

**DESANO**

## Content 介绍内容

■ Company Introduction 公司简介

■ Our sites 生产场地

■ CMO service 委托生产服务



# Shanghai Acebright Pharmaceuticals Group

## 上海创诺医药集团



Acebright Pharma:  
Oncology, anti-infective and Cardiovascular drugs  
创诺制药: 抗肿瘤药、抗感染药物和心脑血管药物

### DESANO

Desano: ARVs, anti-malaria drugs and  
formulation contract manufacturing  
迪赛诺: 抗艾滋病药物、抗疟疾药物和制剂合约加工

### Hegno

Hegno: Vitamins, functional food ingredients  
and food/feed additives  
海嘉诺: 维生素、功能食品原料、食品和饲料添加剂

A photograph of a modern office building with a glass and dark facade, set against a blue sky with clouds. The building has multiple stories and a prominent glass section on the left. A red banner is overlaid on the right side of the image, containing the text 'Company Introduction' and '公司介绍'.

# Company Introduction

## 公司介绍

# Corporate Culture 企业文化

## ■ Mission 使命

We care for life, we work for human health

关爱生命，共享健康

## ■ Core Value 核心价值观

Quality first, Integrity foremost

品质第一，诚信为本

## ■ Vision 愿景

We are striving to establish a globally admired international pharmaceutical enterprise with sustainable development.

我们致力于建设一家受人尊敬的、可持续发展的国际化医药企业。

# Company Profile 公司简介

- ❑ **Founded in 1996, Desano is a leading pharmaceuticals company specializing in developing and manufacturing of ARVs and anti-malaria drugs.迪赛诺成立于1996年，是一家专门从事于开发和生产抗艾滋病抗疟疾药物的领先医药公司。**
- ❑ **Desano is one of the key ARV APIs suppliers and covers more than 35% market shares in Asia, Africa and Latin America, supporting the treatment of over 6 million AIDS patients globally.迪赛诺作为主要的抗艾滋病原料药供应商之一，占有亚洲，非洲和拉丁美洲35%的市场份额，向全球超过600万艾滋病患者提供用药支持。**
- ❑ **Desano is the first company launching generic ARVs in China since 2002, supporting more than half ARV treatment in China。 2002年迪赛诺成为国内首家上市国产ARV仿制药的公司,支持了国内50%的艾滋病患者用药。**
- ❑ **National R&D and Engineering Center of Anti-HIV drugs 国家抗艾滋病药物工程技术研究中心**
- ❑ **Sales revenue: 1.75 billion RMB(250 million USD) in 2019 2019年年收入17.5亿人民币（2.5亿美金）**
- ❑ **Actively exploring CMO business opportunities 积极拓展国内外委托加工业务**





## Our Sites 我们的工厂

# Vertically integrated Supply Chain of Desano

## 迪赛诺垂直一体化供应链

Intermediate  
中间体



- 1. Jiangsu Puxin Pharmaceutical Co., Ltd.  
江苏普信药业
- 2. Yancheng Desano Co., Ltd.  
盐城迪赛诺

API  
原料药



- Shanghai Desano Chemical Pharmaceutical Co., Ltd.  
上海迪赛诺化学制药

FDF  
制剂



- Shanghai Desano Bio-pharma  
上海迪赛诺生物医药



# Manufacturing Sites 生产厂址



**ARV Intermediates/APIs ARV中间体和API**  
Jiangsu Puxin Pharmaceuticals Devp. Co., Ltd.  
江苏普信  
Binhai Economy Development Zone, Yancheng

**ARV Intermediates/APIs ARV中间体和API**  
Yancheng Desano Pharma-Tech Co., Ltd. 盐城迪赛诺  
Dafeng Port Economy Zone, Yancheng

**Headquarter, R&D center, ARV formulations**  
总部，研发，ARV制剂  
Shanghai Zhangjiang Hi-Tech Park 上海张江  
Shanghai Desano Pharmaceuticals Investment Co., Ltd.  
Desano Bio-Pharmaceuticals Co., Ltd.

