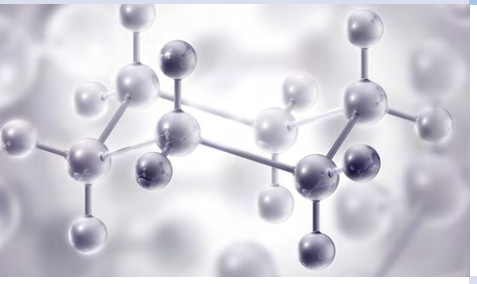
Totally Integrated Solutions

for Pharmaceutical Industry



AUSTAR

ABOUT AUSTAR

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.

AUSTAR HEADQUARTERS

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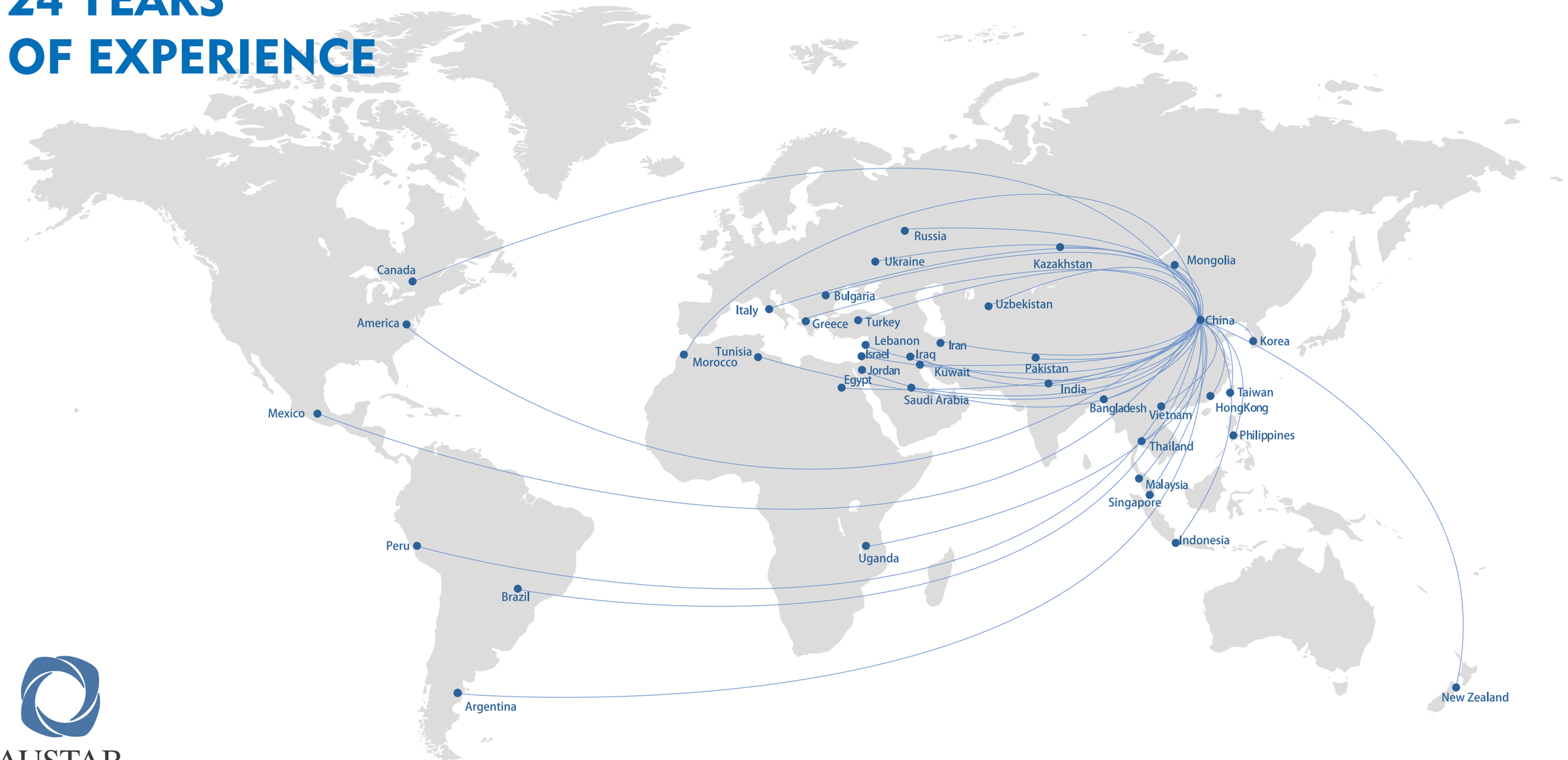
40 COUNTRIES AND REGIONS
24 YEARS OF EXPERIENCE



