



Bellen Chemistry

General Introduction

Q2, 2020

// VISION AND MISSION

Vision

To develop best-in-class customer focused partnerships and be the valued supplier of choice for pharmaceutical products and services based on specialized and innovative Chemistry solutions.

Mission

- Create and promote exceptional one-stop-shop platform for pharmaceutical and chemical services.
- Recognize the potential of our employees and strive to grow our business with dedication, integrity and collaboration, in the same way that we manufacture our products.
- Value our customer partnerships and nurture them by supplying innovative, cost effective and sustainable solutions.

// CULTURE VALUE AND BELIEFS

Bellen

B

Best in class customer services and partnerships. Promoting and applying high ethical standards in everything we do.

执子之手，
棠棣其友

e

Economic astuteness, cost competitiveness, Reliability and Efficiency.

经济乃货殖之本

l

Learning from customer feedback and our own mistakes. Welcoming diversity and including different styles and ideas in our way of working.

二过非君子，
一错真吾师

l

Looking for continuous improvement. Being passionate about Quality, Safety and Environment.

苟日新，
日日新，
又日新

e

Empowering all of our employees to reach their full potentials by allowing them to take ownership, speak up and make things happen.

权责授其分，
潜志自提振

n

Never forgetting our legal, moral, societal and professional obligations.

天职其务，
道德其范，
律法其行

// KEY MILESTONES

Since 2007

- Founded with 6 employees
- Positioned as Catalog company



2011

- Beijing site phase 3 expansion
- Lab area: 75,000sqf
- Employee No: 110



2016

- Around of capital raising
- Construction of manufacturing plant
- Renovation of process R&D Center



2018

- Construction of manufacturing plant P2
- Renovation of R&D process center P2
- C round of capital raising



2020

- Manufacturing plant GMP capability in operation
- D round of capital raising
- Employee No: 550



2008

- Site relocation and expansion
- Relocated to Shunyi, Beijing



2014

- Full CRO capability
- Doubled Kilo lab capability
- Employee No: 150



2017

- Manufacturing plant phase 1 in operation
- Process R&D center phase 1 in operation
- B round of capital raising

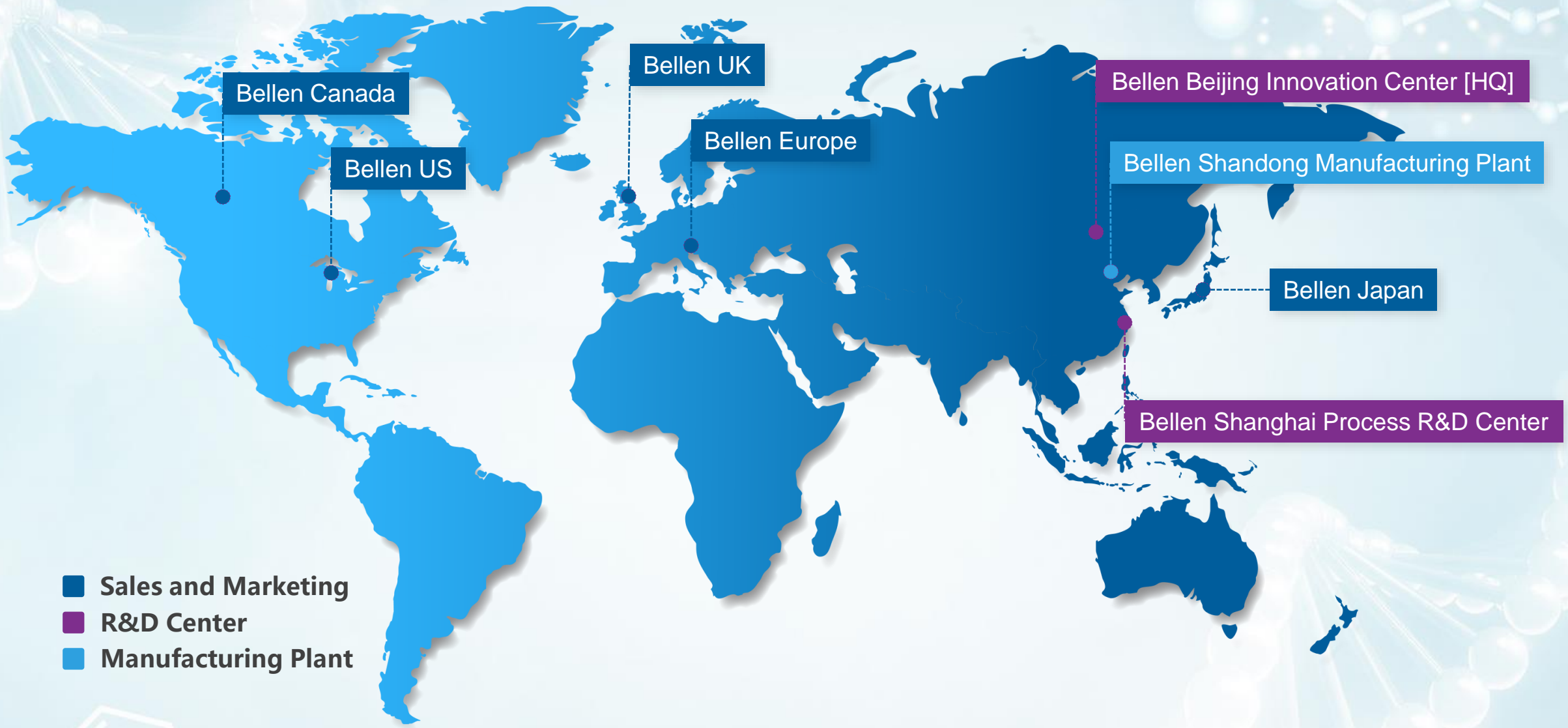


2019

- Manufacturing plant P2 start up
- Process R&D Center P2 in operation
- Construction of New Beijing Innovation Center