**ARV & anti-malaria APIs ARV和抗疟疾药物API**  
Binhai Industrial Zone, Pudong, Shanghai 上海浦东滨海  
Desano Chemical Pharmaceuticals Co., Ltd.

## Shanghai Desano Chemical Pharmaceutical Co., Ltd

### 上海迪赛诺化学制药有限公司

- ❑ Established in 2002 with registered capital 500 million RMB and total assets 1.2 billion RMB 成立于2002年，注册资本5亿人民币，总资产12亿人民币
- ❑ Total sales revenue 1.5 billion RMB, total employee about 900 员工总数900人，销售收入15亿人民币
- ❑ Shanghai High-Tech Enterprise 上海市高新技术企业
- ❑ A National Model Enterprise of Green Manufacturing 国家绿色制造示范企业
- ❑ No.1 API export Enterprise in Shanghai 上海原料药出口排名第1

# Shanghai Desano Chemical Pharmaceutical Co., Ltd

## 上海迪赛诺化学制药有限公司

Date	Milestones & History of Inspection
May 2002	Shanghai Desano Chemical Pharmaceutical Co. Ltd. was established. 公司成立
Feb. 2006	Desano Binhai facility (current location) was constructed to manufacture APIs and intermediates of ARVs and Anti-malarials. 建立原料药工厂
2007~2017	<b>Chinese FDA GMP</b> inspections 中国GMP审计
2009~2017	<b>US FDA</b> inspections (4 times, Apr., 2009/Jun., 2012/May., 2015/Mar., 2017) 4次通过美国FDA审计
Mar.2017	<b>MHRA</b> inspections (joint inspection Mar. 2017) 英国药监局审计
Mar.2017 Oct. 2019	<b>TGA</b> inspections (joint inspection Mar.2017) 澳大利亚药监局审计
2007~2019	<b>WHO</b> inspection (7 times Oct., 2007/Sep., 2009/Mar., 2011/May, 2013/Apr., 2014/Mar., 2017/Jan., 2019) 世界卫生组织审计
2011~2018	<b>ANVISA</b> (Brazil) inspections (3 times, Aug., 2011/Sep., 2014/Apr. 2018) 巴西药监局审计
2013~2017	<b>COFEPRIS</b> (Mexico) inspections(3 times, Apr. 2013/Aug.2015/Jun. 2017) 墨西哥药监局审计

## Site Location 地理位置





## Desano Site is officially included in the Master Plan of Shanghai Pudong Biopharmaceutical Industry Zone 迪赛诺老港基地纳入张江生物医药产业地图