AUSTAR
excellence union

CONTENTS

Design

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

Drug Technology Transfer

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

Consumables

- Personal Protection
- Cleaning
- Sterile Packaging

Drug Technology Transfer

Customized drug technology transfer services

Design

THE DESIGN PROCESS

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

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

Flexible
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 mouths for complex process
- Project completion within budget, quality and predetermined schedule

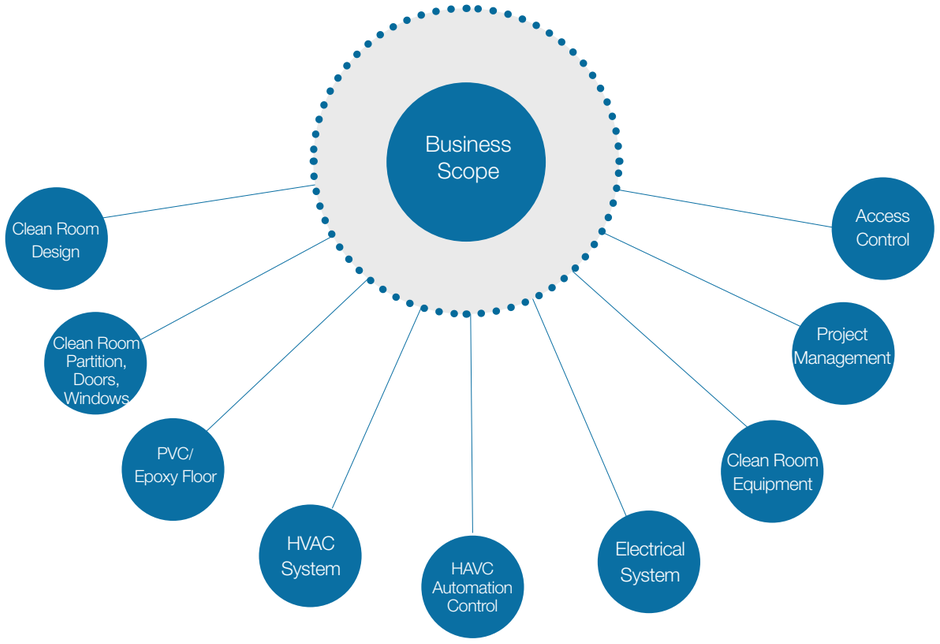
Engineering

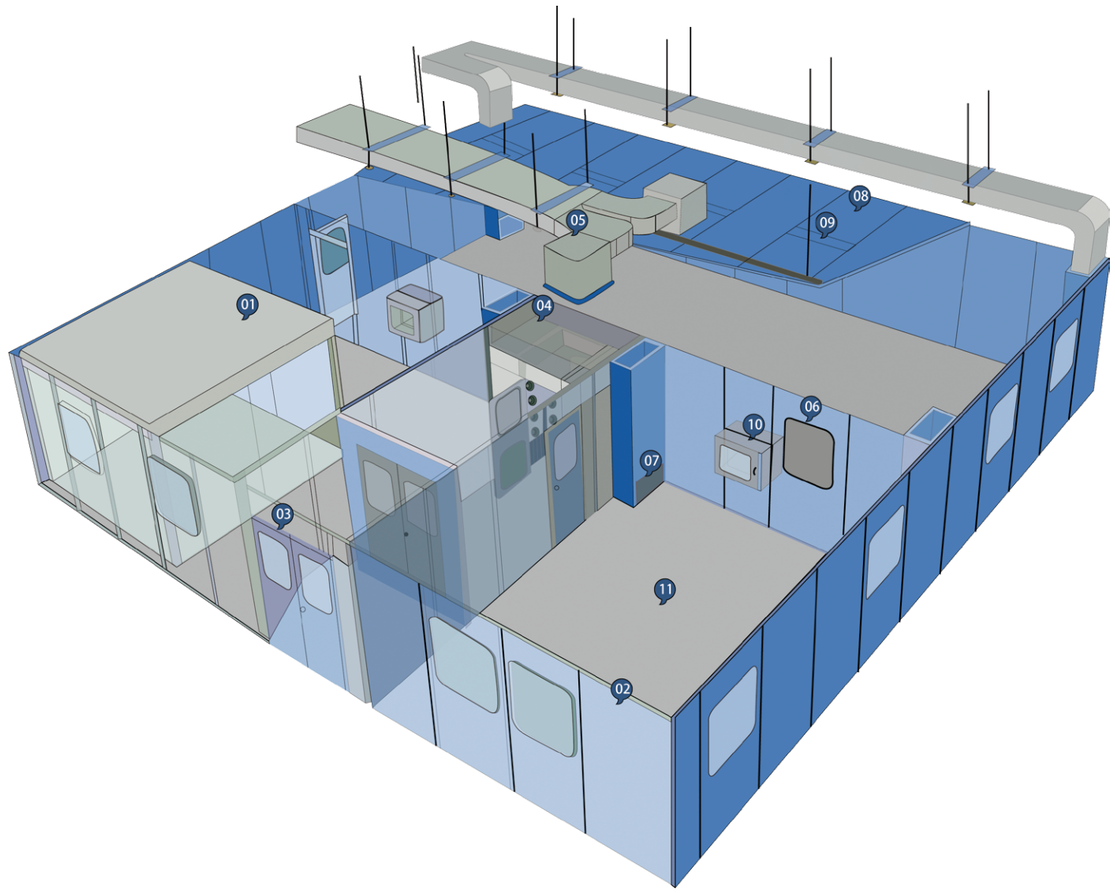
CLEAN ROOM SYSTEM

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.

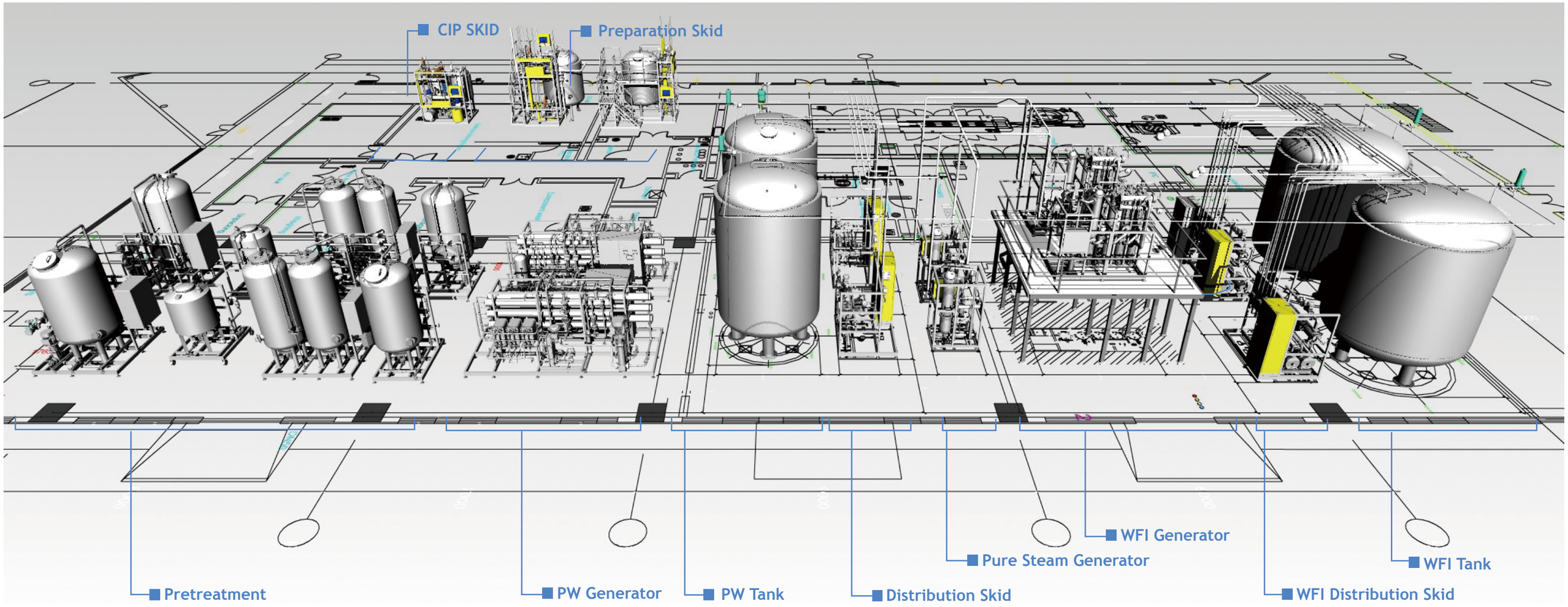
Our clean room system meets the requirement of US FDA cGMP, EU GMP, PIC/S and WHO.