// GLOBAL PRESENCE



- Sales and Marketing
- R&D Center
- Manufacturing Plant

ORGANIZATION STRUCTURE

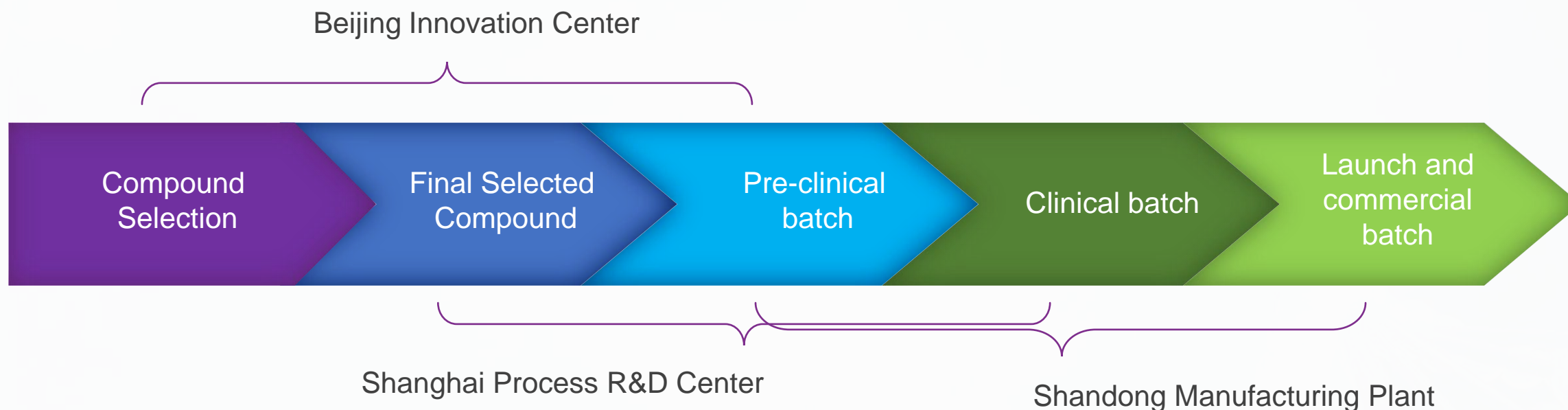


 **Bob Liu**
CEO



// WHAT WE DO _ BUSINESS SCOPE

Bellen commits to continue investing in the capabilities and capacities to enable a one-stop-shop chemistry service platform, from compound selection to final API GMP manufacturing.



// WHAT WE DO _ DISCOVERY CHEMISTRY SERVICES

Since 2007, our team of synthetic and medicinal chemists have consistently delivered high quality and value-added chemistry services to support various synthetic and drug discovery needs of the customers around the world.



Key Service Area

Design and synthesis of focused libraries

Support design and synthesis of hit-to-lead chemistry

Lead optimization and preclinical candidate selection

Synthesis of reference compounds, impurity markers

Preparation of building blocks/key intermediates

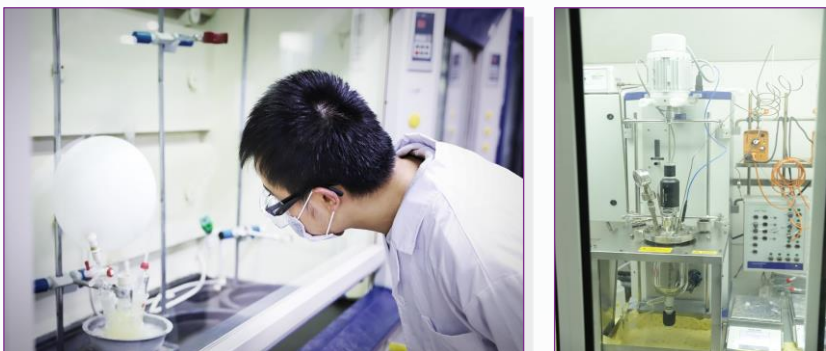
Non-GMP scale-up to support in vivo efficacy and toxicity studies

Method development

Chiral separation

// WHAT WE DO _ PROCESS DEVELOPMENT

Design and develop alternative route of synthesis(ROS) and optimize the existing process, to ensure successful scale-up and timely delivery of the projects.



Key Service Area

- "Fit for Purpose" synthetic route and process design and development
- Alternative reagents and catalysts screening
- Process safety assessment
- Impurity characterization and control
- Analytical method development
- New technology exploration and application
- DoE/QbD
- FFS and FTE mode

Through seamless collaboration with process research and development team, our manufacturing pilot plant provides key intermediates, regulatory starting materials(RSM) and cGMP APIs for the needs of all phases of drug discovery and development



Key Service Area

- Process development/optimization
- Non-GMP advanced intermediates manufacturing
- Regulatory start material manufacturing
- GMP API manufacturing
- Open for long term strategic collaboration with customers by custom design of the equipment/facility

// FACILITIES AND CAPABILITIES _ BELLEN LOCATIONS IN CHINA



R&D Headquarters



Manufacturing Plant



Process R&D





// FACILITIES AND CAPABILITIES

Bellen Beijing Innovation Center

Synthetic chemistry, medicinal chemistry, pCMC chemistry support

A Few Facts

75,000 sqft lab space,
with **200** chemists

168 standard fume hoods,
60 walk-in hoods

Kilo lab with **25** reactors
ranged from 30L-100L

Temperature range:
-78 to 200 degree C

Pressure:
up to **100 bar**

On site **SFC** capability
(waters 80q, 100mg-100g)

