



TRUKING
SCIENCE & TECHNOLOGY
Because of persistence, We are superexcellent

Liquid formulation



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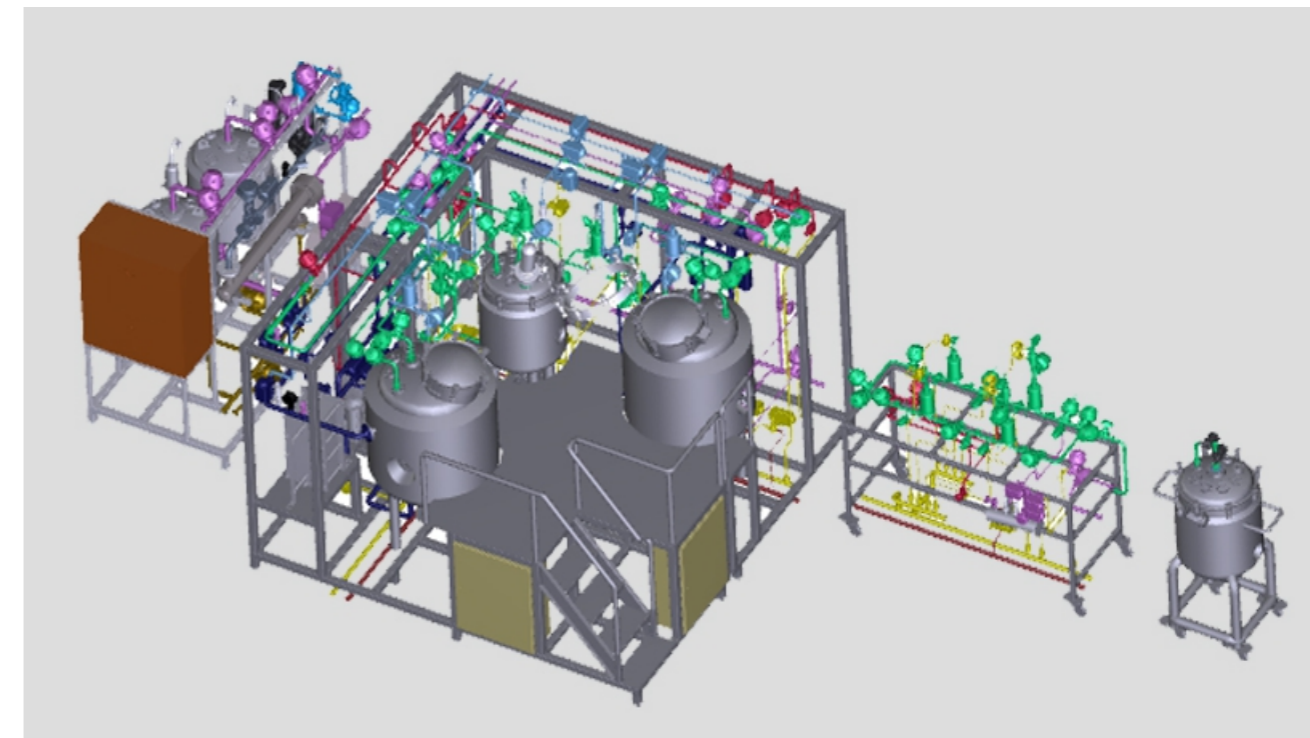


COMPANY INTRODUCTION

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.



Applications

Formulation system is designed according to the client requirements, and implemented by the advanced concept, professional manufacturing, site installation and validation team. The system meets the requirement of Chinese GMP, EUGMP, FDA cGMP, and could be applied in the following fields:

Chemical pharmaceutical

- ▶ Aseptic active pharmaceutical ingredients (API) manufacturing process system
- ▶ Injection formulation system
- ▶ Freeze dried formulation system
- ▶ Large Volume Injection formulation system
- ▶ Oral liquid formulation system
- ▶ Eyedrop formulation system
- ▶ Fat emulsion formulation system

Bio-technology

- ▶ Upstream medium formulation and centrifuge homogeneity auxiliary process compact line
- ▶ Downstream separation & purification auxiliary process integrated system
- ▶ Human blood product process integrated system
- ▶ Vaccine product manufacturing process

Injection formulation system



Fat emulsion

- ▶ Provide a complete set of liquid injection production systems of fat emulsion, and targeted liposomes, micro capsule microspheres.
- ▶ According to the product characteristics and process need to choose a suitable emulsifying process route, provide advanced suitable emulsification equipment for specific application requirements.



