Totally Integrated Solutions
for Pharmaceutical Industry
As a global leading solution provider for the pharmaceutical industry, AUSTAR provides pharmaceutical enterprises with comprehensive products and services.

Headquartered in Beijing, AUSTAR has opened factories, offices and branch companies in Asia and Europe. AUSTAR has globally constituted a gigantic development and research, marketing and service network. AUSTAR products and solutions have been applied to more than 40 countries and regions in the world. Besides our traditional role as a manufacturer and supplier of technological equipment, AUSTAR supports customer from inception to completion of project.

AUSTAR is committed to promoting pharmaceutical industry advancement internationally, and becoming your partner in improving human health.
40 COUNTRIES AND REGIONS
24 YEARS OF EXPERIENCE

AUSTAR IN THE WORLD

AUSTAR excellence union
CONTENTS

Design
- Conceptual Design (CD)
- Basic Design (BD)
- Detail Design (DD)

Engineering
- Clean Room System
- Liquid Process System
- Pharmaceutical Automation Engineering

Production Line
- Vial Liquid Filling Line
- Wet Granulation Line for Oral Solid Dosage
- Soft Bag Production Line

Package Line
- Blister Packing Line
- Bottle Counting Line

GMP Compliance Services
- Validation Consultancy
- Pharmaceutical Quality System Consultancy

Drug Technology Transfer

Consumables
- Personal Protection
- Cleaning
- Sterile Packaging
Drug Technology Transfer

Customized drug technology transfer services

Facility URS
Project definition, Basis of Design, Concept Study

Conceptual Design (CD)
Design basis and conceptual design

Detailed Design (DD)
Planning for construction, preparation of tender documents

Basic Design (BD)
Layout development, utility definition, detailed requirements for DD

AUSTAR ADVANTAGES

THE DESIGN PROCESS

Flexibility and adaptability to requirements

Efficient
- Request for Quotation (RFQ) response within 2 weeks on standard equipment of service
- Total design (CD/BD/DD) 3 months for complex process
- Project completion within budget, quality and predetermined schedule

Standard
- Process core is standard
- Process support functions are adaptable for local conditions
- Equipment manufactured to standard

Professional
- GMP compliance
- Quality by design
- Risk-based approach
- Highly educated, experienced and trained engineers and consultants

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Design

- Large Volume Parenteral
- Oral Solid Dosage
- Small Volume Injectables
- APIs
- Others
- Biological Products

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Design
AUSTAR provides complete project management services including designs, manufacturing and installation.

Our clean room system combines European technology and customized solutions with guaranteed quality and reliable services. AUSTAR clean room system is flexible and easy to install that accepts changes to design in the field and can be reconfigured for use in manufacturing area.

Our clean room system meets the requirement of US FDA cGMP, EU GMP, PIC/S and WHO.
AUSTAR provides pharmaceutical liquid process technology, international level of design, project management services, manufacturing, installation and validation, as well as comprehensive integrated service.

AUSTAR will take experience-gained advantages to provide worldwide pharmaceutical enterprises with world-class pharmaceutical water system solutions. AUSTAR water system meets US FDA cGMP, EU GMP, WHO and other national requirements.
AUSTAR automation engineering provides integrated process automation lifecycle solutions for pharmaceutical companies. With pharmaceutical industry know-how and excellent abilities of automation application, AUSTAR can provide customized solutions to meet client's requirements. AUSTAR also provides information system such as BMS, EMS, SCADA, MES, warehouse management system and LIMS.

Advantages
- 20+ years experience (Focusing on pharmaceutical industry)
- Highly experienced and qualified engineering team (100+ professional technical experts)
- World-class system platform (SIEMENS, Rockwell, Emerson)
- Compliance with FDA, WHO, EMA regulations (System validated to current version of GAMP)
- Reliable after-sale service (20+ worldwide after-sales service engineers)

One Stop Automation Solution Integrator

GAMP5 Compliant Design and Construction Procedures

More than 100 worldwide clients
Vial liquid filling line is composed of rotary or linear washing machine, sterilizing & depyrogenation tunnel, filling & stoppering machine, and capping machine.

This production line is integrated in accordance with process requirements. The vial liquid filling line capacities extend to filling volumes of 2ml–500ml.
AUSTAR offers complete solutions for solid processing plant. With the process of granulation, drying, tableting, capsule filling, coating, handling, weight checking, inspection and washing, AUSTAR process engineers can provide complete production line to customers’ requirements.
Pharmaceutical Non-PVC Soft Bag Production Line

A high level of flexibility and reliability is reflected in soft bag production line. Different types of multi-coextruded polypropylene (PP) films and different types of port can be processed. This line can produce up to 5000 bags per hour. The standard bag sizes vary between 50 ml and 3000 ml.

