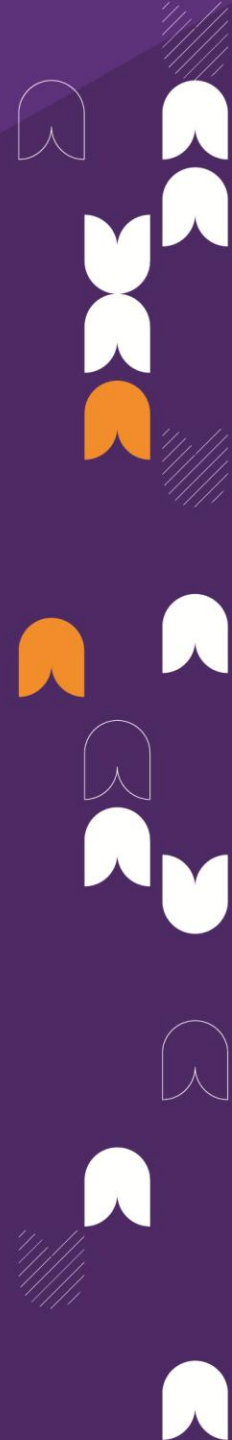




# Case study of OSD Solution

08-26-2024



# Case study

AUSTAR

- ◆ Year : 2024
- ◆ Location : Hangzhou, Zhejiang
- ◆ Regulation: cGMP/FDA
- ◆ Process : OEB4 OSD Turnkey
- ◆ Scope : Material transfer system, wet granulation line, isolator, bin washing station, hoister, etc..
- ◆ Benefit :The 400kg large-capacity and HPAPI equipment TK; material pretreatment, weighing, granulation, mixing and other processes; customized equipment processing is carried out according to the process, including high shear wet granulation machine mixing and discharging ,mixing and sorting, bin bucket in place cleaning,



# Case study

- ◆ Year : 2024
- ◆ Location : Hangzhou, Zhejiang
- ◆ Regulation: NMPA/FDA
- ◆ Process : HPAPI fluid bed processor
- ◆ Scope : Top spray granulation fluid bed, milling system, hoister
- ◆ Benefit :The product of this project is in the clinical trial stage. Based on this characteristic, a one-step granulation replaceable pot fluidized bed with a production capacity limit of 15L was selected to ensure the connection between the process and small-scale and pilot batches.



# Case study

AUSTAR

- ◆ Year : 2024
- ◆ Location : Xi' an, Shaanxi
- ◆ Regulation: NMPA
- ◆ Process : Wet granulation line for Chinese traditional medicine
- ◆ Scope : Automatic weighing system, wet granulation line
- ◆ Benefit : According to the characteristics of traditional Chinese patent medicines and simple preparations raw material composition, optimize the automatic control procedure of product incoming and outgoing materials to achieve fully closed and automatic material transmission, ensure the smoothness of production and product quality, and integrate with automatic weighing equipment to achieve automatic process production.



# Case study

AMSTAR

- ◆ Year : 2024
- ◆ Location : Shanghai
- ◆ Regulation: cGMP
- ◆ Process : Wet granulation, Fluid bed processor, Wurster coating
- ◆ Scope : HSG wet granulator, FBDGC20 fluid bed processor
- ◆ Benefit :Single machine achieves maximum production capacity coverage, wet granulation achieves a working volume range of 0.5L to 15L, and bottom spray coating achieves a working volume range of 0.5-10L, providing more stable equipment parameter control and process services



# Case study

AWSTAR

- ◆ Year : 2024
- ◆ Location : Shanghai
- ◆ Regulation: cGMP
- ◆ Process : Wet Granulation
- ◆ Scope : High Shear Granulator
- ◆ Benefit :Single machine achieves maximum production capacity coverage, wet granulation achieves a working volume range of 0.5L to 8L. Minimum capacity with flexible capacity help customer on process development and research for new API with few amount.



知乎 @

# Case study

- ◆ Year : 2023
- ◆ Location : Nanjing, Jiangsu
- ◆ Regulation: cGMP
- ◆ Process : Fluid bed processor, Wurster coating
- ◆ Scope : FBDGC20 fluid bed processor
- ◆ Benefit : Customized production of melt granulation fluidized bed according to customer needs, which can be used for material high-temperature granulation machine bottom spray coating function, with a wider process adaptation window. AHU with accurate control system of moisture and temperature providing stable



# Case study

AWSTAR

- ◆ Year : 2022
- ◆ Location : Hangzhou, Zhejiang
- ◆ Regulation: cGMP
- ◆ Process : Wet granulation, Fluid bed processor, Wurster coating
- ◆ Scope : HSG25 wet granulator, FBDGC30 fluid bed processor
- ◆ Benefit :Covering small-scale process development and pilot scale production capacity equipment, it can achieve a granulation capacity of 3-21L and a bottom spray coating capacity of 3-15L, with more stable equipment parameter control and process services. It integrates DAE studio to quickly screen the optimal batch for process development



# Case study

AMSTAR

- ◆ Year : 2022
- ◆ Location : Hangzhou, Zhejiang
- ◆ Regulation: cGMP
- ◆ Process : Wet granulation, Fluid bed processor, Wurster coating
- ◆ Scope : HSG15 wet granulator, FBDGC20 fluid bed processor
- ◆ Benefit : Single machine achieves maximum production capacity coverage, wet granulation achieves a working volume range of 0.5L to 15L, and bottom spray coating achieves a working volume range of 0.5-10L, providing more stable equipment parameter control and process services



杭州国瑞生物科技有限公司  
Hangzhou Guorui Bio Technology Co.,Ltd



# Case study

AU STAR

- ◆ Year : 2023
- ◆ Location : Ningbo, Zhejiang
- ◆ Regulation: cGMP/NMPA
- ◆ Process : multi function fluid bed processor
- ◆ Scope : FBDGC530 fluid bed processor
- ◆ Benefit :The software control system that complies with FDA21 CFR part 11 ensures the integrity of process data, and the process system that meets the EU explosion-proof standard of 10 bar anti explosion standard achieves stable and efficient operation. The high-capacity bottom spray coating process and multi Wurster column design help customers with process transfer after equipment changes and R&D process scale up



# Case study

AUSTAR

- ◆ Year : 2023
- ◆ Location : Shenzhen, Guangdong
- ◆ Regulation: GLP
- ◆ Process : multi function fluid bed processor
- ◆ Scope : FBDGC20 fluid bed processor
- ◆ Benefit :The software control system that complies with FDA 21 CFR part 11 ensures the integrity of process data, with extremely low production capacity and a minimum working volume of 0.5 liters. It can achieve drying, top spray granulation, and bottom spray coating function switching in a single pot, and integrates online moisture monitoring PAT



# Case study

AU STAR

- ◆ Year : 2023
- ◆ Location : Shaoxing, Zhejiang
- ◆ Regulation: EU GMP/cGMP
- ◆ Process : Wet granulation line ,tablet/ capsule
- ◆ Scope : HSG200 high shear mixer, FBDG400 fluid bed, HSG400 high shear mixer +FBDG400 fluid bed,1000L blending, 1000L bin washing station
- ◆ Benefit :The software control system complied with FDA21 CFR part11 ensures the integrity of process data. The process system of the 10bar explosion-proof standard of the European Union achieves stable and efficient operation, and the process equipment is packaged for services including granulation, mixing, cleaning, etc.



# Case study

AUSTAR

- ◆ Year : 2023
- ◆ Location : Jinhua, Zhejiang
- ◆ Regulation: EU GMP/cGMP
- ◆ Process : Wet granulation line ,tablet/ capsule
- ◆ Scope : HSG300 high shear mixer, FBDG300 fluid bed, HSG800 high shear mixer +FBDG800 fluid (rotation plate discharge)
- ◆ Benefit :As a CDMO/CMO enterprise, achieve more flexible production capacity coverage in commercial OSD production lines. FDA21 CFR part11 compliant software control system ensures process data integrity, and the 10bar explosion-proof standard process system of the European Union achieves stable and efficient operation



# Case study

AMSTAR

- ◆ Year : 2023
- ◆ Location : Yichang, Hubei
- ◆ Regulation: EU GMP/cGMP
- ◆ Process : Wet granulation line ,tablet/ capsule
- ◆ Scope : HSG600 high shear mixer, FBDGC530 fluid bed
- ◆ Benefit :The automatic impeller lifting of the mixer facilitates quality control and prevents cross contamination. It is a stable large-scale bottom spray coating system and a 10bar explosion-proof multi-functional wet granulation line that meets the ATEX explosion-proof standard of the European Union



# Case study

AMSTAR

- ◆ Year : 2022
- ◆ Location : Hangzhou, Zhejiang
- ◆ Regulation: cGMP
- ◆ Process : Wet granulation line, top spray granulation, Wurster coating
- ◆ Scope : HSG15 high shear mixer, FBDGC20 fluid bed
- ◆ Benefit : Equipment parameter control and process services for achieving maximum production capacity coverage on a single machine, achieving a working volume range of 0.5L to 15L for wet granulation, and achieving a more stable working volume range of 0.5-10L for bottom spray coating



杭州国瑞生物科技有限公司  
Hangzhou Guorui Bio Technology Co.,Ltd



# Case study

AWSTAR

- ◆ Year : 2022
- ◆ Location : Taizhou, Zhejiang
- ◆ Regulation: cGMP
- ◆ Process : Wet granulation line ,tablet/ capsule
- ◆ Scope : HSG800 high shear mixer, FBDGC850 fluid bed
- ◆ Benefit :Flexible production, large-scale bottom spray coating, explosion-proof multi-functional wet granulation line



# Case study

- ◆ Year : 2021
- ◆ Location : Ningbo, Zhejiang
- ◆ Regulation: GMP/ EU-GMP
- ◆ Process : Wet granulation line ,tablet/ capsule
- ◆ Scope : HSG150 high shear mixer, FBDG150 fluid bed
- ◆ Benefit :Scaling up commercial production of products through pilot production processes



# Case study

- ◆ Year : 2021
- ◆ Location : Hangzhou, Zhejiang
- ◆ Regulation: GMP/ FDA
- ◆ Process : Wet granulation line ,tablet/ capsule
- ◆ Scope : HSG150 high shear mixer, FBDGC170 fluid bed
- ◆ Benefit :Scaling up commercial production of products through pilot production processes, impeller lifting.



