



How to guarantee quality supply from China ?

中国におけるどのように品質供給を保証するか？

中宁化集团有限公司
NINHUA GROUP CO., LTD.

2017-04-20

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Sourcing from China

中国からの調達

Opportunities

機会

- Fast growing pharmaceutical industry
迅速に成長している医薬工業
- Continuously improved quality system
続けて改善されている品質システム
- Availability of APIs and intermediates ...
原薬と中間体の有効性...
- Cost competitiveness
価格競争力
- Emerging market
新型なマーケット
- ...

Sourcing from China

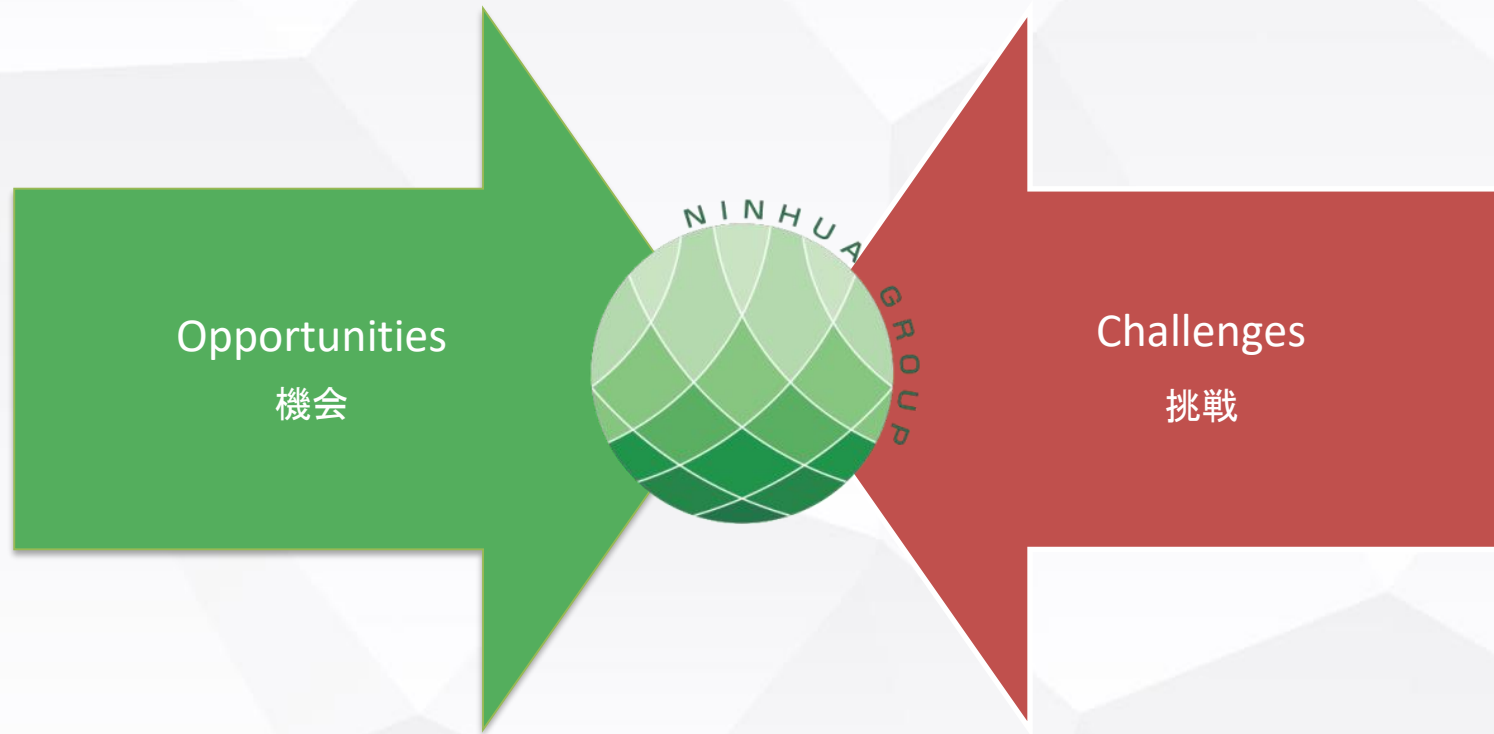
中国からの調達

- How to find reliable supplier ?
どのように信頼的なサプライヤーを見つけるか。
- Good understanding of PMDA regulations
PMDA規制に関する十分な理解
- Quality system and EHS system
品質システムとEHSシステム
- Change control (process , spec , site ...)
変更管理(製法、規格、工場)
- Documentation (not limit to APIs)
ドキュメンテーション(原薬に限らず)
- ...