Highlight
- Capacity: 1000 bags/hr – 5000 bags/hr
- Package material: PP bags
- Bag size: 50ml–3,000ml
- Bag tube system: versatile
- Complete production system
- Customized Design
Package Line

Blister Packing Machine

Application
Blister packing machine can be widely used for tablets, capsules, pills, vials and ampoules with PVC feeding, heating, forming, sealing batch numbering and automatically cutting functions.

Features
- Wide range for solid dosage products
- Processing of all film type: PVC, PVCD, Aluminum
- Camera Inspection
- Continuous flow process: Forming, feeding, identifying mark, bar coding, slipping/cutting

Cartoner Machine

Application
Cartoner machine is suitable for blisters, ampoules blisters, vials, bottles, syringes, cartridges, and similar packaging.

Features
- Multi-purpose use
- Continuous processing
- Cartoning packaging in process quality control

Bundling Machine

Application
All kinds of Pharmaceutical cartons, or similar boxes.

Features
- Film feed protection
- Safeguard door protection
- Friendly design & Space saving
- Servo motor segment accuracy guarantee

Semi-automatic Case Packing Machine

Application
Applicable to packs and various kinds of square boxes.

Features
- Widely used in pharmaceuticals & food industry
- Auto & semi-automatic option
- Sensors control in key segment
- Cylinder as execution component
BOTTLE COUNTING LINE

Complete Tablet / Capsule Counting Line Solution

- Maximum speed up to 200bpm
- CCD scanning sensor with high accurate counting
- Modularized design sensor for different types of solid
- Product detecting sensors to avoid incorrect counting
- Dipping nozzles to increase speed and prevent jams
- 12 channel can work separately when small count required
- Pre-count function to automatically count after buffer stop
AUSTAR provides integrated solutions for validation compliance covering the whole lifecycle of a pharmaceutical product and provides complete commissioning and validation services for the successful completion of the project to satisfy the customer’s requirements for such services as consultancy, commissioning, qualification, validation, re-qualification and re-validation at different stages, and help the project to meet the requirements of US FDA, EMA certification or WHO pre-qualification.

**CONTENT OF INTEGRATED SOLUTION FOR RISK BASED VALIDATION COMPLIANCE**

- **Premises, systems, equipment**
  - Utilities
  - HVAC system
  - Clean gases
  - PW and WFI
  - Pure steam

- **Equipment**
  - API equipment
  - Sterile product equipment
  - MSD equipment
  - Biological product equipment
  - Blood product equipment
  - TCM extraction equipment

- **Computerized Systems**
  - EMS
  - BMS
  - WMS
  - DCS
  - SCADA

- **QC Lab.**
  - Analytical instrument
  - Microbial analytical method
  - Physical and chemical analytical method

- **Validation Master Plan (VMP)**
- **Quality Project Plan (QPP)**
- **Risk Management Plan (QRMP)**
AUSTAR is devoted to providing pharmaceutical enterprises with integrated quality system solutions throughout the whole lifecycle of a pharmaceutical product, including quality system establishment, maintenance and training in compliance with EU GMP, WHO GMP, FDA cGMP and ICH Q10 requirements.

CONTENT OF INTEGRATED SOLUTION FOR Pharmaceutical Quality System

NEW PQS STRATEGIES (ICH Q8/Q9/Q10)

01 Process Based QM
02 Regulatory Compliance Based On 6 Major Systems
03 Science Based Approaches
04 Risk Based Approaches
AUSTAR provides high quality products such as cleanroom cleaning tools, personal protection, sterile packaging and other supplies to meet the stringent requirements of the pharmaceutical and life science industries. We offer products suitable for ISO class 5 (Federal class 100) of cleanrooms. The quality-approved products we offer in the market are widely appreciated by our global clients for their immense quality standards such as durability, longer functional life, reliability and their higher performance.

**Consumables**

*Area 1  The Cleanroom*

Production area: validated and contamination controlled (air, surfaces and personnel) Only cleanroom products allowed.

*Area 2  The Personnel Entrance/Gowning room*

Gowning area reduces the risk of potential source of contamination entering the clean rooms.

*Area 3  The Controlled Environment*

Controlled but not classified (CNC) areas include non GMP and packaging areas. These areas may have impact on clean rooms, suitable cleaning regime can prevent up to 80% of contaminants entering the clean room.

**Personal Protection**
- Clean room Garments
- Clean room Shoes & Boots
- Clean room Gloves
- Clean room Goggles
- Clean room Face Masks

**Cleaning**
- Polyester Wiper
- Non-woven Wiper
- Microfiber Wiper
- Cleaning Mop
- Cleaning System

**Sterile Packaging**
- Ultraclean PE Bags
- Cleansteam Bags/Coils
- Ultraclean Sterile LDPE Freeze-dry Film
- Bioprocess Vessels (BPV)
- Powder Transfer Vessels (PTV)