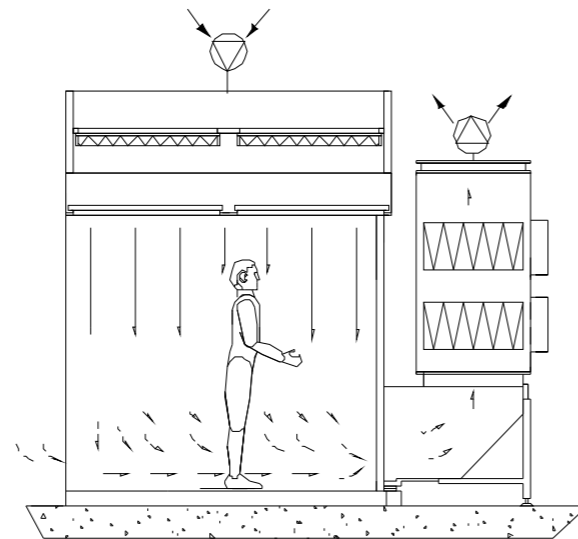
Micro Negative Pressure Down-Flow Booth

Main for low level protection occasion, confirmed as per OEL value and process operation generally.

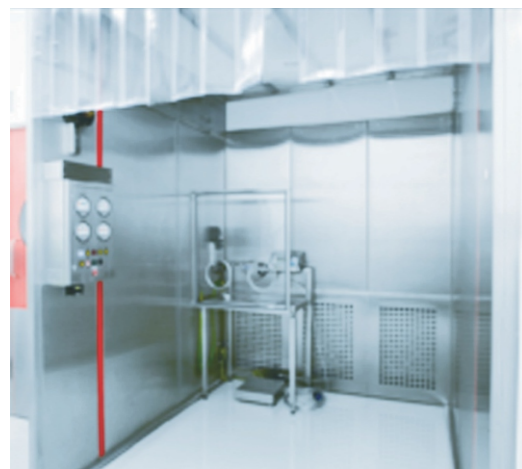
Range of application: compounding, sampling, weighing and transferring of solid products, powder, liquid; or reaction in glass vessels. Matched process equipment can be offered as per user requirement. Bag-in-bag-out technology can be applied in the exhaust system.



Air recirculation down-flow booth



Full air supply and exhaust down-flow booth



Bag-in-bag-out safe change filters



Sterile Isolation System

Mainly for sterility test, weighing, filling and transferring process of sterile or sterile and toxic drug products; to provide safe sterile environment for manufacturing and also protect operators and the environment.

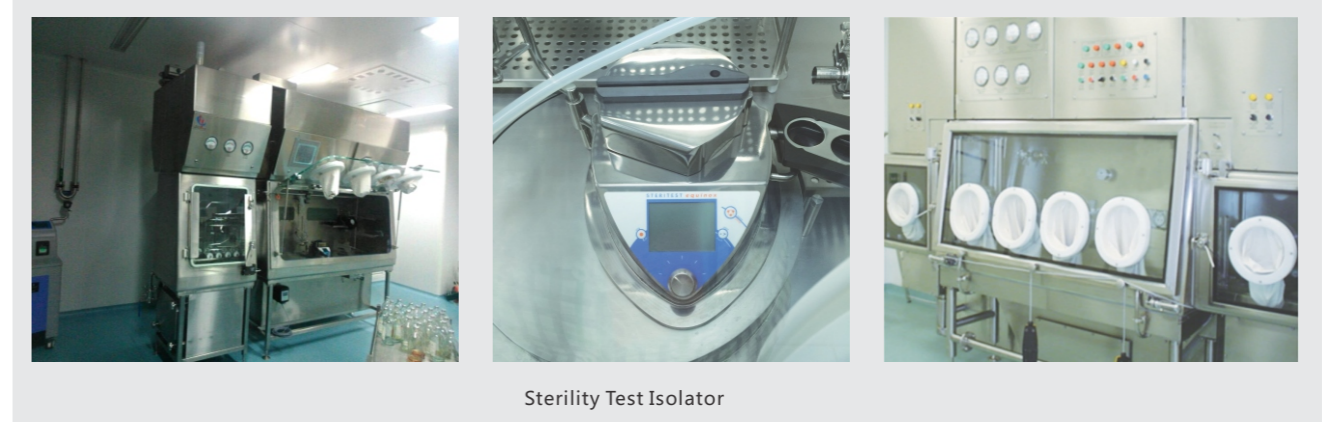
VHP Generator can be matched for sterile isolation system; it may be single equipment or integrated within the technical area of the isolator. (Imported VHP generator also can be supported if required.)