Challenges

挑戦

Sourcing from China
中国からの調達



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Company history

会社沿革

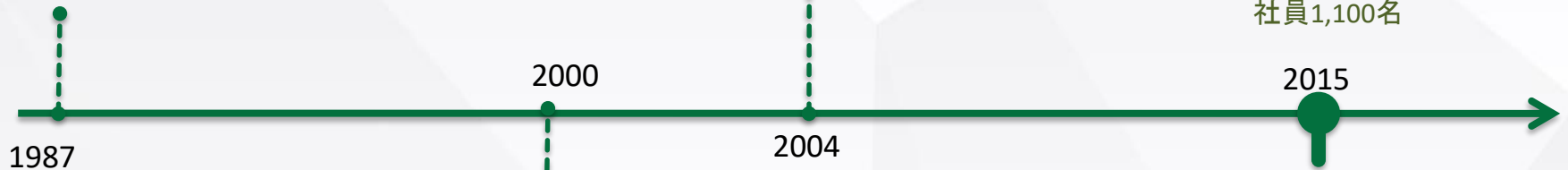
Sinochem Ningbo Imp.&Exp. Co.,Ltd.
100% to Sinochem Group.

Sinochem Ningbo Imp.&Exp. Co.,Ltd.
として設立され、Sinochem Groupに100%所属。

Changed name to Sinochem Ningbo Ltd. (not only trading ,but also R&D and production)

Sinochem Ningbo Ltd.へ変名(貿易に限らず、研究所と製造所も追加)

1,100 persons
社員1,100名



Changed to shareholder company , 51% to Sinochem Group and 49% to Employees

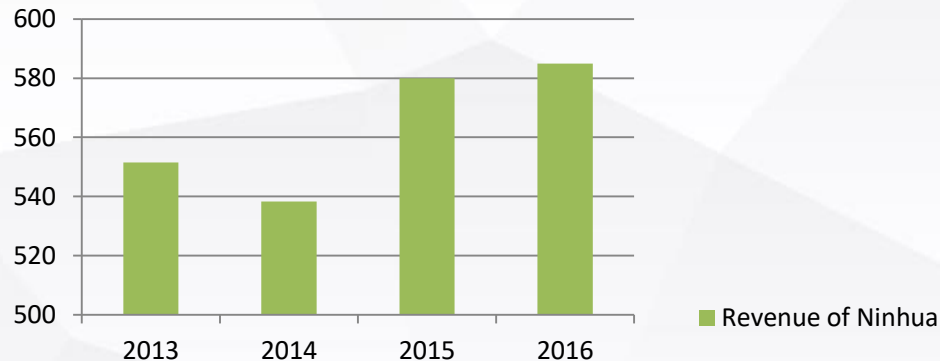
株式会社に変更、51%株をSinochem Groupで持ち、49%株を社員で持つ。

MBO (100% to Employees) and
Changed name to
Ninhua Group Co.,Ltd.

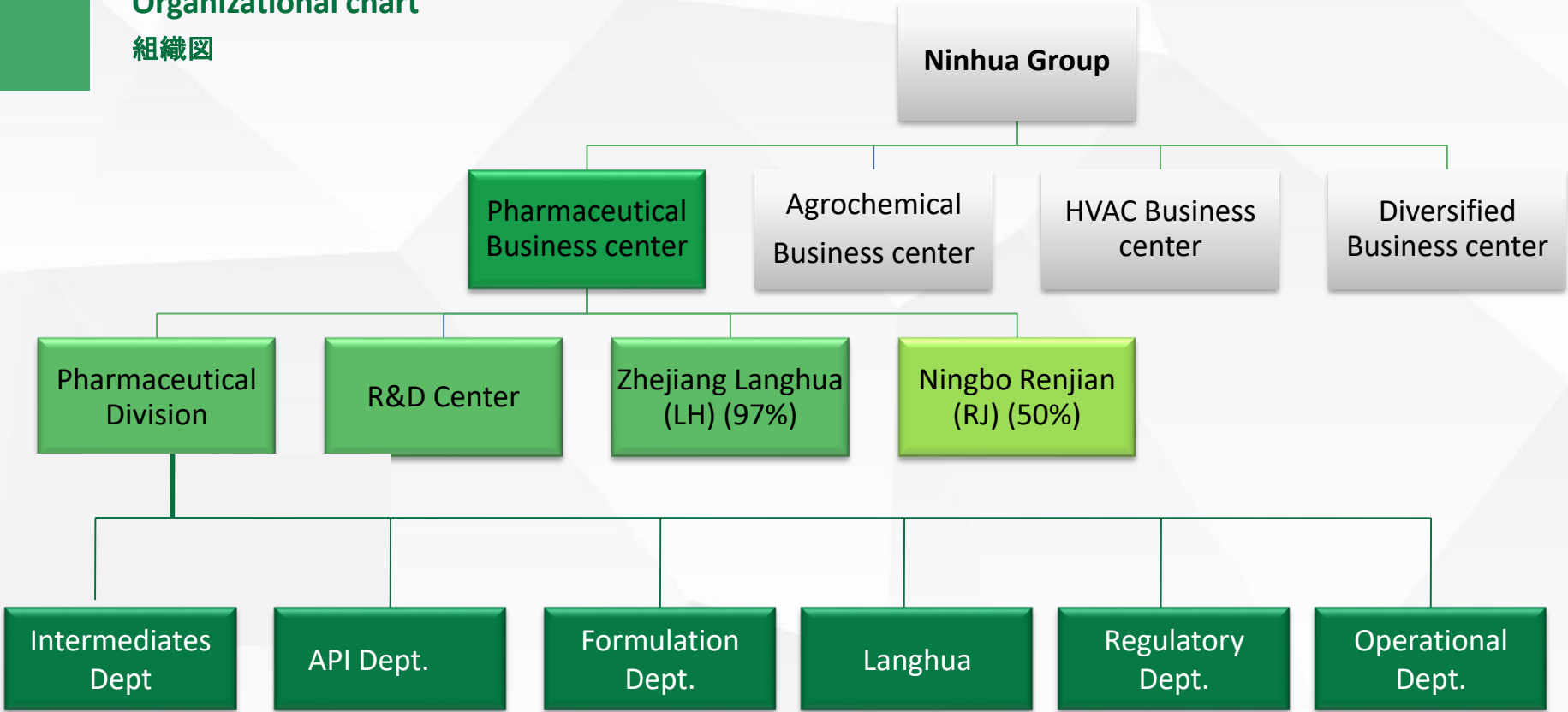
MBO(経営陣買収・100%株を社員で持つ)
社名もNinhua Group Co., Ltd.へ変名。

