

韩飞飞



## 基本信息 Background

韩飞飞 Han Feifei

职位：工程中心运营总监

Title: Operation Director of Engineering Center

照片 Photos:

演讲题目：人用疫苗整体解决方案

Presentation subject: Integrated Solutions for Human Vaccines

个人简介：服务于生物医药行业十多年，从事制药装备工艺设计、设计院工艺设计、项目管理等工作，在人用疫苗、兽用疫苗、单抗、血液制品工艺设计方面积累了丰富的经验。

Self-Introduction: served in biological pharmaceutical industry for more than ten years. Dedicated into process designing of pharmaceutical equipment, process designing of designing institute and projects management. Accumulated with much experience in process designing of human vaccines, animal vaccines, McAb and blood products;

参与并负责多条血制车间工艺装备设计以及建设项目；

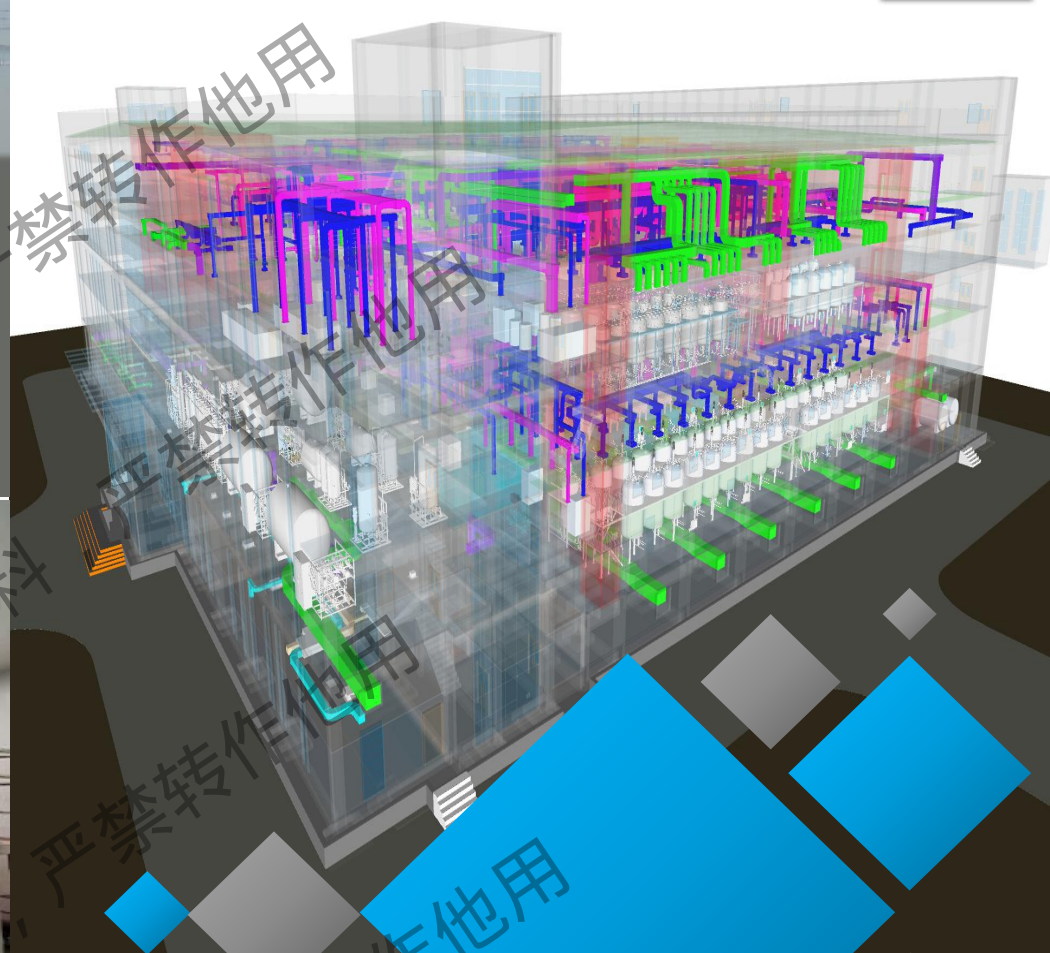
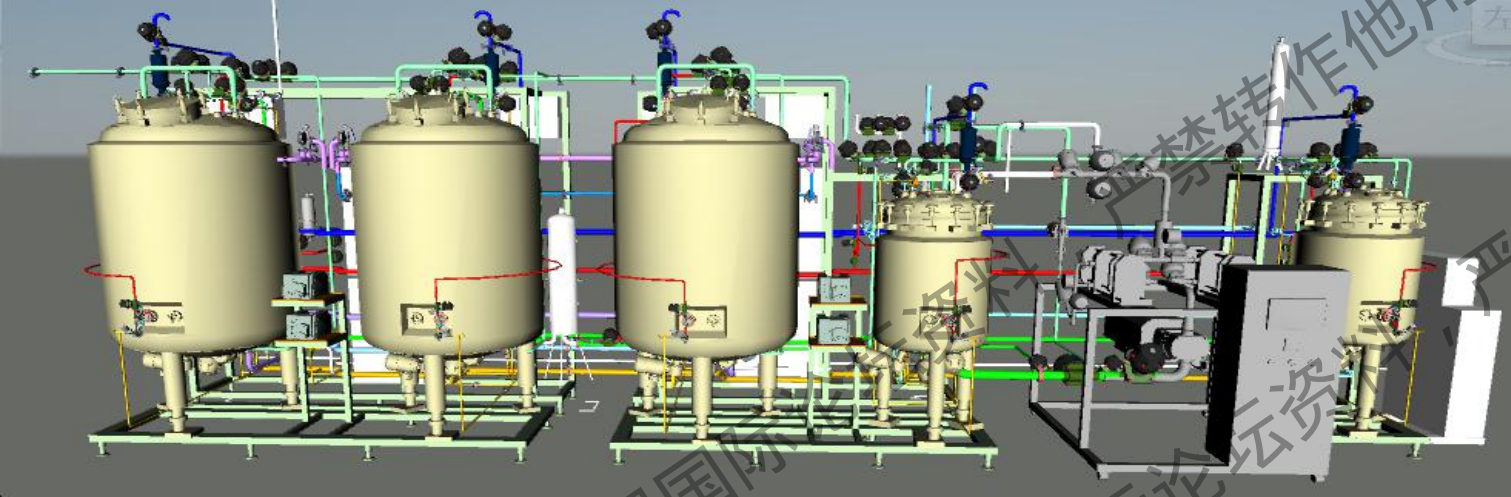
Participated in and taken charge of designing & construction of process equipment of several blood products workshops;