01 Air Flow
02 Wall Panel
03 Door
04 Air Shower
05 HEPA Box
06 Window
07 Return Air Grille
08 Ceiling Panel
09 Light
10 Pass Box
11 PVC/Epoxy Floor

LIQUID PROCESS SYSTEM



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.

PHARMACEUTICAL
AUTOMATION ENGINEERING

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.

20th+

More than 20 years experience
in pharmaceutical industry

100+

More than 100 worldwide clients

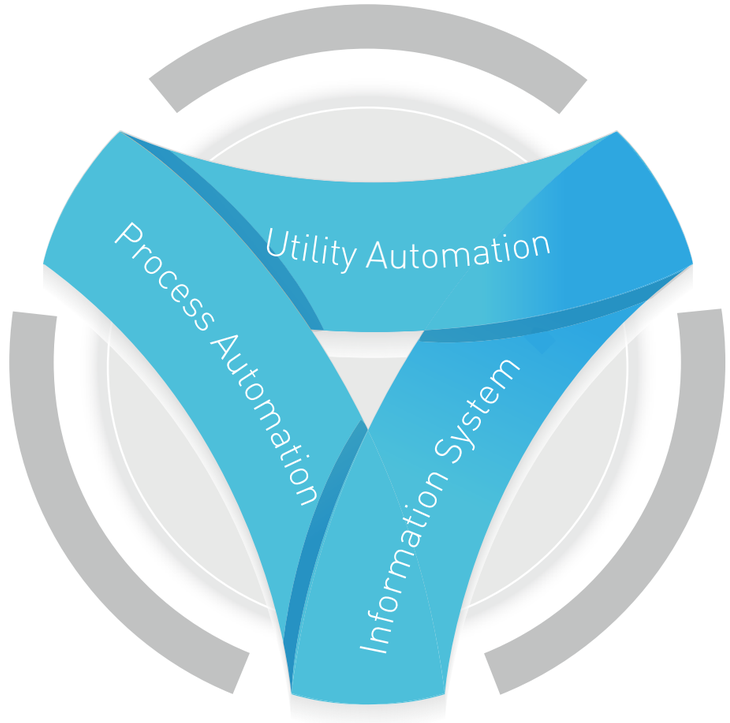
GAMP5

GAMP5 compliant design and
construction procedures

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



Process Automation

- API Process Control System
- Preparations Process Control System
- Biopharmaceutical Process Control System

Utility Engineering Automation

- HVAC Control System
- Environment Monitoring System (EMS)
- PW / WFI System
- Light Current System Integration (IT, Access control, telephone, CCTV)

Factory Information System

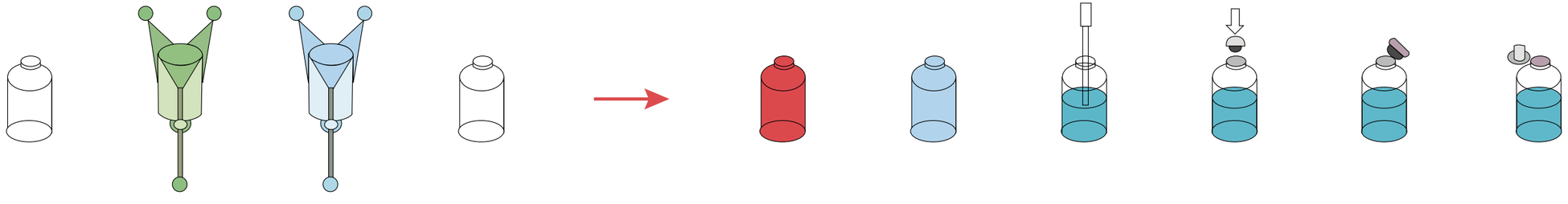
- Supervisory Control And Data Acquisition (SCADA)
- Manufacturing Execution System (MES)
- Laboratory Information Management System (LIMS)