Full range of
analytical instruments

Photo chemistry
20ml-1L

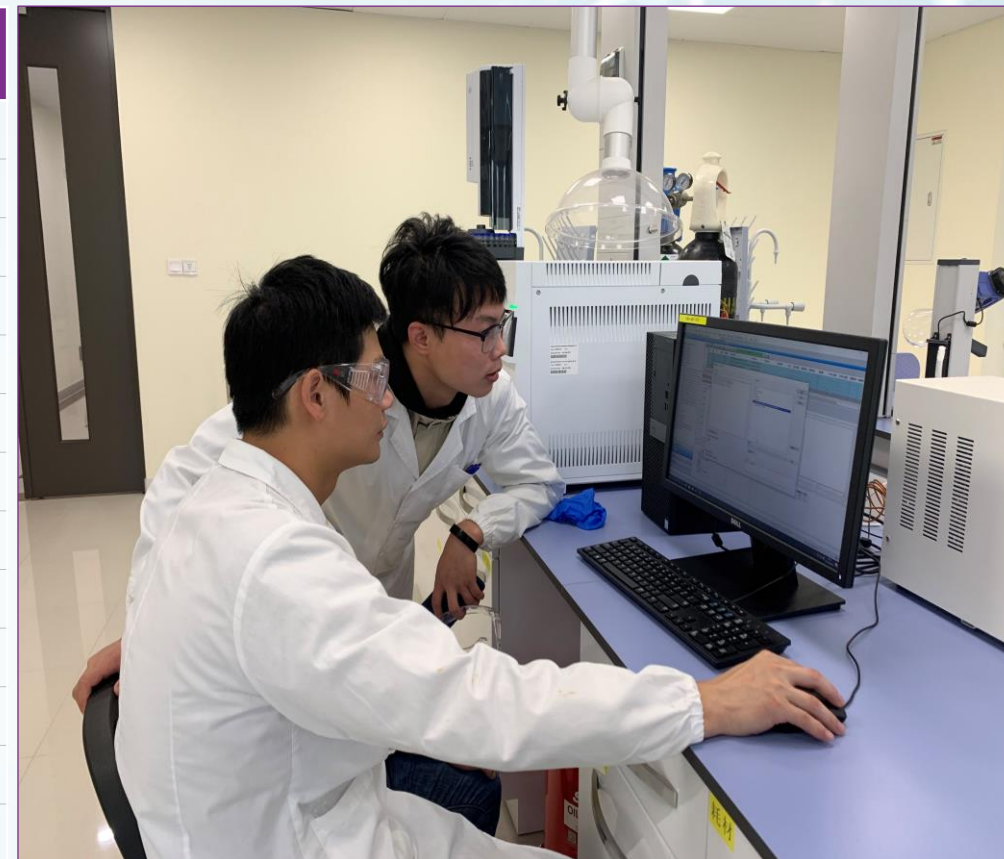
Flow chemistry

Focus on
quick delivery

// FACILITIES AND CAPABILITIES _ BEIJING INNOVATION CENTER

Full range of analytical instruments and strong analytical team to deal with daily analytical R&D, QC and problem solving

Instrument Name	Brand	Model/Type	Quantity
NMR	Bruker	Bruker300/400	1/1
LC-MS	Agilent	1260+6125	3
LC-MS	Agilent	1260+G1956B	1
GC	Agilent	7890	1
GC-MS	Shimadzu	2010	1
GC / HS	Agilent	7820A+HS	2
HPLC	Agilent	1260	20
UPLC	Agilent	1290II	2
HPLC / CAD	Thermo	U3000	1
Prep-HPLC	waters	Prep 150	1
Prep-HPLC	Waters	APS 2545/2767	1
UPCC	Waters	-	1
SFC	Waters	80q(80g/min)	1








// TECHNICAL LEADERS PROFILE – BEIJING INNOVATION CENTER



Name	Title	Education	Experiences
Nick Xing	General Manager	Ph.D in Organic Chemistry, Tsinghua University	<ul style="list-style-type: none">• 13 years with Bellen
Jack Su	pCMC Head, VP	Ph.D in Organic Chemistry, Tsinghua University	<ul style="list-style-type: none">• 11 years with Bellen
Ryan Ren	Catalog Head, VP	M.S in Organic Chemistry, Beijing University of Chemical Technology	<ul style="list-style-type: none">• 2 years in Bioduro Beijing• 13 years with Bellen
Yan Cai	Med-Chem Director	Ph.D in Organic Chemistry, Nankai University	<ul style="list-style-type: none">• 4 years in Bioduro Beijing• 4 years with Bellen
Zhijie Lin	Process Dept. Director	Ph.D in Organic Chemistry, Philipps-Universität Marburg	<ul style="list-style-type: none">• 3 years in Pharmaron Beijing• 4 years with Bellen
Hu Zhang	Associate Director	Ph.D in Organic Chemistry, Chinese Academy of Sciences	<ul style="list-style-type: none">• 3 years in Pharmaron Beijing• 4 years with Bellen
Yanmin Yao	Associate Director	Ph.D in Organic Chemistry, Nankai University	<ul style="list-style-type: none">• 5 years with University of California, postdoctoral research• 2 years with Pharmaron• 1 year with Bellen

Coming Soon..... - New Beijing Innovation Center

Bellen-owned property

-  Relocation by Q2 2021
-  5km from current location
-  90,000 sqft
-  State-of-the-art facility and equipment
-  Focus on drug discovery Chemistry service



// FACILITIES AND CAPABILITIES

Shanghai Process R&D Center

Process Development, Process Optimization,
Scale up support

A Few Facts

Phase 1 in operation
since mid 2017

Phase 2 expansion project
in operation from Oct, 2019

30,000 sqft lab space,
70 process and analytical
chemists

PhD/MSc/BSc ratio:
1/2/3

97 fume hoods
(European standard)

12 walk-in hoods
(Fisher)

2x10L and 2x5L double
layers jacket reactors
with Huber unistat

RC1 safety
assessment tool

Full range of
analytical instruments
and capability

Enzymatic chemistry

Catalysts screening



// FACILITIES AND CAPABILITIES _ SHANGHAI PROCESS R&D CENTER



Instrument Name	Brand	Model/Type	Quantity
300MHz NMR	Bruker	Bruker300	1
LC-MS	Agilent	6150	1
GC	Agilent	7890	2
UPLC	Agilent	1290II	6
ICP OES	PerkinElmer	Avio200	1
Moisture analyzer	Mettler		2
Sadex	SYSTAG	TSC 511	1
Redex	SYSTAG	V5	1
RC1	Mettler		1
Glove boxes			2
Reactors	+huber unistat	5/10L	4
DSC	Mettler		1



// TECHNICAL LEADERS PROFILE – BEIJING INNOVATION CENTER



Name	Title	Education	Experiences
Bo Han	General Manager	Ph.D in Org Chemistry, Tsinghua University. Postdoc in Org Chem, ETH Zurich	<ul style="list-style-type: none"> - 2 years in Roche R&D China - 10 years in Novartis CHAD CN - 3 years with Bellen
Xianglin Zhao	Division VP	Ph.D in Organic Chemistry, Shenyang Pharmaceutical University	<ul style="list-style-type: none"> - 4 years in STA - 6 years in Novartis CHAD CN - 3 years with Bellen
Weizhou Huang	Director	Ph.D in Organic Chemistry, Shanghai Institute of Organic Chemistry	<ul style="list-style-type: none"> - 5 years in STA - 2 years in Summer Sprout - 1 year with Bellen
Jun Yin	PRD Lead	Ph.D in Organic Chemistry, Rice University	<ul style="list-style-type: none"> - 5 years with Roche - 5 years with Wuxi Apptec - 2 years with Bellen
Jingshun Zhang	PRD Lead	Ph.D in Organic Chemistry, Jilin University	<ul style="list-style-type: none"> - 5 years with Sundia - 2 years with Bellen
Tao Sui	ARD Head	M.S. in Organic Chemistry, SIMM, Chinese Academy of Sciences	<ul style="list-style-type: none"> - 5 years at Roche China for analytical development, - 6 years at GSK China - 2 years with Bellen
Karri Bhaskara Rao	Team Leader	Ph.D in Organic Chemistry, Jawaharlal Nehru University, New Delhi, India	<ul style="list-style-type: none"> - 5 yeas at CSIR-CDRI, Lucknow, India - 3 years at Shanghai Jiaotong University, Post doc - 1 year with Shanghai Haini Pharmaceutical Co., Ltd - 1 year with Bellen