Revenue of Ninhua (Million USD)

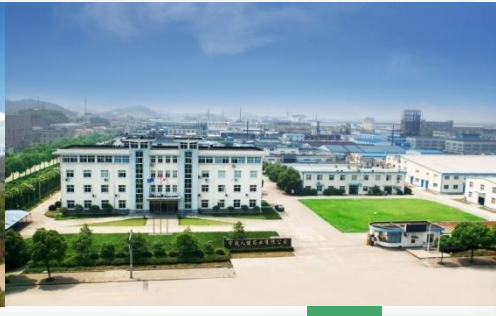
Ninhuaの収益

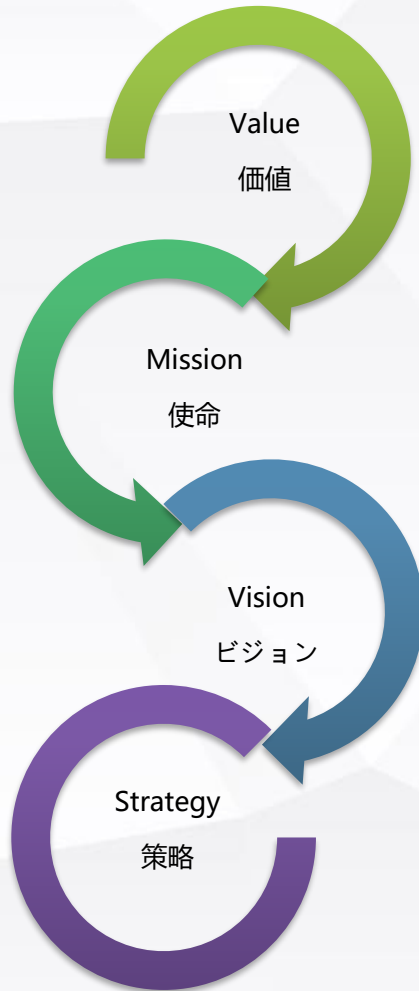


Organizational chart
組織圖



PMDA **USFDA** **EDQM** **WHO** **CFDA**
Approved Approved Approved Approved Approved





Patient-centered
 Excellent
 Reliability
 Flexibility
 Efficiency
 Collaboration
 Technology-driven

患者中心性
 優秀性
 信頼性
 適応性
 効力性
 協働性
 テクノロジー主導

Contribute to healthcare by supporting the improvement of medicine availability and affordability
 医薬品の有効性と値頃感への改善をサポートするように医療に貢献する。

To be the most valuable and preferred, innovative API manufacturer and CDMO partner
 高価値及び望ましくて、革新的な原薬製造所とCDMOパートナーになる。

Reliability	信頼性
Flexibility	適応性
Efficiency	効率性

Our value
我々の価値

PERFECT

Patient
centered

患者中心

Excellence

優秀性

Reliability

信頼性

Flexibility

適応性

Efficiency

効率性

Collaboration Technology-
driven

協力性 テクノロジー主導

Business activities
 ビジネスの働き

Your one-stop solution for sourcing !