Process solution

manufacture process	Solution
Water supply / metering	Inlet flowmeter in-suit weighing
Feed	Adding the raw-material in aseptic situation manually Suction through feed inlet With aseptic sampling hole
Mix	Variable frequency agitator Annular rotation sealing & aseptic liquid sealing system Magnetic agitator at the bottom of tank Homogenizer
Temperature control	Open or close circuit with proportional control by double jacket Heating & cooling system
Sample	Sterilizable sample system Cleanable and sterilizable centrifugal pump, rotation pump, drain
Transfer	Aseptic compress air or nitrogen
Product filtration	Pre-filtration & aseptic filtration On-line integrity detection
Storage	Magnetic agitator and temperature control system Nitrogen protection Aseptic sampling

Feature

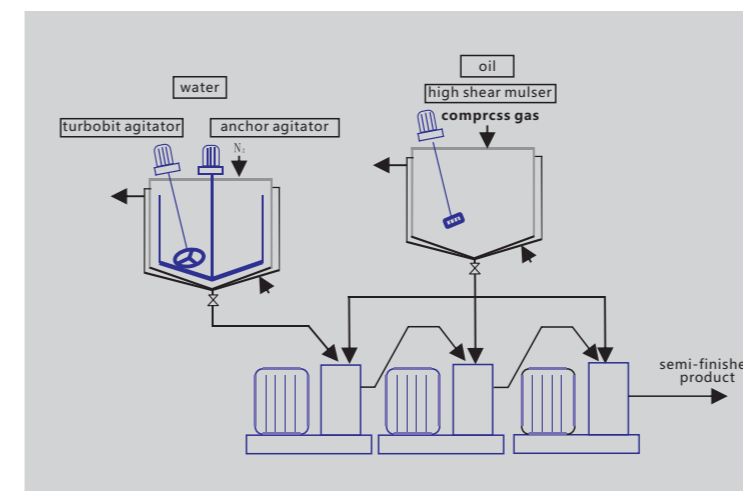
- ▶ Automatic formulation and transfer
 - ▶ Automatic clean in the place system (automatic conductivity detection)
 - ▶ Automatic sterilization in the place system (automatic temperature detection)
 - ▶ Automatic on-line filter element integrity test system (automatic input from the integrity detector)
 - ▶ Automatic on-line water supply & weight-transmitter system (automatic weight-transmitter)
 - ▶ Automatic air tightness detection before SIP
 - ▶ Automatic pressure maintenance after SIP
 - ▶ Parameter invocation according to the type of product.
- The system is executed automatically, which can record the runtime & parameter, and to print & alarm automatically.

Common emulsification process

- ▶ Vertical super speed emulsor and high pressure homogenizer
 - ⊙ This combine mode improves the efficiency and reduces the width of particle size distribution, which made the system could work continuously, and avoided the operation mode of manifold cycles when using the super-speed emulsor.
- ▶ Continuous emulsification
 - ⊙ The latest technology , high speed emulsors combination ,a single emulsification without circle.