Shanghai Process
R&D Center- ➤

State-of-the-art facility



4 Access controlled labs
For dedicated FTE service



Central Nitrogen Supply



HVAC system enables constant temp and humidity

Shandong Manufacturing Plant

Advanced intermediates, KSM and API GMP manufacturing

A Few Facts

Phase 1 in operation since mid 2017 with 5 non-GMP reaction trains

Phase 2 expansion project in operation from Oct, 2019, released 5 non-GMP reaction trains

In total 25 non-GMP reaction trains will be available in 2020

4 cGMP reaction trains is scheduled to start up in Q2,19

50 general reactors range from 200L to 5000L, liners including SS316L, GL, HC276

Full range of isolation and drying equipment

Hydrogenation, 100L to 2000L

Temp range: -70 to 200 degree C

ISO 9001 certified

EHS management system according to ISO 14001 and OSHAS 18001

State-of-the-art analytical labs










Phase 1 – Since 2017

Phase 2 – Since Oct, 2019

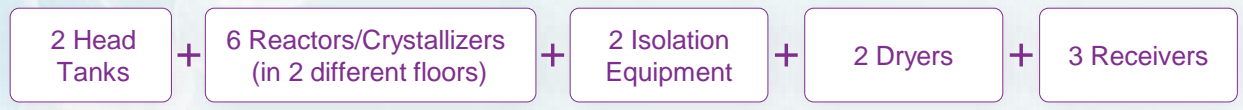
Phase 1 non-GMP Pilot Plant – B10

-  Reactor volume 16.5m³
-  Reaction Temp. range: -10oC to +120oC
-  15 Glass lined Reactors/Stainless Steel Reactors, size range from 200L to 3000L
-  4 sets of filtration and drying equipment, including 3 Centrifuges (800*3 (one halar-coated))
-  2 sets of Tray dryers, 1 set of Double cone dryer and 1 Nutsche Dryer (1000*1)

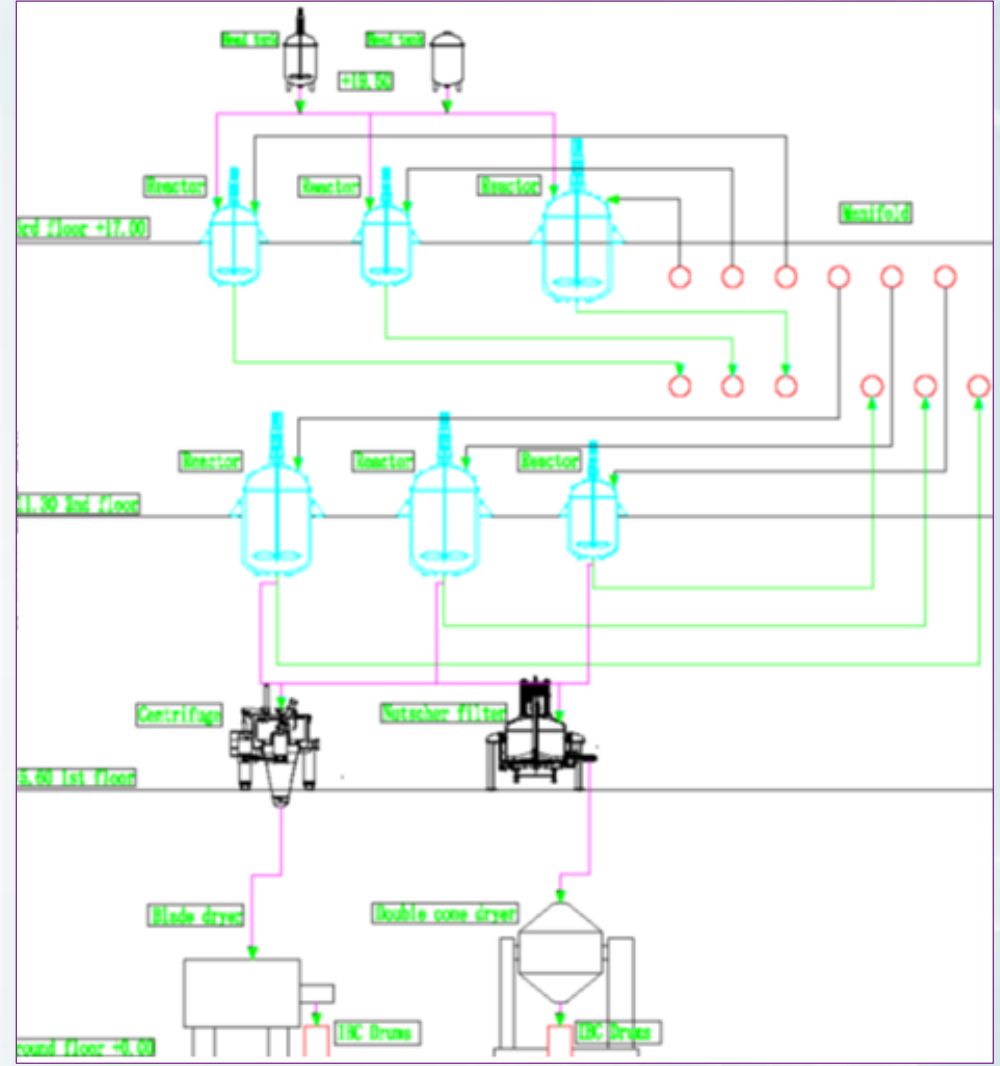


Phase 2 non-GMP Pilot Plant – Design Concept

- Reasonable size of equipment grouped to achieve maximum flexibility as multi-purpose production trains:



- Optimal use of gravity combined with manifold system.
- Closed material handlings in consideration of occupational hygiene requirements.
- Full range of isolation and drying equipment:
 - Centrifuge and Nutsche
 - Double Cone Dryer
 - Cone Screw Dryer
 - Paddle Dryer or Tray Dryer
- Distributed Control System
- Cleanability in full consideration (cleanable rooms, CIPs)



