

AUSTAR

Brief Introduction of OSD Process System

Your OSD Solution Partner



Business Milestones

30+ Years' Growth
Dedicating to Providing
Exceptional Values to
Our Clients



Powder & Solid Process Systems

AUSTAR provides turnkey solutions for sophisticated production processes of pharmaceutical intermediates, API, OSD, and pharmaceutical excipients clients and offers a comprehensive service including formulation process technology, containment technology, innovative R&D, process design and project management.



Process Engineering Solution

- Turnkey solution
- Process system
- Core engineering equipment
- Components/Consumables

Process Design & Consultation

- Feasibility study
- Conceptual design
- Basic design
- Detailed design

Process Optimization Scale-up Research Services

- Process engineering laboratory
- Joint laboratory with partners
- Formulation technology experts
- Cooperation with universities

Introduction/Bio - Ron Ciaglia

Qualifications – Director of OSD Engineering and Technology with AEG

- Experience – Over 30 years Engineering, Design, Technical Sales and Support, Installation, Start Up Commissioning, Validation, & Processing of OSD equipment for the Pharmaceutical, food, flavor, Industrial and chemical facilities.
- Education
 - Bachelors Science Aerospace Engineering
 - Degree Mathematics
 - Degree Engineering Administration
 - EIT/FE professional engineer, Member of ISPE, SAE, AIAA, continued training/education
- System Engineering, Retrofits/Upgrades Support/Service
 - **High Shear Granulators (Mixer)** **Diosna, Glatt, Niro, Vector, Fluid Air**
 - **Fluid Bed Dyer/Granulation/Coating** **Glatt, Niro, Vector, Ohara Aeromatic, GEA, Fluid Air**
 - **Coating Pans** Thomas, Vector, Fryma, Glatt, O’Hara, Pelligrini
 - **Bead Making Systems / Pelletizing** (Maruemerizers/Extruder) LCI
 - **Spray Drier** Spraying System Fluid Air, Anhydro, SPX
 - **Milling** **Fluid Air, Fitzmill, Co-mill**
- Design, Installed, Commissioned, Validated systems in more than 22 countries on 5 continents, worked in china since 1998
- **Over 30 years of combined solid dosage processing expertise Tested, Developed or Manufactured over 1000 products.**
- **Numerous countries, Class of products, manufacturing levels**



Introduction of OSD technical Manager

Mr. Amrit Tiwari has more than 17 years of rich experience in execution of OSD & sterile projects (Greenfield and Brownfield Projects) , Business Development ,Installation & Commissioning, Maintenance ,Validation & Processing of OSD equipment in Pharmaceutical companies in different parts of world .

■ Past Companies & key equipment handled :

- ✓ High Shear Granulators (Mixer) Diosna, Glatt, GEA ,ACG worldwide ,Tapasya
- ✓ Fluid Bed , Wurster ,Flexstream based Fluid Beds – Glatt, GEA, ACG Worldwide
- ✓ Coating Pans – Glatt ,ACG worldwide, Sejong
- ✓ Tablet Press – GEA, Sejong
- ✓ Continuous Granulation – Glatt , GEA
- ✓ Sandoz India Ltd (Novartis Group)



Topics

01

What can we provide to the OSD Process System

02

Experience Sharing

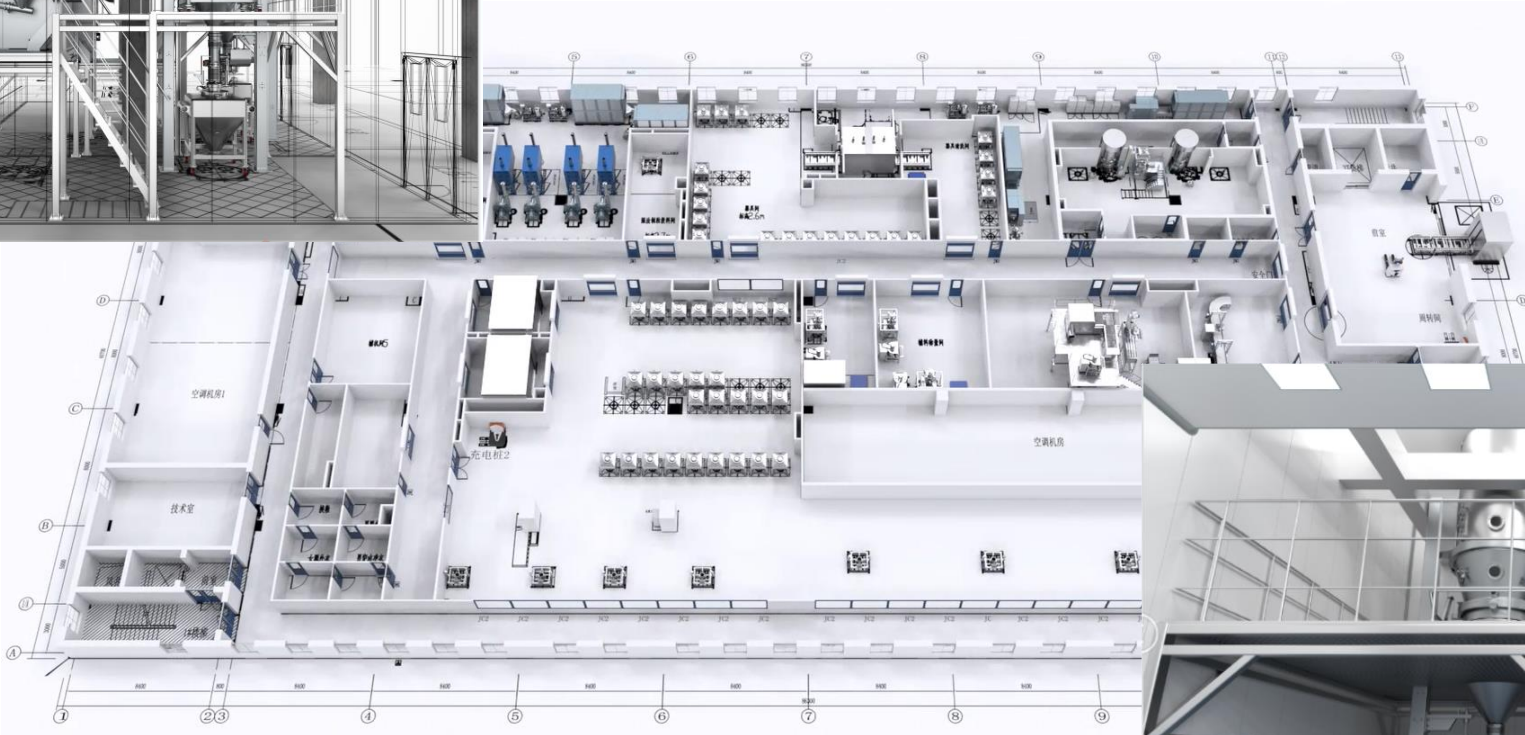
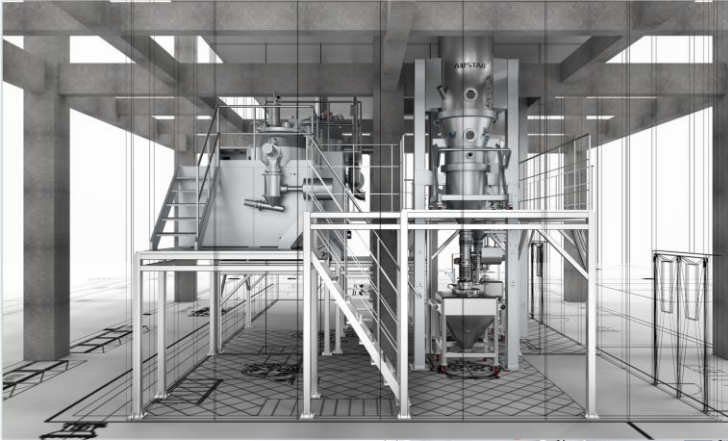
03