Production Line

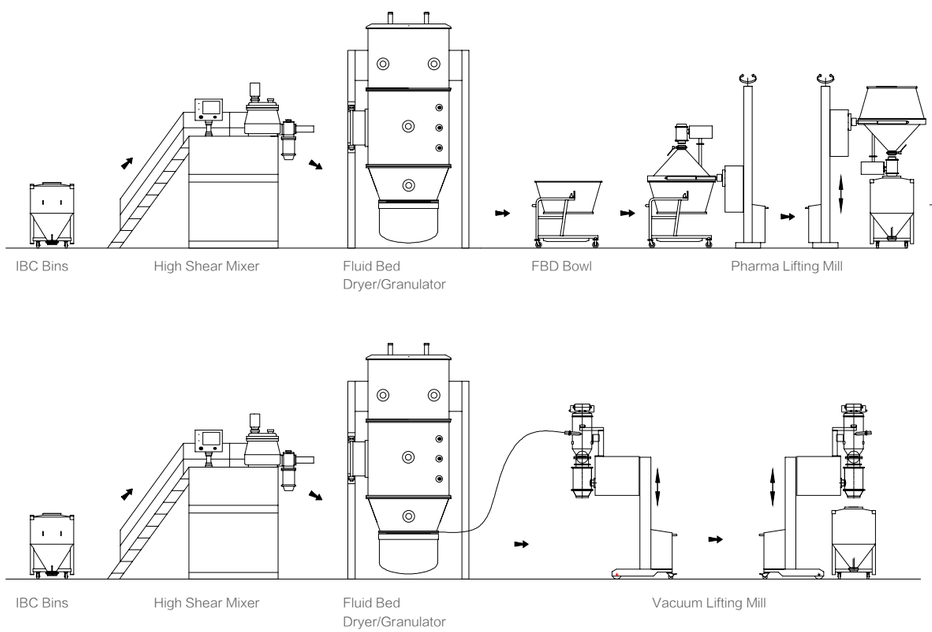
VIAL LIQUID FILLING LINE

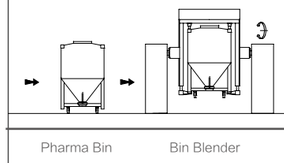
Vial liquid filling line is composed of rotary or linear washing machine, sterilizing & depyrogenation tunnel, filling & stoppering machine, and capping machine.

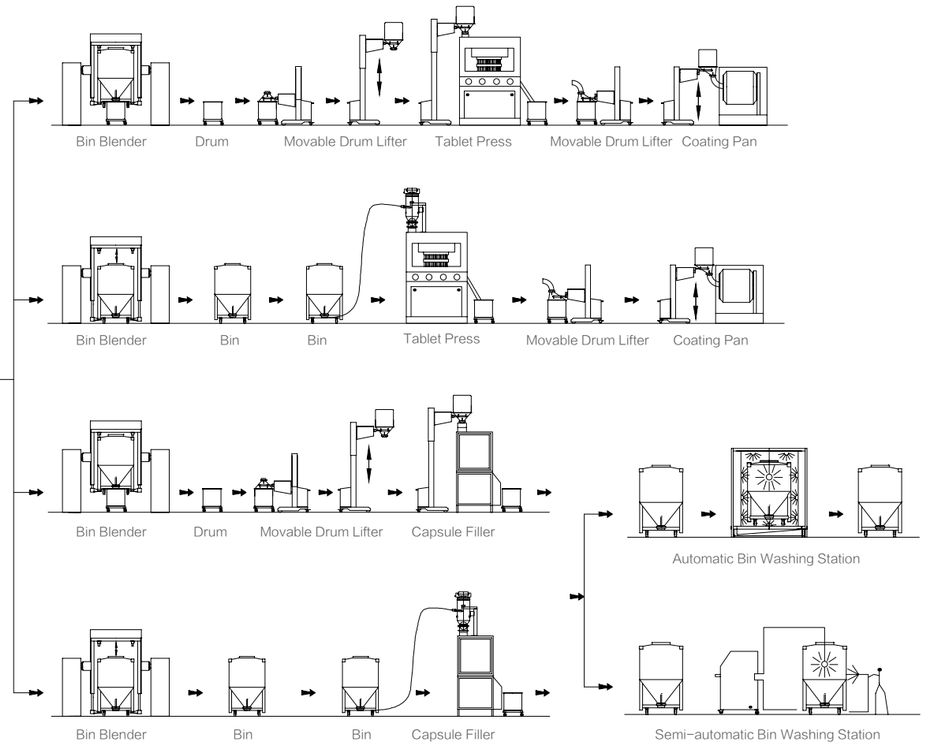
This production line is integrated in accordance with process requirements. The vial liquid filling line capacities extend to filling volumes of 2ml–500ml.



WET GRANULATION LINE
FOR ORAL SOLID DOSAGE







ORAL SOLID DOSAGE SOLUTION

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.

