



Zhejiang Langhua Pharmaceutical Co., Ltd.

-Your Valuable CDMO Partner

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Reliability, Flexibility, Efficiency, Innovation

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Langhua Pharma Introduction



Reliability, Flexibility, Efficiency, Innovation

→ General Information



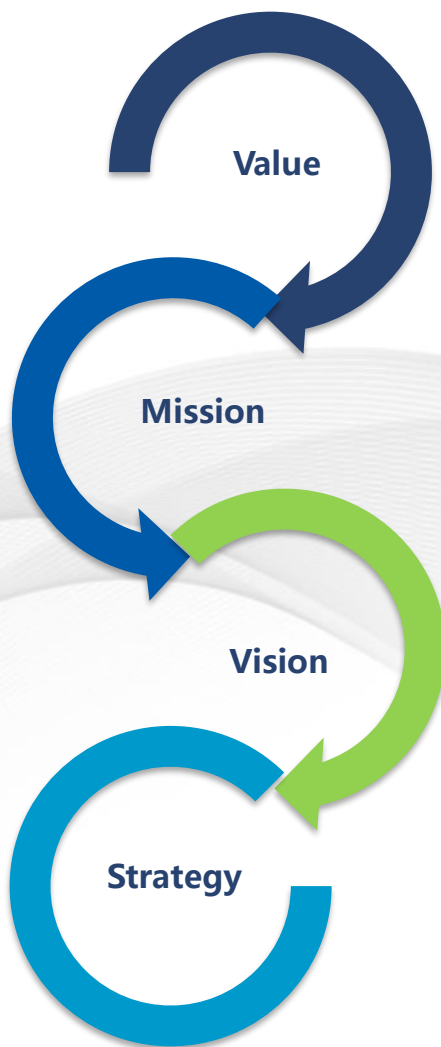
- *U.S.FDA/WHO/EDQM/CFDA/ANVISA approved manufacturer*
- *Focus on APIs, GMP intermediate & CDMO Business*
- *Located in National Level Pharmaceutical Industry Zone, Zhejiang Province.*

Zhejiang Provincial Pharmaceutical Industry Zone



Reliability, Flexibility, Efficiency, Innovation

→ Langhua-Vision & Mission



Value

*Patient-centered
Excellent
Reliability
Flexibility
Efficiency
Collaboration
Technology-driven*

Mission

*Contribute to healthcare by supporting the improvement of
medicine availability and affordability*

Vision

*To be the most valuable and preferred, innovative API
manufacturer and CDMO partner*