# Case study

- ◆ Year : 2021
- ◆ Location : Ningbo, Zhejiang
- ◆ Regulation: GMP/ EU-GMP
- ◆ Process : Wet granulation line ,tablet/ capsule
- ◆ Scope : HSG1000 High Shear Mixer, FBDG1500 fluid bed Granulator
- ◆ Benefit : Vertical design of whole facility, PHS with bottom discharge system cross the layer to next floor save the process time from powder loading to the dry milling of particle. AHU with accurately control system of moisture of temperature providing stable process air to fluid bed to ensuring the best performance.



# Case study

- ◆ Year : 2021
- ◆ Location : Hengdian, Zhejiang
- ◆ Regulation: GMP/ FDA
- ◆ Process : Wet granulation line ,tablet/ capsule
- ◆ Scope : HSG600 high shear mixer, FBDG800 fluid bed
- ◆ Benefit :Internationalized workshop exports to the North American market, FDA standard, dust free production



# Case study

- ◆ Year : 2021
- ◆ Location : Hengdian, Zhejiang
- ◆ Regulation: GMP/ FDA
- ◆ Process : Top spray granulation, Wurster coating
- ◆ Scope : FBDGC530 fluid bed
- ◆ Benefit :AHU's precise temperature and humidity control ensures stable production processes, meets GMP 5 control system requirements, and meets FDA data integrity requirements. The product is exported to the North American market



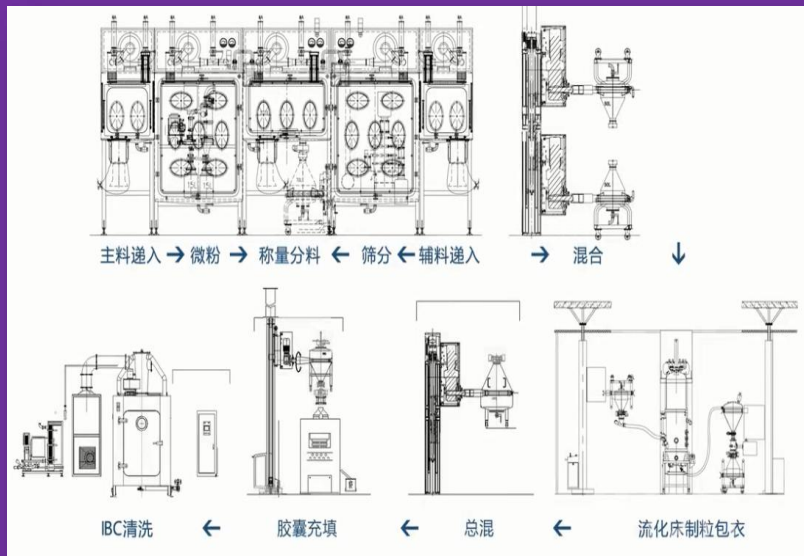
# Case study

- ◆ Year : 2021
- ◆ Location : Hengdian, Zhejiang
- ◆ Regulation: GMP/ FDA
- ◆ Process : Wet granulation
- ◆ Scope : HSG300 high shear mixer
- ◆ Benefit : Update the granulator, improve production efficiency, control on-site dust, and achieve closed production



# Case study

- ◆ Year : 2019
- ◆ Location : Jinzhou , Liaoning
- ◆ Regulation: GMP/ FDA/OEB4
- ◆ Process : HAPI particle size control and weighing, top spray granulation and Wurster coating, capsule
- ◆ Scope : Containment equipment turnkey, design consulting, isolator, jet mill, FBDGC70 fluid bed
- ◆ Benefit :High density closed multifunctional flexible production line, compliant with cFDA OSD process production line



# Case study

AMSTAR

- ◆ Year : 2019
- ◆ Location : Yueyang , Hunan
- ◆ Regulation: GMP/ FDA/OEB3
- ◆ Process : OSD wet granulation line, capsule
- ◆ Scope : Containment equipment turnkey, isolator, HSG75 high shear mixer FBDGC70 fluid bed
- ◆ Benefit :Flexible anti-tumor drug production line



AMSTAR 奥星  
奥星制药设备(石家庄)有限公司  
售后服务信息卡

客户名称	湖南科伦制药有限公司药研分公司
设备名称	<input type="checkbox"/> 筛分制粒机 <input checked="" type="checkbox"/> 多功能流化床 <input type="checkbox"/> 其它:
设备用途	<input type="checkbox"/> 小试设备 <input type="checkbox"/> 中试设备 <input checked="" type="checkbox"/> 商业化生产设备
设备购买时间	2017年
客户问题反馈	研究人员使用多功能流化床进行某品种的工艺放大中该品种为湿法制粒工艺,湿法制粒时颗粒质量很小,物料容易吸湿,制粒情况不理想,所量大的颗粒较大,小颗粒少,颗粒流动性差,制粒效果不佳; 生产后颗粒大小分布含量在批与批间不符情况。
售后服务人员	杨心松 王江波
售后服务时间	2021年7月28日
实际服务内容	1. 与客户沟通,明确了颗粒制粒的问题,以及颗粒流动性不佳的原因,并制定了解决方案。 2. 客户现场生产过程中,对客户提出的问题,调整了设备参数,使颗粒流动性改善,解决了颗粒流动性差,最大颗粒减小了颗粒吸湿。 3. 与客户现场沟通,调整了工艺参数,使颗粒流动性改善,解决了颗粒流动性不佳的问题。
售后服务结果	解决客户现场生产中,物料流动性差,制粒效果不佳的问题,使颗粒流动性改善,制粒效果符合客户要求。
售后服务评价	客户现场,满分10分,得分:10分
客户签字/日期	李国柱 陈春 2021.7.28
客户联系方式	手机号:1370221
备注	无



# Case study

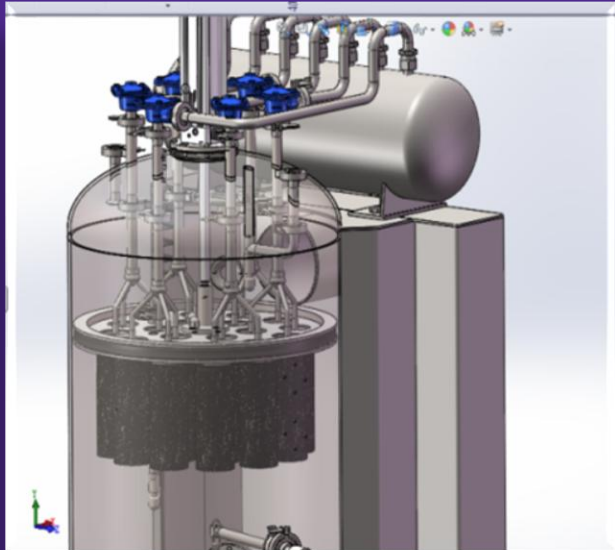
- ◆ Year : 2017
- ◆ Location : Datong, Shanxi
- ◆ Regulation: GMP/ FDA
- ◆ Process : OSD wet granulation line, capsule, tablet
- ◆ Scope : HSG600 high shear mixer, FBDG800 fluid bed
- ◆ Benefit : Assist customers in optimizing the process of traditional Chinese medicine products and achieve closed automated commercial production; Multiple product have passed BE



# Case study

AUSTAR

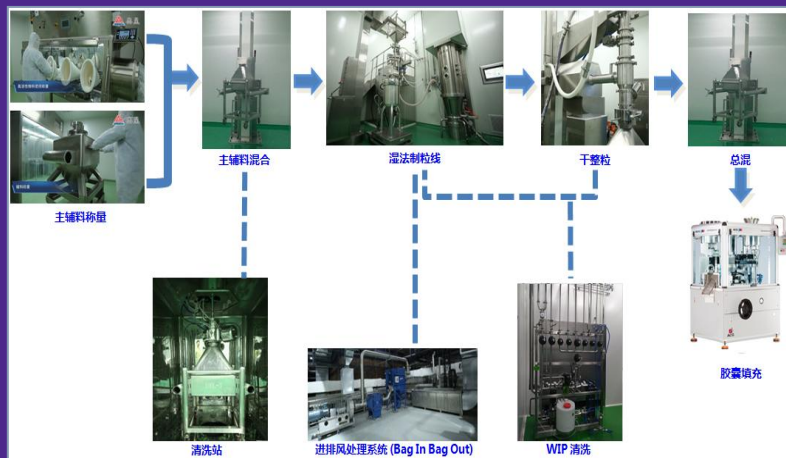
- ◆ Year : 2017
- ◆ Location : Zibo, Shandong
- ◆ Regulation: GMP/ FDA/OEB3
- ◆ Process : OSD wet granulation line, tablet
- ◆ Scope : FBDG800 fluid bed
- ◆ Benefit : Assist customers in establishing cFDA compliant antibiotic production lines