Feature

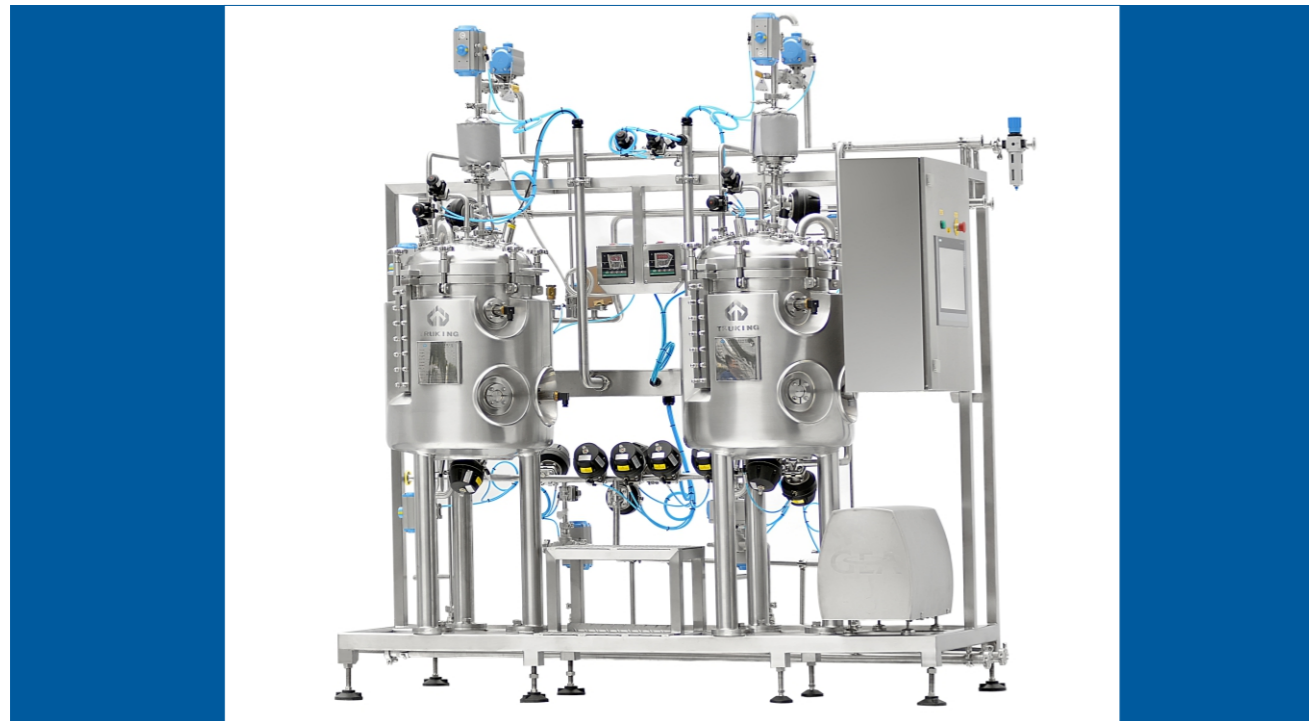
- ▶ Meeting Chinese GMP, EU GMP and FDA cGMP regulation
- ▶ Meeting process requirement aseptic process tank, tube and fluid components.
- ▶ Advanced and flexible modularization process unit
- ▶ All core process components and equipments are provided by well-known suppliers.



Continuous emulsification diagram

We integrate the advanced continuous emulsification technology, to reduce equipment investment, improve production efficiency. The system can be operated continuously in 24h with high stable product quality. Moreover, the system has the function of CIP and SIP. It is the best choice for a big batch production, due to the advantages, such as high equipment utilization rate, quick transfer, reducing the investment on mix tank and plant space.

Bio-products



Human blood product

Feature

- ▶ Prospective design concept
- ▶ First class selection and manufacture
- ▶ Rich project experience
- ▶ High integrated automatic system with manual intervention ability



Upstream integrated system

- ▶ Culture medium preparation unit.
- ▶ Culture medium filtration unit
- ▶ Culture medium storage unit
- ▶ Harvest unit
- ▶ CIP system unit
- ▶ Centrifugation and homogenization unit