HANDLING
Dispensing and Transfer System, Bins, Drums, Lifting Columns, Blenders

COATING
Perforated Coating Pan for Film and Sugar Coating

TABLETING
Force Feed Tablet Press Machines and Peripheral Machines

INSPECTION
Semi Automatic and Automatic Inspection Machine for Tablets and Capsules

GRANULATION & DRYING
High Shear Mixer, Fluid Bed Dryer/Processor

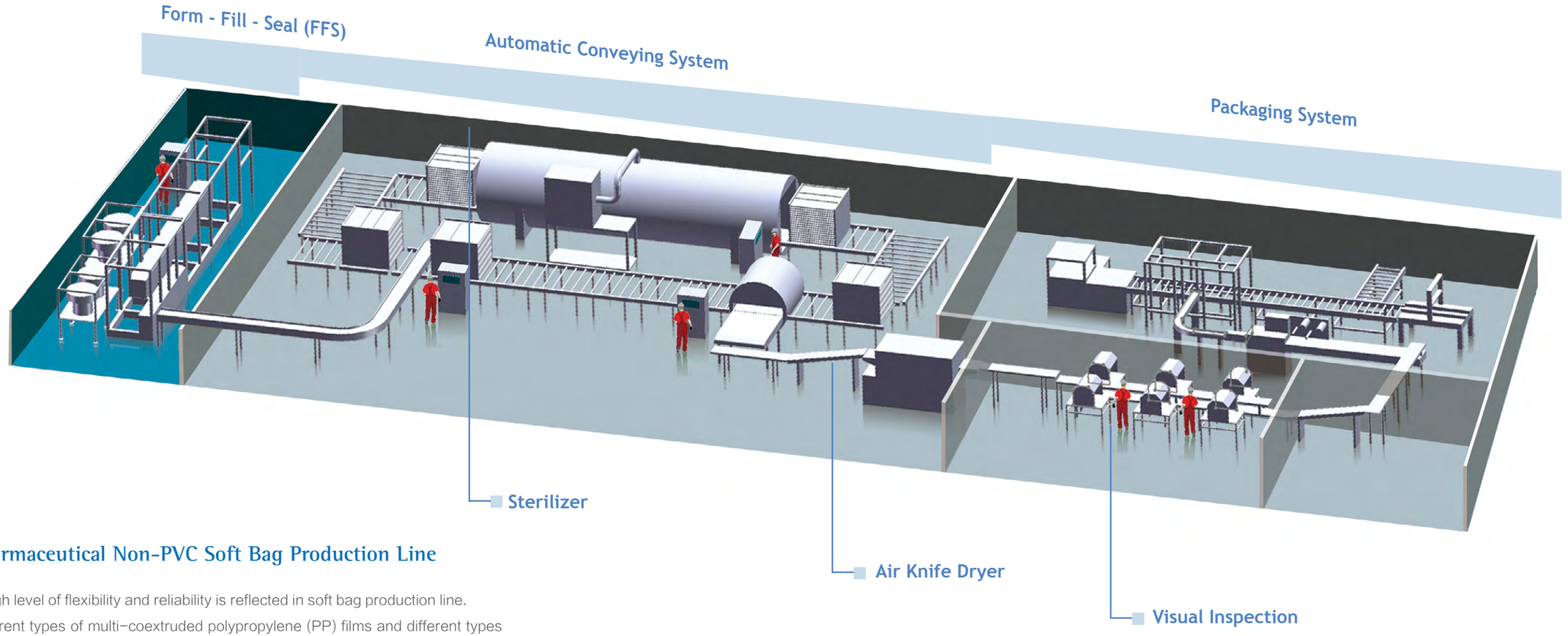
WEIGHT CHECKING
Machine for 100% Weight Checking of Capsules/Tablets

CAPSULE FILLING
Intermittent and Continuous Motion Capsule Filling Machine and Peripheral Machine

WASHING
Wash-In-Place Station, Semi-Automatic and Fully Automatic Bin Washing Station