# Case study

AMSTAR

- ◆ Year : 2017
- ◆ Location : Xi' an, Shaanxi
- ◆ Regulation: GMP/ FDA/OEB4
- ◆ Process : OSD wet granulation line, tablet, capsule
- ◆ Scope : Design review, containment strategy, isolator, HSG200 high shear mixer, FBDGC330 fluid bed, roller compactor, capsule filling machine, SBV, validation service.
- ◆ Benefit : Assist customers in establishing a flexible production line for OEB4 anti-tumor drugs that complies with current EU GMP and FDA regulations, and meet EU GMP and cGMP data integrity requirements



# Case study

AUSTAR

- ◆ Year : 2018
- ◆ Location : Xi' an, Shaanxi
- ◆ Regulation: GMP/ FDA/OEB3
- ◆ Process : OSD wet granulation line, tablet, capsule
- ◆ Scope : Design review, containment strategy, isolator, HSG100 high shear mixer, FBDGC170 fluid bed, validation service.
- ◆ Benefit : Assist customers in establishing OEB3 antibiotics that comply with current EU GMP and FDA regulations β The lactam drug production line meets the data integrity requirements of EU GMP and cGMP



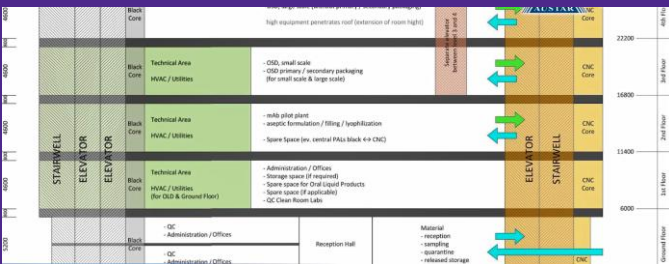
# Case study

- ◆ Year : 2017
- ◆ Location : Xi' an, Shaanxi
- ◆ Regulation: FDA
- ◆ Process : tablet coating
- ◆ Scope : Flex 100, drum exchangeable, AC48
- ◆ Benefit : Assist customers in establishing an internationalized pharmaceutical workshop, achieving a transformation layout from traditional Chinese medicine preparations to chemical drugs



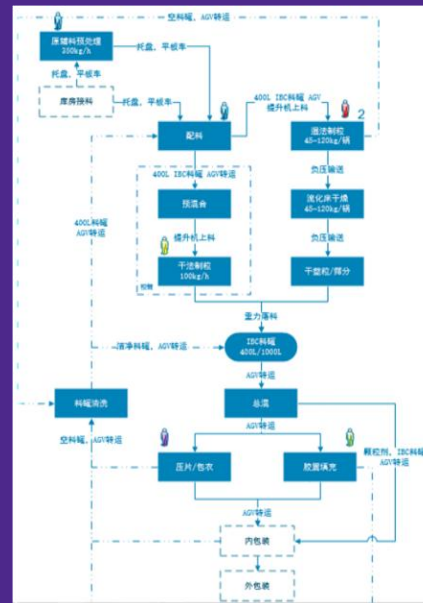
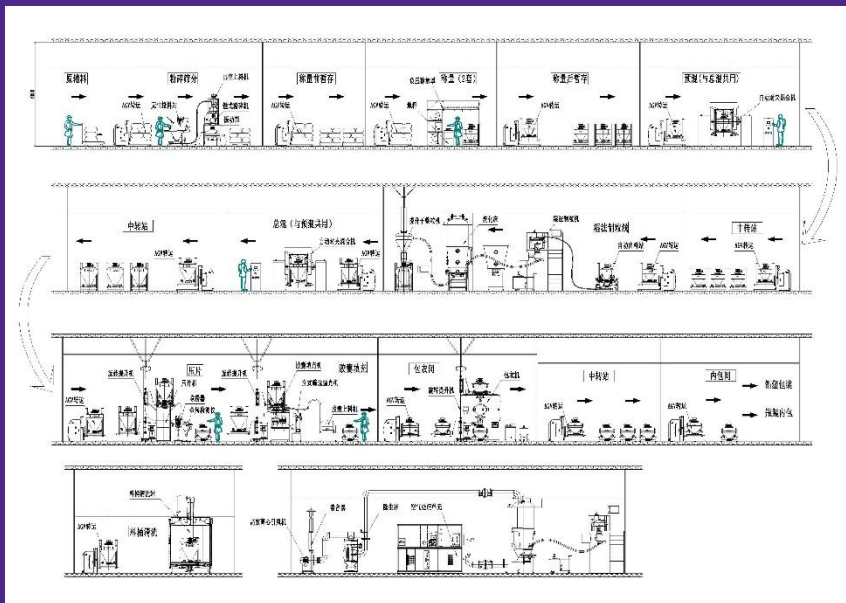
# Case study

- ◆ Year : 2015
- ◆ Location : Suzhou, Jiangsu
- ◆ Regulation: GMP/ FDA/OEB4
- ◆ Process : OSD roller compactor,
- ◆ Scope : Design (CD/BD), containment strategy, isolator, DFB, roller compactor, capsule filling machine, SBV, validation service, water system, HVAC system
- ◆ Benefit :The production line products are aimed at the North American market and meet the data integrity requirements of FDA and cGMP



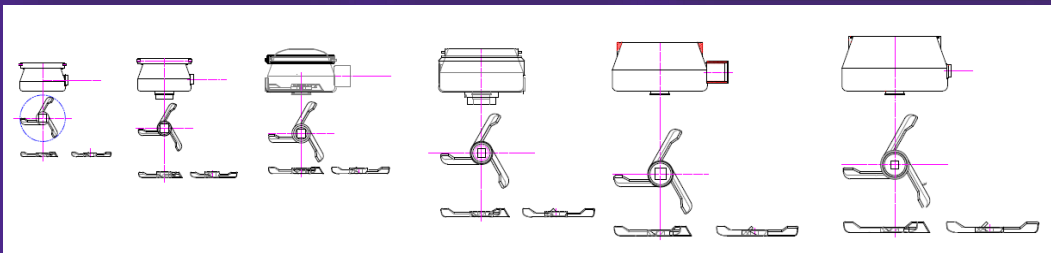
# Case study

- ◆ Year : 2020
- ◆ Location : Heze, Shandong
- ◆ Regulation: GMP/ FDA/EU-GMP
- ◆ Process : OSD table, capsule
- ◆ Scope : Charging station, mill, sieve, weighing, granulation, blending, tablet compressing, coating
- ◆ Benefit : This project is a key construction project supported by the government, with "intelligent manufacturing" as the core and designed according to the Industry 4.0 intelligent manufacturing plan. Realizing unmanned material transfer systems



# Case study

- ◆ Year : 2019
- ◆ Location : Shunde, Guangdong
- ◆ Regulation: GMP
- ◆ Process : Wet granulation line, top spray granulation, Wurster coating
- ◆ Scope : HSG15 high shear mixer, FBDGC20 fluid bed
- ◆ Benefit : 0.5L, 1L, 2L, 4L, 6L, 8L, 15L granulator pot body achieves a working volume of 0.15L-11L, achieving a wider process coverage with special mixing and pot body design, achieving a single pot loading capacity of 20% -90% wider; The integrated application of PAT technology adopts an online torque sensor monitoring device to more scientifically determine the granulation endpoint



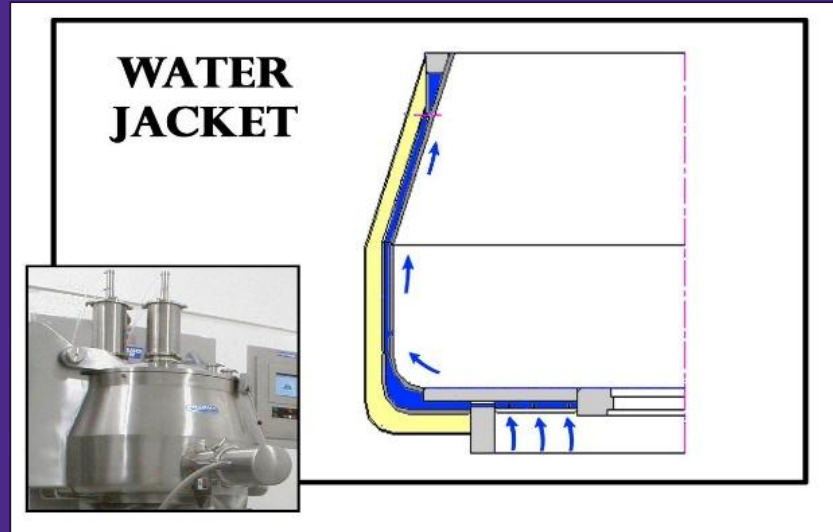
# Case study

- ◆ Year : 2018
- ◆ Location : Shunde, Guangdong
- ◆ Regulation: FDA
- ◆ Process : Wet granulation
- ◆ Scope : HSG300 high shear mixer
- ◆ Benefit : High viscosity slurry added, PAT achieves torque online endpoint judgment



# Case study

- ◆ Year : 2018
- ◆ Location : Zhenbaodao, Heilongjiang
- ◆ Regulation: GMP
- ◆ Process : Wet granulation
- ◆ Scope : HSG300 high shear mixer
- ◆ Benefit : Equipment replacement for more stable process control



# Case study

- ◆ Year : 2015
- ◆ Location : Ulan Bator, Mongolia
- ◆ Regulation: FDA/ EU-GMP
- ◆ Process : Wet granulation, tablet, capsule
- ◆ Scope : Design services (CD/BD/DD), process production systems, material transfer and feeding systems, clean engineering, pure water systems, validation services
- ◆ Benefit : Integrate domestic resources and launch overseas TK projects