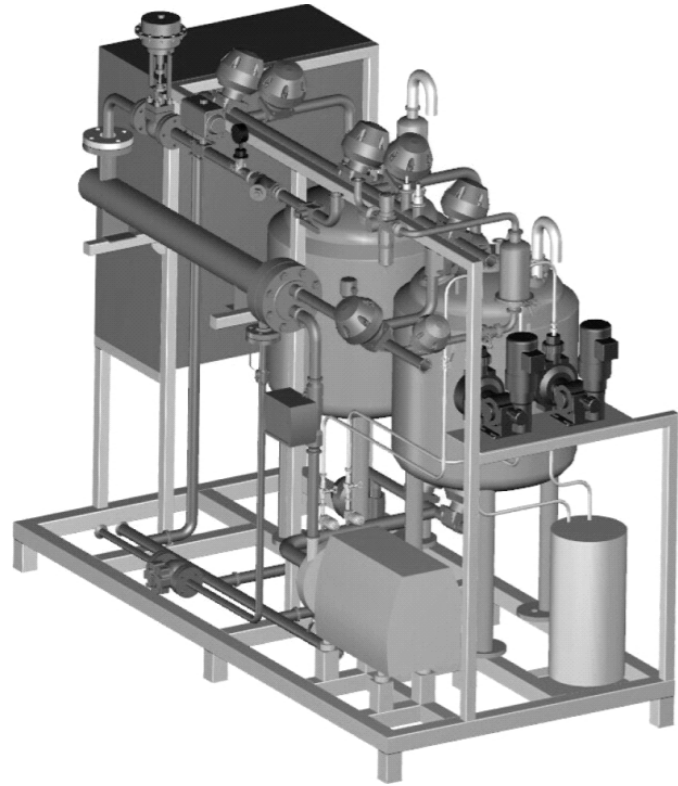
Downstream separation and purification integrated system

- ▶ Buffer preparation unit
- ▶ Buffer filtration unit
- ▶ Buffer storage unit
- ▶ Product storage unit
- ▶ Bio-waste inactivation unit
- ▶ UF& chromatography unit
- ▶ CIP circulation piping system in downstream process module

Overall solution for human blood product including BD, DD and optimization, equipment selection, installation, commission and validation

- ▶ Plasma thawing & fractionation
- ▶ IgG, albumin, special immune globulin, TB, PCC, FVIII, FNG ect.
- ▶ Unit design and integrity: protein centrifuge, plate frame filtration, UF, chromatography, pasteurization automatic temperature control system, hot water bath temperature control system.
- ▶ Compact line of cleaning, sterilizing, drying, filling and sealing & freeze dryers.
- ▶ Automatically controlled CIP and SIP system.

CIP station



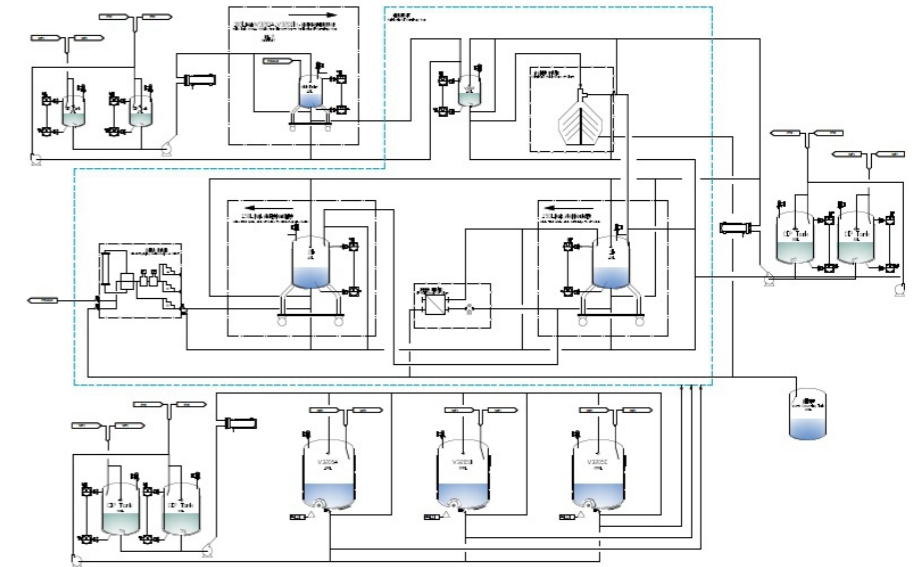
CIP station is a set of stable equipment, which can achieve the online cleaning, adopting the H&M interface and image display, the station could be able to switch the process parameters and regulate cleaning time, pH & temperature etc. automatically. The traceable operation records can facilitate your validation.

Various combinations: stationary type or movable type, single tank system or double tanks system; with or without heating.
The CIP station enables automatic different concentrated solution preparation and self detection. It conforms to the validation requirements of Chinese GMP, FDA cGMP and EMA.