——調達にワンストップソリューションを提供。

Marketing - Your sourcing partner	R&D	Production
<ul style="list-style-type: none"> - Professional team - Intermediates , APIs and formulations - 30 years experience - Strong market intelligence - Strong net work - QA and EHS support (QA team in the marketing team) - QC and R&D support 	<ul style="list-style-type: none"> -110 persons team - Focus on new process development and further optimization - 11 years working experience as R&D partner for big pharmaceutical companies - More than 100 processes developed - Involved in more than 10 new APIs launch - 100% scaling up success 	<ul style="list-style-type: none"> -High compliance both quality and EHS - GMP (FDA ,EDQM ,WHO,CFDA) - Whole process in house - Reliability, Flexibility, Efficiency and Innovation - API experience - Tech transfer experience - CDMO experience - Professional project management team

Your reliable CDMO partner !

——あなたの信頼的なCMDOパートナーである!

Our Services
我々のサービス



R&D

Gaoke R&D
110 persons

Zhejiang Langhua R&D
25 persons

Ningbo RJ
35 persons



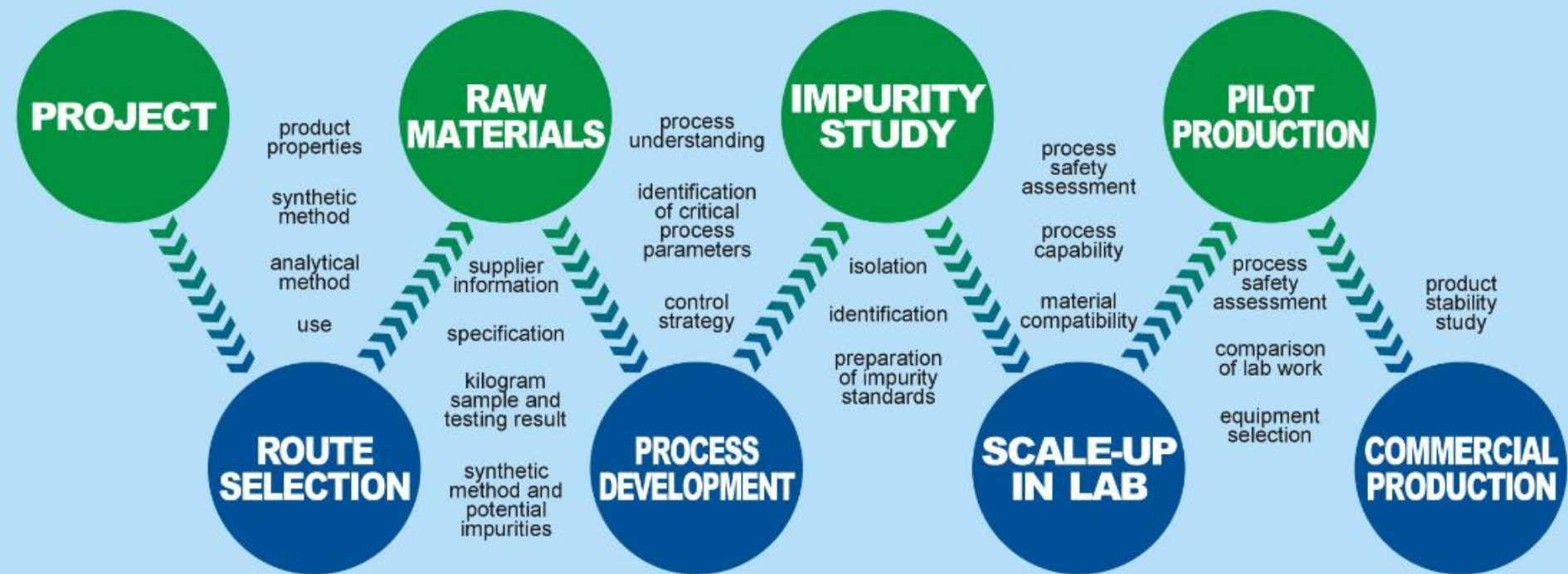
R&D working philosophy
R&D の働き信条



R&D process
R&D のプロセス

Whole life-cycle management

全ライフサイクルの管理



Same team lead technical transfer from lab to plant

同じチームでラボから工場まで技術移転する



R&D process R&Dのプロセス

Input

Route selection;
Safety assessment;
Cost calculation

DOE;
Reaction calorimetry;
Impurity study;
Material compatability study

Process safety assessment;
Equipment selection;
Process robustness testing

CPV;
Process continuous optimization

Project evaluation

Process development

Pilot production

Commercial production

Output

Final route

CPP, CMA;
NOR, PAR;
Specification setting;
CHA;
Impurity profile

PHA;
Pilot equipment;
Quality product

Production data analysis

Report

Feasibility report

Draft CA report;
R&D report;
CHA report

Updated CA report;
PHA report;
Equipment qualification report;
Pilot production report

Updated CA report;
CPV report

Process development and scale up
製法開発とスケールアップ

Lab

How to guarantee the success ?