# Case study

AMSTAR

- ◆ Year : 2015
- ◆ Location : Seoul, Korean
- ◆ Regulation: FDA/ EU-GMP/K-GMP
- ◆ Process : Wet granulation, tablet, capsule
- ◆ Scope : Process equipment TK (wet granulation machine+ fluidized bed+ tablet press+ capsule machine+ coating machine+ blister machine+ counting machine+ light inspection machine), verification services
- ◆ Benefit : Integrate domestic resources and launch overseas TK projects

**INTRO** BIO PHARMA



# Case study

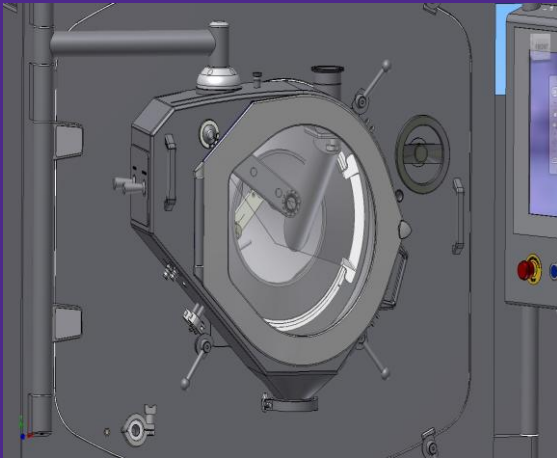
- ◆ Year : 2020
- ◆ Location : Wuxi, Jiangsu
- ◆ Regulation: FDA/ GMP
- ◆ Process : tablet coating
- ◆ Scope : Thomas Flex100, Flex200, installation & commissioning



# Case study

AUSTAR

- ◆ Year : 2020
- ◆ Location : Wuxi, Jiangsu
- ◆ Regulation: FDA/ GMP
- ◆ Process : OEB 5 tablet coating
- ◆ Scope : Flex200, installation & commissioning



# Case study

- ◆ Year : 2020
- ◆ Location : Guangzhou, Guangdong
- ◆ Regulation: FDA
- ◆ Process : tablet coating
- ◆ Scope : AC Pro 60XC \*2, installation & commissioning
- ◆ Benefit :The construction of a new international workshop project has optimized the existing product coating process, reducing the coating time from 20 hours to less than 5 hours



# Case study

- ◆ Year : 2017
- ◆ Location : Tianjin
- ◆ Regulation: FDA (CDMO)
- ◆ Process : tablet coating
- ◆ Scope : Flex05, Flex100, installation & commissioning
- ◆ Benefit : Helping customers establish a CDMO platform to achieve tablet coating technology, this equipment is the only mature technology in the industry to achieve pilot batch micro pill coating, serving domestic and foreign pharmaceutical companies for subsequent new drug research and development



technology



# Case study

- ◆ Year : 2015
- ◆ Location : Wuxi, Jiangsu
- ◆ Regulation: FDA
- ◆ Process : tablet coating
- ◆ Scope : Flex 1000 \*3 , drum exchangeable
- ◆ Benefit : Helping customers complete the production scheduling of a single batch of 1200L loading capacity for Caerqi products, changing the process of coating a single batch through two sub batches, improving economic efficiency, and simplifying batch management



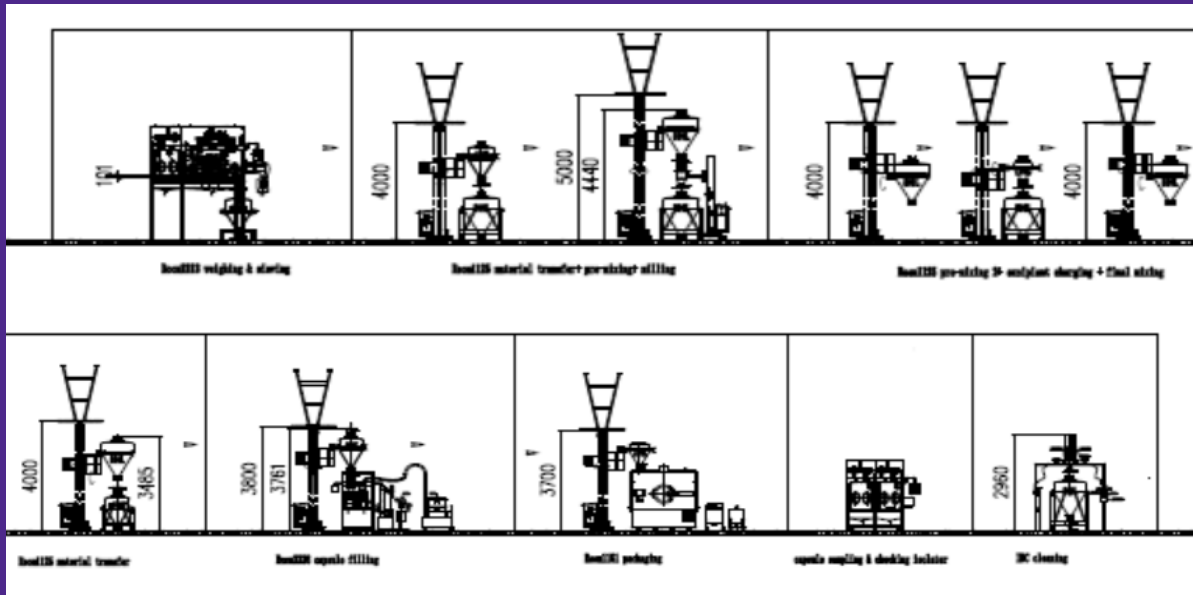
# Case study

- ◆ Year : 2011
- ◆ Location : Dongguan, Guangdong
- ◆ Regulation: FDA
- ◆ Process : tablet coating
- ◆ Scope : Lab 36, drum exchangeable
- ◆ Benefit : Assist customers in building an approval platform to meet the needs of pilot scale up process parameter development and establishment



# Case study

- ◆ Year : 2021
- ◆ Location : Jinan, Shandong
- ◆ Regulation: GMP/OEB4
- ◆ Process : capsule filling
- ◆ Scope : Equipment TK, isolator, hoister, SBV, BIN washing station, SMEPAC test service.
- ◆ Benefit : " one shirt " production concept, containment target data support



# Case study

- ◆ Year : 2021
- ◆ Location : Chengdu, Sichuan
- ◆ Regulation: GMP/OEB4
- ◆ Process : OSD line
- ◆ Scope : Containment transfer strategy, SBV
- ◆ Benefit : " one shirt " production concept



# Case study

AUSTAR

- ◆ Year : 2021
- ◆ Location : Zhejiang & Heilongjiang
- ◆ Regulation: GMP/FDA/OEB5
- ◆ Process : HME, roller compactor
- ◆ Scope : HME, roller compactor with isolator
- ◆ Benefit : AUSTAR containment Isolation and Material Transfer System, Alexander roller compactor from Germany, Leistritz Hot Melt Extruder from Germany; Integrated sealing system, providing customized sealing solutions for non-standard equipment



# Case study

- ◆ Year : 2021
- ◆ Location : Chongqing
- ◆ Regulation: GMP/FDA/EU-GMP/OEB5
- ◆ Process : roller compactor
- ◆ Scope : Weighing isolator, roller compactor with isolator, SMEPAC test
- ◆ Benefit : A highly enclosed OEB5 OSD R&D and pilot platform that complies with industry-leading regulations, gaining greater competitive advantage in the CDMO market



# Case study

- ◆ Year : 2022
- ◆ Location : Shijiazhuang, Hebei
- ◆ Regulation: GMP/FDA/EU-GMP/OEB5
- ◆ Process : Flexible production line for cytotoxic API
- ◆ Scope : Weighing isolator, material transferring system, API reaction module, SMEPAC test
- ◆ Benefit : A more flexible API production system and a highly enclosed OEB5 API pilot platform that complies with industry-leading regulations



# Case study

- ◆ Year : 2018
- ◆ Location : Wuxi, Jiangsu
- ◆ Regulation: FDA/OEB5
- ◆ Process : Flexible production line for cytotoxic API
- ◆ Scope : Weighing isolator, SMEPAC test
- ◆ Benefit : The overall operation has achieved a high level of airtightness, reaching OEB5; The sealed chamber is combined with a continuous bag transfer type to achieve high sealing level transmission and easy operation; Closed integration of glass reaction kettle, closed docking and interlocking control



# Case study

AUSTAR


- ◆ Year : 2017
- ◆ Location : Wuxi, Jiangsu
- ◆ Regulation: FDA/OEB5
- ◆ Process : High toxicity, high activity, and sterile API for anticancer drugs
- ◆ Scope : Weighing isolator, PSL nutche dryer, jet mill, RTP transfer system
- ◆ Benefit : The overall operation has achieved a high level of aseptic sealing, reaching OEB5; PSL's three in one approach is aimed at high value-added small batch products, achieving a high recovery rate of up to 99.5%; RTP transfer mode is adopted between two high sealed isolators, achieving high sealing level transmission and easy operation;



# Case study

- ◆ Year : 2017
- ◆ Location : Suzhou, Jiangsu
- ◆ Regulation: GMP/FDA/OEB5
- ◆ Process : High toxicity, high activity, and sterile API for anticancer drugs
- ◆ Scope : Weighing isolator, nutche dryer, reaction tank, crystallization tank
- ◆ Benefit : The overall operation has achieved a high level of airtightness, reaching OEB5; Close transportation and docking of reaction kettle, crystallization tank, and nutche dryer;



