

AUSTAR

Oral Solid Dosage Solution



AUSTAR

Formulation

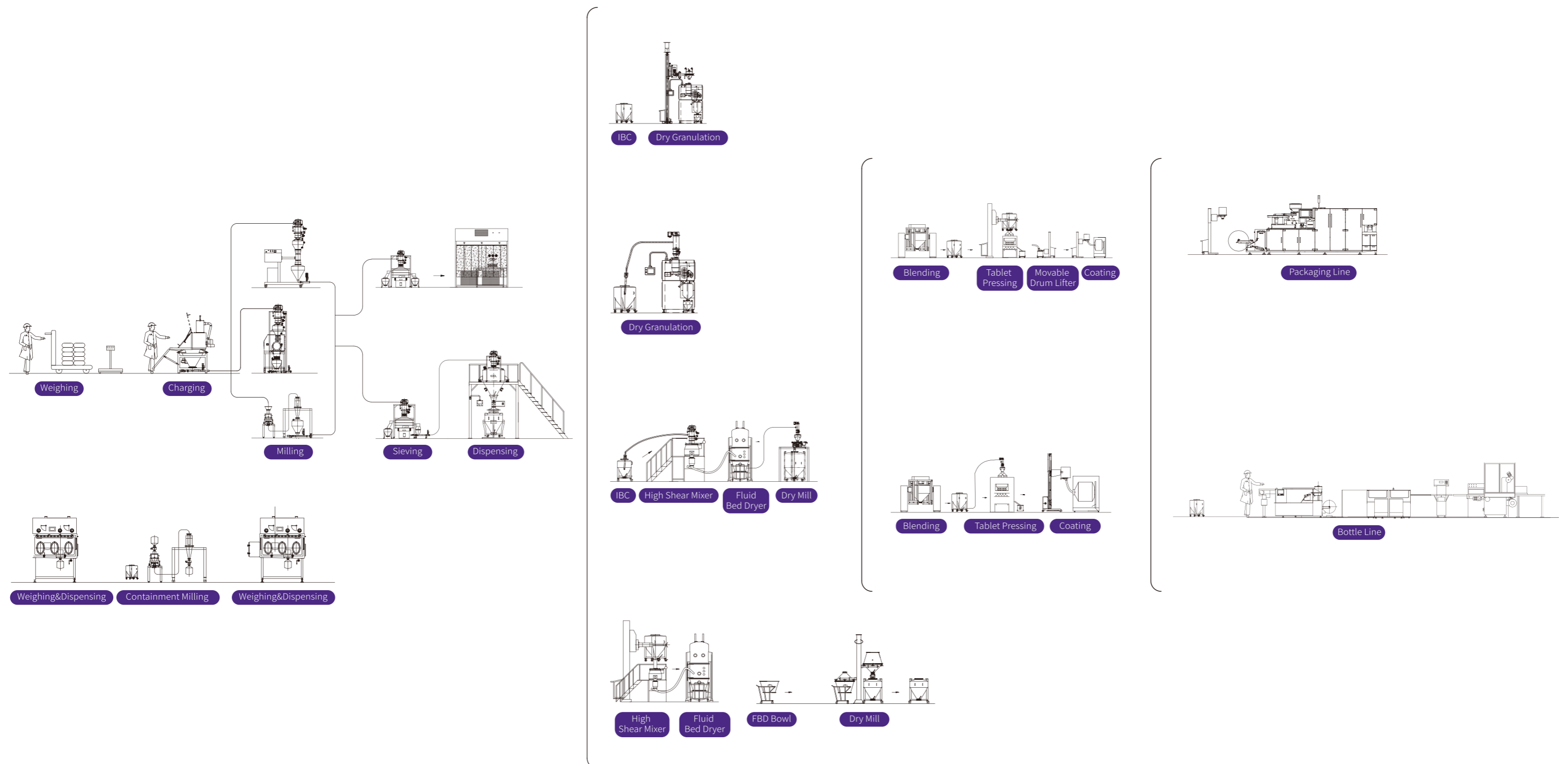
AUSTAR is a technology-based pharmaceutical engineering solution provider with deep understanding of pharmaceutical industry regulations and processes. Integrating global high-quality resources and being committed to helping clients improve pharmaceutical process and operational effectiveness. Through boosting global drug safety and efficacy to protect and promote human health.