どのように成功を保証するのか。

Plant
(Scale up)

From Lab to Plant

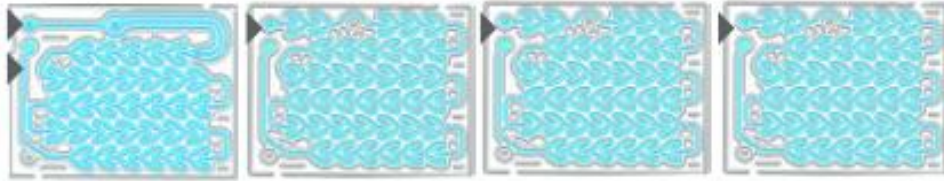
- Process design is essential!
 - Quality by Design (QbD)
 - Design of Experiment (DoE)
 - Possibility to scale up
 - Quality and EHS requirements
 - Competitiveness (low cost, environment-friendly etc.)
 - ...
- Good understanding of the process is fundamental!
 - CMA (Critical Material Attributes)
 - CPP (Critical Process Parameters)
 - CQA (Critical Quality Attributes)
 - Control strategy development
 - Equipment requirements
 - ...

Our practice for scale up

- **Same team** leads technical transfer (lab to plant) !
- Follow the scale up procedure
 - Process safety information
 - Process Hazard Analysis
 - Process Safety Management
 - Control strategy
 - Good Engineering Practice
 - Continuous improvement
 - ...
- Try to guarantee the process consistency from lab to plant (data collection and comparison)

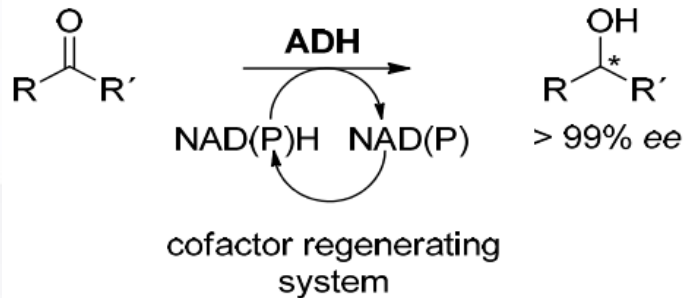
Core competence 中核的な能力

- Chemical development including using hazardous chemicals , low temperature, Chiral chemistry ...
- Chemical and enzymatic process development
- Continuous flow technology
- Asymmetric hydrogenation process
- Solid state chemistry (polymorph screening, crystallization process development etc.)
- ...



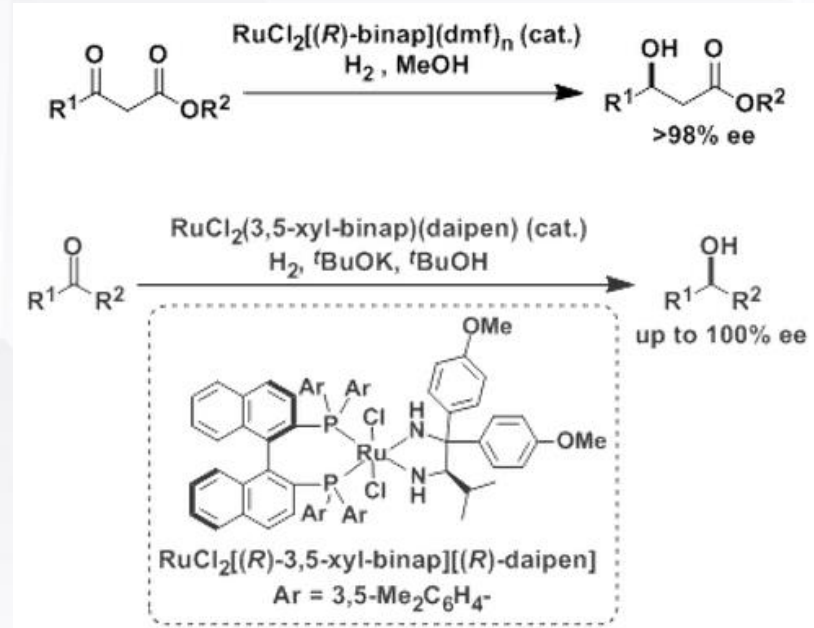
Continuous flow technology

連続流技術



Enzymatic chemistry

酵素反応



Asymmetric hydrogenation process

非对称水素化

R&D development - safety lab is available

R&D開発——安全ラボ可能

- Process information collection (EasyMax and OptiMax) プロセス情報調査(EasyMaxと OptiMax)
- Process safety data (RC1 and DSC) プロセス安全データ(RC1 and DSC)
- Inherent safety and reaction type extension (Flow reactor) 固有安全性と反応設備応用(連続流反応)
- Process Analytical Technology (React IR and Focused Beam Reflectance Measurement) プロセス分析技術(React IRとFBRM)