Advanced Tech/Competitive Advantage of AEG

04

About PSS

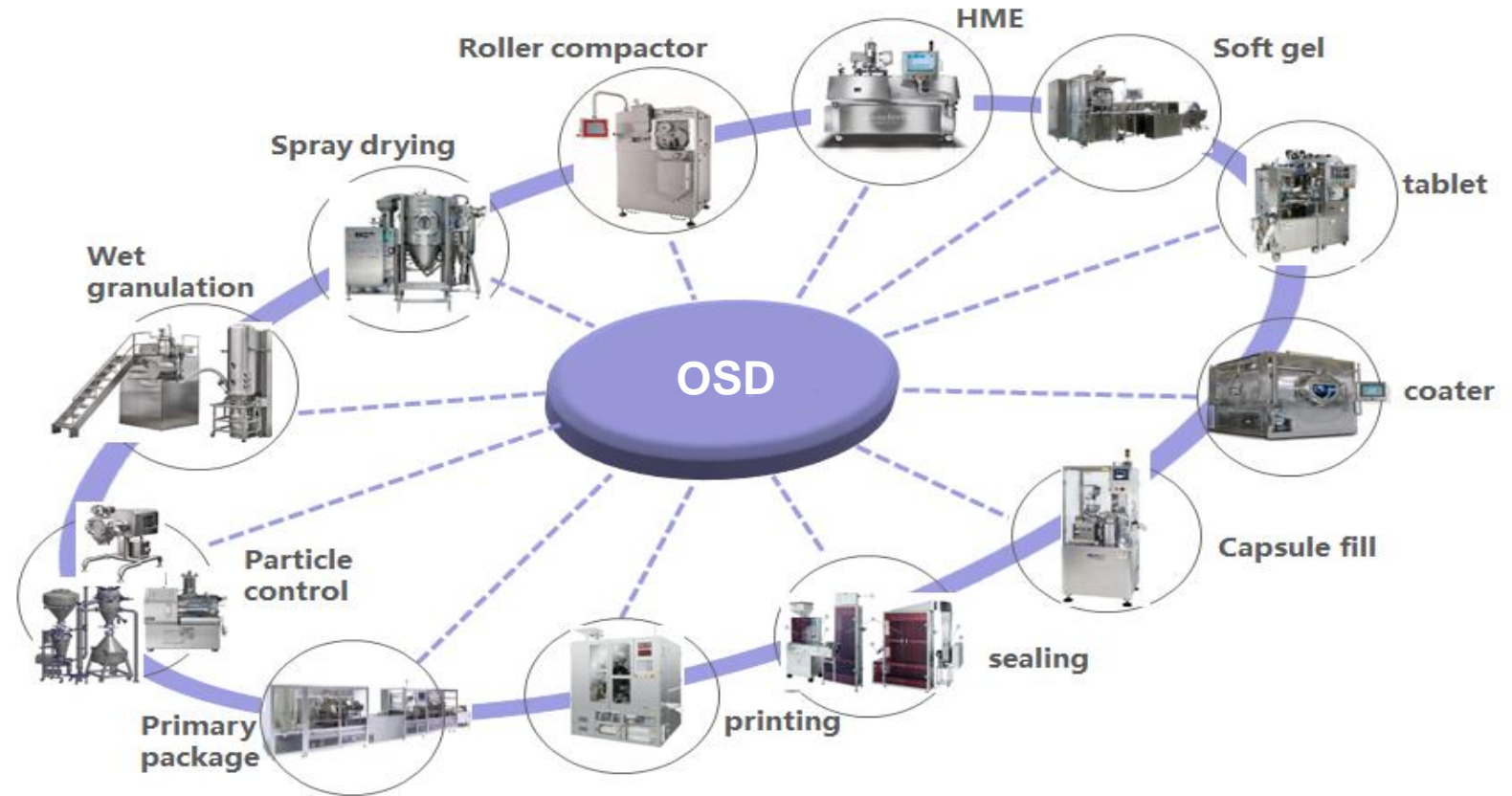
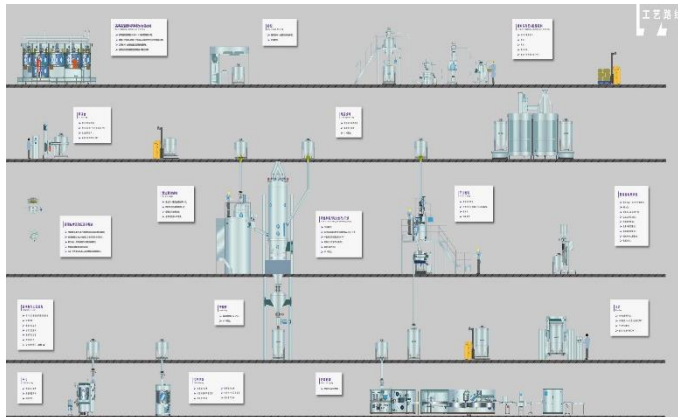
OSD Process Systematic Solution



OSD Process Systematic Solution

OSD project—High quality resource integration ability

- Mainly focus on Formulation technology
- Lab scale machine from world leading technology providers
- Solid oral dosage engineering team with rich experience
- Various partners provide professional engineering support