Common features of sterile isolators

- ▶ Main body is fabricated of SS 316L and tempered glass
- ▶ RTP port
- ▶ Suitable ergonomics gloves size, amounts, type and location arrangement
- ▶ Positive /Negative system
- ▶ Class A environment
- ▶ Cleaning and drainage port
- ▶ VHP bio-decontamination in place
- ▶ Air supply and HEPA filtration system
- ▶ Environment monitoring system
- ▶ Illumination level: 500-700Lux

Option

- ▶ Temperature and RH monitoring
- ▶ Air velocity monitoring
- ▶ Non-viable and viable particles monitoring in line
- ▶ Safe-change filters for air exhaust system (Bag-in-bag-out technology)
- ▶ Integrated with sterile operation equipment (e.g. sterile filling machine in the lab) or testing instrument (e.g. Millipore sterility tester).
- ▶ WIP cleaning in place or automatic decontamination system



Sterility Test Isolator



Sterile manufacturing or experiment isolator

VHP Pass box

VHP Generator

Isolation System for Sterile Filling & Lyophilizing Line

Integrated with sterile filling and freezing-drying line for aseptic process drug products; contained environment is maintained to enhance sterile assurance level and also prevent operators and environment from hazardous of high potent products.

System features

- ▶ Customization based on filling process
- ▶ Hard cabinet and made of SS 316L and tempered glass
- ▶ Air supply and HEPA filtration system to form class A unidirectional flow
- ▶ Positive system
- ▶ Appropriate differential pressure gradient.
- ▶ RTP port for material in and out
- ▶ VHP sterilization in line
- ▶ Bio-decontamination, cleaning and drainage system
- ▶ Environment monitoring system
- ▶ Illumination level: 500-700Lux

Option

- ▶ Temperature and RH monitoring
- ▶ Non-viable and viable particles monitoring in line
- ▶ SVP Lamp for light sensitive products
- ▶ Safe-change filters for air exhaust system (Bag-in-bag-out technology)
- ▶ VHP cycle development



Isolator for High Potent Solid Dosages Forms Drugs

Mainly for weighing, dispensing, granulation, mixing, tablet pressing, capsule filling, coating, blister packaging and sampling, etc. process operation of high potent solid dosage forms product. Containment process operation or material transfer can be realized; operator and product itself and process operation can be protected simultaneously.

We can provide isolation system and matched WIP and decontamination technology for drug production and process protection which level reach OEB4 or OEB5.

Isolator Application Example of OSD Drug Products



Sampling/ Weighing/ Dispensing



Jet Mill



Capsule Filling

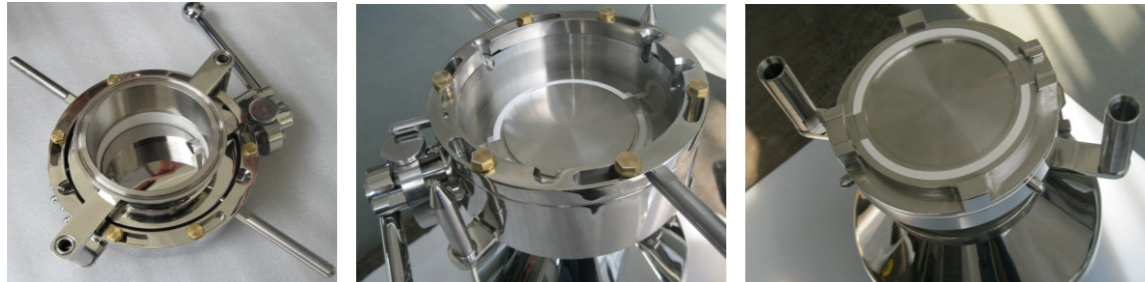


Blister Packaging

Auxiliary Transferring System/ Testing Fittings

Sterile Split Valve (α/β valve)

- ▶ High contained valve for material transferring; CIP & SIP can be realized.