参与并负责多品种人用疫苗生产线设计以及建设，如百白破疫苗车间、新冠肺炎车间、流感项目等；

Participated in and taken charge of designing & construction of multiple human vaccine production lines, such as DPT vaccine workshop, COVID-19 workshop and influenza vaccine projects etc.;

参与并负责多品种兽用疫苗生产线设计以及建设，如口蹄疫项目、猪圆环疫苗项目、布病疫苗项目等。

Participated in and taken charge of designing & construction of multiple animal vaccine production lines, such as MFD vaccine project, PCV project and brucellosis vaccine projects etc..



# 人用疫苗整体解决方案

Integrated Solutions for Human Vaccines

| 专业 | 务实 | 全面

Talents come from diligence,  
and knowledge is gained by accumulation.

# 目录

## CONTENTS

01

### 人用疫苗介绍

Introduction of Human Vaccines

02

### 解决方案

Solutions

03

### 案例分析

Examples Analysis



# 人用疫苗介绍

Introduction of human vaccines

01

CONTENTS

- 疫苗分类 Vaccine Classification
- 政策法规 Laws & Regulations
- 批签发 Release

# 人用疫苗简介 Introduction of Human Vaccines

## 疫苗简介 Vaccines Introduction

### 疫苗的定义 Definition of vaccine

疫苗是将病原微生物（如细菌、立克次氏体、病毒等）及其代谢产物，经过人工减毒、灭活或利用转基因等方法制成的用于预防传染病的自动免疫制剂

Vaccine is a kind of automatic immune preparation for the prevention of infectious diseases made of pathogenic microorganisms (such as bacteria, rickettsia, virus, etc.) and their metabolites through artificial attenuation, inactivation or transgenic methods.

### 疫苗的分类 Classification of vaccine

按照生物材料分类：细菌性、病毒性、类毒素

Per biomaterial: bacterial, viral, toxoid

按照研制生产技术分类：减毒活疫苗、灭活疫苗、裂解疫苗、亚单位疫苗、基因工程疫苗

Per development and production technology: live attenuated vaccine, inactivated vaccine, lytic vaccine, subunit vaccine, genetic engineering vaccine.