Strategy

*Reliability
Flexibility
Efficiency*

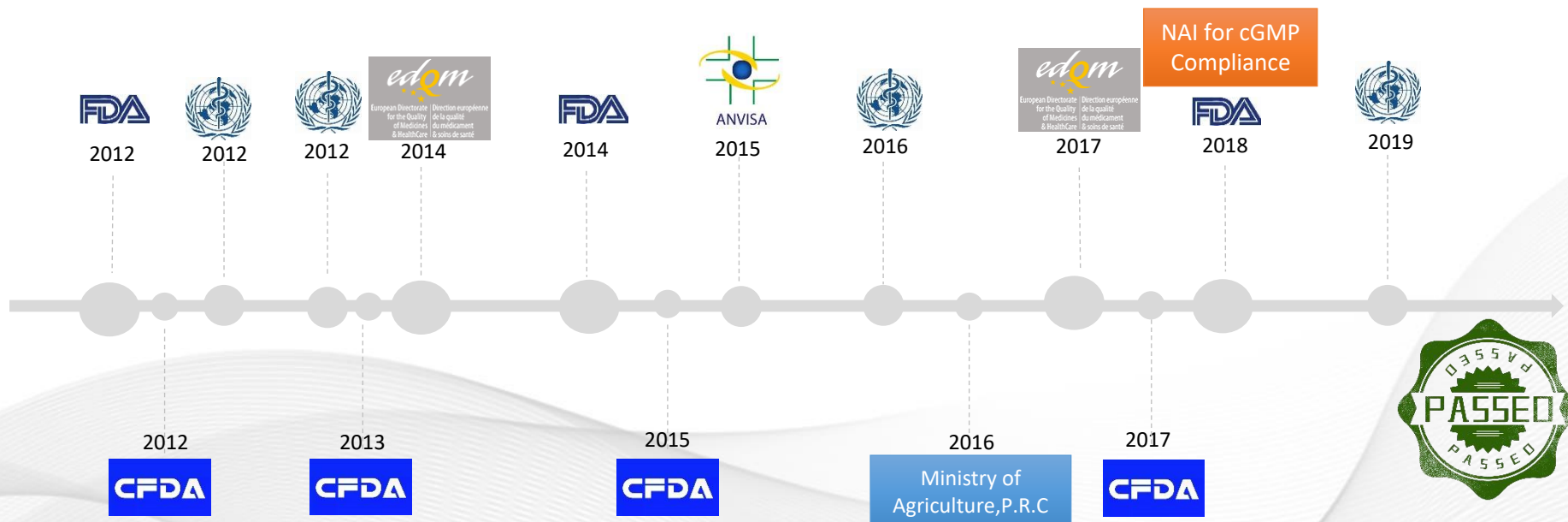
Quality & EHS



Reliability, Flexibility, Efficiency, Innovation



Inspection Track Records



-  Passed all GMP inspections
-  2 EU-GMP
-  2 WHO-PQ
-  4 CEP



PSCI Inspection passed



ISO14001,45001,EcoVadis



Passed Partner's Audit



50%+ Capacity Free



CDMO Introduction



Reliability, Flexibility, Efficiency, Innovation



Business activities

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- QC and R&D support	<ul style="list-style-type: none">- 110 persons team- Focus on new process development and further optimization- 15 years working experience as R&D partner for big pharmaceutical companies- More than 200 processes developed- Involved in more than 20 new APIs- 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 & Innovation- API experience- Tech transfer experience- CDMO experience- Professional project management team

→ R&D Center



Rich experience team



15 years working experience as R&D partner for big pharmaceutical companies



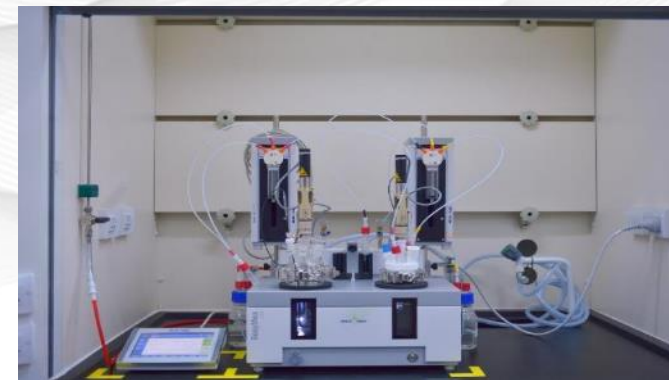
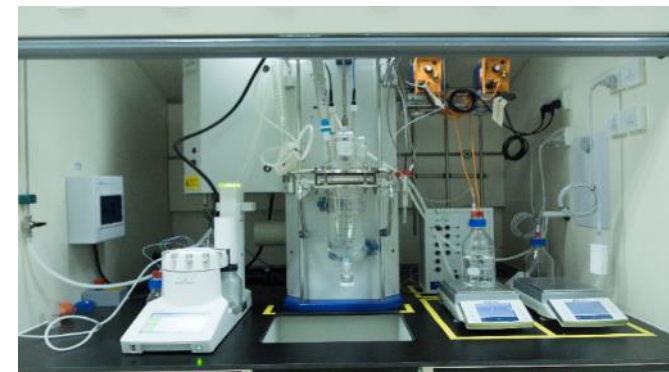
Safety Lab