  
HIGH PEAKS ASSOCIATES  
CONSULTING

Industrial Hygiene Monitoring Report

---

Title: Isolator SMEPAC Testing  
Location: BrightGene, Suzhou, Jiangsu, China  
Monitoring Date(s): December 8-10, 2020  
Issue Date: February 18, 2021  
Author: Barry Ballinger, CIH  
Managing Director, HPA Consulting  
[CP7801 ABIH Public Roster Credential Search](#)  
To: Hardy Hu, Arthur Rong, Harriet Wang

---

**EXECUTIVE SUMMARY**  
An industrial hygiene assessment was undertaken at the BrightGene, Suzhou facility over the course of three days, December 8<sup>th</sup> through 10<sup>th</sup>, 2020 to assess the containment performance of two installed glovebox isolators that were supplied, commissioned and installed by Anstar. Specifically, evaluations were performed to assess the containment performance of the gloveboxes using simulated work practices with Lactose as a surrogate testing material in all sections of the isolators including packaging. The following processes were tested as stated in the written test protocol and established on December 8<sup>th</sup> (See Attachment 1, Written Test Protocol)

- Left section of Isolator #1, Reaction chamber
- Right section of Isolator #1, Weighing chamber
- Left section of Isolator #2, Refining chamber
- Right section of Isolator #2, Weighing and Packaging Chamber

As a result of this assessment, it has been determined both isolators passed the test. All personal and area samples for both isolators were found to be below the design test limit of 1.0 µg/m<sup>3</sup>. (See Table 2 for full results)



# Case study

AUSTAR



仙琚制药

- ◆ Year : 2018
- ◆ Location : Taizhou, Zhejiang
- ◆ Regulation: GMP/FDA/OEB4
- ◆ Process : dry powder inhaler
- ◆ Scope : Weighing isolator
- ◆ Benefit : The overall operation has achieved a high level of airtightness, reaching OEB4; RTP transfer mode is adopted between two high sealed isolators, achieving high sealing level transmission and easy operation



# Case study

AU STAR



- ◆ Year : 2019
- ◆ Location : Xinxiang, Henan
- ◆ Regulation: GMP
- ◆ Process : Vaccine
- ◆ Scope : P3 level biosafety isolator, STERIS VHP sterilization, BIBO safety replacement filter, RTP system, CO2 virus incubator
- ◆ Benefit : Adopting fully automatic hydrogen peroxide biological sterilizer. A rapid response system for the pressure inside the isolator chamber. Specially designed glove installation structure allows for glove replacement without further damage to the enclosed environment when gloves are damaged



# Case study



- ◆ Year : 2019
- ◆ Location : Yantai, Shandong
- ◆ Regulation: GMP/FDA/EU-GMP
- ◆ Process : Psych hormone OEB4, sterile powder filling
- ◆ Scope : OEB4 grade aseptic filling isolator, M&O Perry powder packaging, STERIS VHP sterilization system, RTP closed transfer, BIBO safe replacement high-efficiency filtration, particle planktonic bacteria environmental monitoring system, atmospheric pressure control system, etc
- ◆ Benefit : The overall operation has achieved a high level of airtightness, reaching OEB4. The rapid response system for the pressure inside the isolator chamber prevents API diffusion into the production environment; Use highly sealed RTP valves and buckets for material transportation; Adopting fully automatic hydrogen peroxide biological sterilizer;



# Case study

AUSTAR

- ◆ Year : 2019
- ◆ Location : Yantai, Shandong
- ◆ Regulation: GMP/FDA
- ◆ Process : High toxicity and high activity API for anticancer drugs
- ◆ Scope : OEB5 negative pressure isolator, weighing system, and dispensing system
- ◆ Benefit : The overall operation has achieved a high level of airtightness, reaching OEB5; Weighing and airtight transfer of toxic small molecules;

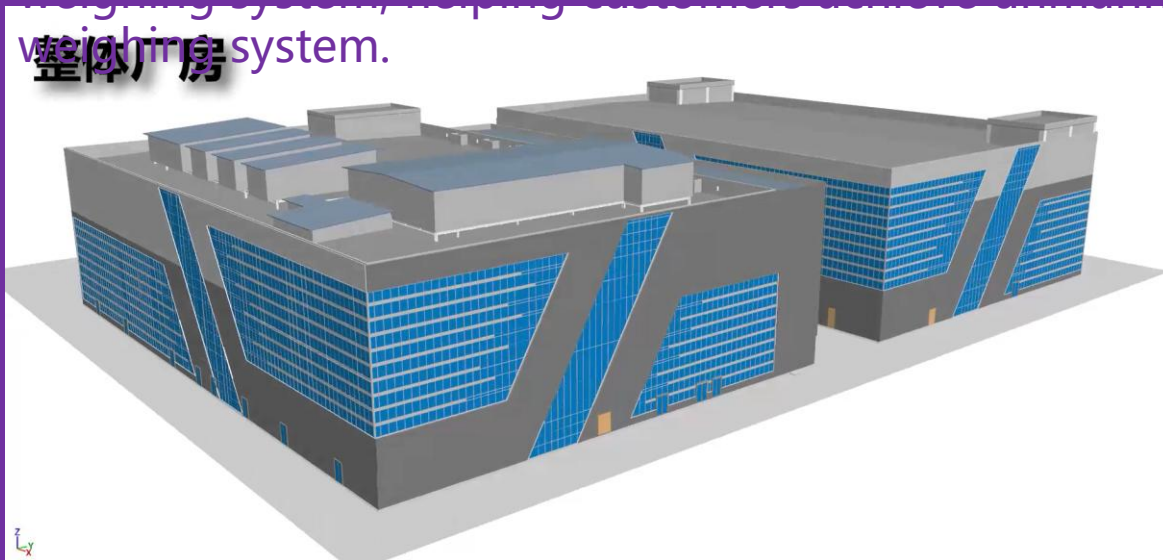


# Case study



- ◆ Year : 2020
- ◆ Location : Shijiazhuang, Hebei
- ◆ Regulation: GMP/FDA
- ◆ Process : Automatic weighing system and material management system TK for 15 billion solid formulations
- ◆ Scope : Integrate MES and material control systems, WCS systems, AGV scheduling systems, and automatic weighing systems
- ◆ Benefit : The first automated logistics transportation and weighing system for billions of tablets in China. Automatic material unpacking, material identification, coding, automatic transmission and transportation, material purification, crushing and screening, automatic weighing system, AGV transportation overall packaging project, integrating MES and material control system, WCS system, AGV scheduling system to provide customers with intelligent and information-based automatic material transportation and automatic

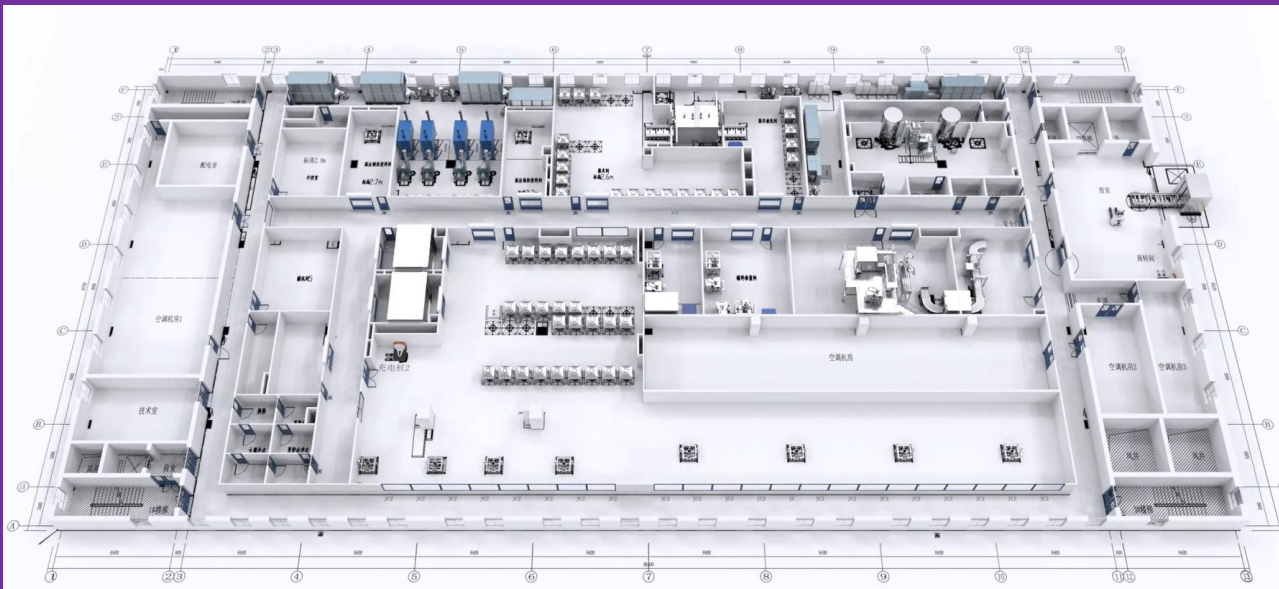
weighing system,  
weighing system.  
整体厂房