OSD Formulation/Lab Equipment/Process Service



Nutsch Filter



Bead Mill



Hammer Mill



Jet Mill



Impact Mill



Extruder



Roller Compactor



High Shear Mixer



Fluid bed



TURBULA®
Mixer



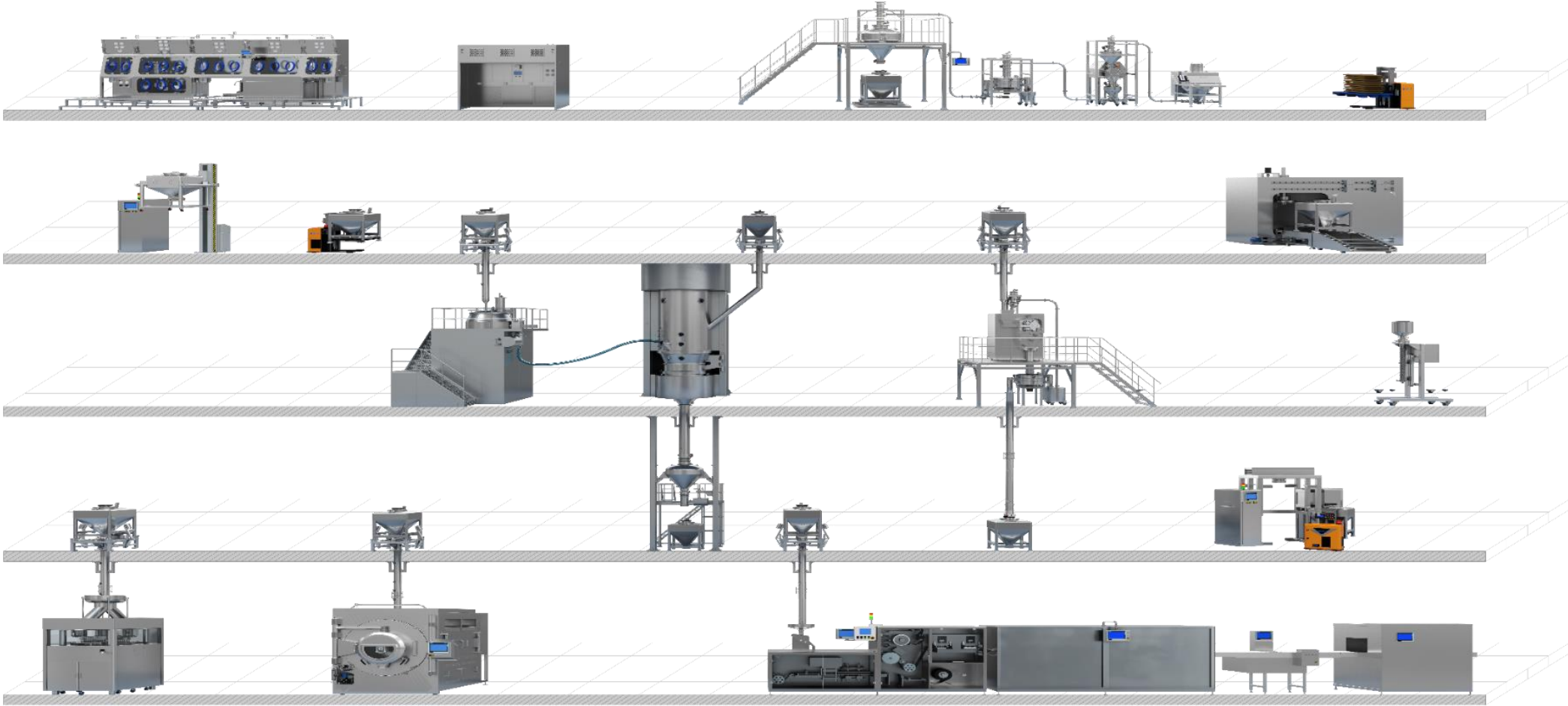
Tablet Coater



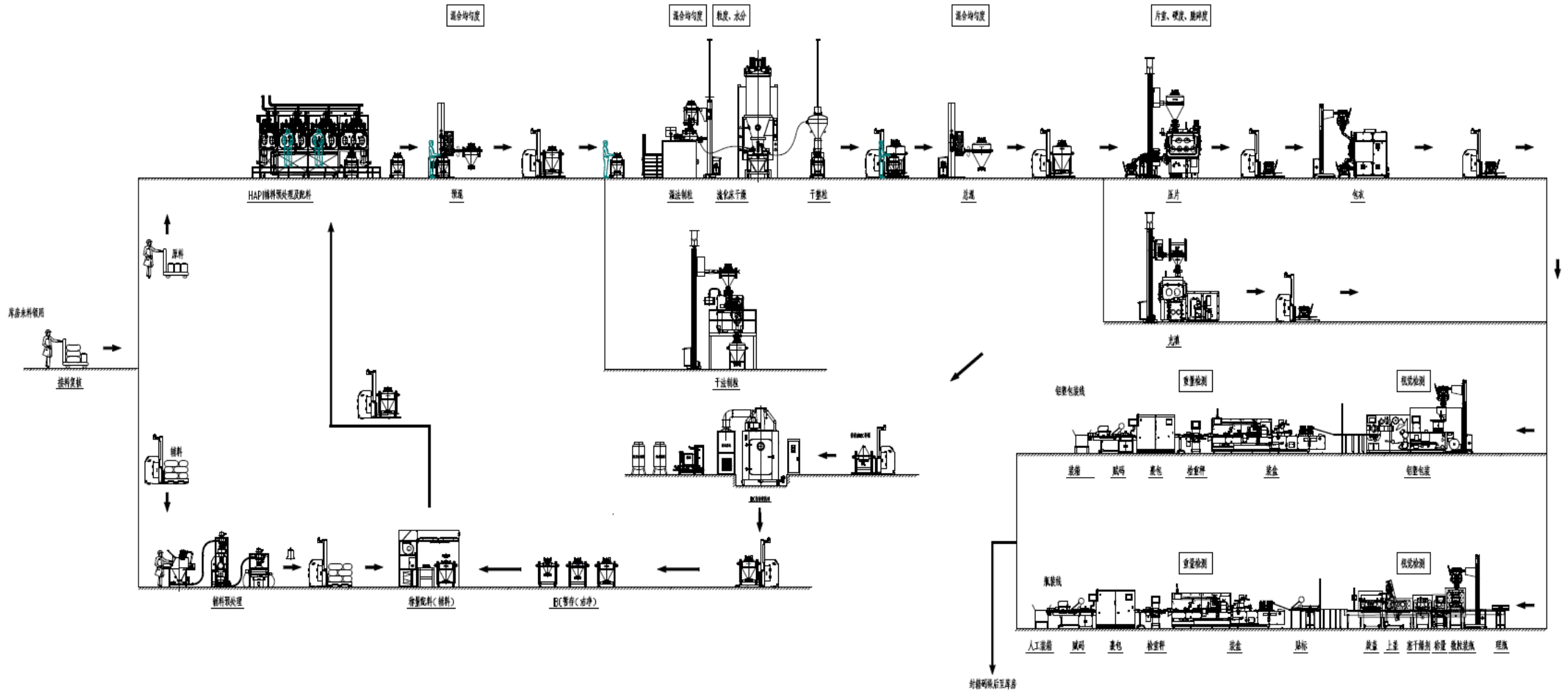
Soft capsule
filling



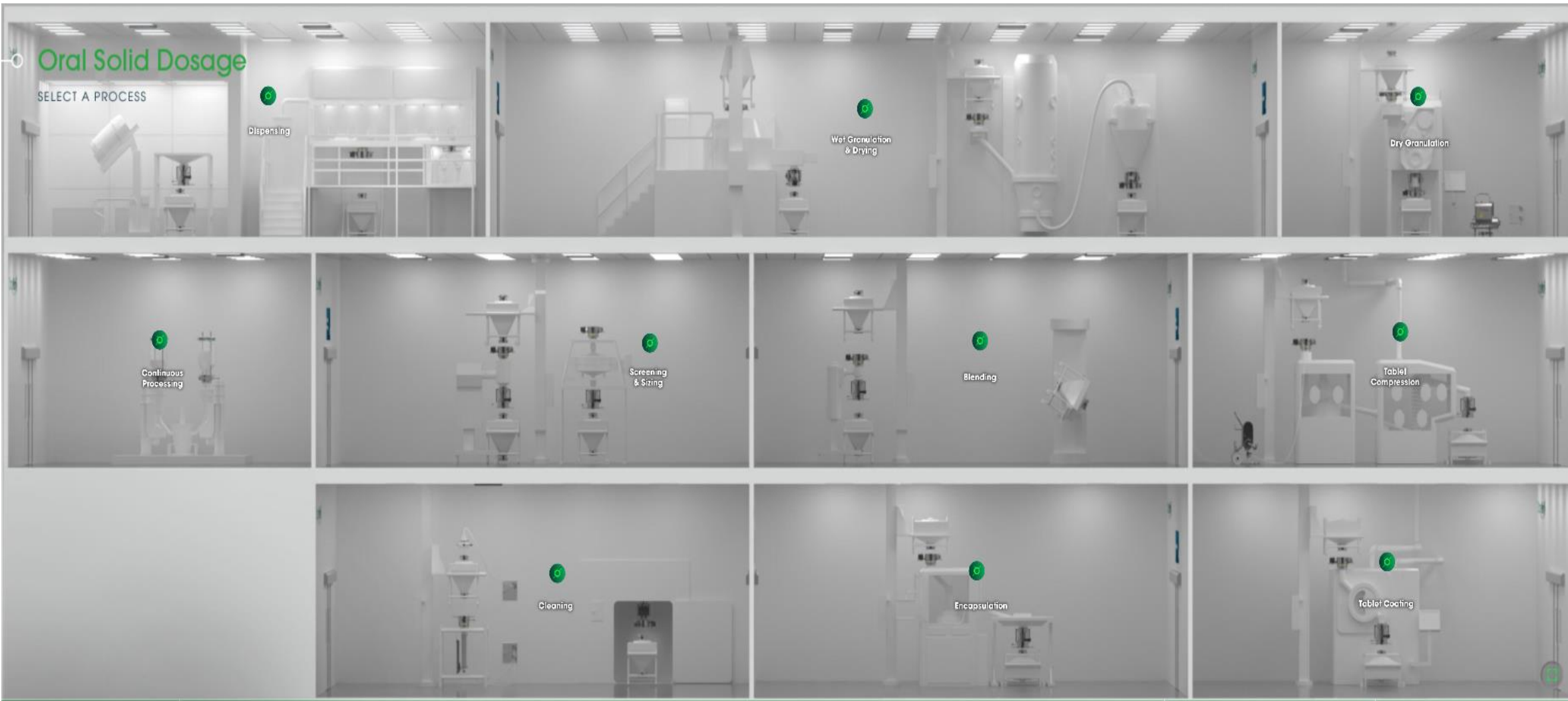
OSD Process System / Commercial Solution



OSD CT Solution



OSD CT Solution



High containment secondary pharmaceutical manufacturing

Common interface from dispensing through to compression / filling

Key: Passive Active

Dispensing

- Weight Isolation available for integration with weighing systems.



Manual or Automatic Versions

- Even larger PharmaSafe valves can be operated manually.
- Maintain simple and easy handling processes.



Powder Dispensing

- Higher containment performance systems can be utilised prior to ingredient dilution without need for different Passive designs.



Washing In Place (WIP)

- WIP Passive devices can be installed in the upright or inverted orientation
- Washing media can be inserted via the WIP Passive device or from the process



Safe IBC Blending / Mixing

- Passive valve safely interlock
- Additional Passive cover provides assurance
- Pressure rated versions available



Repeatable docking accuracy

- PowerDock - automated raise and lower docking corrects lateral misalignment to ensure repeatable performance
- Assisted manual raise and lower docking versions available



Trouble free docking with hoist systems

- Smooth integration with hoist systems can be assured with the use of a compensator device to accommodate and absorb the forces generated during docking processes.



Effective IBC Washing

- Wash Active valve can be integrated into IBC wash stations
- Specifically designed to optimise results.
- This valve can be used in high temperature and ATEX rated environments.



Topics

01

What can we provide to the OSD Process System

02

Experience Sharing

03

Advanced Tech/Competitive Advantage of AEG

04

About PSS

Experience on Oral Solid Dosage Forms



Top Biosimilar Companies With Approved & Pipeline Products In The US & EU

AMGEN	APOTEX	Biocon	Biogen	Boehringer Ingelheim
CELLTRION	Coherus	PRESENUS KABI	FUJIFILM IRYOWA KIRIN	Grünbeck Richter
INTAS	mabion	MERCK	mundipharma	Mylan
Pfizer	SAMSUNG BIDEPIS	SANDOZ	STADA Arzneimittel	teva



Experience on Oral Solid Dosage Forms

Program	Commercial rights	Indication	Zai Lab clinical stage	Partnerships
ZL-2306 (Niraparib)	China, HK and Macau	Ovarian cancer	CTA approved for Phase 3	TESARO
		Breast cancer	CTA approved for Phase 3 (protocol currently under discussion with CFDA)	
		Lung cancer	CTA approved for Phase 2 (protocol currently under discussion with CFDA)	
ZL-2401 (Omadacycline)	China, HK, Macau and Taiwan	ABSSI	Preparing for CTA Submission for Phase 3	PARATEK
		CABP	Preparing for CTA Submission for Phase 3	
ZL-2301	China, HK and Macau	HCC	Phase 2	Bristol-Myers Squibb
ZL-3101 (Fugan)	Global	Eczema, Psoriasis	Phase 2	gsk
ZL-2302	Global	NSCLC	CTA submitted for Phase 1	SANOFI
ZL-1101	Global	GVHD, SLE	Pre-clinical	ucb

Clear Specialty Focus

Inflammation	Nephrology	Bone	Oncology	Cardiovascular
 Brodalumab AMGEN BIOSIMILARS Adalimumab Infiximab	 EPOGEN (EPOETIN ALFA) RECOMBINANT Sensipar (cinacalcet) Tablets 30mg-60mg-90mg Mimpara (cinacalcet) Aranesp (darbeoetin alfa) AMG 416	 prolia (denosumab) injection Romozosumab	 XGEVA (denosumab) Vectibix (panitumumab) injection for IV infusion Kyprolis (carfilzomib) for Injection Nplate romiplostim Nexavar (sorafenib tosylate) tablets Aranesp (darbeoetin alfa) Neulasta (pegfilgrastim) Talimogene laherparepvec Blinatumomab Trebhanib AMGEN BIOSIMILARS Rituximab Bevacizumab Trastuzumab Cetuximab	Ivabradine Evolocumab Omecamtiv mecarbil

Actavis + Forest Laboratories, Inc.