按照预防种类分类：单价苗、多价苗、联合疫苗

Per type of prevention: monovalent vaccine, multivalent vaccine, combined vaccine

按是否纳入国家免疫计划分：免疫规划疫苗（一类苗）、非免疫规划疫苗（二类苗）

Per whether included in the National Immunization Program: Epi vaccines (Class I vaccines), Non-EPI vaccines (Class II vaccines)

**特点（解决生物病原大流行唯一有效方法） Characteristics (the only effective solution to a biological pandemic)**

监管严、行业壁垒高

Strict supervision and high industry barriers

研发周期长，技术性强，抢先附加值高

Long R & D cycle, strong technicality, highly added value for foresight



# 前言-人用疫苗分类 Foreword-Classification of Human Vaccine

按生物材料分 Per biomaterial	细菌性 Bacterial	流脑疫苗、Hib疫苗、卡介苗、伤寒疫苗、炭疽疫苗等 Meningitis vaccine, Hib vaccine, BCG vaccine, typhoid vaccine, anthrax vaccine etc.	多糖疫苗刺激婴幼儿产生抗体的能力差，对婴幼儿几乎无效，结合疫苗能刺激婴幼儿产生抗体，可以用于2岁以内的儿童 Polysaccharide vaccine has a poor ability to stimulate the production of antibodies in infants and young children, and is almost ineffective in infants and young children. Conjugate vaccine can stimulate the production of antibodies in infants and young children, and can be used in children under 2 years old.	
	病毒性 Viral	流感疫苗、HPV、乙肝、麻疹、狂犬和脊灰疫苗等 Influenza vaccine, HPV, Hepatitis B vaccine, measles vaccine, rabies vaccine and polio vaccine etc.		
	类毒素 Toxoid	破伤风疫苗、白喉疫苗等 Tetanus vaccine, diphtheria vaccine etc.		
按研制（生产）技术分 Per development and production technology	传统 Traditional	减毒活疫苗 Live attenuated vaccine	甲肝减毒疫苗、卡介苗、麻疹、脊灰减毒活疫苗等 Attenuated hepatitis A vaccine, BCG vaccine, measles vaccine, live attenuated polio vaccine etc.	接种次数少，对免疫缺陷者有危害，相对不稳定 The inoculation frequency is few, while it is harm to the immune deficiency person, is relatively unstable.
		灭活疫苗 Inactivated vaccine	伤寒、霍乱、百日咳、乙脑等 Typhoid, cholera, pertussis, encephalitis vaccines etc.	死亡病毒、不具备感染性、稳定，免疫效果弱，接种次数多 Dead virus, not infectious, stable, weak immune effect, more times for inoculation.
		裂解疫苗 Lytic vaccine	流感疫苗等 Influenza vaccine etc.	含有数量极少的物质可以刺激免疫系统产生抗体和作用于特定的病毒或细菌的细胞 Cells containing small amounts of substances that stimulate the immune system to produce antibodies and act on specific viruses or bacteria.
	新型 Noval	亚单位疫苗 Subunit vaccine	白喉、A群脑膜炎球菌多糖疫苗等 Diphtheria, Group A meningococcal polysaccharide vaccine etc.	病毒外壳，不均被感染性，安全性高 Virus coat, uneven infection, high security.
		基因工程疫苗 Genetic engineering vaccine	HPV、重组乙肝疫苗等 HPV, Recombinant hepatitis B vaccine etc.	体外重组表达，开发难度高；生产成本低、安全性高；可交叉保护 In vitro recombinant expression is difficult to develop. Low production cost and high safety; Cross-Protectable.
按预防种类分 Per type of prevention	单价 Monovalent vaccine	Hib疫苗、甲肝、乙肝、麻疹、风疹等 Hib vaccine, hepatitis A vaccine, hepatitis B vaccine, measles vaccine, rubella vaccine etc.	多联多价是趋势。减少接种次数 multi-combination and multivalent is a trend. Reduce the number of inoculation.	
	多价 Multivalent vaccine	13价肺炎、23价肺炎、2价HPV、4价HPV、9价HPV等 13-valent pneumonia vaccine, 23-valent pneumoniavaccine, double-valent HPV vaccine, quadrivalent hpv vaccine, 9-valent hpv vaccine etc.		
	联苗 Combined vaccine	百白破疫苗、麻疹-三联疫苗、百白破-Hib四联、百白破-灭活脊灰-Hib（结合）五联等 DPT vaccine, measles combined vaccine, DPT-Hib combined vaccine, dpt-inactivated polio-Hib vaccine etc.		
按是否纳入国家免疫计划分 Per whether included in the National Immunization Program	免疫规划疫苗（一类苗，13苗15病） Epi vaccines(Class I vaccine, 13kinds 15 diseases)	乙肝、卡介苗、脊灰、百白破、白破、麻腮风三联、乙脑、A群流脑多糖、A+C群流脑多糖、甲肝 hepatitis B vaccine, BCG vaccine, polio vaccine, DPT vaccine, DT vaccine, Measles-Mumps-Rubella vaccine, live Japanese Encephalitis vaccine, Group A CPS vaccine, Group A+C CPS vaccine, hepatitis A vaccine	价格较低，3-35元不等 lower price, with 3-35 RMB.	
	非免疫规划疫苗（二类苗） Non-EPI vaccines (Class II vaccine)	免疫规划苗之外所有疫苗 All vaccines excluded the Epi vaccines	占据主要市场空间 Obtain the major market.	