# Case study



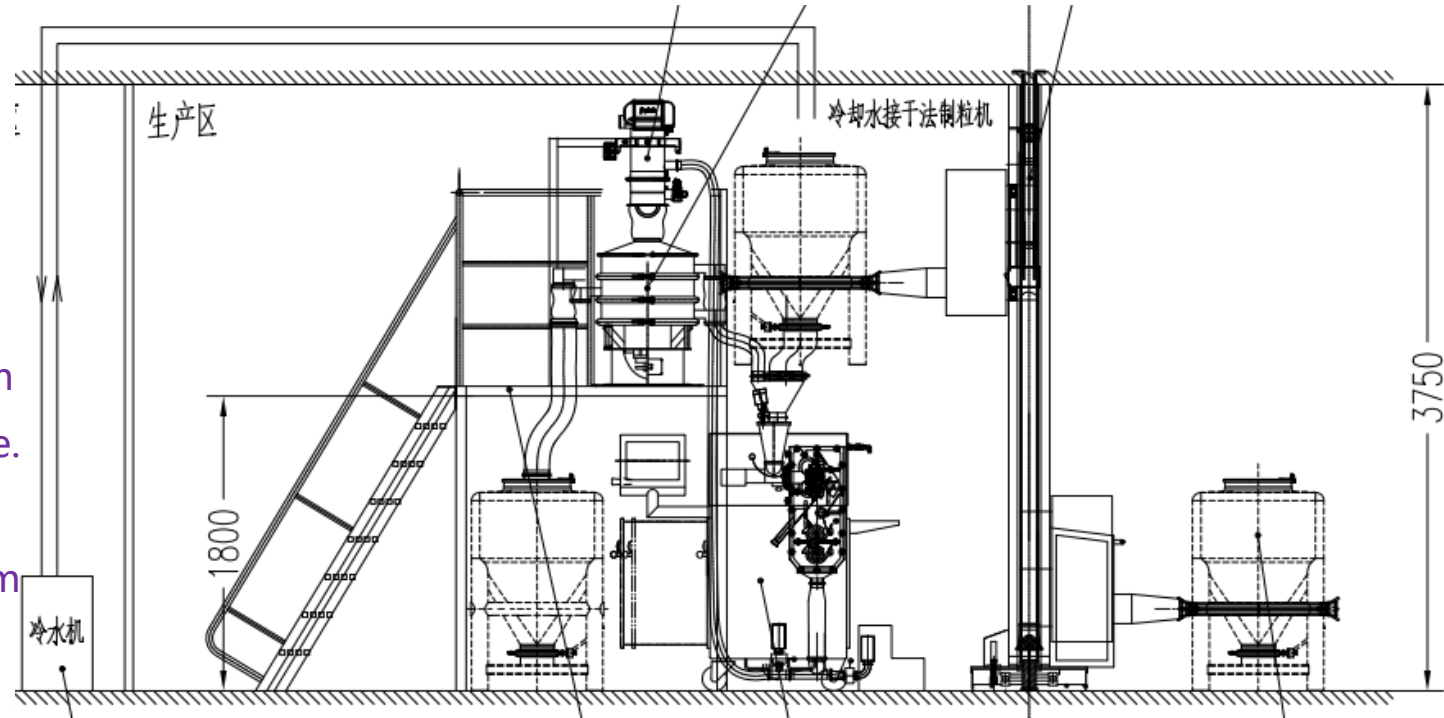
- ◆ Year : 2021
- ◆ Location : Haikou, Hainan
- ◆ Regulation: GMP
- ◆ Process : OSD Process System&Material Management System TK
- ◆ Scope : Integrate MES and material control systems, WCS systems, and AGV scheduling systems
- ◆ Benefit : The overall packaging project for logistics transportation integrates MES and material control systems, WCS systems, and AGV scheduling systems to achieve unmanned production of workshop material transfer systems, and to achieve automatic interaction between AGV and factory facilities, process equipment, and outdoor logistics transportation systems.



## Zhaoke Pharmaceutical Limited

### Scope of supply:

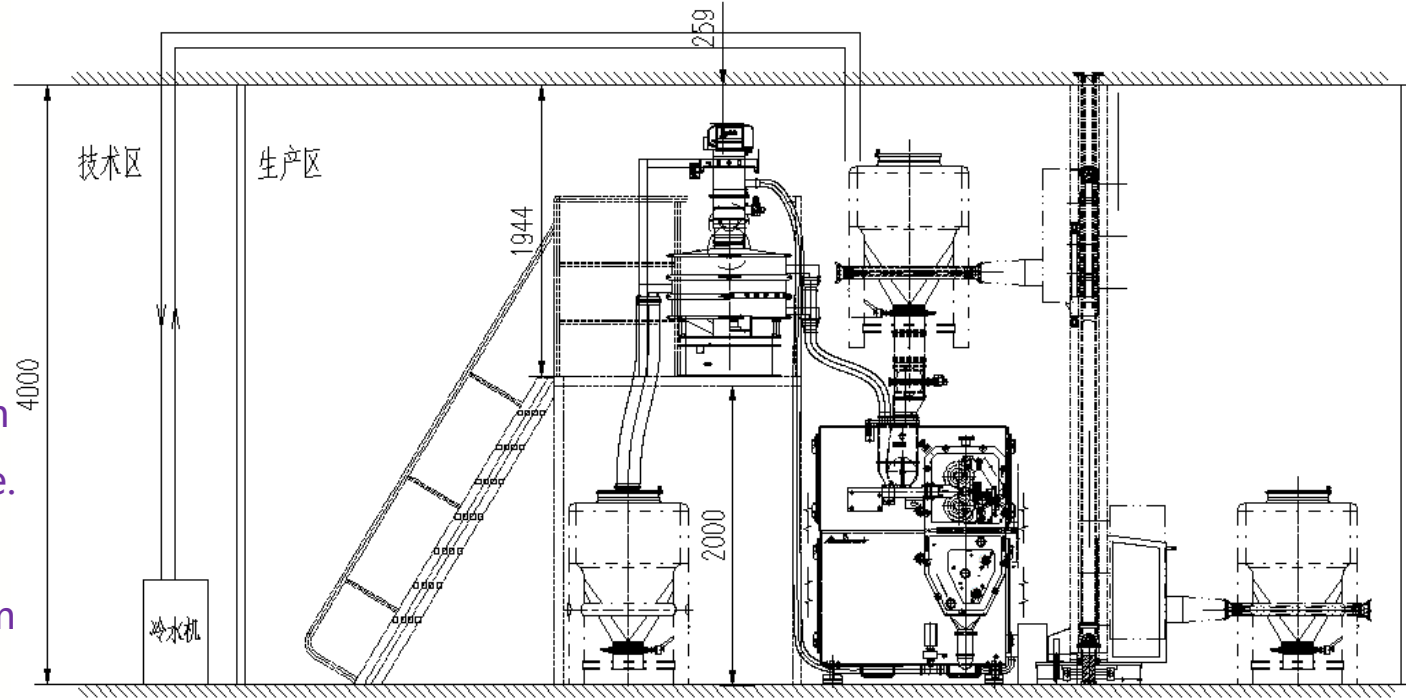
- ◆ Vacuum loader: 1 set, PIAB, P.P200
- ◆ Sieving machine: 1 set, S49-1000-LB-2S
- ◆ Steel platform: 1 set, Used to install vacuum loader and sieving machine
- ◆ Lifter: 1 set
- ◆ Connecting pipes: 1 set, including the pipe of vacuum loader and the connecting pipes between IBC and valve.
- ◆ Control system: 1 set, used to control the vacuum loader and sieving machine. And receive the signal from level control of roller compactor.
- ◆ Buffer bin: 1 set.
- ◆ Installation and commissioning:
  1. The installation of steel platform, vacuum loader, lifter, sieving machine and pipes.
  2. Electrical installation between roller compactor and control system, including making and installation of the bridge of cables, wiring.
  3. Electrical installation and pipes connection between roller compactor and re-cooling unit.



## Hinye Pharmaceutical Co., Ltd

### Scope of supply:

- ◆ Vacuum loader: 1 set, PIAB, P.P200
- ◆ Sieving machine: 1 set, S49-1000-LB-2S
- ◆ Steel platform: 1 set, Used to install vacuum loader and sieving machine
- ◆ Lifter: 1 set
- ◆ Connecting pipes: 1 set, including the pipe of vacuum loader and the connecting pipes between IBC and valve.
- ◆ Control system: 1 set, used to control the vacuum loader and sieving machine. And receive the signal from level control of roller compactor.
- ◆ Buffer bin: 1 set.
- ◆ Installation and commissioning:
  1. The installation of steel platform, vacuum loader, lifter, sieving machine and pipes.
  2. Electrical installation between roller compactor and control system, including making and installation of the bridge of cables, wiring.
  3. Electrical installation and pipes connection between roller compactor and re-cooling unit.