Phase 2 Reactor
Floor View ▶

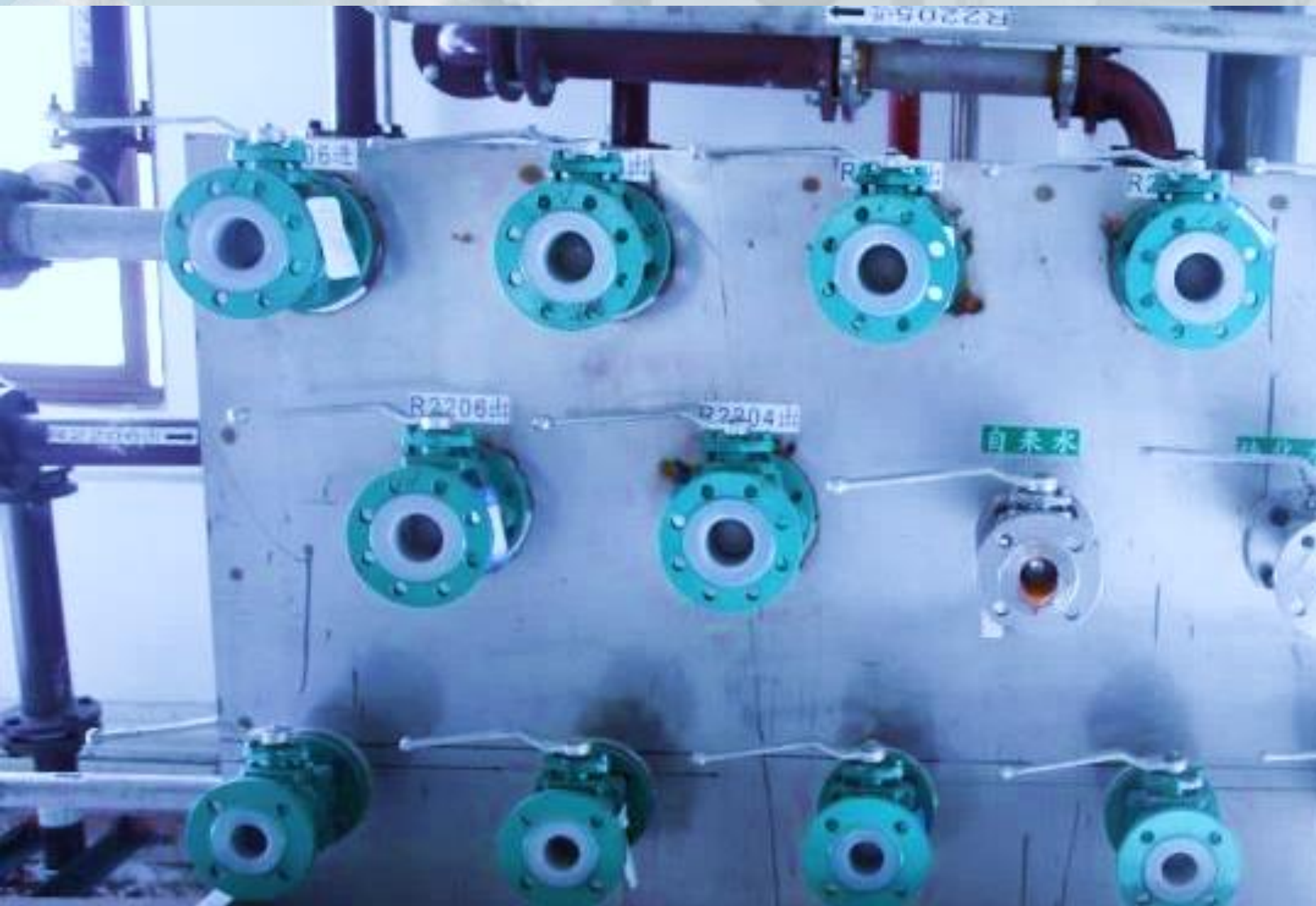
B12





DCS Control System





Manifold Station Material Transfer System



Closed Transfer System



Reactor to Centrifuge



Centrifuge to Dryer



Centrifuge to Dryer
and Pack-off ▶

Closed Transfer

// FACILITIES AND CAPABILITIES – B12 non-GMP pilot plant equipment



	Cryogenic Area	Equipment Group 1	Equipment Group 2	Equipment Group 3	Equipment Group 4	Hydrogenation Area
Head Tanks	500L GLx2	500L GLx2	500L GLx2	500L GLx2	1000L GLx2	200L GL 500L GL
Reactors	1000L HC 276 1000L SS 316L 2000L SS 316L Crystallizer x2	500L GL x2 500L SS316L 1000L GLx3	1000L GLx4 2000L GL 2000L SS316L	1000L GLx2 2000L GLx2 1000L SS316L 2000L SS316L	3000L GLx2 3000L SS316L 5000LGLx2	100L SS316L 500L SS316L 1000L HC276 2000L SS316L Crystallizer x2
Filtration	Centrifuge DN1000 Halar	Centrifuge DN1000 Halar Centrifuge DN1000 SS316L	Centrifuge DN1250 SS316L Nutsche Filter DN1600 Halar	Centrifuge DN1250 SS316L Nutsche Filter DN1600 Halar	Centrifuge DN1250 SS316L	Centrifuge DN1000 Halar
Drying	Tray dryer SS316L	Tray Dryer SS316Lx2	Double Cone Dryer DN1000 GL Paddle Dryer DN1000L GL	Double Cone Dryer DN1000 GL Paddle Dryer DN1000L GL	Double Cone Dryer DN1500 Halar Nutsche Filter Dryer DN1600 SS316L	Tray dryer SS316L
Receivers	1000L GLx3	1000L GLx5	2000L GLx5	2000L GLx5	3000L GLx5	1000L GLx3

GMP Capabilities

- GMP zoning concept:
 - Production of intermediates and post API SM steps in Uncontrolled area
 - Zone D Clean room for production and open handling of API following the final filtration step

- Equipment groups arranged so as to achieve maximum flexibility of multi-purpose production trains in Uncontrolled Area:



- Refining-drying-packaging in Zone D clean room

- Purified water system



// FACILITIES AND CAPABILITIES – B11 GMP pilot plant equipment

	Equipment Group 1	Equipment Group 2	Clean Room 1 (Refining-drying- packaging)	Clean Room 2 (Refining-drying- packaging)
Head Tanks	500L GLx2	500L GLx2	500L GLx2	500L GLx2
Reactors	500L GL 500L SS316L 1000L GL 1000L SS316L	1000L GL 2000L GL 1000L SS316L 2000L SS316L	Dissolver 500L GL Crystalliser 500L SS316L	Dissolver 500L GL Crystalliser 500L SS316L
Filtration	Centrifuge DN1050 SS316L	Centrifuge DN1050 SS316L	Centrifuge DN800 SS316L	Centrifuge DN800 SS316L
Drying	Tray Dryer SS316L	Double Cone Dryer 1000L GL	Tray Dryer SS316L	Double Cone Dryer 500L 316L
Receivers	1000L GLx5	2000L GLx5	500L GLx5	500L GLx5