CNS	GI	Women's Health	URO
 Namenda XR (memantine HCl) extended-release capsules 1 mg, 14 mg, 28 mg Viibryd (vilazodone HCl) 15 mg, 30 mg capsules Fetzima (levomefipran) extended-release capsules 20mg-40mg-80mg-120 mg Saphris (esaperone) sublingual tablets 5 and 10 mg Lexapro (escitalopram) oral suspension	 DELZICOL (mesalamine) delayed-release capsules 400 mg Asacol HD (mesalamine) delayed-release tablets Linzess (linaclotide) capsules Carafate (sucralfate) suspension Canasa (mesalamine) 400 mg capsules PYLERA (barium sulfate) capsules Rectiv (nitroglycerin) ointment 0.4%	 Minastrin 24 Fe (norethindrone acetate and ethinyl estradiol) chewable tablets and ferrous fumarate tablets 1 mg/20 mg Lo Loestrin Fe (norgestimate and ethinyl estradiol) tablets and ferrous fumarate tablets 1 mg/0.02 mg/18 mg Generes Fe (norethindrone and ethinyl estradiol) chewable tablets and ferrous fumarate tablets 0.8 mg/25 mg Crimone (progesterone gel) 8% Actonel (risedronate sodium) tablets Atelvia 35 mg (hydroxyprogesterone acetate) delayed-release tablets ESTRACE CREAM (estradiol vaginal cream) 0.01%	 RAPAFLO (sildenafil) capsules Enblex (darifenacin) capsules Gelnique (polybutynin chloride) gel 10% ANDRODERM (testosterone) transdermal system AndroGel (testosterone gel) 1% * Co-promoted TRELSTAR (triptorepate pamoate) for injectable suspension



Experience on Oral Solid Dosage Forms

Americas Central, South , North :

- Abbvie
- Astra Zeneca – *** (150L, 300L, 500L)
Bottom discharge
- Actavias
- Frontida
- Genzyme
- Alkermes
- Boehringer Ingelheim
- Teva
- Hoffman La Roche
- Pfizer
- Bristol Myers Squibb
- Forest
- Endo
- Ortho McNeil
- Merck ***
Bottom discharge
- Reckitt Benckiser
- Mallinckrodt ***
Bottom discharge
- Covidien
- Avon
- Kimberly-Clark
- Upsher-Smith
- Perrigo
- BiogenIdec
- Watson
- Abbvie
- Amgen
- Glaxo Smith Kline
- Estee Lauder
- Astra Zeneca
- Gilead
- Bayer
- Pharmaceutical Int.
- Alza
- Amgen
- Eisai
- Biogen/IDEC
- TEVA
- Perrigo
- Catalent
- Biogen
- Neogen
- Sanofi
- Pfizer
- Westward
- Wyeth
- Abbott
- Takeda
- SUN
- Chao center – Purdue
- Novell
- Sperics
- Norwich
- Execlixis

Europe:

- Forest Ireland
- Reckitt Benckiser
- Actavias - Ireland
- Abbott UK
- Nestle Switzerland
- Bristol Myers Squibb Ireland

Latin America:

- Merck Brazil ***
Bottom discharge
- Schering Plough _Brazil ***
Bottom discharge
- Christalia Brazil
- Pfizer Argentina

Middle East:

- Advanced Pharma
Jordan
- Hickma – Isreal

Africa:

- Xechem Nigeria

Canada:

- Lonza
- Apotex ***
Bottom discharge
- Biovail
- Tetragenics
- Pharmasource

China/Asia:

- Janssen
- Pfizer - *** (2- 800L)
Bottom discharge
- Avon
- Asymchem
- Apptec
- Hisun
- Pen-Tsao
- ZaiLab – coater
ready
- Shenzhen Zhijun
- Pharmaron
- Hengreui
- Zailab

Customers with common need – An engineered Solution to a Process Services Provided

- Feasibility
- R&D
 - Formulation Development
 - Process Development/Optimization
 - Scale Up
 - Tech Transfer
- Contract Manufacturing
 - Clinical Supplies
 - Commercial Production

Built to Meet Today's Processing Challenges

- Ability to Handle Many Types of Products:
 - Aqueous Based 水溶性
 - OTC Oncology, Controlled substance, etc
 - Solvent Based (No Chlorinated 氯 Solvents)
 - Controlled Substances
 - License for Schedule II-V
 - Listed as a manufacturer of Diazepam 安定, Codeine 可卡因 (II and III), Phenobarbital 苯巴比妥 (III and IV), Morphine 吗啡, Amphetamine 苯丙胺, Hydrocodone 氢可酮, and Methyl Phenylate 哌醋甲酯.

Experience on Oral Solid Dosage Forms

Our Range of Batch Sizes / Scalability

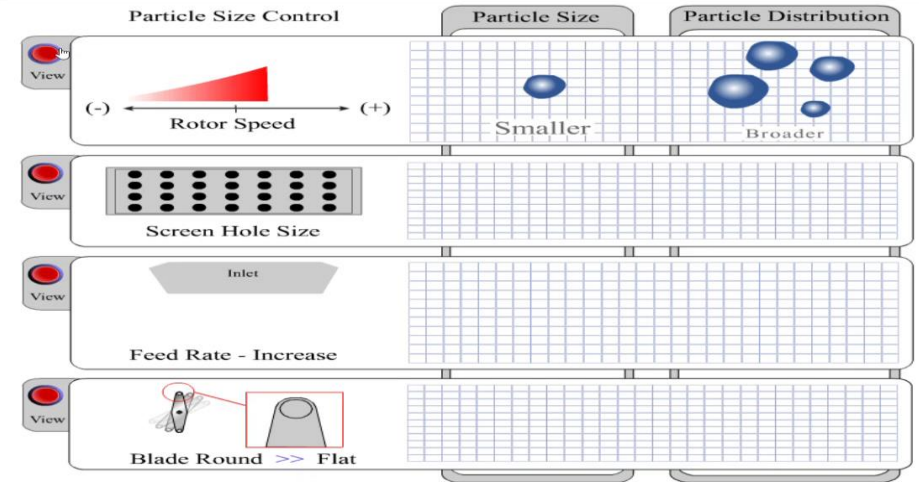
-- Feasibility & Development

➤ **Bench Top – ½ to 2 Kg Batches**

-- Clinical, Stability & Tech Transfer (GMP)

➤ **Pilot Suite – 25 to 75 Kg Batches**

Lab Coating, Granulation & Milling



Equipment Features Provide Flexibility to Handle the Most Difficult Products...

- For Drying/Granulating
 - Multiple Air Distribution Plate Types
 - Solvent Handling
 - Spray and Liquid Delivery Systems
 - Desiccant Dehumidification
- For Coating
 - Coating Zone/Holding Zone Air Flow Control
 - Multi-Partition System
 - Solvent Handling
 - Spray and Liquid Delivery Systems

Unique Production Process Control Capabilities

- Process Control Systems incorporate:
 - Process Analytical Technologies (PAT)
 - Flexible Automated Process Recipes
 - Metrology
 - Fully Electronic Part 11 Records with Signatures
 - Integration of Multiple Equipment Processing Control Centers with BAS
 - Wireless Technologies

Advantages of AUSTAR AS YOUR PARTNER

- We are focused on you!
 - Your success is our success!
 - Our primary focus is the Pharmaceutical Market .
 - We're easily accessible:
 - Factories around the world with global support
- Advanced Processing Features and Techniques *not offered* by Competitors!
- Superior and Immediate Service!

Experience on Oral Solid Dosage Forms

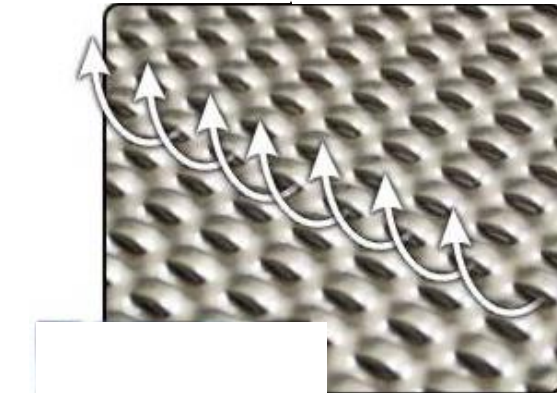
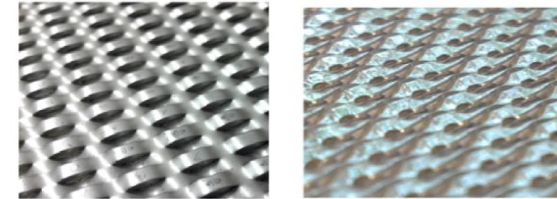
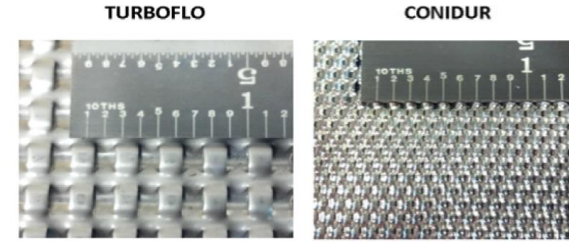
Challenge # 6

- Product discharging for high containment products, to meet industry safety standard.

Bottom Discharge – 1500 liter



Side Discharge



*Turboflo
Bed Plate*

Challenge # 7

- Traditional dryer/granulator drilled hole bed plate assembly with wire mesh screen is difficult to assemble, is not very durable and is hard to clean.
- Conidur or TurboFlo Bed Plates are constructed of one piece and are easy to install, remove and clean.
- Also generates greater pressure drop across the bed plate to minimize air channeling tendency.