SOFT BAG PRODUCTION LINE

Non-PVC Soft Bag Complete Production Line



Pharmaceutical Non-PVC Soft Bag Production Line

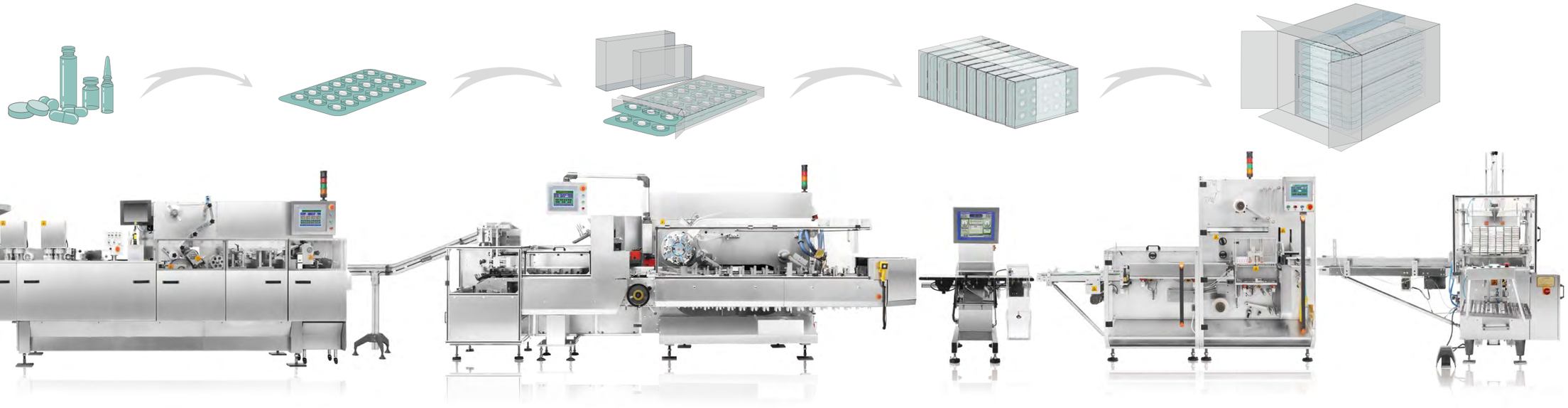
A high level of flexibility and reliability is reflected in soft bag production line. Different types of multi-coextruded polypropylene (PP) films and different types of port can be processed. This line can produce up to 5000 bags per hour. The standard bag sizes vary between 50 ml and 3000 ml.

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 LINE



Blister Packing Machine

Application

Blister packing machine can be widelyused for talbets, 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, slitting/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 quadrate boxes.

Features

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

BOTTLE COUNTING LINE

Unscrambler | Counter | Desiccant Inserter | Screw Capper | Sealer | Labeler

Complete Tablet / Capsule Counting Line Solution

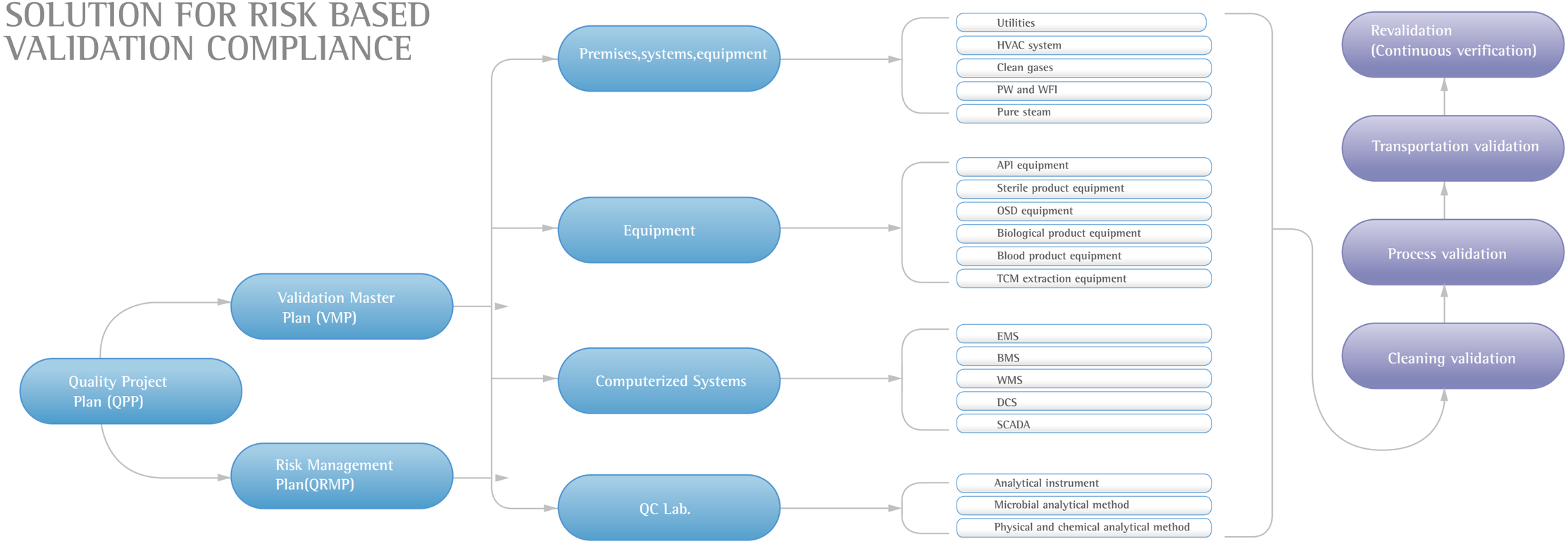
- Maximum speed up to 200bpm
- CCD scanning sensor with high accurate counting
- Modularized design sensor for different types of solid
- Product detecting sensors to avoid incorrect counting
- Dipping nozzles to increase speed and prevent jams
- 12 channel can work separately when small count required
- Pre-count function to automatically count after buffer stop