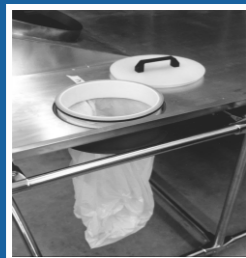


RTP System

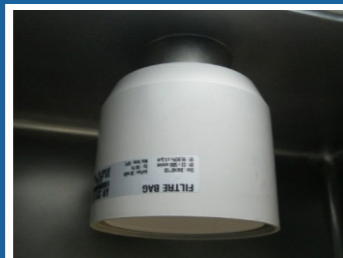
- ▶ The use of the RTP system allows for contained transfer of sterile or rejected materials from within and/or out of the isolator without breaking containment.
- ▶ Various size meet international standards; matched container can be provided as per process operation.



Continuous Bagging System



Safe-Change HEPA Filters (PUSH-PUSH)



Glove Integrity Tester



Our Services

We have professional team working on design, modeling, fabrication, site installation, commissioning and validation of isolation systems. Systematic analysis and design are conducted based on actual process requirement; professional experience is incorporated; special user requirement can be satisfied; operators are trained.

Application of isolation system in different types of high potent drug products:

API (Powder handling)

- ▶ Weighing, sampling, dispensing and compounding
- ▶ Filtration, drying, milling & sifting, filling and sampling

Solid Dosage Forms

- ▶ Weighing, sampling, dispensing and compounding, granulation, mixing;
- ▶ Tablet pressing/ dedusting/ metal-detecting; capsule filling/ polishing/ metal-detecting;
- ▶ Coating, blister packaging.

Sterile finished drug products

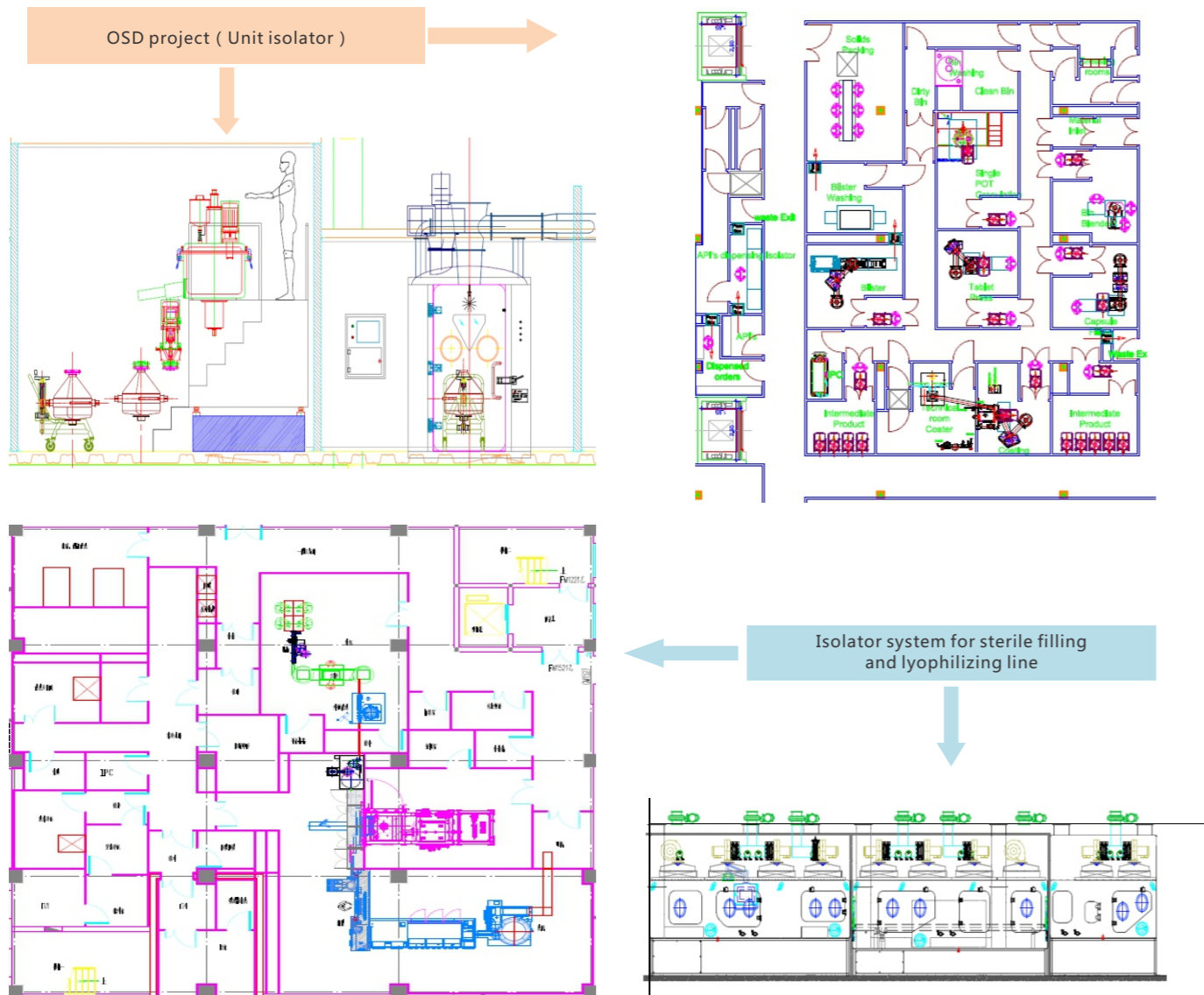
- ▶ Raw material weighing and dispensing, sampling, compounding;
- ▶ Filling & plugging of sterile liquid product; loading and unloading of lyophilization process, capping, external washing.