# 前言-新冠疫苗Foreword- Coronavirus Vaccine

## 新冠疫情分析 Coronavirus Epidemic Analysis

截至2020.8.6日，全球累计确诊1870万人，死亡70万人。其中国内累计确诊8万8千多人，死亡4684人，美国累计确诊4921万人，死亡16万人。

As of 2020.8.6, 18.7 million people had been diagnosed and 700,000 had died. Among them, more than 88,000 people have been diagnosed in China with death of 4,684. In the United States, 49.21 million have been diagnosed with death of 160,000.

根据国家统计局官方公布的2020年第一季度我国经济运行情况的数据显示，第一季度我国GDP为206504亿元，全国GDP同比下降了6.8%，创下了40年来的新低。其中分产业来看，第一产业增加值下降了3.2%，第二产业增加值下降了9.6%。第三产业增加值下降了5.2%。其中，交通运输、餐饮、娱乐、旅游等消费服务业受此次疫情冲击最大。

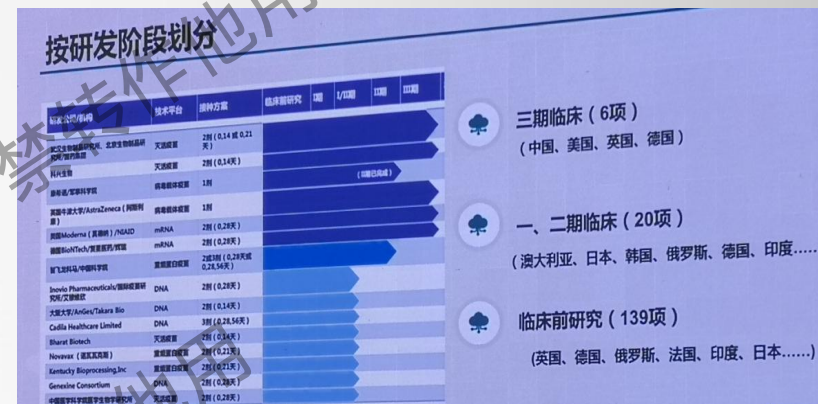
According to the data of China's economic performance in the first quarter of 2020 released by the National Bureau of Statistics, China's GDP in the first quarter of 2020 was 20,6504 trillion, a year-on-year decline of 6.8%, hitting a 40-year low. In terms of sub-industries, the added value of the primary industry declined by 3.2% while that of the secondary industry declined by 9.6%. The added value of the third industry declined by 5.2%. Among them, transportation, catering, entertainment, tourism and other consumer services have been the hardest hit by the epidemic.

截至2020.7.31日，根据WHO公布的数据，全球新冠候选疫苗共165个，进入临床的26个

As of July 31, 2020. According to the data released by WHO, a total of 165 candidate COVID-19 vaccine have been made available worldwide, and 26 of them have entered clinical trials.