OptiMax



EasyMax



React IR



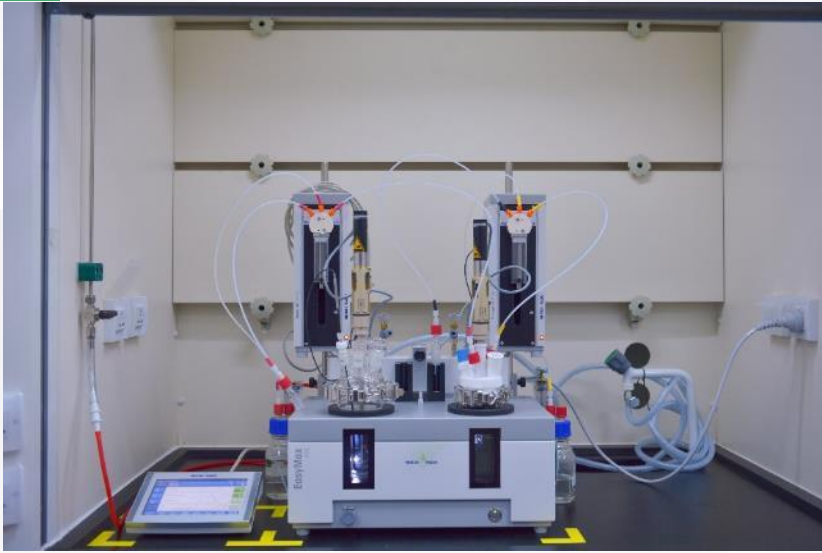
RC1



R&D



R&D



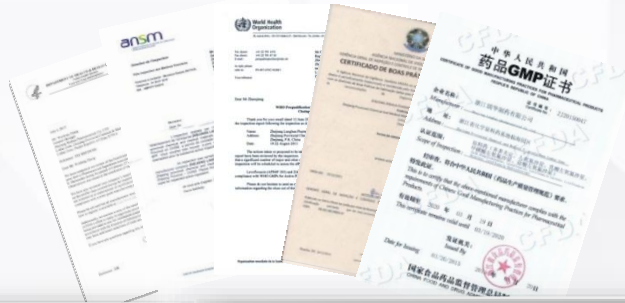
Zhejiang Langhua Pharmaceutical Co.Ltd.

Strategy	Reliability, Flexibility and Efficiency
Establishment	2005
Total area	about 188,000 m ²
Building area of workshop	about 10,500 m ²
Employee	532
Location	Zhejiang Provincial Chemical Base Linhai Zone, China
Website	www.Langhuapharma.com

- A U.S.FDA/WHO/EDQM/CFDA/Anvisa approved manufacturer, focus on APIs, advanced intermediate & CDMO project
- ISO 14001; OHSAS 18001; EcoVadis Evaluation