Automation

The advanced automatic control system can optimize the effectiveness of the production process, ensure the stability of product quality, reduce the manufacture cost and improve the flexibility of production. Our experienced local electrical automatic department can provide high cost performance automatic control system to fit your needs.

- ▶ Electric design
- ▶ Control cabinet manufacture
- ▶ FDS development
- ▶ Software programming
- ▶ System testing
- ▶ User training
- ▶ System commissioning



Automation

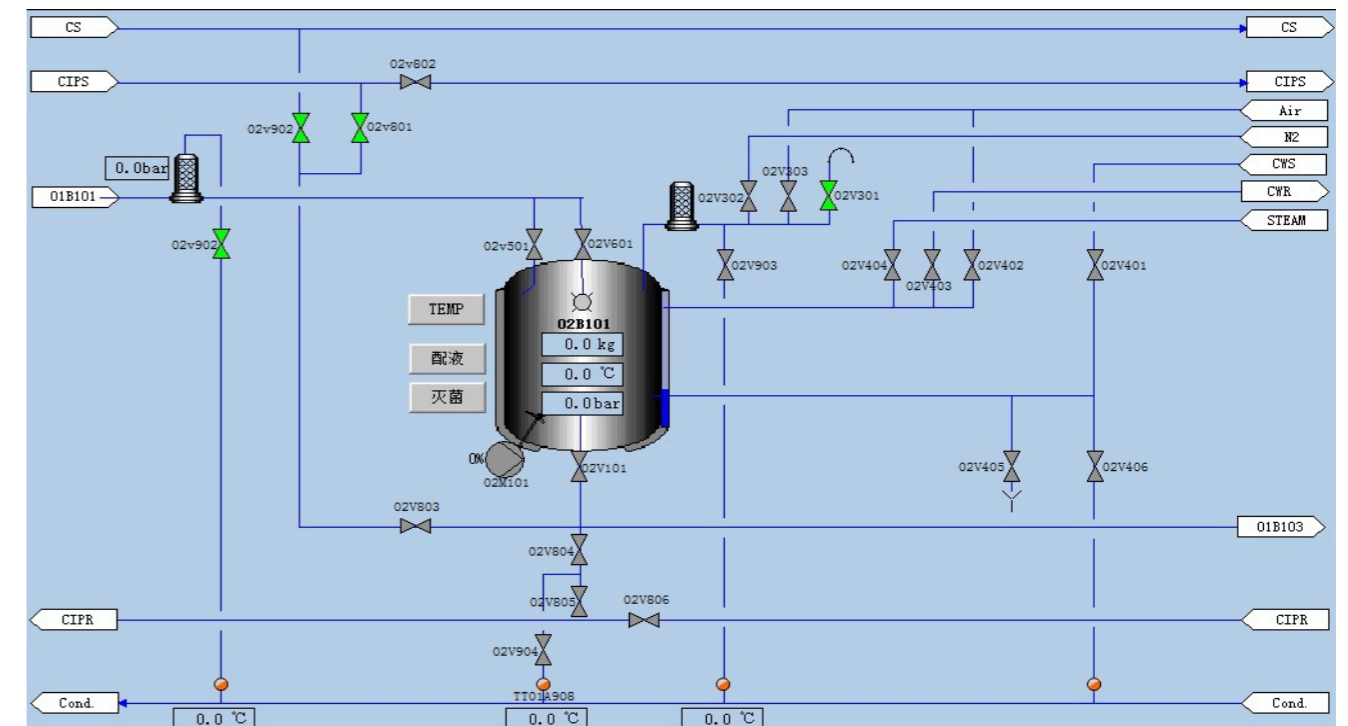
- ▶ Automatically controllable, Parameter detection
- ▶ Circulation, improving reliability
- ▶ Human errors elimination