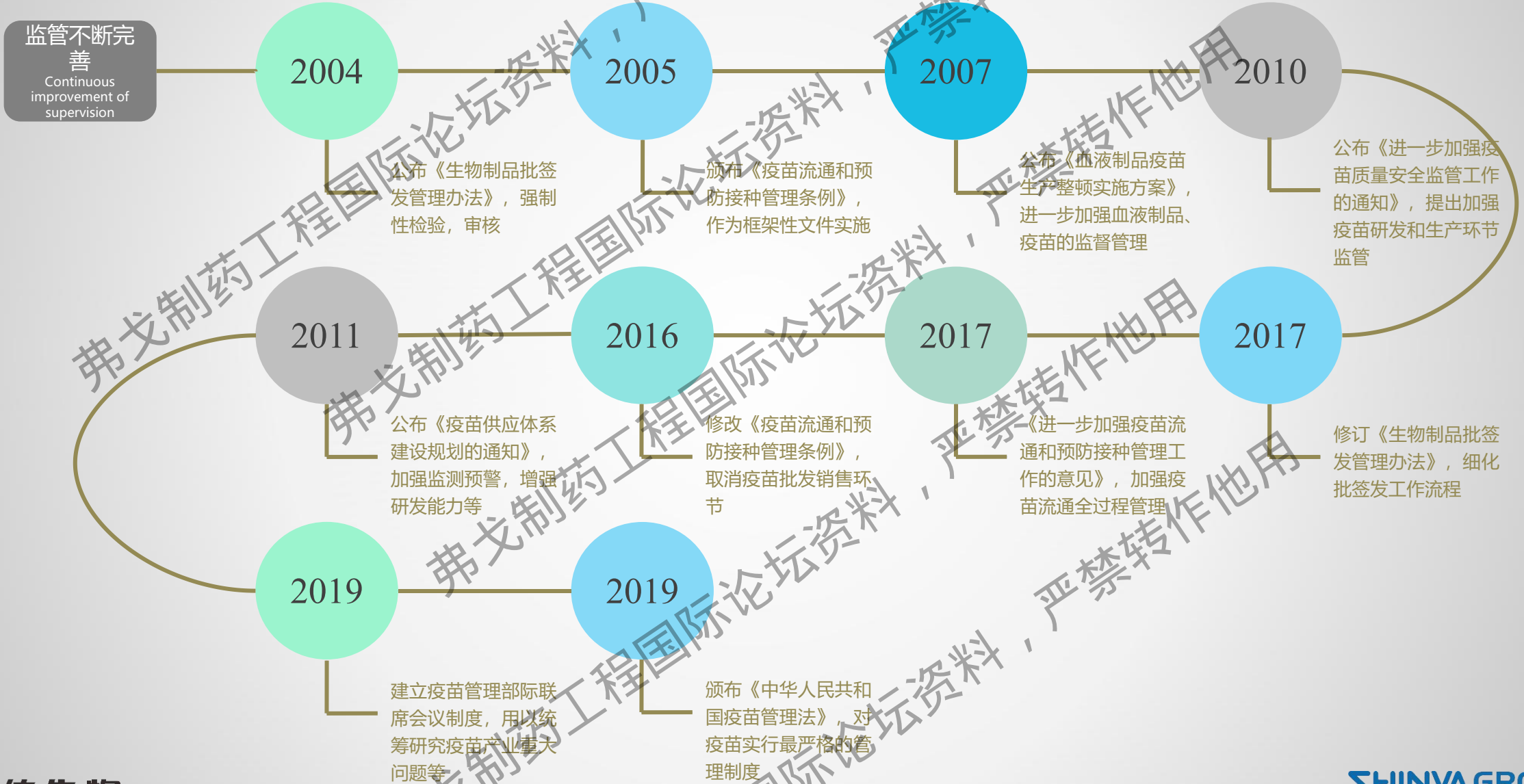
全球疫苗设计路线：灭活疫苗、病毒载体疫苗、重组蛋白疫苗、核酸疫苗、减毒活疫苗

Global vaccine designing route: inactivated vaccine, viral carrier vaccine, recombinant protein vaccine, nucleic acid vaccine, live attenuated vaccine.