Up coming New Capacity and Capabilities

Pilot plant B11

Phase 2 expansion, double cGMP capacity for post GMP starting materials and API

Pilot Plant B13

Further versatility with addition of high temp reaction capability, flow chemistry, rectification and column chromatography

Pilot Plant B14

Reserved for further expansion and tailor-made plant design

Pilot Plant B11 – cGMP Phase 2 Start up by Q2, 2021

- General reaction area (2 equipment groups)
- Clean rooms (2, refining-drying-packing)

Pilot Plant B13 - non GMP Start up by Q1, 2021

- High temperature reaction area (200 degree C)
- Flow Chemistry area
- Column chromatography
- rectification column

New Technology Application

Flow Chemistry:

- Stainless Steel Micro Reactor SSZ2010 with max capacity at: 600L/day
- Silicon Carbide Micro Reactor MRCS180(Capacity (max.): 400L/day)



Photo Chemistry:

- Glass Photocatalytic reactor, 100L



Plant synthetic and analytical lab capability

Instrument Name	Brand	Model/Type	Quantity
HPLC	Agilent	1260	7
UHPLC	Agilent	1290	2
GC+HS	Agilent	8890/7890+7697A	1/1
GC	Agilent	8860/8890	1/1
FT IR	Perkin Elmer	Spectrum Two	1
KF Titrator	Metrohm	870KF Titrino plus	1
KF Titrator	Metrohm	831 KF Coulometer	1
Potential Titrator	Metrohm	848 Titrino plus	1
Standard fume hoods	-	-	20
100L reactor	-	-	5
Flow reactor	Haomai	MRCS180 SSZ2010/HFZ2005	3

- State-of-the-Art laboratory design and analytical instrumentation
- Good Documentation Practice and Data Integrity fully embedded in QC operations
- Segregated GMP and non-GMP laboratories.
- OpenLab ECM data management system with full regulatory compliance in GMP QC Lab
- Analytical method transfer and validation
- Stability tests for API and intermediates



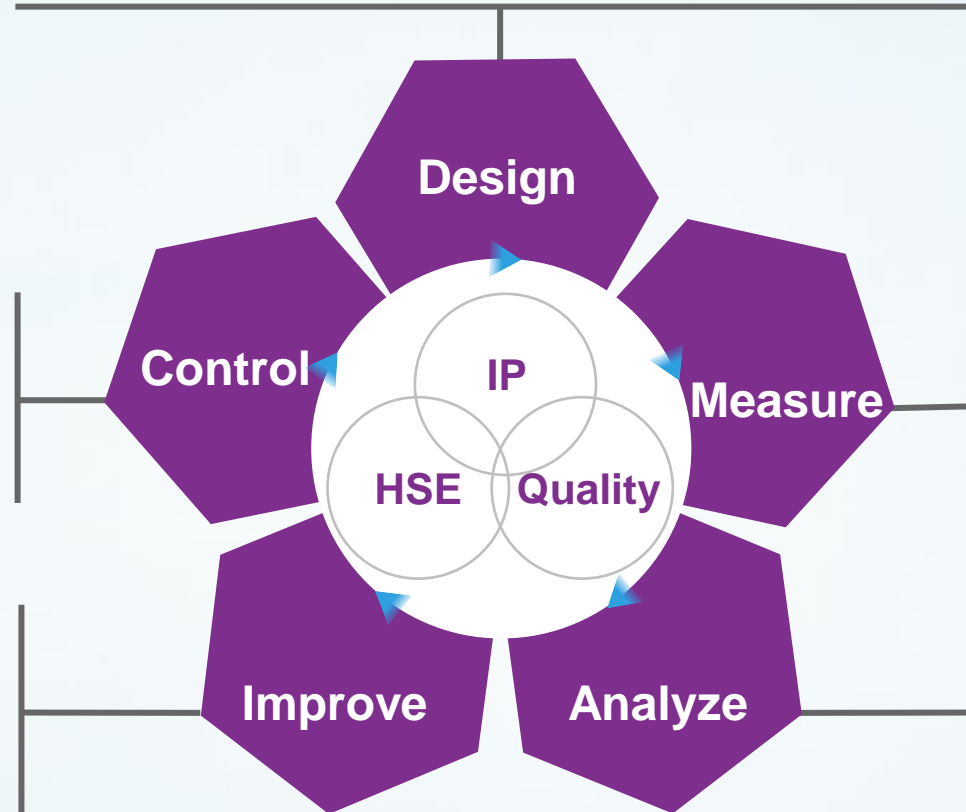
// PLANT LEADERS PROFILE

Name	Title	Education	Experiences
Qiang Ma	General Manager	M.S in Organic Chemistry, Tsinghua University	<ul style="list-style-type: none"> - 10 years API manufacturing experiences with Novartis - 2 years in Bellen
Tao Wang	Operation and EHS Head	M.S in Enterprises Management, Tambov State Technical University, Russian	<ul style="list-style-type: none"> - More than 15 years experiences in chemical production and safety management.
Libo Ma	Quality Head	M.S in Analytical Chemistry, Qingdao University of Science and Technology	<ul style="list-style-type: none"> - 15 year experiences in quality control and quality assurance, previously working in Novartis Chemical and Analytical Development, Johnson Matthey (Yantai)
Xi Luo	Engineering Head	M.S in chemical equipment and machine, Zhejiang university	<ul style="list-style-type: none"> - More than 25 years in Engineering management includes 11 years in Novartis Changshu manufacturing site as Engineering leader. - 1 year with Bellen
Tom Jiang	Technical Leader Group VP	M.S in Organic Chemistry, Nanchang University	<ul style="list-style-type: none"> - More than 20 years of chemical and drug intermediates production experiences, as well as safety and quality management
Qiuyong Wang	Associate Production Director	M.S in Organic Chemistry, Shandong University	<ul style="list-style-type: none"> - 3 years research and manufacturing experiences in Asymchem - 9 years manufacturing and EHS experiences in Johnson Matthey(Yantai), - 2 years with Bellen

// IP - HSE - QUALITY

Top priority of all what we do

- System is designed according to international standards and industrial best practices
- Design with feedback from customers and government



- Implementation is the key to ensure system effectiveness

- Counter measures are available to ensure system efficiency
- Personal performance links directly with IP/HSE/Quality compliance

- Continuous improvement is essential to ensure sustainability and long term success

- Timely and periodically review of the outages, behaviors and system failures
- CAPA analysis available to guide for systematic solutions

// BELLEN'S IP PROTECTION COMMITMENT

We fully recognize that IP is our customer's most valuable asset. Protecting IP and respecting the confidentiality are the top responsibility of everyone at Bellen. We developed a rigorous protocol and policy to ensure IP safety and security throughout a project life cycle.