Operation cost reduction

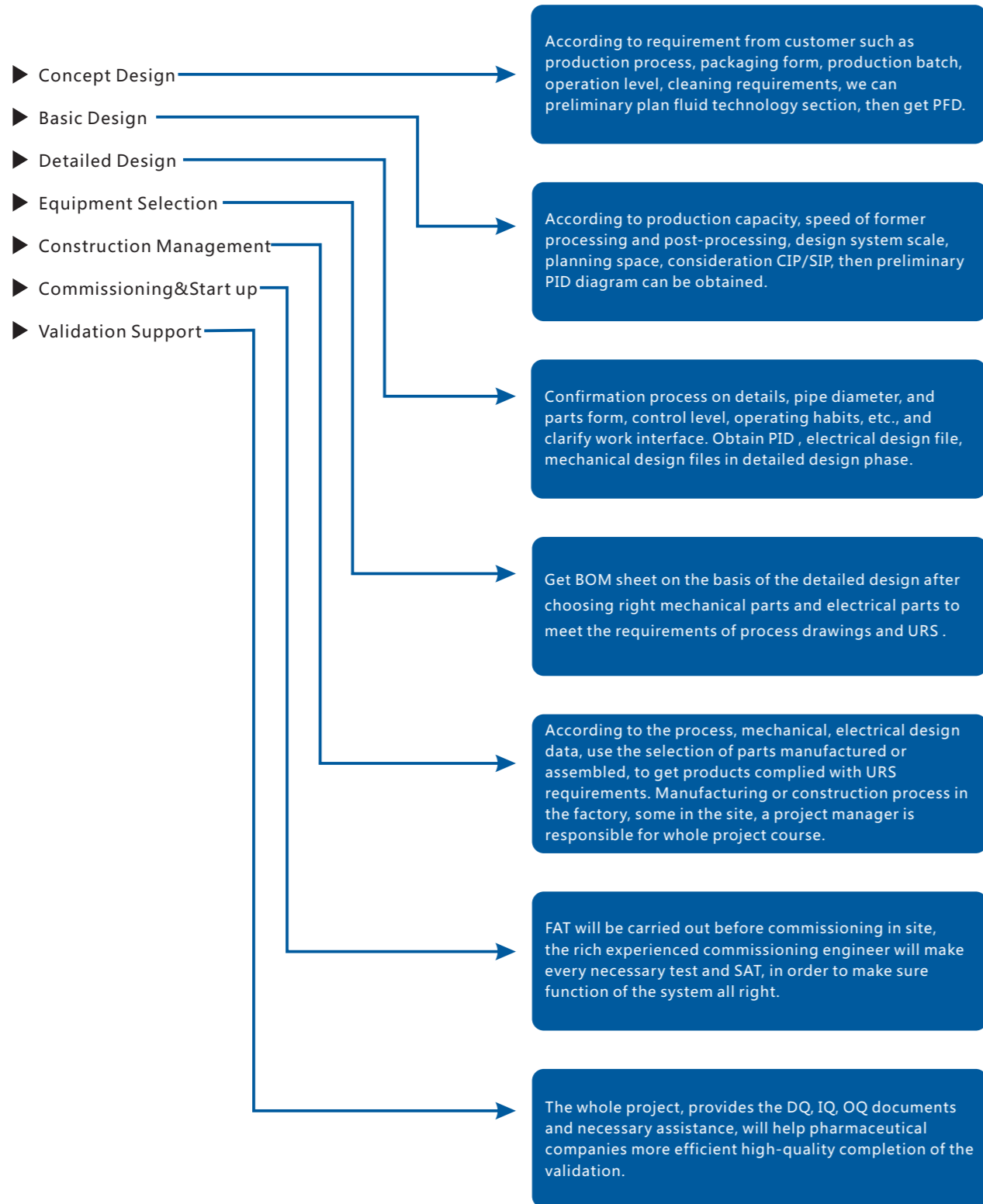
- ▶ Reducing Labor cost
- ▶ Reducing Cleaning time, improving efficiency
- ▶ Reducing the consumption of water/ solvent/ detergent