国内自主研发项目			国际合作研发项目		
序号	疫苗类型	研究单位	序号	疫苗类型	研究单位
1	灭活疫苗	康希诺/国药集团	1	RNA疫苗	BioNTech/辉瑞/拜耳
2	灭活疫苗	中生北控/武汉病毒所	2	DNA疫苗	INOVIO/艾博迪欣
3	灭活疫苗	中生北控/中国CDC	3	重组蛋白疫苗	三叶草生物/GSK/Dynavax
4	灭活疫苗	国药中生/中国CDC	4	重组蛋白疫苗	Medigen 台湾/葛兰素/NIAD/Dynavax
5	灭活疫苗	国药中生/中国CDC	5	灭活疫苗	科兴/Dynavax
6	重组蛋白疫苗	国药中生/中国科学院微生物所	6	载体疫苗	GeoVax/博沃
7	mRNA疫苗	康希诺/国药集团/沃森	7	重组蛋白疫苗	iBio/CC-Pharming (北京/香港/海江)
8	重组蛋白疫苗	康希诺	8	重组蛋白疫苗	厦门万泰/康大/GSK
9	重组蛋白疫苗	依生生物	9	RNA疫苗	复旦大学/上海交通大学/RNA Cure Biopharma
10	重组蛋白疫苗	北京艾美			
11	重组蛋白疫苗	北京康乐卫			
12	重组蛋白疫苗	浙江普康			
		香港大学/华大/百克/厦门大学			
		华兰生物			
		康泰生物			
		山东大学/新微			