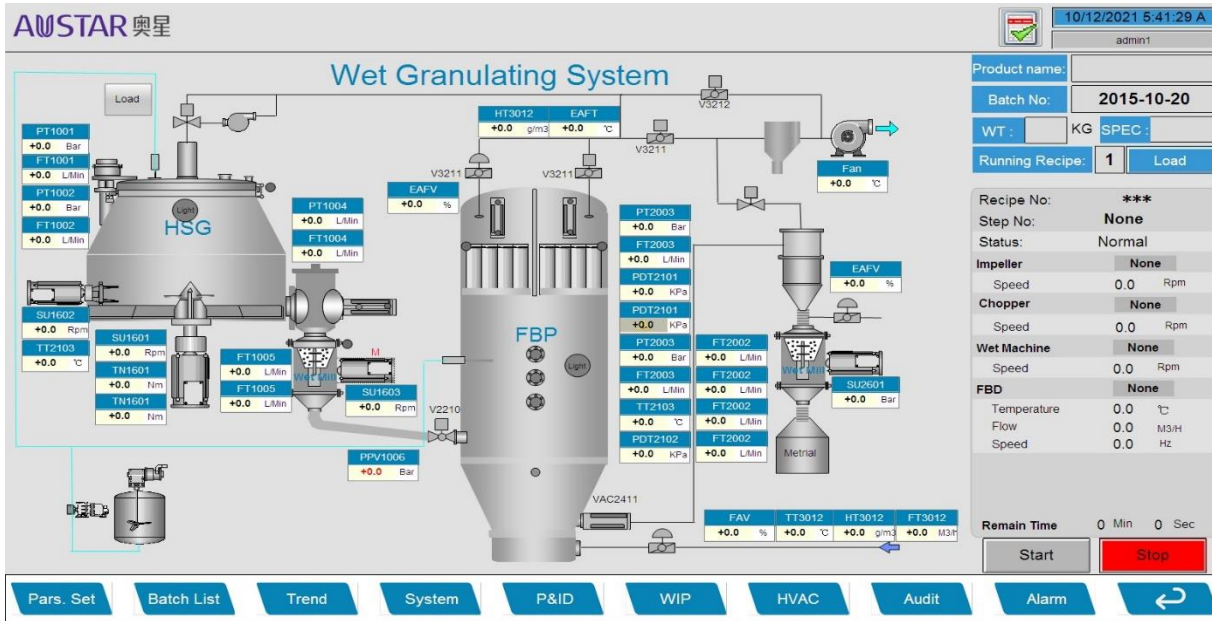
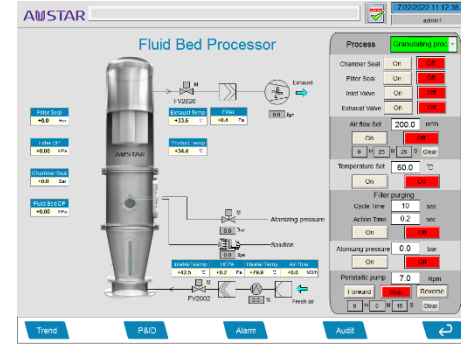
Experience on Oral Solid Dosage Forms

Key Project Review – fully realized systems - Controls

AUSTAR controls system utilizing Siemens PLC, HMI technology with GUI with multi language capability

Recipe driven with manual control and change

Datalogging and CFR 21 Par 11 capability down and upstream utilities.



The previous are only a few examples of the evolution of machine engineering to meet specific customer needs. This evolution is Not limited to only equipment but also the process

MARKET CASE STUDY

DURABLE GRANULES MABUFACTURING IDEAL FOR WURSTER COATING

- North / South / Central America alone spent \$12.5 Billion on [prescription PPIs](#)
 - Study by University of Arkansas suggests that substituting Prilosec OTC will save \$7 Billion annually
 - Prescription PPIs cost about \$4 per pill
 - Prilosec costs ~ 67 cents “on sale” at Walgreen’s
- P&G forecasted yearly sales of OTC to be between \$200-400 Million. Sales for the first 6 months were \$135 Million for a total estimated first year sales volume of \$270 Million.*
- Health insurers are beginning not to reimburse since OTC is available. The active ingredient, is the same in both.
- OTC exclusive granted by the FDA expired
- Formulation strategy and patent-pending mfg. technique that permits marketing of replacement OTC without infringing any other patents.

Topics

01

What can we provide to the OSD Process System

02

Experience Sharing

03

Advanced Tech/Competitive Advantage of AEG

04

About PSS

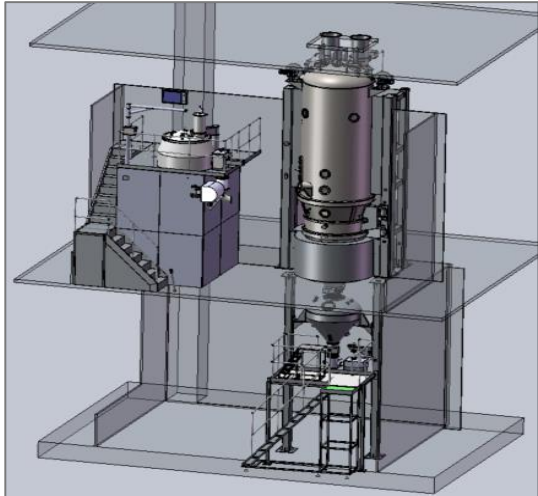
Features & Leading Advantage of PHS

AMSTAR



Features & Leading Advantage of PHS

AMSTAR

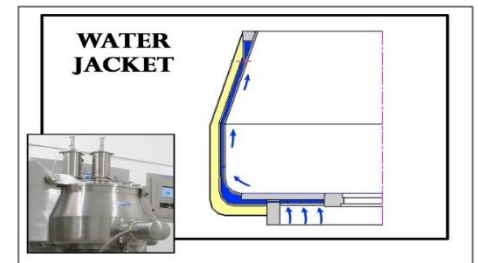
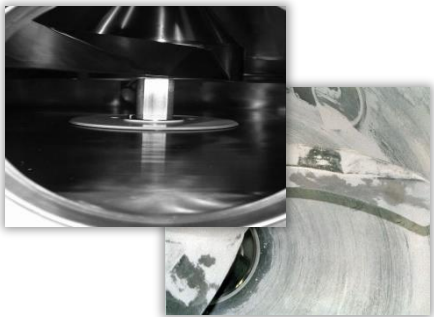
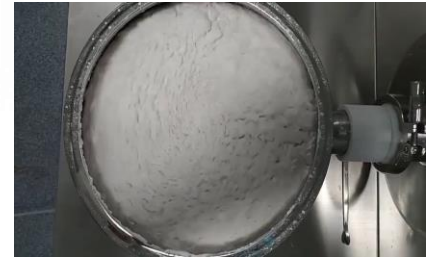


Features & Leading Advantage of HSG

Technical Data Sheet(Standard)		HSG-12 (Container Interchangeable)						HSG-15	HSG-25	HSG-50	HSG-75	HSG-100	HSG-150	HSG-200	HSG-300	HSG-400	HSG-500	HSG-600	HSG-800	HSG-1000	HSG-1250	HSG-1500	
Capacity	Full Capacity, L	0.5	1	2	4	8	12	15	25	50	75	100	150	200	300	400	500	600	800	1000	1250	1500	
	Working Capacity (30%), L	0.15	0.3	0.6	1.2	2.4	3.6	4.5	7.5	15	22.5	30	45	60	90	120	150	180	240	300	375	450	
	Working Capacity (85%), L	0.425	0.85	1.7	3.4	6.8	10.2	12.75	21.25	42.5	63.75	85	127.5	170	255	340	425	510	680	850	1062.5	1275	
	Max Batch Size kg (0.5g/cm ³)	0.2125	0.425	0.85	1.7	3.4	5.1	6.375	10.625	21.25	31.875	42.5	63.75	85	127.5	170	212.5	255	340	425	531.25	637.5	
Drive	Impeller	Drive kw range required	1.0 - 1.1	1.0 - 1.1	1.1-1.3	1.3-1.5	1.5-1.7	1.1 - 1.5	1.1 - 1.5	1.1 - 1.5	1.5 - 2.2	5.3 - 5.6	3.7 - 4.8	7.3 - 7.5	13 - 15	17-20	17 - 20	20 -30*	32 - 38	35 - 55	50 - 72	58 - 80	58 - 80
		Drive, kW	2.2						3	4	4	5.5	7.5	11	15	22	22	37	45	55	75	90	110
	Speed, rpm	10-1340	10-1130	10 - 890	10 - 720	10 - 560	10-460	10-440	10 - 375	10 - 295	10 - 250	10 - 235	10 - 210	10 - 190	10 - 165	10 - 150	10 - 140	10 - 130	10 - 120	10 - 115	10 - 105	10 - 100	
	Chopper	Drive, kW	1.1						1.1	3	4	4	4	5.5	7.5	11	11	15	15.0	18.5	22	30	33
Speed, rpm		1000 - 5000	1000 - 5000	1000 - 5000	1000 - 5000	1000 - 5000	1000 - 5000	1000-4000	1000 - 4000	1000 - 4000	1000 - 4000	1000 - 4000	1000 - 4000	1000 - 3500	1000 - 3500	1000 - 3500	1000 - 3500	1000 - 3500	1000 - 3500	1000 - 3500	1000 - 3500	1000 - 3500	
Discharge Port nominal Size (mm)		na	na	35	35	60	60	75	100	100	100	100	100	150	150	200	200	200	200	250	250	250	