Providing customized solutions to process system of solid dosage forms by introducing advanced process monitoring and analytical technology.
 In cooperation with research team of international excellent granulating technology to carry out granulating technology research and development work.
 Trace-able production data by Batch Management System.
 GAMP5 complied automatic control system to provide high quality, high standard and high efficiency computerized system validation services.
 Intelligent quality management system, innovative team and senior high quality technicians.
 Validation system in compliance with FDA, EMA, WHO and cFDA Regulation.
 Quick Response by experienced after-sales team.

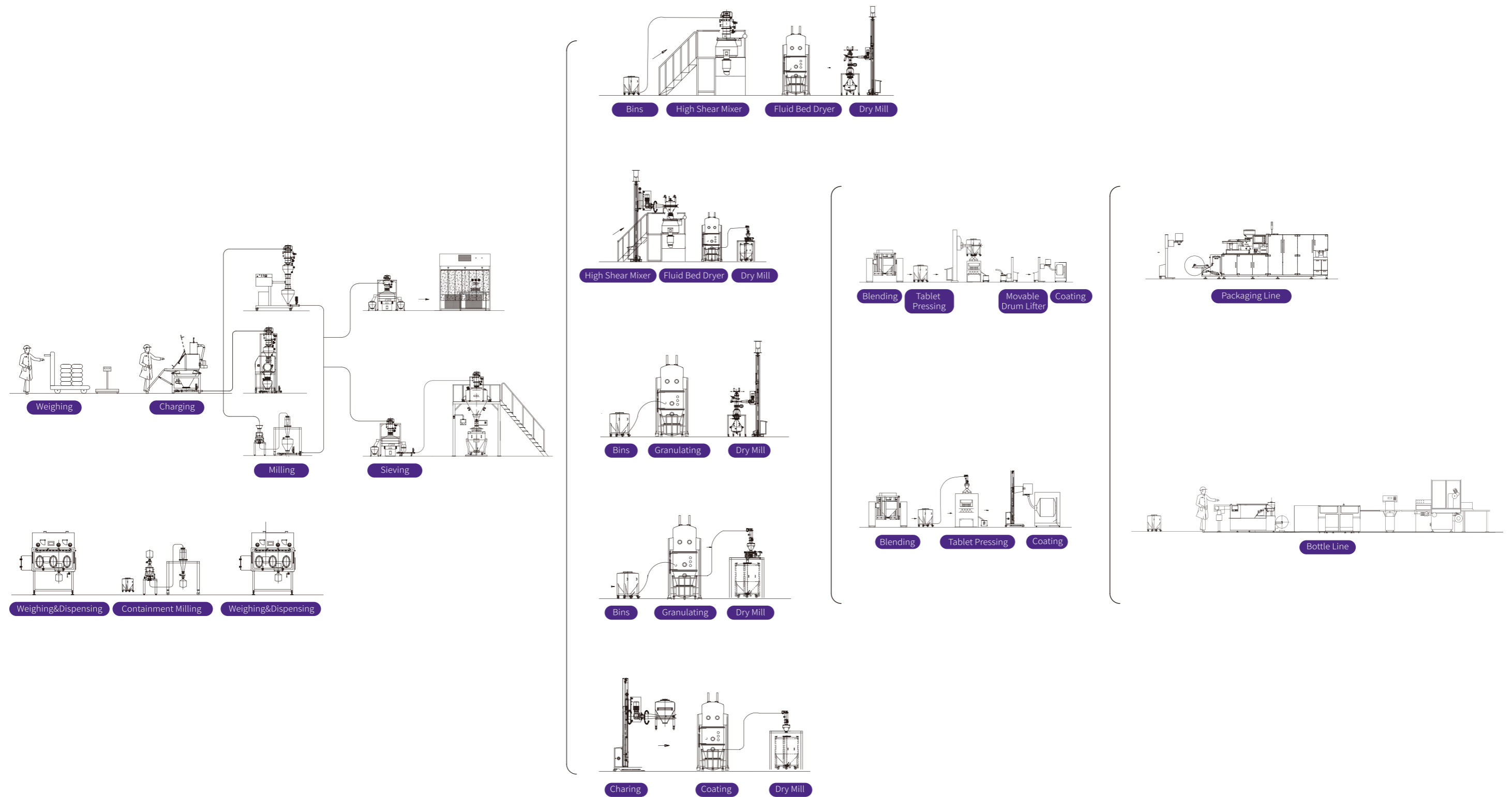
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Process of Oral Solid Dosage