Process Safety
Thermal Stability
Reaction Calorimetry
Adiabatic Calorimetry

Reaction Mechanism
Online Monitoring
Impurity Isolation

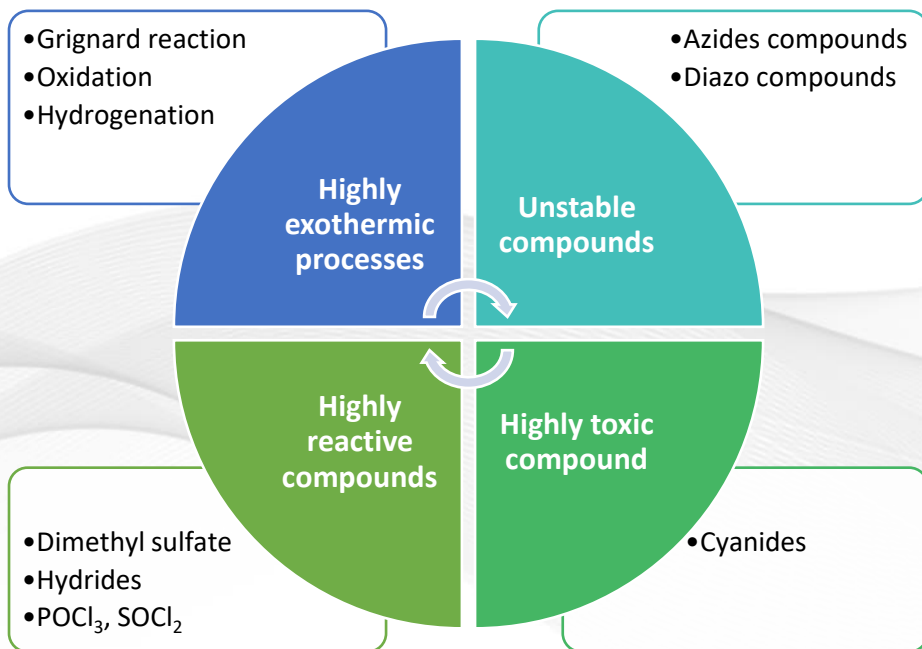
Process Optimization
Reaction Conditions
(Temperature/dosing rate/pH……)
Hazard Reactions