Features & Leading Advantage of HSG

AWSTAR



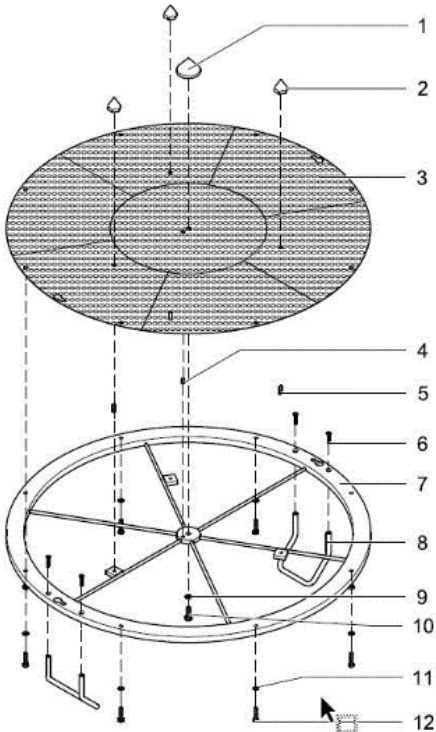
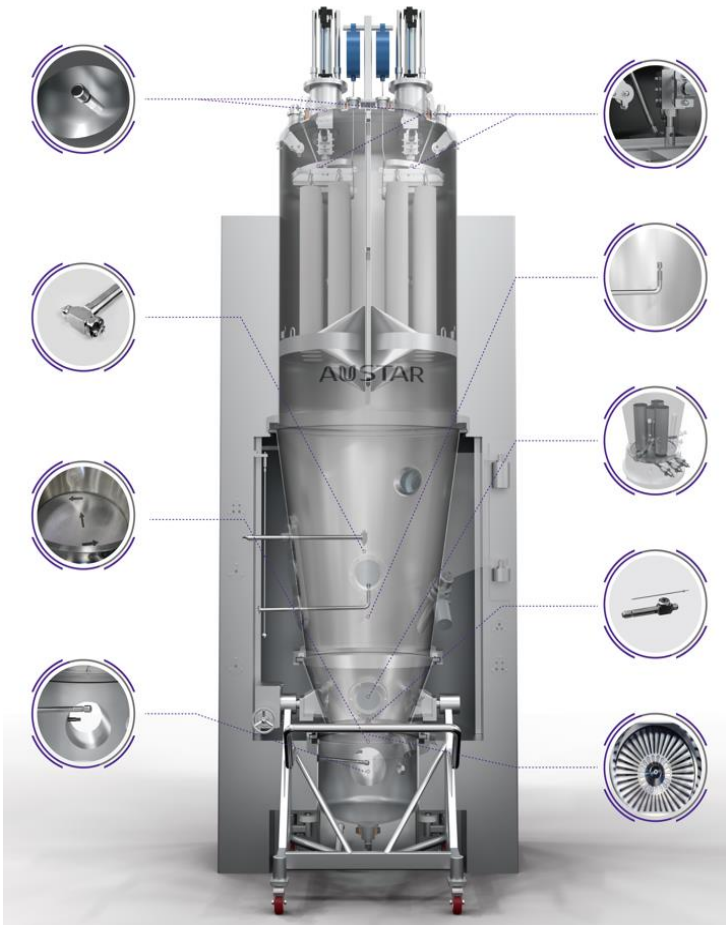
Features & Leading Advantage of Fluid Bed



Drying / Top Spray Granulaing / Coating ... changeable chamber and conical chamber																
	portable		portable			fied or portable										
Model Number	FBDGC-5		FBDGC-20			FBDGC-30		FBDGC-70			FBDGC-170	FBDGC-330	FBDGC-530	FBDGC-850	FBDGC-1400	FBDGC-1900
Design Gross volume Granulation - Dry/TSG Bowl Size (Liters)	2	5	5	10	17	20	30	30	50	70	170	330	525	850	1400	1900
Min Batch - Dry/TSG Bowl Size (Liters) 20%	0.4	1	1	2	3.4	4	6	6	10	14	34	66	105	170	280	380
Max Batch - Dry/TSG Bowl Size (Liters) 80%	1.6	4	4	8	13.6	16	24	24	40	56	136	264	420	680	1120	1520
2 - Min batch - Wurster Coating (liters) NO COLUMN	0.2	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na
2 -Max Batch - Wurster Coating (liters) NO COLUMN	0.5	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na
4 - Min batch - Wurster Coating (liters)	na	0.5	0.5	na	na	na	na	na	na	na	na	na	na	na	na	na
4 -Max Batch - Wurster Coating (liters)	na	1.5	2	na	na	na	na	na	na	na	na	na	na	na	na	na
6 - Min batch - Wurster Coating (liters)	na	na	na	0.6	na	na	na	na	na	na	na	na	na	na	na	na
6 -Max Batch - Wurster Coating (liters)	na	na	na	5	na	na	na	na	na	na	na	na	na	na	na	na
7 - Min batch - Wurster Coating (liters)	na	na	na	na	1.2	1.2	na	na	na	na	na	na	na	na	na	na
7 -Max Batch - Wurster Coating (liters)	na	na	na	na	8.5	8.5	na	na	na	na	na	na	na	na	na	na
9 - Min batch - Wurster Coating (liters)	na	na	na	na	na	na	3	3	na	na	na	na	na	na	na	na
9 -Max Batch - Wurster Coating (liters)	na	na	na	na	na	na	14	14	na	na	na	na	na	na	na	na
12 - Min batch - Wurster Coating (liters)	na	na	na	na	na	na	9	na	9	na	9	na	na	na	na	na
12 - Max Batch - Wurster Coating (liters)	na	na	na	na	na	na	40	na	40	na	40	na	na	na	na	na
18 - Min working batch - Wurster Coating (liters)	na	na	na	na	na	na	na	na	na	15	15	20	20	na	na	na
18 -Max working Batch - Wurster Coating (liters)	na	na	na	na	na	na	na	na	na	75	95	120	120	na	na	na
24 -Min working batch - Wurster Coating (liters)	na	na	na	na	na	na	na	na	na	na	na	35	35	na	na	na
24 -Max working Batch - Wurster Coating (liters)	na	na	na	na	na	na	na	na	na	na	na	162	162	na	na	na
32 -Min working batch - Wurster Coating (liters)	na	na	na	na	na	na	na	na	na	na	na	na	90	90	na	na
32 -Max working Batch - Wurster Coating (liters)	na	na	na	na	na	na	na	na	na	na	na	na	390	390	na	na
46 - Min batch - Wurster Coating (liters)	na	na	na	na	na	na	na	na	na	na	na	na	na	300	300	125
46 - set up -Max Batch - Wurster Coating (liters)	na	na	na	na	na	na	na	na	na	na	na	na	na	790	790	800
55 - Min batch - working Wurster Coating (liters)	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	170
55 - Max Batch - working Wurster Coating (liters)	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	1110

Features & Leading Advantage of Fluid Bed

AUSTAR



AUSTAR 奥星

制药工程解决方案专家

International Standards

NFPA 70, National Electrical Code (NEC)

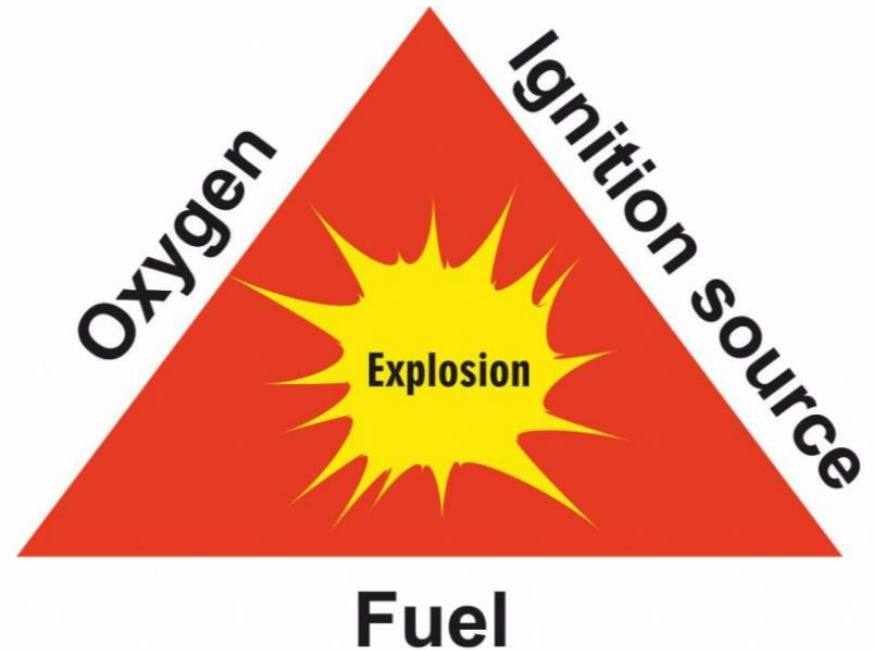
NFPA 79: Electrical Standard for Industrial Machinery

ATEX is the abbreviated name of the European Directive 2014/34/EC

NFPA 68: Standard on Explosion Protection by Deflagration Venting

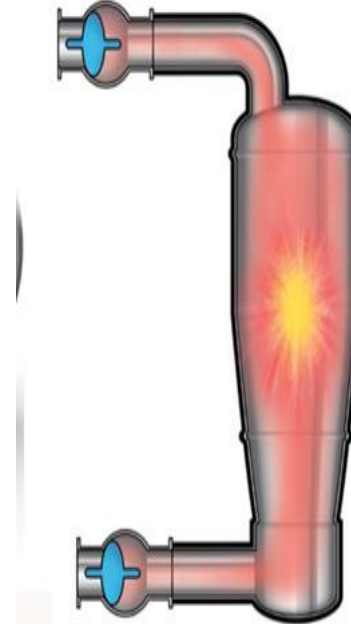
NFPA 69, Standard on Explosion Prevention Systems