Improve safety

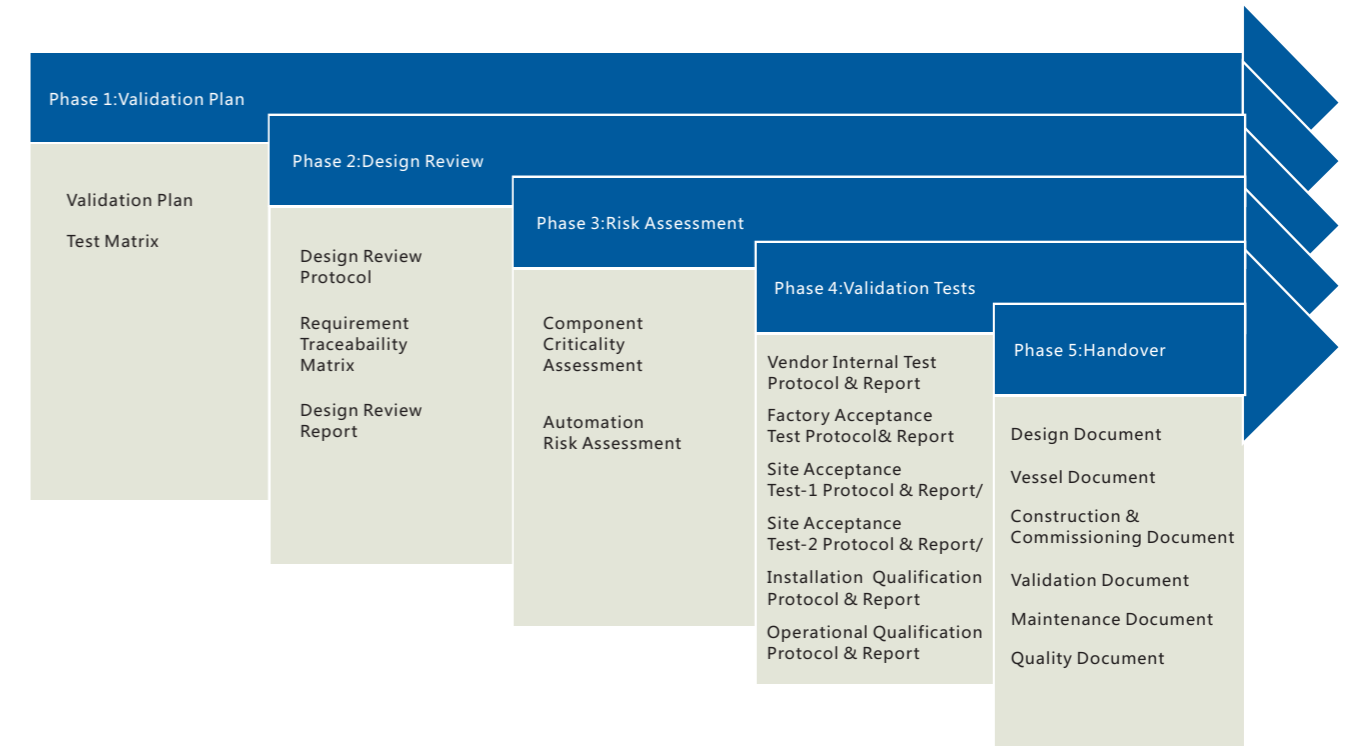
- ▶ Reducing the direct exposure risk of the product
- ▶ Equipment cleaning without splitting equipment or entering equipment.
- ▶ Voiding the risky operation, such as high pressure water torch operation



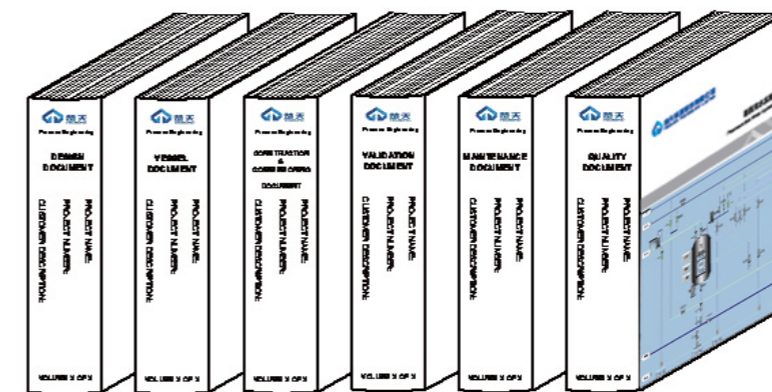
Project Services



Validation phase



Documents



- ▶ Design documents
- ▶ Tank&Vessel documents
- ▶ Construction&commissioning documents
- ▶ Validation documents
- ▶ Quality documents
- ▶ Operation&maintainance manual