# 前言-政策法规Foreword-Laws & Regulations

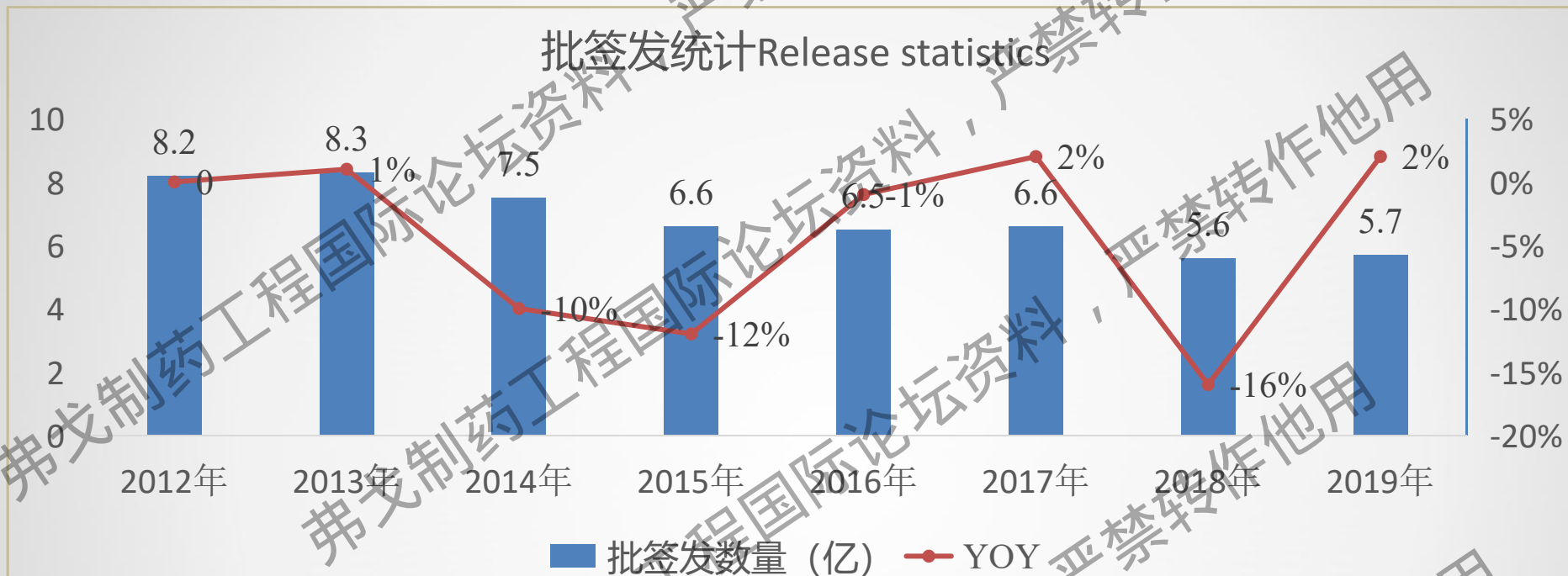




# 前言-政策法规Foreword-Laws & Regulations



# 前言-人用疫苗的前景 Foreword-Prospects of Human Vaccine

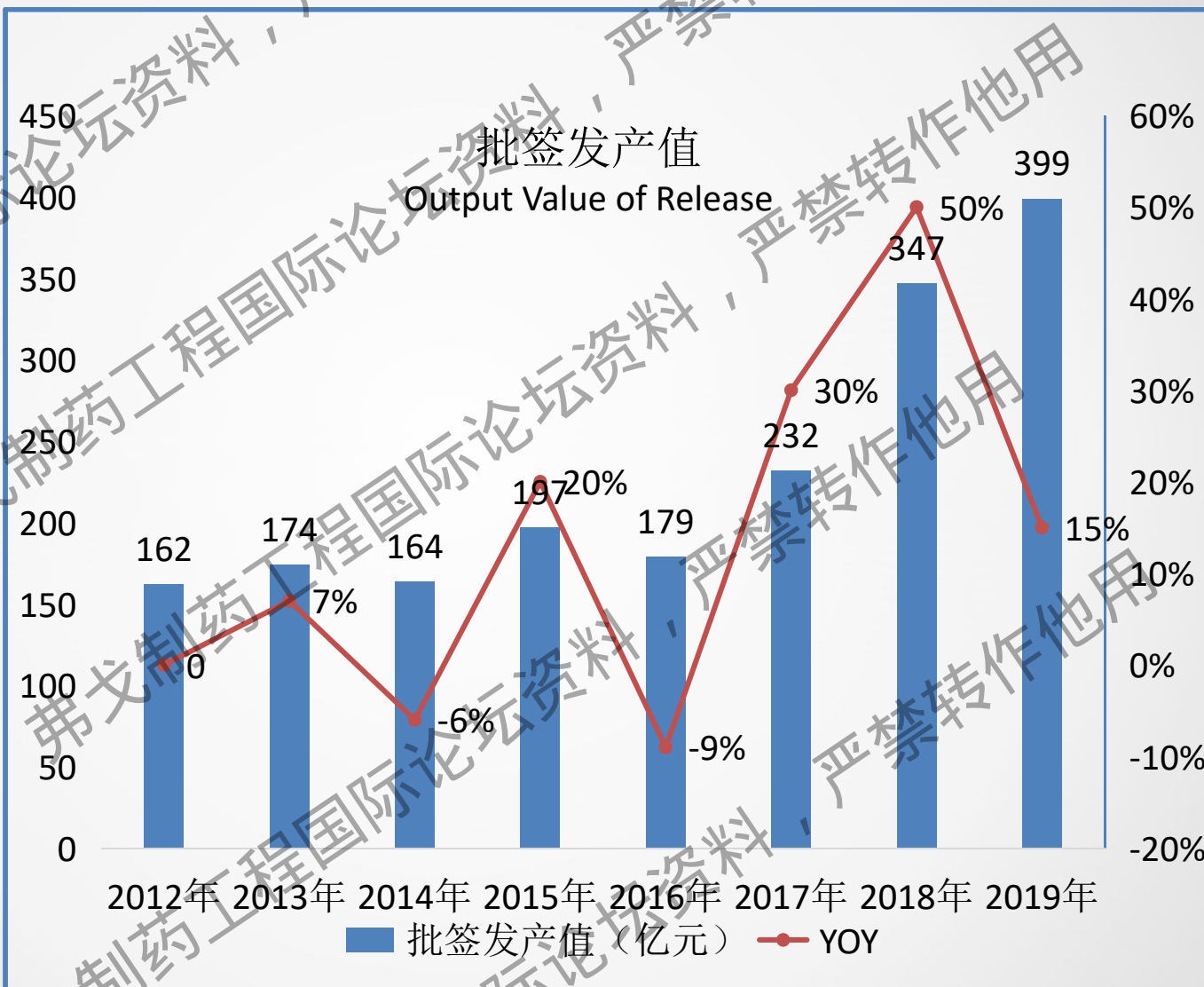


年份	批签发数量 (亿) Release No.(a hundred million)	YOY
2012	8.2	0%
2013	8.3	1%
2014	7.5	-10%
2015	6.6	-12%
2016	6.5	-1%
2017	6.6	2%
2018	5.6	-16%
2019	5.7	2%

# 前言-人用疫苗的前景Foreword-Prospects of Human Vaccine

我国疫苗市场产值从2016年开始快速上升，2016-2019年行业年均复合增速高达31%，2019年虽然受到长生生物时间影响，疫苗市场上少了原先长生生物的狂犬疫苗、水痘疫苗、流感疫苗等（至少15亿以上的空间），并且批签发速度受到很大影响，但是在HPV疫苗、百白破-IPV-Hib五联苗、五价轮状疫苗等大品种放量下，整体行业仍然有15%的增速。

Output of vaccine market in China was rapidly risen since 2016, and the industry average annual compound growth rate is up to 31% in 2016-2019. 2019, although affected by Changsheng biotechnology case, Rabies vaccine, varicella vaccine, influenza vaccine are reduced in vaccine market (at least more than 1.5 billion space), and the release speed affected a lot, under the release of HPV vaccine, -IPV-Hib vaccine, 5-valent rotavirus vaccine, the whole industry still has a 15% growth.