Process of Oral Solid Dosage



Charging Equipment

Dust free loading system applies to the loading procedure of non-sterile APIs from aluminum drum to hopper. Dust free loading station has three working stages: buffer of infeed drums, weighing and loading, and buffer of outfeed drums. The whole loading process is carried out in full containment condition, which can effectively assure the protection of operators and ambient environment. Professional design in compliance with production requirement about solid stability and reliability of EU GMP and FDA. CIP and SIP functions are available for the parts in direct contact with the products.



- Standardized design, which is convenient for upgrading and innovation
- Suitable for simple and fully integrated system
- Inertial design



Products	Capacity	Options
Dust-free Station (Bag Dump Station)	Up to 100 bags per hour (suitable for different bag size)	Ex-proof feature, integrated sieve or lump breaker, automatic bag opening system, automatic transfer in system, CIP feature, real-time weighing and automatic control charging
DCS (Drum Containment System)	Up to 30 drums per hour (suitable for different paper package drum)	Ex-proof feature, suction lance with breaker, CIP feature, real-time weighing and automatic control charging
Bulk Bag Charging Station	Suitable for different bulk bag size	Ex-proof feature, CIP feature, integrated big part breaker, real-time weighing and automatic control charging
Laminar Flow Booth	Used for small volume material dispensing	

Crushing / Milling Equipment

Main components Milling Head, Conical Screen, and Rotator.

Working principle By means of the shearing force and squeezing force of the rotor and screen.

Working characteristics

- Suitable for crushing dry and wet powder lumps, particularly for crushing lumps and screening granular materials
- Large effective screen area with flow rate being increased significantly
- Delicate design with a minimum quantity of moving parts
- Quick and simple cleaning, with low costs for CIP, SIP, maintenance, and operation



Products	Model	Options
Hammer Mill	AHM-270	Ex-proof feature, variety sieve mesh, oval and eight adjustable bracket, CIP/SIP features
	AHM-390	
Conical Mill	AWC-150	
	AWC-250	

Powder Transfer Equipment

Vacuum conveyor is a kind of conveying unit for transferring granules and powders by means of vacuum suction. It is widely applied in pharmaceutical, food, chemical, ceramics, feeds, pigments, dyes, and agricultural fields for production and scientific research purposes. Vacuum conveyor can remarkably reduce dust pollution in the workshop to improve cleanliness; and production capacity, save large amounts of labor cost, and reduce contamination.



Characteristics

- In compliance with GMP requirements
- Mirror polishing of inner and outer machine surfaces to Ra<0.8um
- Low energy consumption, high efficiency, and low noise level
- Modular design for making combinations according to working conditions
- Fluent cosmetic design for the convenience of inspection, cleaning, and disinfection
- Five years' quality warranty

Powder Transfer System is a kind of extremely high efficient and reliable system for transferring and distributing dry and moist powders and granular materials. It adopts unique flat sheet membrane filtration system and is the only dense phase vacuum conveying system in the market.