- ⦿ Systematic conceptual design integrated with customer' s project and process requirement.
- ⦿ Detailed technical design (program, drawings)
- ⦿ Ergonomics engineering test
- ⦿ System manufacturing, fabrication and testing (FAT)
- ⦿ Site installation and commissioning (SAT)
- ⦿ Qualification protocols preparation and site execution(DQ/IQ/OQ)
- ⦿ Site OEL validation (Third party which qualified by international standards)
- ⦿ VHP sterilization cycle development and validation (For sterile isolators)
- ⦿ Personnel training
- ⦿ Long-term technical supporting

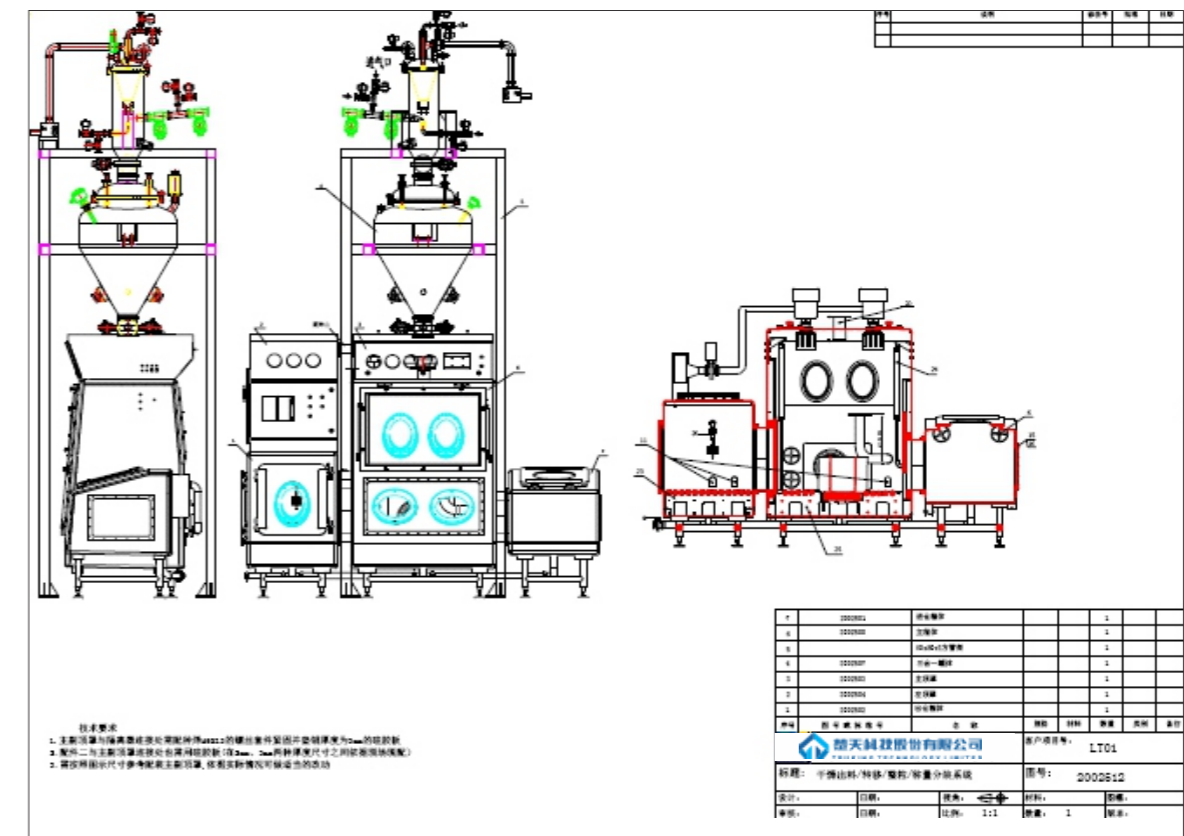
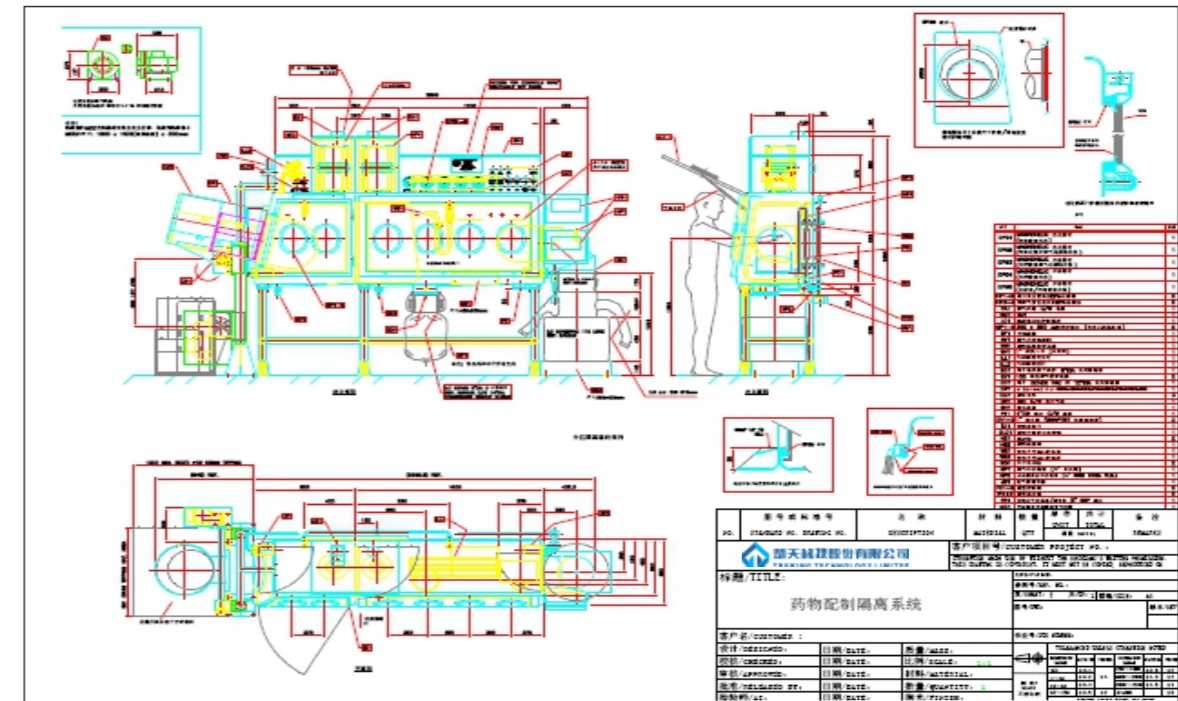
Project Conceptual Design (CD)

- ▶ Professional knowledge based on process requirement, GMP regulations/ guidance and EHS standards.
- ▶ Seize critical factors by risk analysis and communication.
- ▶ Quality by Design (QbD) idea is put in effect.
- ▶ Reasonable balance between project initial budget and long-time running cost.