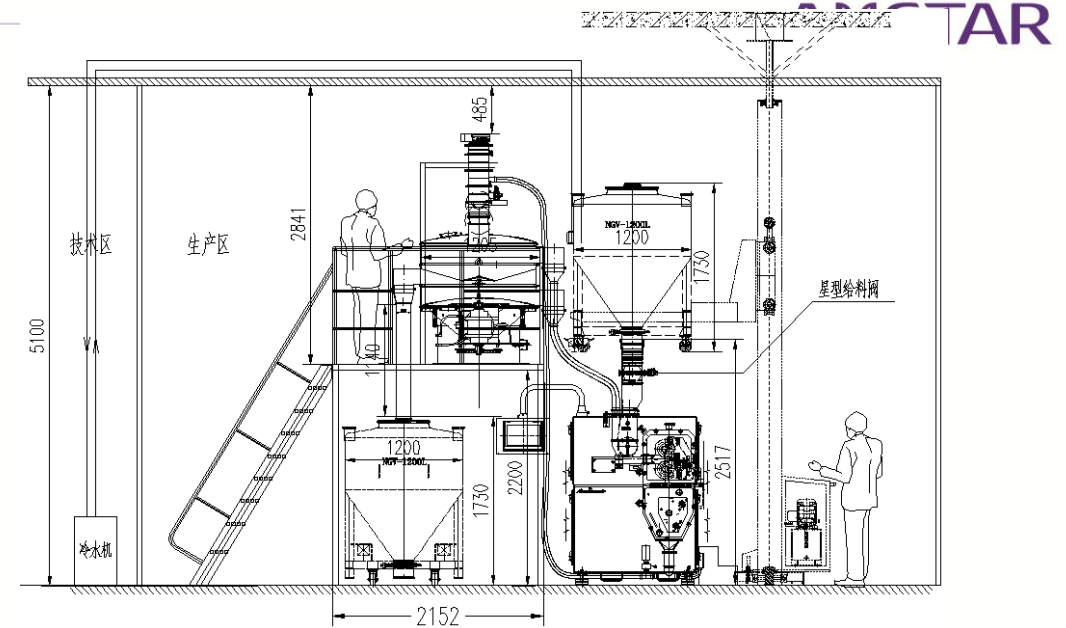


# Application-Screening circulatory system of Roller Compactor

## Qilu Pharmaceutical Co., Ltd (workshop 6500)

### Scope of supply:

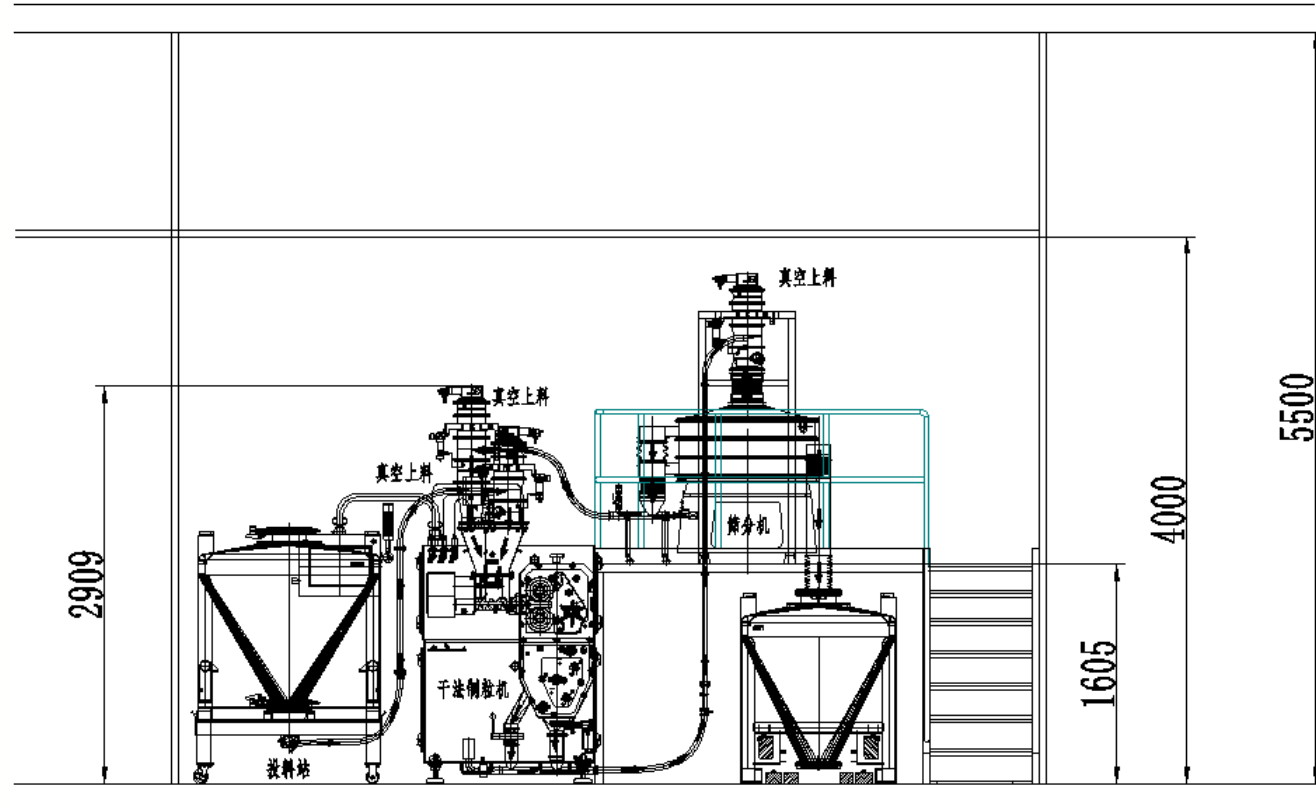
- ◆ Vacuum loader: 1 set, PIAB, P.P200
- ◆ Sieving machine: 1 set, S49-1000-LB-2S
- ◆ Steel platform: 1 set, Used to install vacuum loader and sieving machine
- ◆ Lifter: 1 set
- ◆ Connecting pipes: 1 set, including the pipe of vacuum loader and the connecting pipes between IBC and valve.
- ◆ Control system: 1 set, used to control the vacuum loader and sieving machine. And receive the signal from level control of roller compactor.
- ◆ Buffer bin: 1 set.
- ◆ Installation and commissioning:
  1. The installation of steel platform, vacuum loader, lifter, sieving machine and pipes.
  2. Electrical installation between roller compactor and control system, including making and installation of the bridge of cables, wiring.
  3. Electrical installation and pipes connection between roller compactor



## Qilu Pharmaceutical Co., Ltd (workshop 18)

Scope of supply:

- ◆ Vacuum loader: 3 sets, PIAB, P.P200
- ◆ Sieving machine: 1 set, S49-1000-LB-2S
- ◆ Steel platform: 1 set, Used to install vacuum loader and sieving machine
- ◆ Connecting pipes: 1 set, including the pipe of vacuum loader and the connecting pipes between IBC and valve.
- ◆ Control system: 1 set, used to control the vacuum loader and sieving machine. And receive the signal from level control of roller compactor.
- ◆ Buffer bin: 2 set.
- ◆ Installation and commissioning:
  1. The installation of steel platform, vacuum loader, lifter, sieving machine and pipes.
  2. Electrical installation between roller compactor and control system, including making and installation of the bridge of cables, wiring.
  3. Electrical installation and pipes connection between roller compactor and re-cooling unit.



## Hutchison Medi Pharma

Scope of supply:

- ◆ Vacuum loader: 1 set, PIAB, P.P200
- ◆ Sieving machine: 1 set, S49-800-LB-2S
- ◆ Lifter: 2 set
- ◆ Connecting pipes: 1 set, including the pipe of vacuum loader and the connecting pipes between IBC and valve.
- ◆ Control system: 1 set, used to control the vacuum loader and sieving machine. And receive the signal from level control of roller compactor.
- ◆ Buffer bin: 1 set.
  
- ◆ Installation and commissioning:
  1. The installation of vacuum loader, lifter, sieving machine and pipes.
  2. Electrical installation between roller compactor and control system, including making and installation of the bridge of cables, wiring.

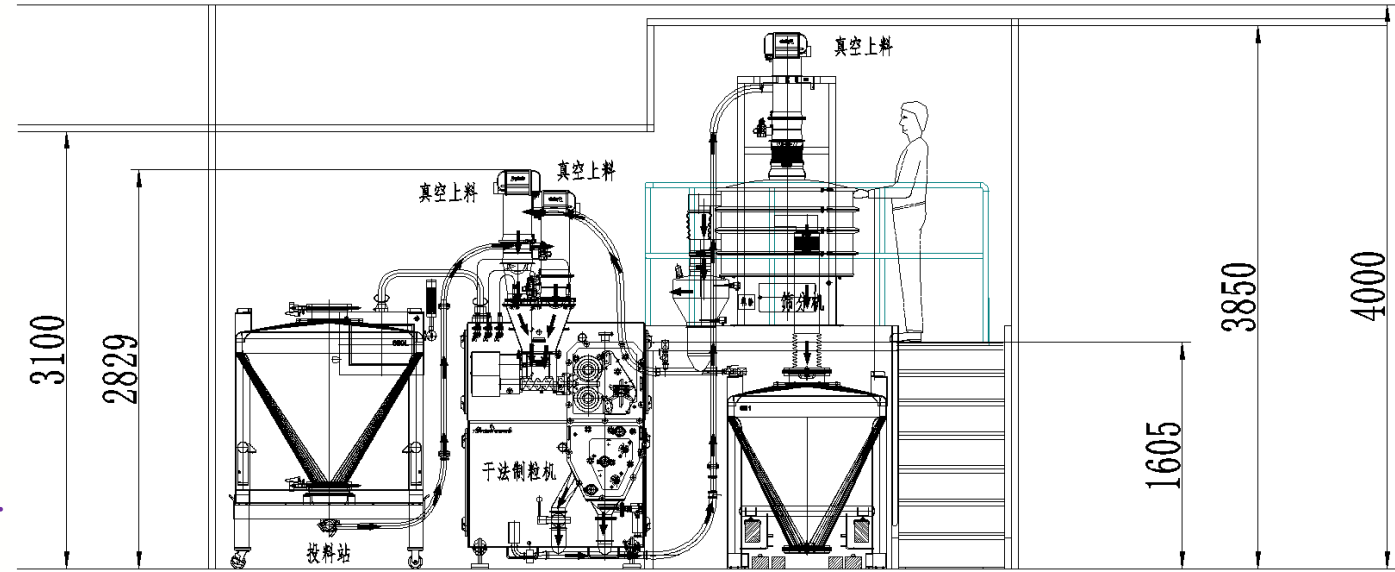


# Application-Screening circulatory system of Roller Compactor

## Fosun Pharmaceutical (xuzhou) Co., Ltd

### Scope of supply:

- ◆ Vacuum loader: 3 sets, PIAB, P.P100
- ◆ Sieving machine: 1 set, S49-1000-LB-2S
- ◆ Steel platform: 1 set, Used to install vacuum loader and sieving machine
- ◆ Moving step ladder: 1 set
- ◆ Connecting pipes: 1 set, including the pipe of vacuum loader and the connecting pipes between IBC and valve.
- ◆ Control system: 1 set, used to control the vacuum loader and sieving machine. And receive the signal from level control of roller compactor.
- ◆ Buffer bin: 2 set.
- ◆ Installation and commissioning:
  1. The installation of steel platform, vacuum loader, lifter, sieving machine and pipes.
  2. Electrical installation between roller compactor and control system, including making and installation of the bridge of cables, wiring.