2019年4月，浦东新区举行促进生物医药产业高质量发展发布会，宣布将迪赛诺老港基地纳入张江生物医药产业地图。

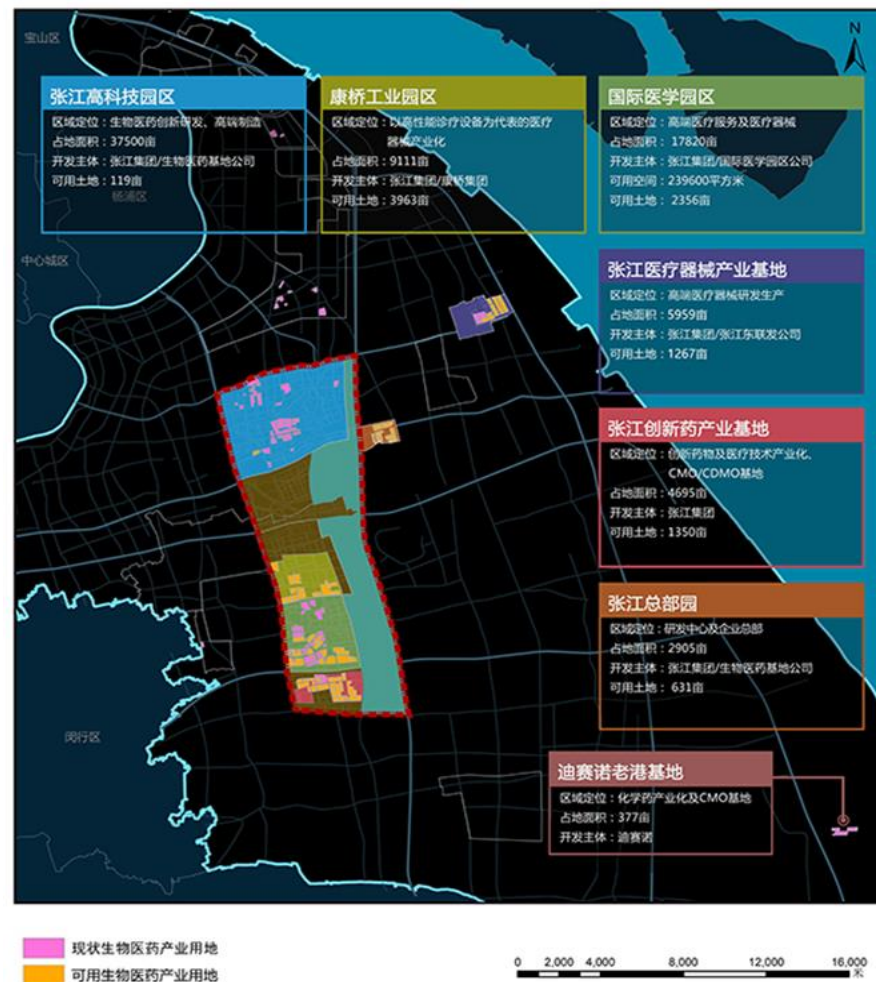
迪赛诺老港基地面积近0.5平方公里，定位为化学药产业化及CMO基地，重点布局化学药物的高端生产以及化学药物创新品种的产业化平台建设。

2019年8月，上海市政府批准了迪赛诺老港基地专项规划，相关工作正在积极落实中。

In Apr. 2019, Laogang Site of Shanghai Desano Chemical Pharmaceutical Co., Ltd. positioned as the Industrialization base of Chemical Pharmaceuticals and CMO, is officially included in the master plan of High Quality Development of Shanghai Pudong Biopharmaceutical Industry. It is established as the industrial platform for high-end production of chemical pharmaceuticals and innovative chemical pharmaceuticals.

In Aug. 2019, The specific master plan of Desano Lao Gang Manufacturing Site was approved by Shanghai Municipal Government. Related actions are under implementation.