NFPA 652, Standard on the Fundamentals of Combustible Dust



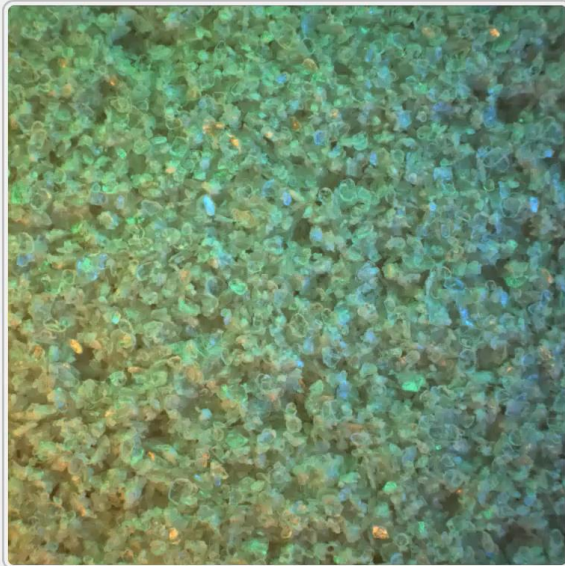
Specifics Pressure Containment

- Eliminate risk of electrical or static spark
- Prevent propagation of explosion to other areas through the use of isolation – Quick acting valves
- Provide the plenum, bowl, chamber, tower capable of withstanding a 12 Bar over pressure. This is relatively simple engineering but costly.
 - Eliminate edges and use round surfaces – reduce stress
 - Certify welding and inspection process
 - Thicker heavier stainless
 - CON
 - Bowl becomes heavy to move by hand – swing arm design
 - Chamber becomes heavy and change over more difficult
 - Building – Design for loading



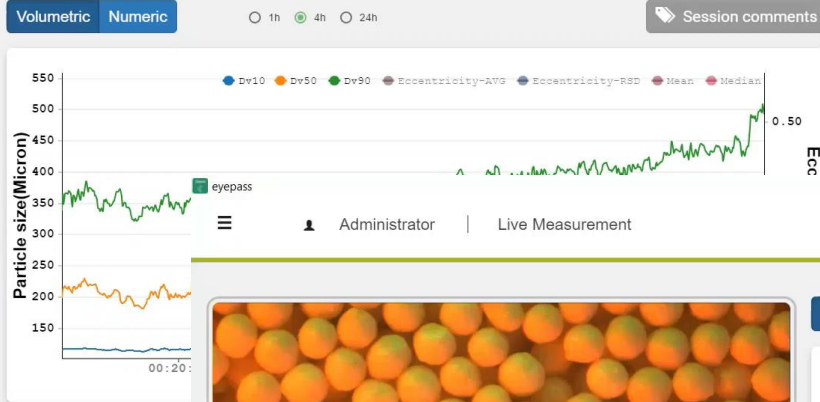
PAT Integrated Application

eyepass Administrator | Live Measurement HW OK Stop



Material: dns1
Sublot:
Starting operator: admin
Elapsed time: 0d 02:02:06

Batch Number: 2021121-2
Configuration: wudi
Time started: 2021-12-02 00:46:39
Integration Period: 60s



Size Distribution

Mean: 185 (µm)
Median: 153 (µm)

Volumetric

Dv10: 175 (µm)
Dv50: 321 (µm)
Dv90: 493 (µm)

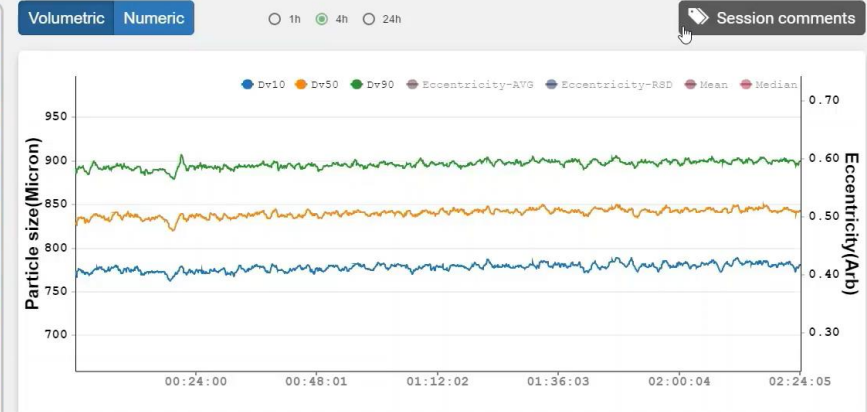
Eccentricity

AVG: 0.3991 (Arb)
RSD: 0.4402 (Arb)



Material: pellets
Sublot:
Starting operator: admin
Elapsed time: 0d 02:24:20

Batch Number: 2021112901
Configuration: JOSON
Time started: 2021-11-30 04:47:11
Integration Period: 60s



Size Distribution

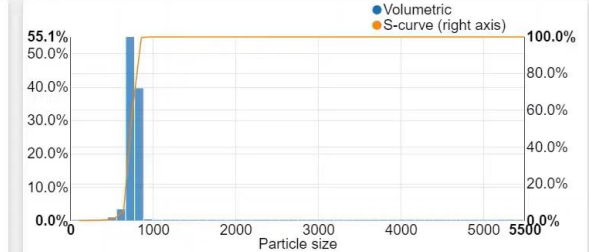
Mean: 786 (µm)
Median: 831 (µm)

Volumetric

Dv10: 783 (µm)
Dv50: 844 (µm)
Dv90: 901 (µm)

Eccentricity

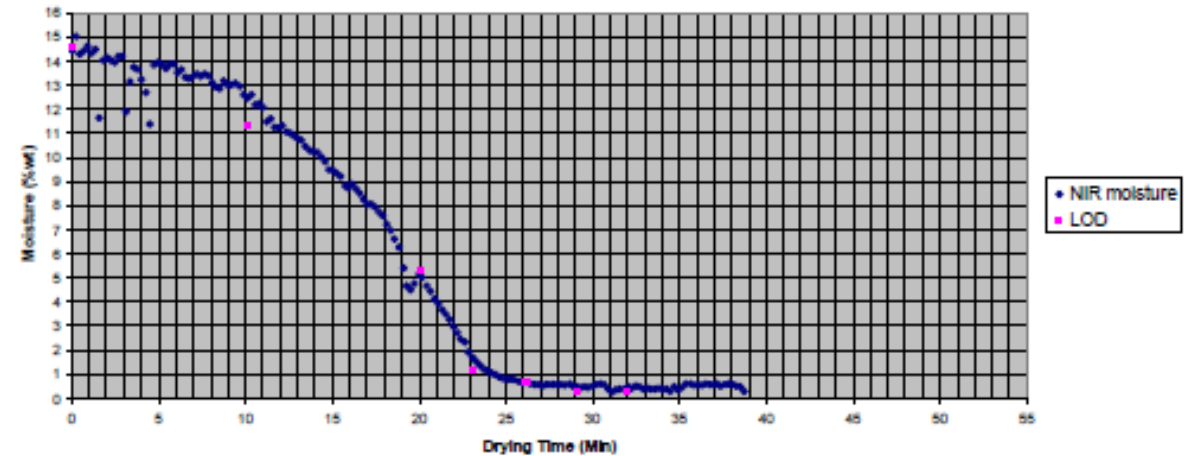
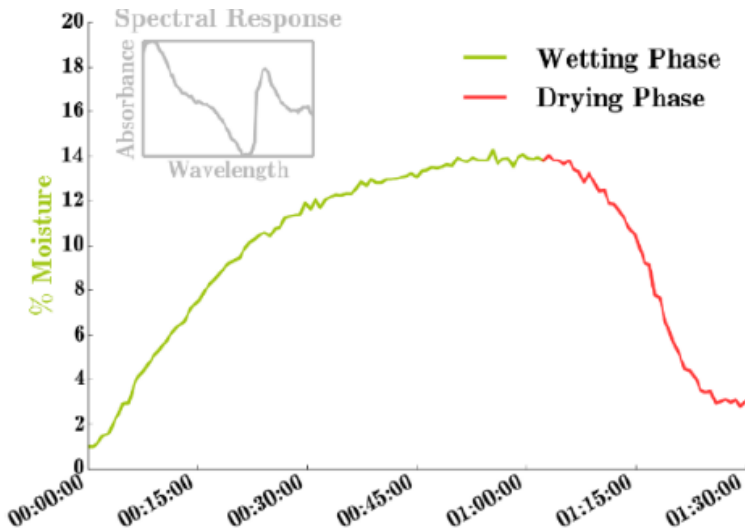
AVG: 0.5810 (Arb)
RSD: 0.3033 (Arb)



PAT Integrated Application

Blending homogeneity, Water content online monitoring

The application of integrated PAT in wet granulation will facilitate the understanding to the wet granulation process/ product, and shorten the R&D period of new drug and/ or generic drug



Documentation	Specification
GXP	The applicability of equipment/system assessment to potential effect on product quality, GAMP software category, and FDA 21 CFR Part 11.
QPP	Quality and Project Plan
QSD	Providing specific instruction to the scope of commissioning and qualification activities.
FS	Functional Specification
HDS	Hardware Design Specification
SDS	Software Design Specification
SIA	System Impact Assessment
DQ	Design Qualification
FRA/CCA	Functional risk assessment /Component Criticality Assessment
COM	Equipment or system commissioning documents
FAT	Factory Acceptance Test
SAT	Site Acceptance Test
IQ	Installation Qualification
OQ	Operating Qualification
PQ	Performance Qualification (Protocol)
RTM	Requirement Traceability matrix
VSR	Validation Summary Report

	Validation	Doc.No: IQE-TBW-FIQ-01	
	Installation Qualification Report for Fluid-bed Dryer	Version	01
		Page	1 of 7

Project No.: H21741100

Installation Qualification Report for Fluid-bed Dryer
流化床颗粒干燥器安装确认报告

谁准备Prepared by:
职位 Position 验证工程师 Validation Engineer
姓名 Name 签字 Sign 日期 Date:

谁接收Received by:
职位 Position 项目经理 Project Manager
姓名 Name 签字 Sign 日期 Date:

职位 Position 高级EHS专员Senior EHS Supervisor
姓名 Name 签字 Sign 日期 Date:

职位 Position 制药品应用经理Production Manager (Talent)
姓名 Name 签字 Sign 日期 Date:

职位 Position 验证主管 Qualification Supervisor

	Validation	Doc.No: IQE-TBW-FIQ-01	
	Installation Qualification Report for Fluid-bed Dryer	Version	01
		Page	4 of 7

3. Test Item List 测试项目列表

The tests that have been performed in this report are listed in the following form.
在下表中列出了本报告中执行的测试。

Test No. 测试号	Test Item 测试项目	Result 结果	Verification 验证
11.1	Prerequisite Verification 先决条件确认	<input checked="" type="checkbox"/> Pass合格 <input type="checkbox"/> Fail不合格	<input type="checkbox"/> Yes是 <input checked="" type="checkbox"/> No否
11.2	Personnel Verification 人员确认	<input checked="" type="checkbox"/> Pass合格 <input type="checkbox"/> Fail不合格	<input type="checkbox"/> Yes是 <input checked="" type="checkbox"/> No否
11.3	Documentation Verification 文件确认	<input checked="" type="checkbox"/> Pass合格 <input type="checkbox"/> Fail不合格	<input type="checkbox"/> Yes是 <input checked="" type="checkbox"/> No否
11.4	Training Verification 培训确认	<input checked="" type="checkbox"/> Pass合格 <input type="checkbox"/> Fail不合格	<input type="checkbox"/> Yes是 <input checked="" type="checkbox"/> No否
11.5	Installation Qualification 安装确认	<input checked="" type="checkbox"/> Pass合格 <input type="checkbox"/> Fail不合格	<input type="checkbox"/> Yes是 <input checked="" type="checkbox"/> No否
11.6	PAID Verification PAID 确认	<input checked="" type="checkbox"/> Pass合格 <input type="checkbox"/> Fail不合格	<input type="checkbox"/> Yes是 <input checked="" type="checkbox"/> No否
11.7	Component Verification 组件确认	<input checked="" type="checkbox"/> Pass合格 <input type="checkbox"/> Fail不合格	<input type="checkbox"/> Yes是 <input checked="" type="checkbox"/> No否

IQ/OQ (EU GMP/Germany)

	Performance Qualification Protocol for Fluid Bed Granulator System in Workshop Eight 八车间流化床颗粒系统性能确认方案	编号: PQP-M-0716-2014-19 版本号: 02 修订号: 00
--	--	---

Protocol Approval/方案批准:

姓名 Name	部门、职务 Department, Title	签名 Sign
编制人 Author	奥星验证部门 AUSTAR Validation Department	
谁审核人 Reviewed by Scieur	验证部门负责人 Validation Department Manager	
	车间主任 Plant Director	
	工程中心负责人 Project Center Director	
	生产中心负责人 Production Center Director	
质量保证部主管 QA Supervisor		

	Performance Qualification Protocol for Fluid Bed Granulator System in Workshop Eight 八车间流化床颗粒系统性能确认方案	编号: PQP-M-0716-2014-19 版本号: 02 修订号: 00	页数: 5/107 机密等级: 秘密
--	--	---	-----------------------

目录 TABLE OF CONTENTS

1. 介绍Introduction	5
2. 目的Purpose	5
3. 范围Scope	6
3.1 范围In Scope	6
4. 职责Responsibility	6
4.1 奥星职责Scieur Responsibilities	6
4.2 奥星职责 AUSTAR Responsibilities	7
5. 缩略语Abbreviations	7
6. 法规和指南 Regulations and Guidelines	8
6.1 法规Regulations	8
6.2 指南Guidelines	8
7. 参考文件 References	10
8. 设备描述Equipment Description	11
8.1 设备用途Equipment Use	11
8.2 能力Capacity	11
9. 性能确认策略PQ Strategy	12
10. 文件管理规范Documentation Control Procedure	13
11. 测试项目列表Test Item List	14
12. 性能确认测试Performance Qualification Test	15
12.1 先决条件确认Prerequisites Verification	15

PQ (MHRA GMP)

Topics

01

What can we provide to the OSD Process System

02

Experience Sharing

03

Advanced Tech/Competitive Advantage of AEG

04

About PSS

Manufacturing Center

AU STAR has three production sites in Mainland China, which are located in Shanghai, Nanjing and Shijiazhuang.

Two high-tech and quality assembling workshops are located in Dresden, Germany (majority holding) and Huddersfield, UK.

Huddersfield UK



- Containment Isolators
- Aseptic Isolators
- Filling Line Isolators
- DownFlow Booths

Shijiazhuang Manufacturing Center



- Manufacture of Pressure Vessels
- Automatic Control Systems
- Powder and Solid Systems
- Liquid Process Systems
- Clean Room Systems

Dresden Germany



- Water Pretreatment Units
- Purified Water Equipment
- Cold WFI Equipment
- PW & WFI Distribution



Shanghai Manufacturing Center

- Purified Water Generator
- Pure Steam Generator
- Multiple Effect Water Distiller
- Bioreactor and Fermentor
- Various Process Skids Including Medium and Buffer Preparations
- Sanitary Vessels & Heat Exchangers

Nanjing Manufacturing Center



- Freeze-drying System
- Freeze-drying Laboratory
- Filling Line
- Isolator for Filling Line



More Than 1000 Global High-quality Partners

AMSTAR



TAC Advisors

Knowledge Trust Legacy

AMSTAR



Peter Haseley



Ewart Richardson



Austin McDonald



Stephen Robert Ferrell



Rory Budihandojo



Wilfried Kappel



Bill Shifeng Wei



José Castillo



Michael Li



Jack Chu



Jon Nottingham



Frank Eng



Andreas Flückiger



Danny Chou



Nico Oosterhuis



Feng Lei



Rey T Chern



Robert Fretz



Li Shi

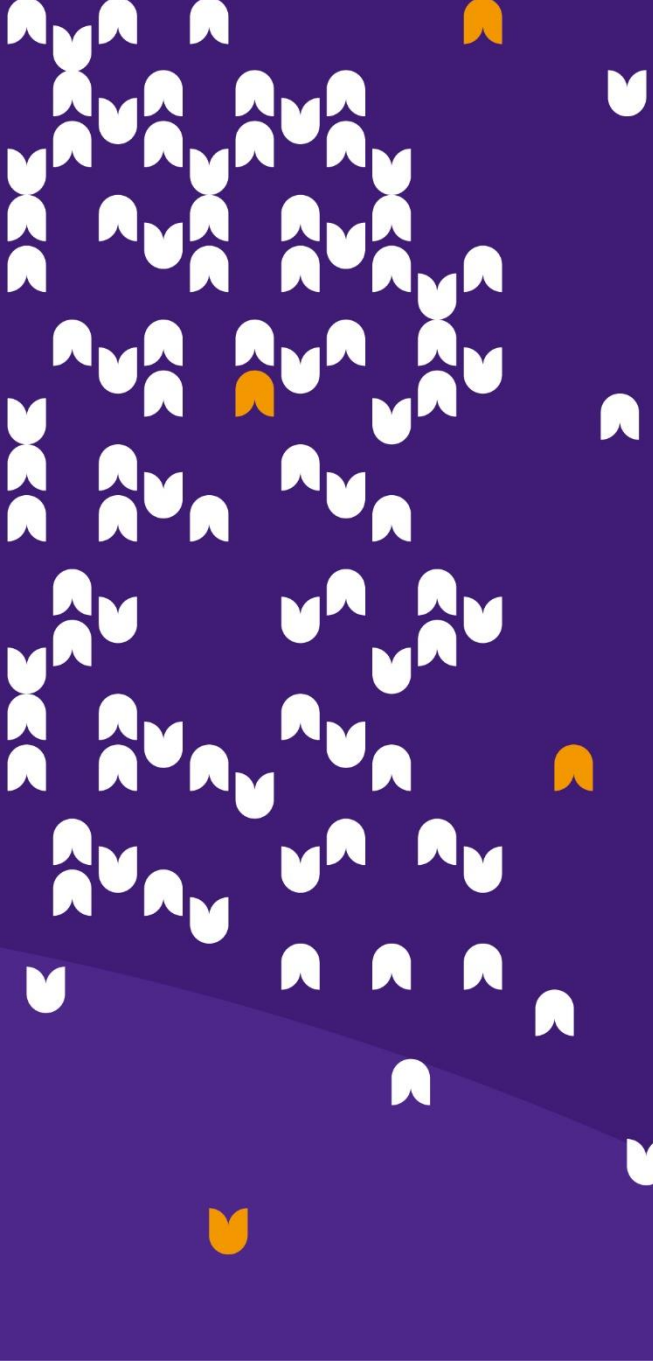


Michael H Prior



Shoubai Chao

- Your partner of OSD TK solution
- **Safety first.** All core components are validated and tested。
- Balance of process, equipment and automatic monitoring system, and provide a stable process **automatic control system**.
- Based on excellent **know-how** design and quality process control, provide perfect engineering equipment project execution
- Control system software system with **intellectual property rights**. Independent design provides the possibility of customized production for customers, and a reliable and friendly human-computer interaction interface
- The AUSCON **automatic control system** designed based on the requirements of data integrity meets the requirements of EU, FDA, who, pic/s, TGA and other high-end international regulations
- Perfect verification execution service (IQ/OQ/FAT/SAT, execution and report delivery), providing one-stop service



Thank You

www.austarunion.com