- Professional loading system for reactor
- Pneumatic transfer (vacuum/pressure) system for transferring powders to any type of container at destination, particularly pressurized, high temperature and high moisture container containing solvents
- Not containing any inflammable materials and being more suitable for applications with explosion proof requirement
- Capable of mass products transferring: kilograms to tons of powders
- Patented 100% CIP and SIP technology

Vacuum Conveyor	PHSP series	Working capacity from 0 to 10 tons per hour	CIP and SIP feature
	PTS series		

Particle Reduction & Blending

Intermittent mixing machine has the advantages of high speed and flexibility feature. In comparison to traditional system, the total processing time has been shortened, and it can enable the operator to handle and mix the powders of different characteristics in a containment environment. The system is especially suitable for pharmaceutical system, the handling of active substances must be contamination-free and the physical properties of the materials will not be changed.



Rotary vibration sieve is a kind of circular sieve driven by vibration motor. By means of the adjustment of eccentric masses at both ends of the vibrating motor, the sieve is driven to make horizontal and circular three-dimensional movements, which means that plane circumferential movement is superimposed with vertical movement in small amplitude.



Batch Mixer	From 60L to 3000L per batch	Ex-proof feature, CIP/SIP feature
Vibration Sieve	Diameter from 400mm to 1.5m	Sieve mesh changble

Wet Granulating System Solution

- WIP (wash in place) device: telescopic spray nozzles are used for the complete machine and movable spray design is adopted for fluid bed chamber to assure good washing performance.
- Sintered sight glass: sintered sight glass is adopted for the view window, which is easy to clean and has no residue of material.
- Containment valve: loading/unloading containment valves of different OEB levels.
- Automatic filter bag lifting device can realize automatic lifting of the filter bags for fluid bed dryer with accurate positioning.
- Air tight device: air tight design is adopted for main shaft of wet granulator and granulating chopper.
- Determination of granulating end point: time, current, torque (optional).
- Online monitoring device for granules size / moisture content: providing data support for production process analysis and control.
- Automatic control system: AUSCON automatic control system is stable, reliable and validated. We have sets of completed validation documents.



CT & PAT Application on Granulation Line

AUSTAR is devoted to providing more innovative technology so as to improve production efficiency and solve occupational safety issues. The solid dosage solutions integrate all respects of technical advantages, such as enclosed powders transfer, automated control, process technology and validation.

Contained Powder Transfer Technology

Providing customers with solutions to high containment system

High Containment Transfer

Powder handling for wet granulating (loading, crushing, weighing, and screening) to realize high containment formulation system(OEB3-OEB5).

Containment Valve

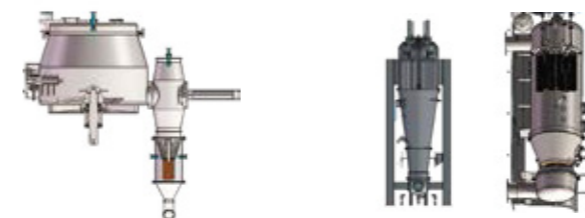
High containment valves for materials loading/unloading



Wash in Place (WIP)

Unique washing design to realize full coverage

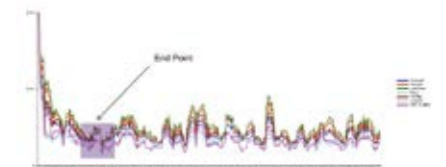
Washing of Wet Granulator Washing of Fluid Bed Dryer



Process Analytical Technology (PAT)

Providing data support for production process control through the monitoring of torque, granule size, and moisture content:

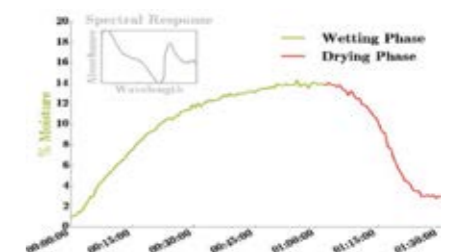
Blending Uniformity Monitoring



Online Monitoring of Granule Size



Online Moisture Monitoring

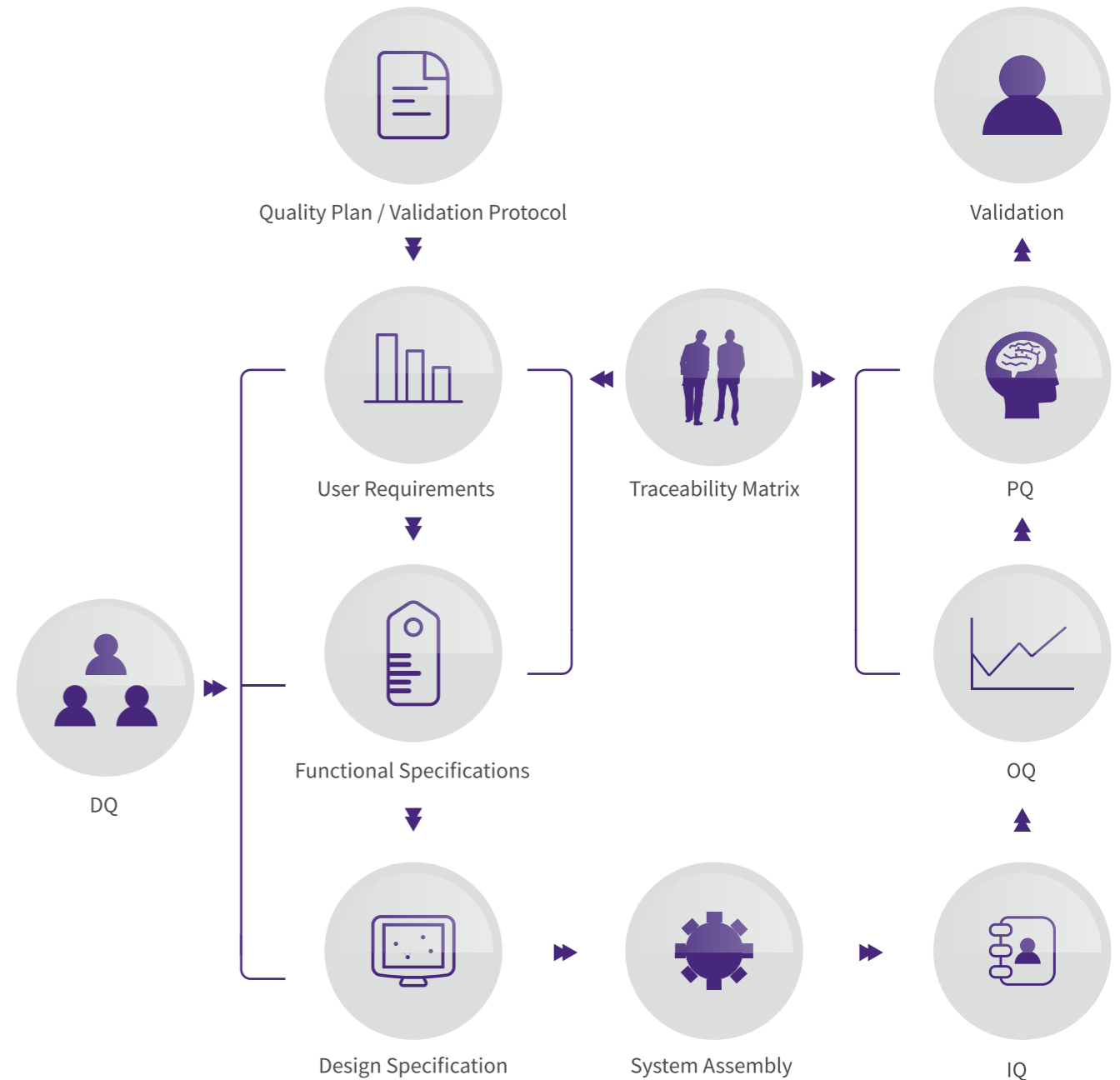


Pharmaceutical Quality System Solutions

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.



Project Management



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