上海市浦东新区生物医药产业规划图



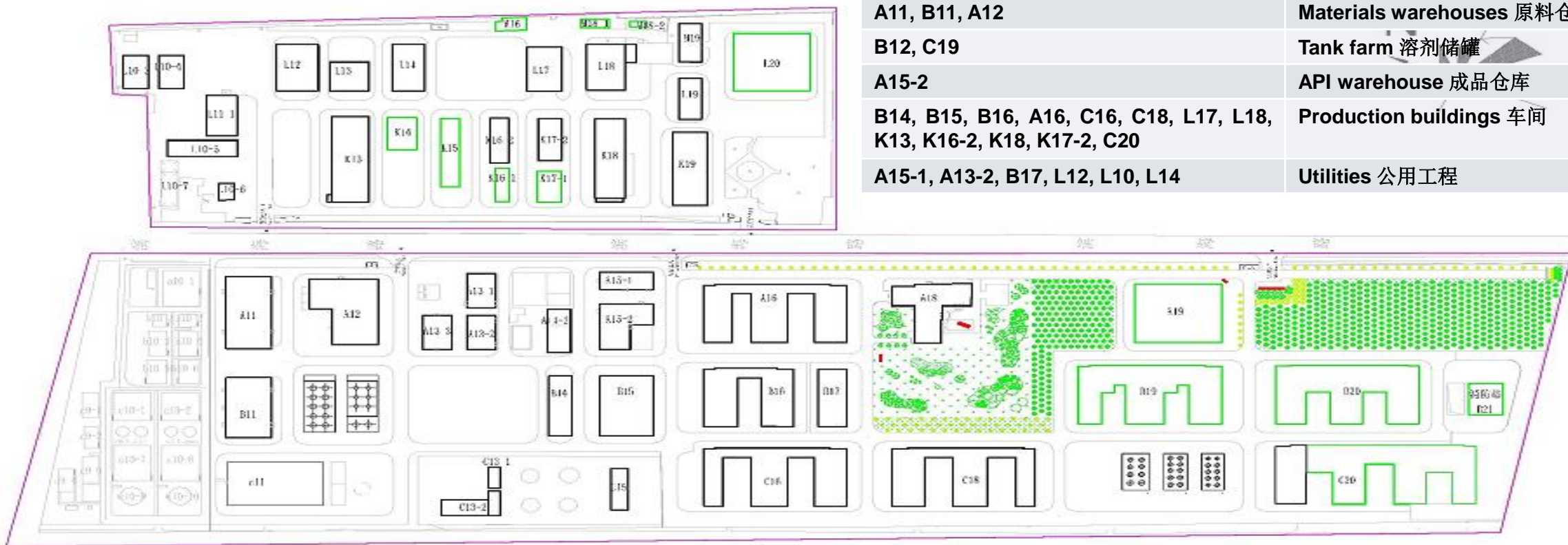


# EHS 环境、健康和安

- ISO14001 and ISO45001 (OHSAS18001) certified by Intertek since 2009  
2009-2018连续接受 Intertek 现场审核并取得ISO14001,ISO45001 (OHSAS18001)体系认证。
- EHS audit by TOP 20 Multinational Pharmas in 2011, 2015 and 2018.  
Continuous improvement is going on.  
连续多年接受全球排名前20大药厂的EHS审计，持续改进和提升。



# Site Layout 场地信息



Bldg. No.	Functions
A18, K19	QC & Office 分析实验室
A11, B11, A12	Materials warehouses 原料仓库
B12, C19	Tank farm 溶剂储罐
A15-2	API warehouse 成品仓库
B14, B15, B16, A16, C16, C18, L17, L18, K13, K16-2, K18, K17-2, C20	Production buildings 车间
A15-1, A13-2, B17, L12, L10, L14	Utilities 公用工程

\*具有年产1500T 原料药的生产能力





迪赛诺化学制药 Shanghai Desano Chemical Pharmaceutical Co., Ltd.





迪赛诺化学制药 Shanghai Desano Chemical Pharmaceutical Co., Ltd.



迪赛诺化学制药 Shanghai Desano Chemical Pharmaceutical Co., Ltd.



# Shanghai Desano Biopharma Co., Ltd.

## 上海迪赛诺生物医药

- ❑ Location: Zhangjiang High-tech Park, Shanghai 厂址:上海市张江高科技园区
- ❑ Area: 9.3 acres (including Headquarters and R&D Center) 占地面积9.3亩,包括总部和研发中心
- ❑ Products: Solid Oral Dosage formulations 产品:固体口服制剂
- ❑ Annual capacity: 1 billion tablets + 200 million capsules 年产能:10亿片剂+2亿胶囊
- ❑ cGMP standard, passed WHO inspection in 2015 在2015年通过WHO审计,符合 cGMP 标准
- ❑ Obtained US FDA EIR in 2017 and 2019 2017、2019年获得US FDA EIR
- ❑ Obtained the approval of first generic EFV tablets in 2017 2017年获得EFV片中国首仿上市
- ❑ Obtained WHO and FDA approval of Lami/Zido tablet in 2017  
拉米夫定/齐多夫定片剂2017年获得世界卫生组织和美国FDA批准
- ❑ Obtained WHO and NMPA approval of Lami/Zido/NVP tablet in 2018  
三联片2018年获世界卫生组织 和中国药监局批准



制剂生产场地 Shanghai Desano Biopharmaceutical Co., Ltd.





制剂生产场地 Shanghai Desano Biopharmaceutical Co., Ltd.





制剂生产场地 Shanghai Desano Biopharmaceutical Co., Ltd.