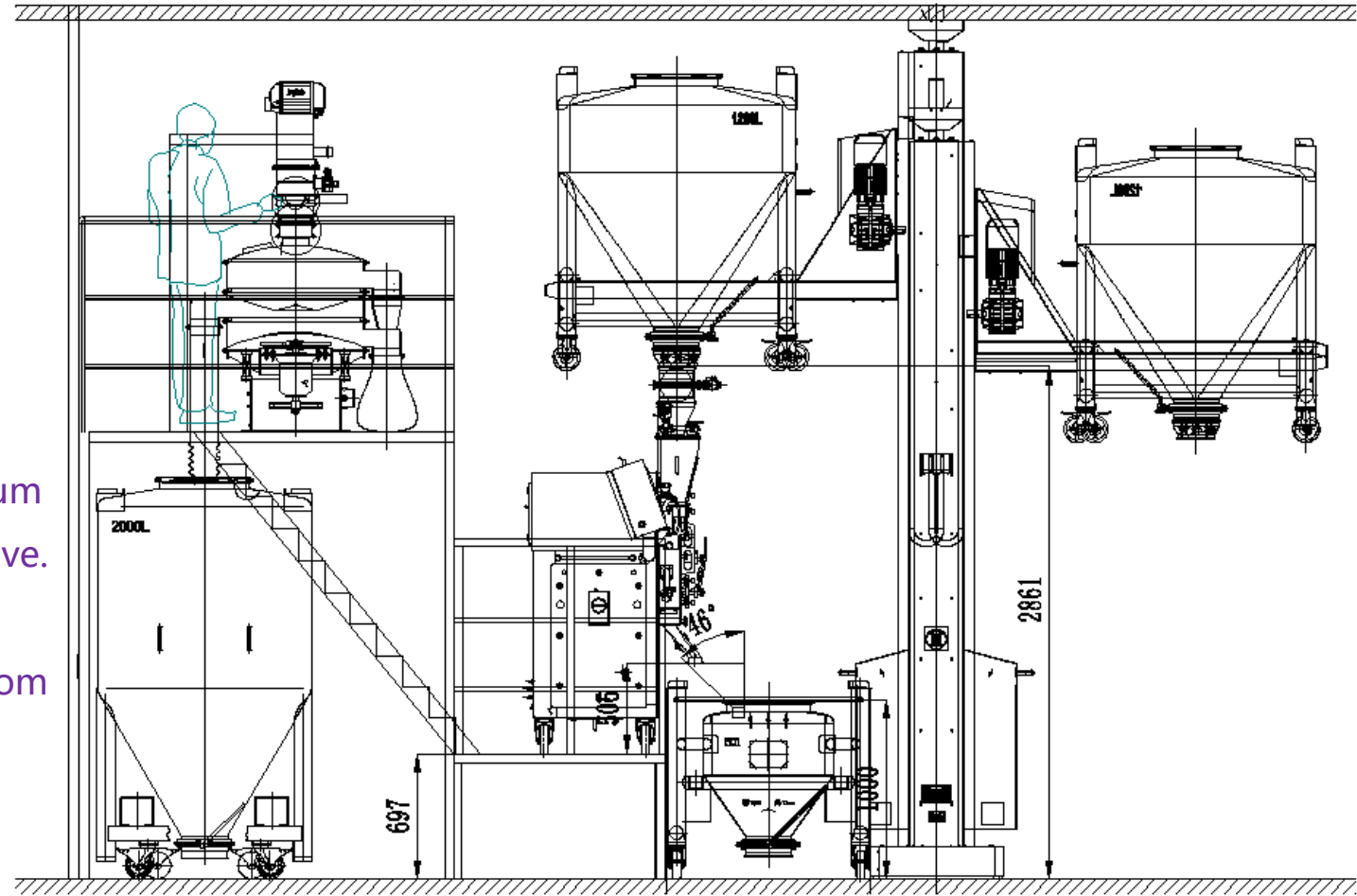
# Application-Screening circulatory system of Roller Compactor

## BeiGene (SuZhou) Co., Ltd

### Scope of supply:

- ◆ Vacuum loader: 1 set, PIAB, P.P100
- ◆ Sieving machine: 1 set, S49-800-LB-2S
- ◆ Steel platform: 1 set, Used to install vacuum loader and sieving machine
- ◆ Lifter: 1 set
- ◆ Connecting pipes: 1 set, including the pipe of vacuum loader and the connecting pipes between IBC and valve.
- ◆ Control system: 1 set, used to control the vacuum loader and sieving machine. And receive the signal from level control of roller compactor.
- ◆ Buffer bin: 1 set.
- ◆ Installation and commissioning:

1. The installation of steel platform, vacuum loader, lifter, sieving machine and pipes.
2. Electrical installation between roller compactor and control system, including making and installation of the bridge of cables, wiring.

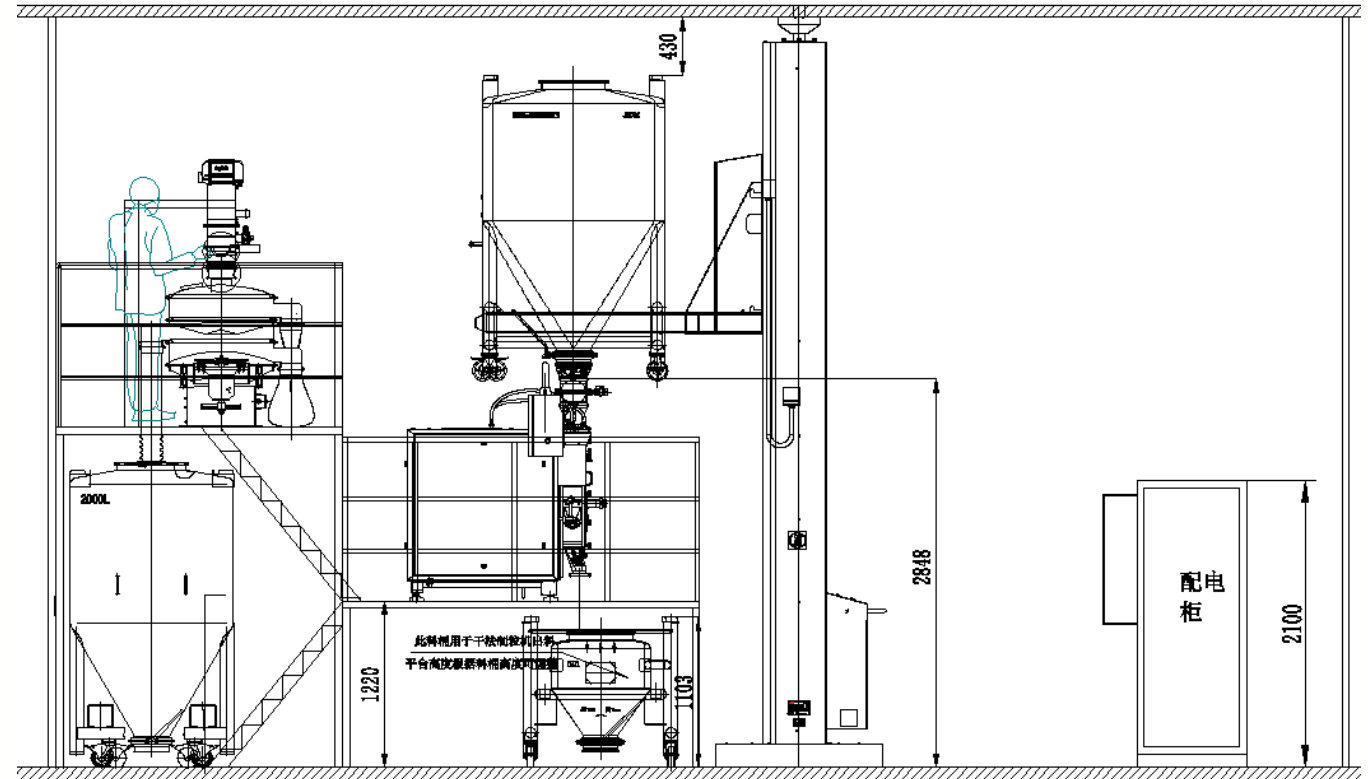


# Application-Screening circulatory system of Roller Compactor

## BeiGene (SuZhou) Co., Ltd

Scope of supply:

- ◆ Vacuum loader: 1 set, PIAB, P.P100
- ◆ Sieving machine: 1 set, S49-800-LB-2S
- ◆ Steel platform: 1 set, Used to install vacuum loader and sieving machine
- ◆ Lifter: 1 set
- ◆ Connecting pipes: 1 set, including the pipe of vacuum loader and the connecting pipes between IBC and valve.
- ◆ Control system: 1 set, used to control the vacuum loader and sieving machine. And receive the signal from level control of roller compactor.
- ◆ Buffer bin: 1 set.
- ◆ Installation and commissioning:
  1. The installation of steel platform, vacuum loader, lifter, sieving machine and pipes.
  2. Electrical installation between roller compactor and control system, including making and installation of the bridge of cables, wiring.





# Thanks

[www.austar.com.hk](http://www.austar.com.hk)