Core competence

Hazardous chemistry



Reaction Type



Flow Chemistry

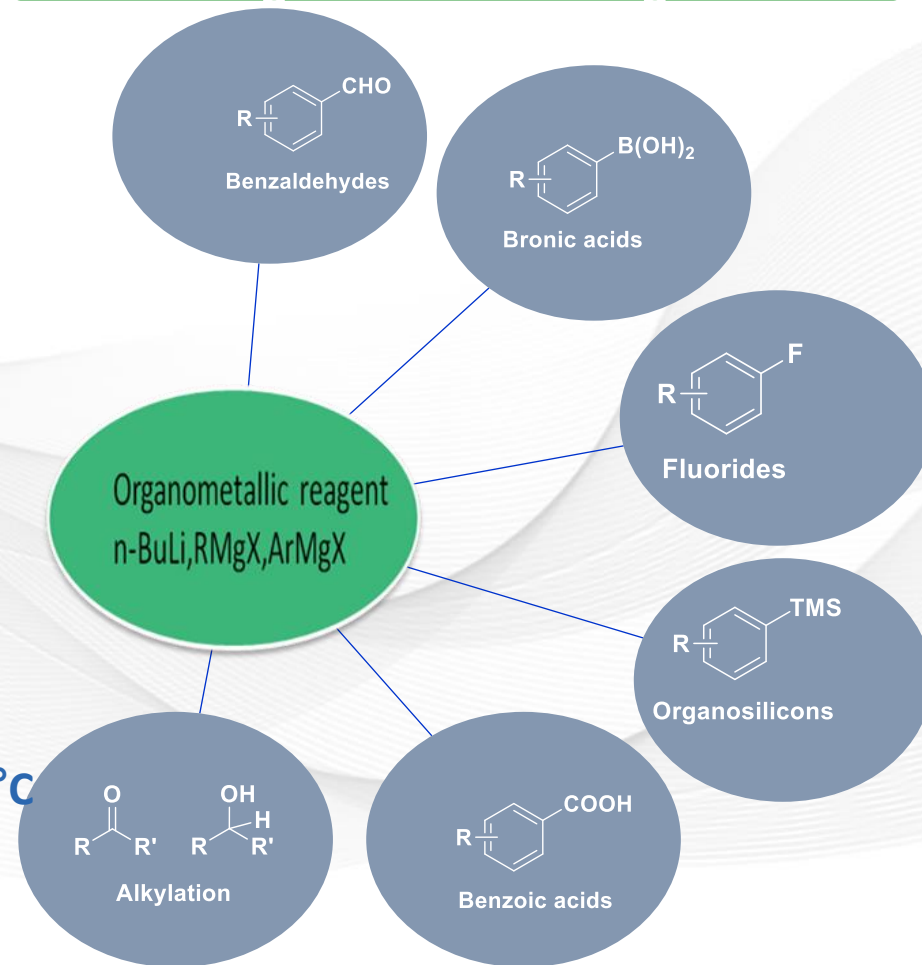


Enzymatic Reaction

Chiral chemistry

Low Temp. & Organometallic Reagent

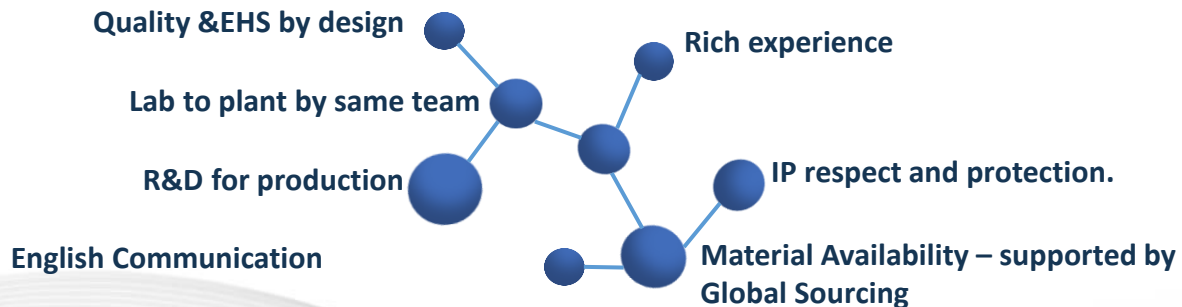
Asymmetric synthesis	Classic resolution
Bio Conversion	Chiral pool SM



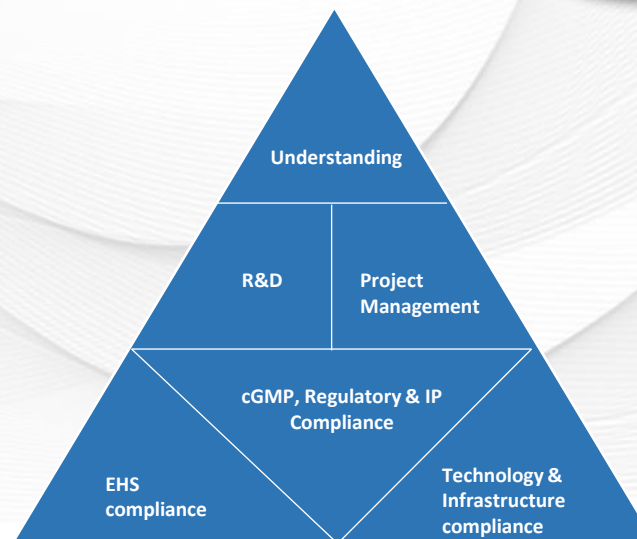
Commercial: up to 2000 L and down to $-80\text{ }^{\circ}\text{C}$

→ Strength

Strength



Primary objective: Deliver the project, on time, on budget and to the expected quality standard.



Project Management



Reliability, Flexibility, Efficiency, Innovation



How we do?



Project management is critical for project success !

*Information and
requirement from customer*

INPUT

*Clear Procedure with
Transparency !*

Deliverables

- Product
- Information
- ...

OUTPUT

No Black Box!