# CMO Capability 定制业务能力

通过各主要药品认证机构的审计、能按时按质按量提供CMO服务  
SRA (US FDA, EDQM, MHRA, WHO, EMA, TGA ect.) approved manufacturer,  
to provide high quality CMO service on-time and in full.

➤ Completed Due Diligence, Passed EHS inspection and Quality inspection

完成尽职调查，通过EHS审计和质量审计

➤ Tech. transfer from R&D, registration batch to validation batch

从研发开始的技术转移（包括实验室规模、注册批和验证批规模）

➤ Good project management

良好的项目管理

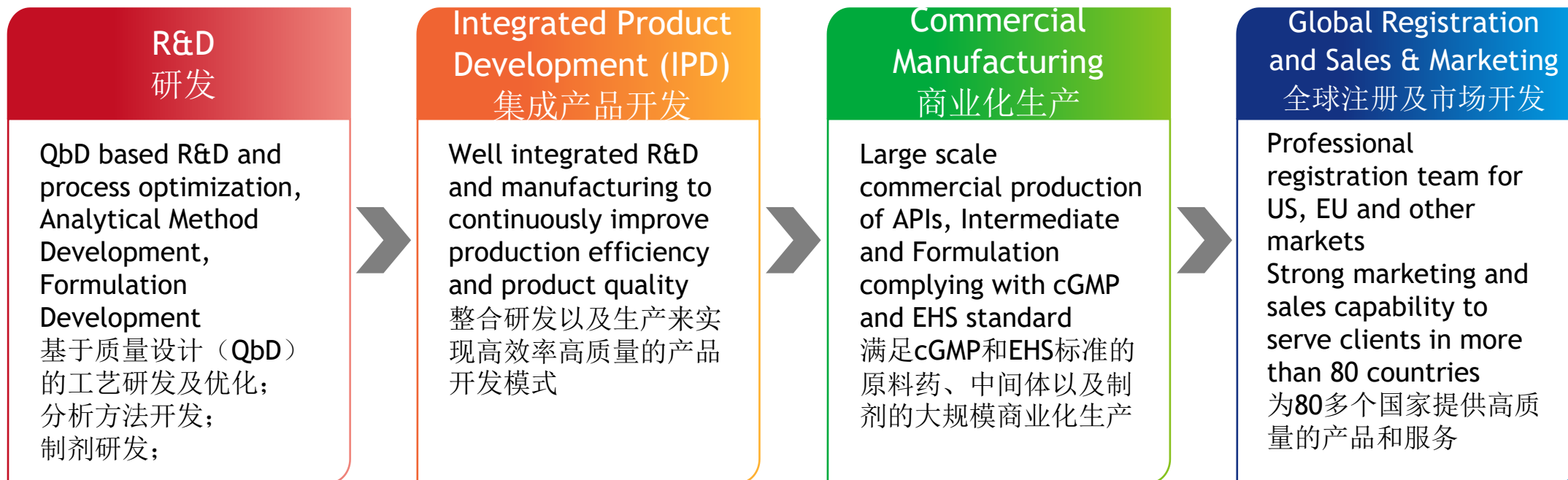
➤ Seamless communication and connection of R&D, Analysis, Technology, Engineering, Production,  
Quality, EHS, Registration and Supply Chain