IP protection throughout of a project life cycle

- Customer-Service

- Customer-Service
- R&D directors

- Project Directors
- Bench Chemists
- Analysts
- QC/QA
- Process Chemists

- Project Directors
- Bench Chemists
- Logistics

- Project Directors
- Bench Chemists
- Analysts

- ISMC(Information Security Management Committee) headed by a group VP, responsible for IP protection
- 10 SOPs provide detailed guidelines and requirements for every function with regards to ensure information security

// BELLEN'S IP PROTECTION – Behavior Management System



- 设备状态
- 实时监控
- 系统配置
 - 工作模式
 - 系统维护
 - 系统管理员
 - 网管策略
 - 日期/时间
 - 系统信息
 - HA 配置
 - 高级配置
- 第三方接口
- 系统对象
- 网络配置
- 用户认证
- 流量管理
- 行为管理
- 系统日志
- 故障排除
- 数据中心

Bellen introduced behavior management system across our IT infrastructure, to enhance IP protection measures and efficiency.

- Only dedicated accounts can send emails to external partners, all other emails communication remain within Bellen address.
- Website access control – only allowed website can be accessed, individual control based on the roles and needs
- Activities tracking on each computer(static IP address), including download, upload, website browse history etc

上网行为监控 全部 不刷新 过滤条件

过滤类型: 组过滤:Root : 访问网站 搜索引擎 邮件 IM聊天 发帖-网评 帐号登录 外发文件 . :允许 拒绝 告警

序号	时间	用户名	用户组	IP地址	行为类型	动作	内容
1	0秒前	192.168.100.1 52	Root	192.168.100.1 52	访问网站	允许	https://pop.bellenchem.com 网站域名: pop.bellenchem.com
2	1秒前	192.168.100.1 52	Root	192.168.100.1 52	访问网站	允许	https://pop.bellenchem.com 网站域名: pop.bellenchem.com
3	1秒前	192.168.100.1 59	Root	192.168.100.1 59	访问网站	允许	http://msc.wlxrs.com/~Live.ConfigServer.SuiteUpdate/~!~/~!~/~op-G... 网站域名: msc.wlxrs.com
4	1秒前	192.168.100.1	Root	192.168.100.1	访问网站	允许	https://sec-m.ctrip.com


// BELLEN'S IP PROTECTION – Access controlled project management System



In order to improve project management efficiency and ensure IP protection is addressed systematically, Bellen invested and developed our internal project management system(LIFT) with the objectives of:

- Increase efficiency, enhance security
- Reduce email/offline exchange of technical information
- Information, data access control
- Track the actions, log on time and activities(download, modify, delete, copy etc)

change the password Send password reset command



Xianglin Zhao
Xianglin.zhao@bellenchem.com

Access first choice

application

Order Confirmation	user
product information	
Sales Contract	
Customer file	
Purchase list	
Website background	Staff
Product quotation	
Order List	
Staff	

Working hours statistics

user	<input checked="" type="checkbox"/>	Statistician	<input type="checkbox"/>
Executive	<input type="checkbox"/>		

Product shipment

Warehouse user	<input type="checkbox"/>	Customer service user	<input type="checkbox"/>
administrator	<input type="checkbox"/>		

Raw material inquiry

administrator	<input type="checkbox"/>	Inquiry user	<input type="checkbox"/>
Purchase user	<input type="checkbox"/>		

Production tasks

Customer service user	<input type="checkbox"/>	general user	<input type="checkbox"/>
Production user	<input checked="" type="checkbox"/>	administrator	<input type="checkbox"/>

other

Access to Private Addresses	<input type="checkbox"/>		
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// BELLEN'S EHS MANAGEMENT - OVERVIEW

At Bellen, we consider EHS as the fundamental component of long-term business strategy and as a driver for sustainable growth. Our EHS policy, clearly outlines the organization's aspirations and provides our employees the guidance to comply the EHS standards.

- ISO14001 and OHSAS18001 certified
- EHS policy in place and aspiration/commitment from leadership team to instill a proactive safety culture
- EHS management system is formulated, implemented and maintained according to international standards and local regulations:
 - Intrinsic chemical process safety by design
 - Robust process safety and operational safety systems
 - Focus on occupational hygiene
 - Incident/accident investigation
 - Minimized environmental impact and energy consumption
 - Emergency management and business continuity
- Waste solvent/Solid waste are incinerated by a qualified service provider
- Major investment of a state-of-the-art multi-purpose chemical/pharmaceutical Waste Water Treatment Plant in the phase II project – under construction (1,500 tons/day)
- Off gas treatment in consideration in the building and WWTP design



BELLEN'S EHS MANAGEMENT - Intrinsic Process Safety

With our fully-equipped Process Safety Labs, we conduct rigorous, data-driven & comprehensive process and operational safety evaluation, to ensure the potential process risk is fully understood and managed during the project execution.

Shanghai R&D Center

Activities	Deliverables
<ul style="list-style-type: none"> Safety tests utilising: DSC, RC1, RADEX, SEDEX Risk Assessment Team reviews 	<ul style="list-style-type: none"> Approved Lab Procedures with safety test reports Process Safety Evaluation Form

Tech-transfer

Shandong Manufacture Plant

Activities	Deliverables
<ul style="list-style-type: none"> Use tests and scale-up demo batches Plant Process Safety Reviews 	<ul style="list-style-type: none"> Production Risk Assessment Reports Approved Master Batch Records



- Risk based approach to occupational health management
 - Hazard x Exposure = Risk
 - Application of **STOP** principle to manage risks
 - Use of OEL values as the basis for exposure evaluation, determination of Containment Solutions and methods of working with appropriate RPE
- New chemicals with unknown OEL levels requires liaison with customers prior to defining appropriate exposure control (OHB level 3 by default)
- Demonstrable capability for OHB level 3 discharging and OHB level 4 material charging



BELLEN'S EHS MANAGEMENT - Containment Solutions & RPE



Containment Solutions



Glove box charging



Charging with ECTFE film



PTS (Powder Transfer System)

Respiratory Protection Equipment



Half mask



Full mask



Air supply

// BELLEN'S EHS MANAGEMENT - Minimized environmental impact

Bellen

- Waste solvent/Solid waste is incinerated by a qualified service provider
- State-of-the-art on-site multi-purpose chemical/pharmaceutical Effluent Treatment Plant – in operation by Q4,2020