GMP Compliance Services

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

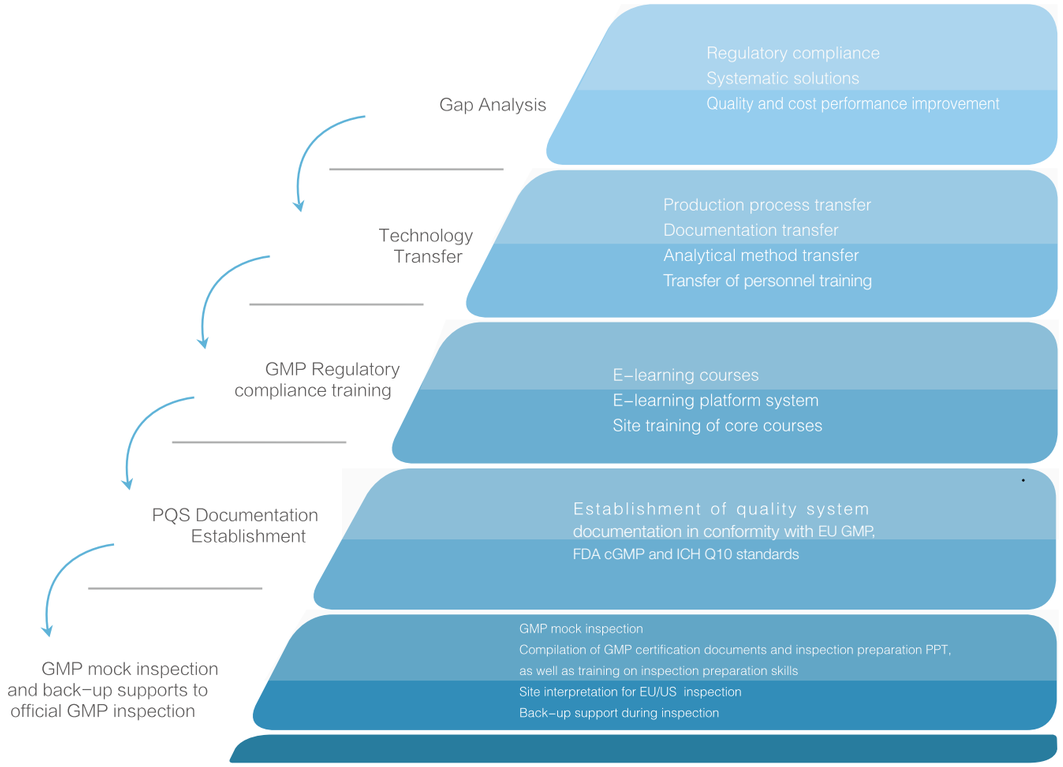
SOLUTION FOR RISK BASED VALIDATION COMPLIANCE



CONTENT OF INTEGRATED SOLUTION FOR

Pharmaceutical Quality System

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.



NEW PQS STRATEGIES

(ICH Q8/Q9/Q10)

Consumables

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.

Area 1 The Cleanroom

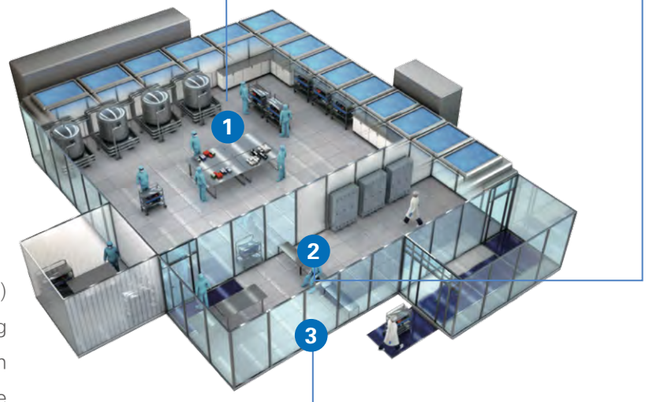
Production area: validated and contamination controlled (air, surfaces and personnel) Only cleanroom products allowed.

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)

Offices and Factories

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