研发，分析，技术，工程，生产，质量，EHS，注册和供应链的无缝沟通和对接

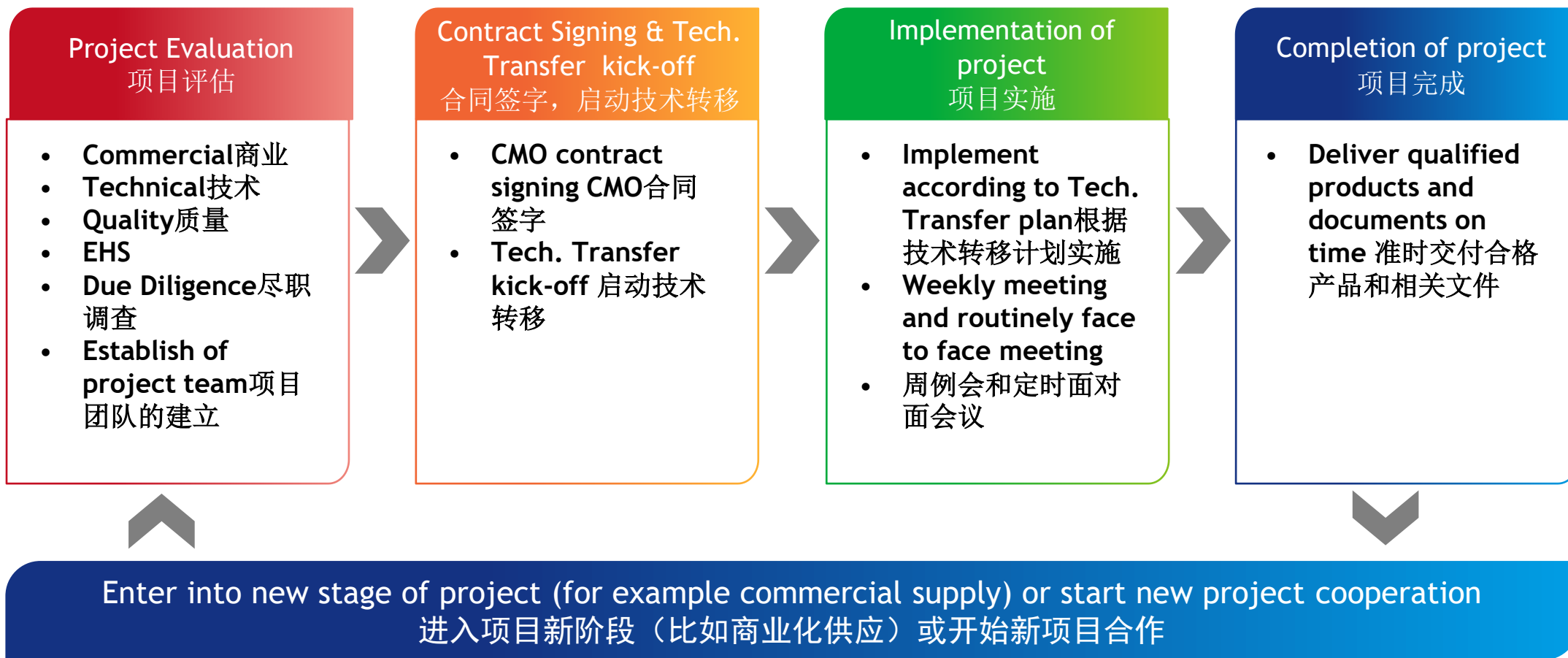


# CMO Business 定制业务

One stop solution provider from R&D, Pilot Trial, Commercial Production to Global Registration and Marketing 从研发、中试、商业化生产到全球注册及市场开发的一站式解决方案



# CMO Procedure 业务流程



Note: The procedure will be fine tuned according to the requirement of project or customer 注意：具体流程会根据项目或客户需求适当调整

# A reliable partner for your healthcare business

## 您医疗保健产业可靠的合作伙伴

**Our products: APIs, Intermediates, Formulations and Vitamins**

我们的产品: APIs, 中间体, 制剂和维生素

- ARV & Anti-Malarial & other APIs 抗逆转录病毒和抗疟疾及其他原料药
- Anti Cancer 抗肿瘤
- Nutrition and additives 营养品和添加剂
- Finished pharma products 成品药

**Our services: One stop solution provider from R&D to Commercialization** 我们的服务: 从研发到商业化的一站式解决方案

- QbD based R&D 基于质量设计的工艺研发
- Integrated Product Development 整合产品开发
- State-of-the Art facilities with large scale, cGMP & EHS standard 满足cGMP和EHS标准的一流设备设施和团队
- Professional and high effective team 专业高效的团队
- Global Registration and marketing 全球注册及市场开发

Contact us 欢迎垂询

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**Thank You 谢谢**