Communication



We believe transparent, clear and timely communication with customer is important



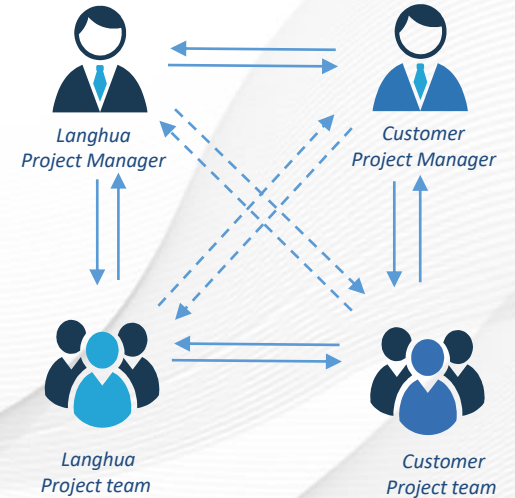
We can have the communication with customer as customer preferred (leader to leader, function to function ...)



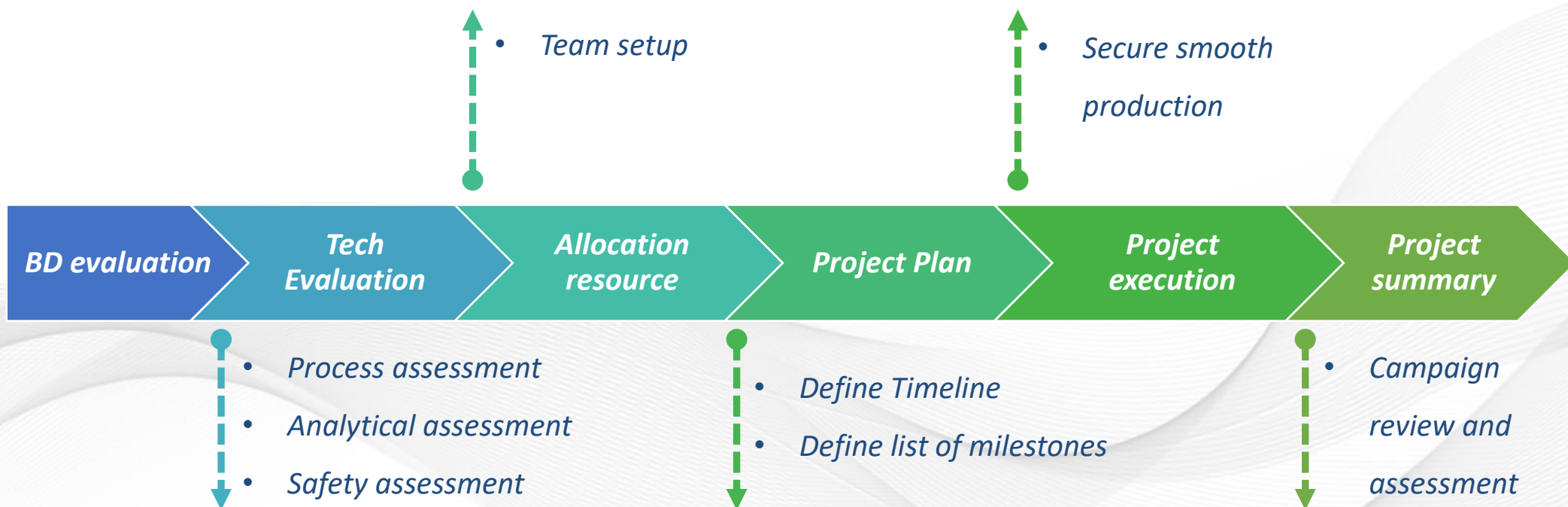
We will always keep the customer updated on the progress of project



Important project documents can be prepared in bilingual



Workflow of Technical Transfer





Project Management-4C



Clear Objective
On time delivery



Clear Understanding
Understand regulatory requirement and customers' expectation and make overall timeline for the whole project and dispatch to related teams



Clear Working Plan
Assign detailed task with time limit for production, engineering, regulatory, quality, supply chain, EHS team etc. and be checked periodically



Clear Communication
Inform customer immediately if there is any unexpected incident , and solve the issue with joint effort and decision



THANKS!

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