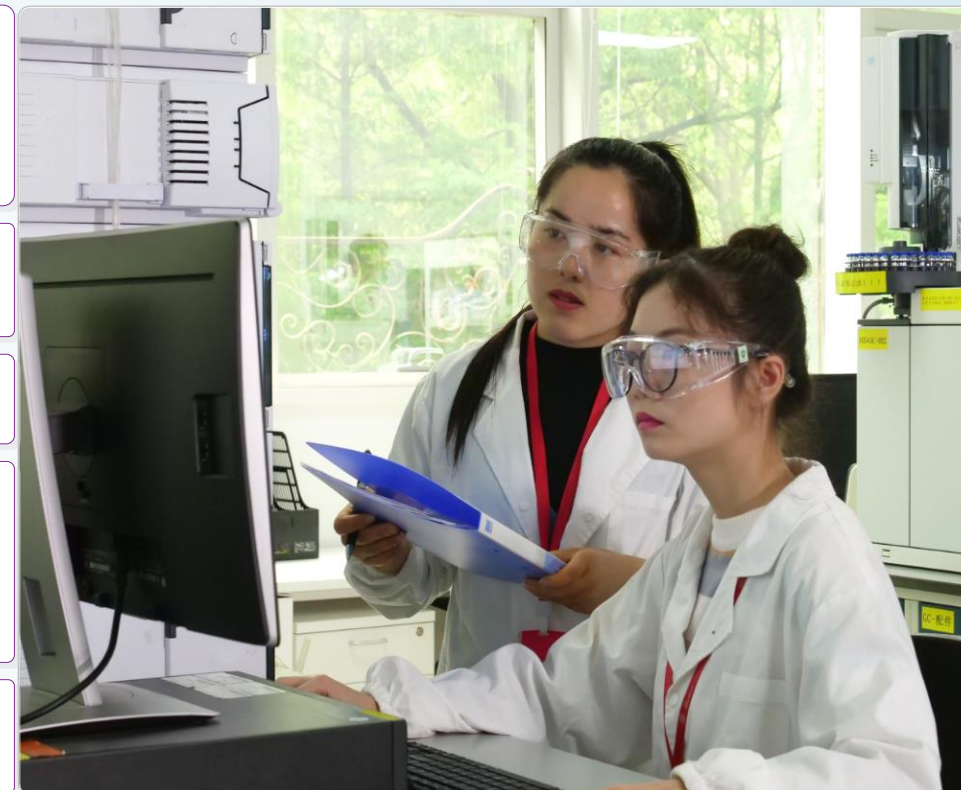


// BELLEN'S QUALITY ASSURANCE – cGMP Quality Management System



Our quality system is designed to meet the most stringent global regulatory standards. This enables us deliver products that consistently meet the expectations of the clients we serve. We ensure quality through a robust governance framework encompassing our facilities, people, procedures and Bellen's culture emphasizes on integrity and continuous improvement.

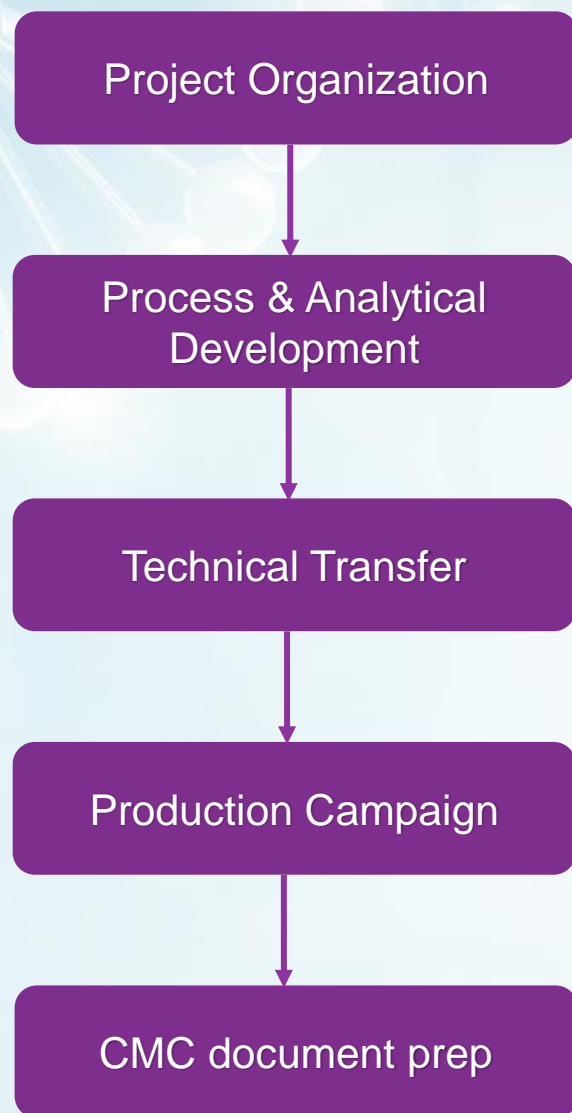
- Quality Management System established aiming to ensure that product complies with its specified requirements and is manufactured in accordance with appropriate standards
- The QMS adopts the basic principles of quality management as required under EN ISO 9001(Certified) and requirements of ICH Q7a
- Appropriate level of cGMP requirements applied to non-GMP manufacture
- Sufficient level of Sr. management team involvement to ensure the Quality Management System is reviewed, updated in a timely fashion and always complying with all regulatory requirements and industry best practices
- QA function reporting to CEO directly, responsible for quality system effectiveness and final product quality assurance



// BELLEN'S QUALITY ASSURANCE – Key Elements



// BELLEN'S QUALITY ASSURANCE – GMP project execution



- Well defined Process Development and technical transfer process in place to ensure smooth execution of GMP projects
- Process validation, cleaning validation, deviation management system, change control system and analytical method validation processes established
- Competent operations and management team with rich experiences in GMP manufacture and regulatory relevant activities



// BELLEN STRENGTH AND CAPABILITIES HIGHLIGHT

For over a decade, we have consistently delivered high quality and value-added services to our global customers. With our strong technical capability and increased capacity, we are up to any challenges in involving complex chemical synthesis from discovery, route scouting, process development and scale-up to commercial scales.

- Customer focus to meet tight timeline/urgent need
- Innovative route design and exploration to mitigate the process risk and shorten the supply timeline
- Process optimization based on the default screening scenarios.
- New technologies in place/being built up that aligned with Customer needs.
- Special reagents/reactions safe handling – cyanide, diazonium, azide, BuLi, LAH, Dess-Martin, etc.
- Rich experience for long steps complex molecule manufacture. (18 steps)
- High productivity, and as a result, more competitive for the defined tasks.
- Transparent communication for both positive and negative results
- Hardworking teams



Bellen

Thank You

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