USFDA/WHO/EDQM/ANVISA/CFDA Approved

- 1 EUGMP
- 2 WHO-PQ GMP
- 2 Brazilian GMP
- 3 CEP
- 17 CFDA GMP
- 3 US-DMF/ 1 VMF



Langhua current capacity
Langhuaで現有の生産力

Big and flexible capacity
大きいでフレキシブルな生産力

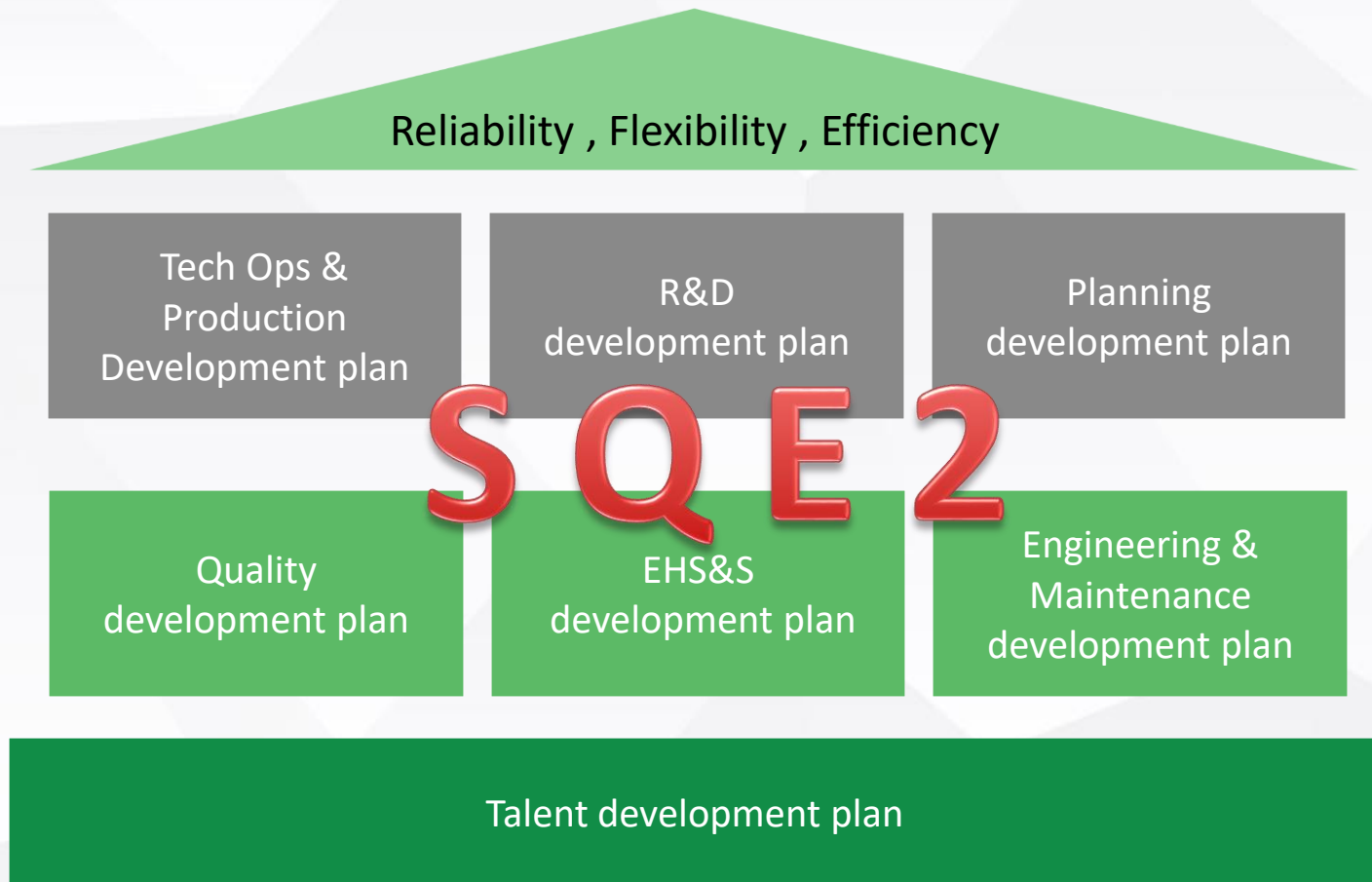
Building No	Capacity	Total reaction volume	Environment	Remark
05#	60t	65m ³	General area Control area Clean area	Intermediate Crude API API
09#	1800t	141m ³	General area	Intermediate
10#	600t	74m ³	Control area	Intermediate
11#	500t	31m ³	General area	Intermetiate
12#	1500t	100m ³	Control area	API
14#	80t	91m ³	General area	API
15#	20t	58m ³	Control area	Intermediates
16#	300t	86m ³	General area	Intermediates

Total 4,860t 646m3

Langhua additional capacity (plan to build)
Langhuaのさらに追加する生産力(建造計画)

Building No	Capacity	Total reaction volume	Environment	Remark
04#	60t	21m ³	General area	Multi-purpose Pilot Plant (Construction will be finished in Q3, 2017)
17#	TBD	81m ³	General area	Multi-purpose plant for Intermediate (Concept Design will be finished in Q4, year 2017)
68#	2200t	285m ³	General area	Multi-purpose plant for Intermediate (Concept Design will be finished in Q4, 2017).
51#	TBD	285m ³	General area	Multi-purpose plant for Intermediate & API, (Concept Design will be finished in the Q4, 2017;
* There are still about 50,000m ² area for future expansion except above plan.				