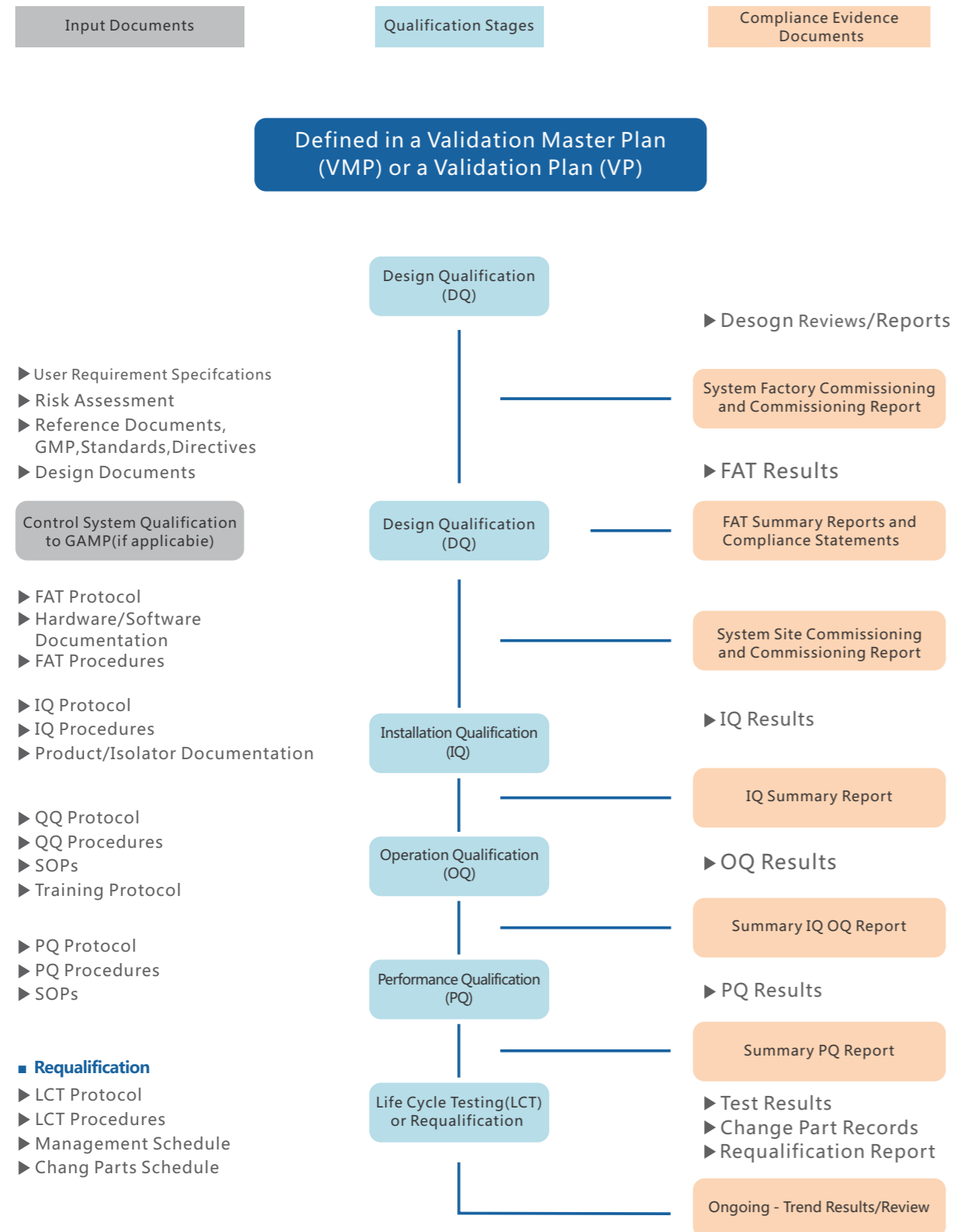
Outcome example of CD



Examples of Isolators Integrated With Process Equipment



Validation Flow Chart for Bespoke Isolators



Typical Customer



Pfizer (China)



Dupont (China)



Merk Millipore (Shanghai)



Huahai Pharmaceutical (Zhejiang)



Hisun Pharmaceutical (Zhejiang)



Livzon Pharmaceutical (Zuhai)



Wuxi Apptec (Shanghai)



Qilu Pharmaceutical (Shandong)