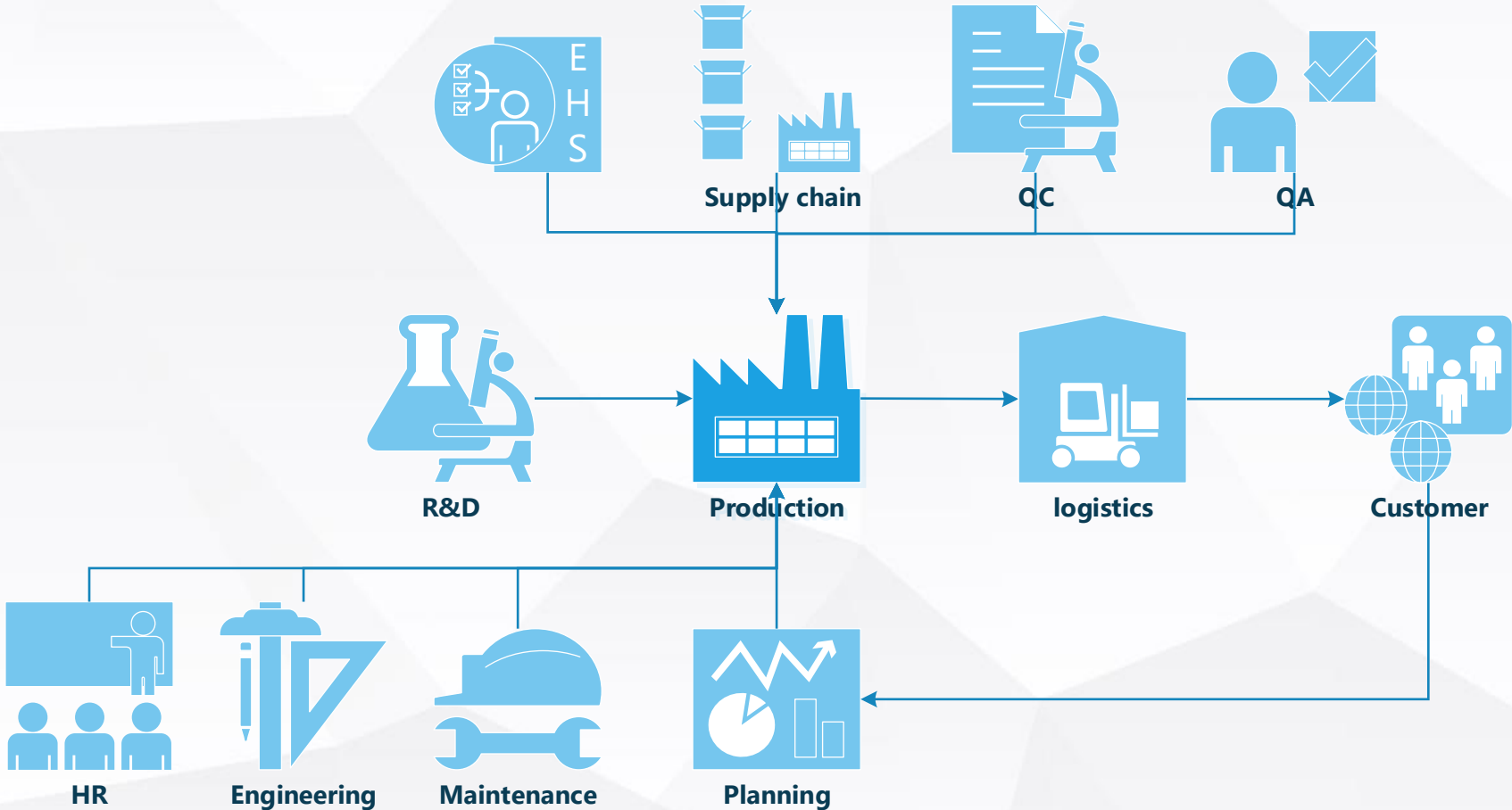
Site development plan
工場発展計画



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Quality and Reliability
品質と信頼性



Sourcing for customers
客先為の調達



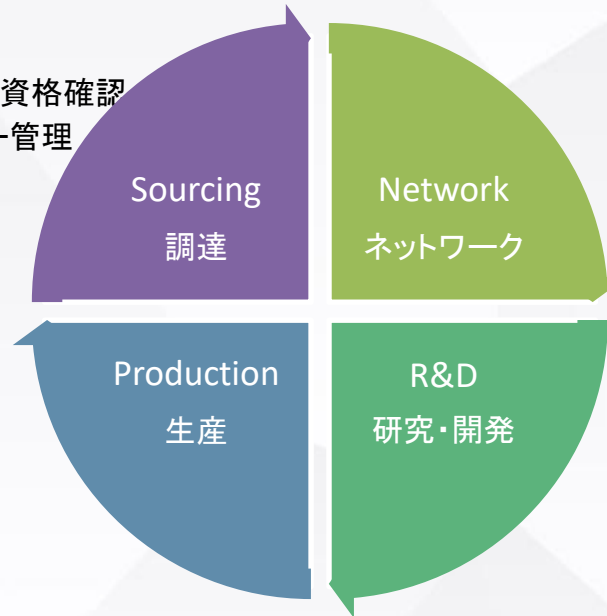
R&D and production
R&D と生産



One-stop solution ワンストップ ソリューション

Sourcing from China 中国から調達

- Market screening 市場適格審査
- Supplier qualification サプライヤー資格確認
- Supplier management サプライヤー管理
- Project management 項目管理
- Testing in China 中国での試験
- Sample taking and sending
サンプル取得と送付
- Logistic working 物流サポート



Leverage cooperation with other manufacturers based on our net work
ネットワークにより他の製造所と相互協力
Project management
項目管理
Tech and regulatory support
技術と規制サポート

Big and flexible capacity
大きいでフレキシブルな生産力

Cost improvement by innovation and efficiency

API experience (China for China , China for the world)
革新と高効率の原薬経験でコスト改善(中国国内・中国から全世界へ)

Brand-generic approach
ブランド-ジェネリックへ近寄る

Innovation for customer

客先為に革新

IP for customer

客先ための知的保護

Process development and optimization
製法開発と最適化

Open in joint-development and open to transfer

共同開発中情報シェアと技術移転中シェア

Reliability | Flexibility | Efficiency



Thank you!

どうもありがとうございました!