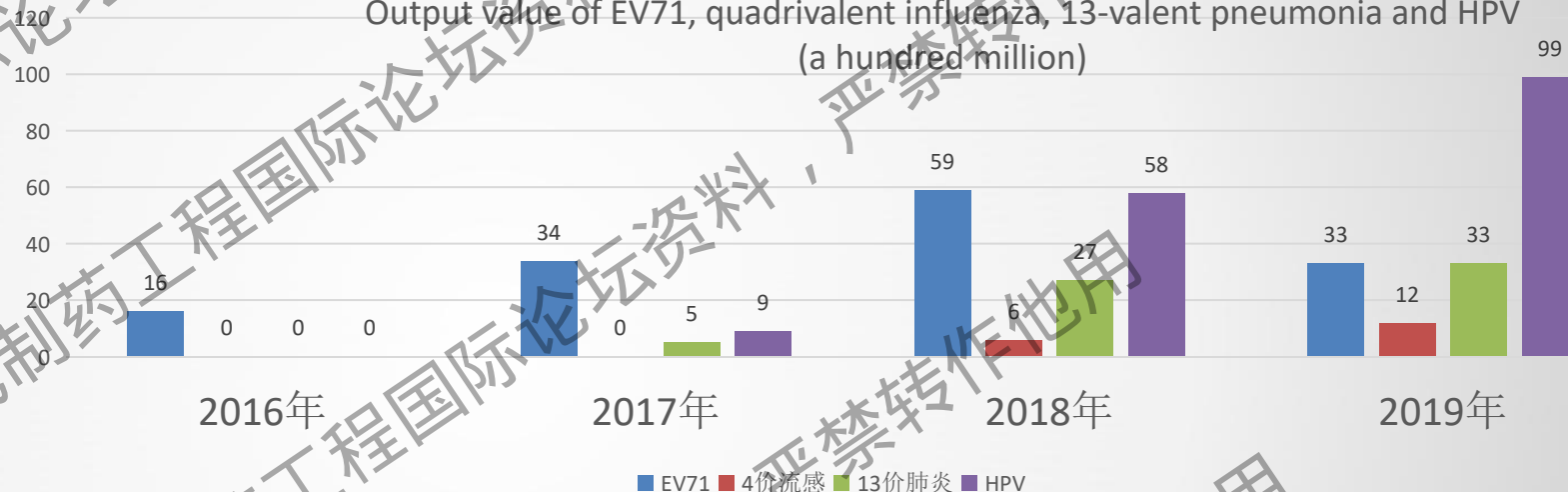
年份	批签发产值 (亿元)	YOY
2012	162	0
2013	174	7%
2014	164	-6%
2015	197	20%
2016	179	-9%
2017	232	30%
2018	347	50%
2019	399	15%

# 前言-人用疫苗的前景Foreword-Prospects of Human Vaccine

2016年开始，疫苗新品种包括EV71、4价流感、13价肺炎、HPV等迅速放量，以HPV为例，仅仅上市三年，2019年就有99亿的市场空间，超过2016年疫苗行业市场空间的50%。加上狂犬、水痘疫苗，六种疫苗的市场空间就超过了2017年整个疫苗市场。

Since 2016, new vaccine varieties including EV71, quadrivalent influenza, 13-valent pneumonia and HPV have been rapidly released. Taking HPV as an example, after only three years on the market, there was a market space of 9.9 billion in 2019, which is more than 50% of the market space of the vaccine industry in 2016. Add with the rabies vaccine and varicella vaccine, the market space for the six vaccines exceeded that for the entire vaccine market in 2017.

EV71、4价流感、13价肺炎、HPV产值（亿元）  
Output value of EV71, quadrivalent influenza, 13-valent pneumonia and HPV (a hundred million)



年份 Year	EV71	4价流感 Quadrivalent influenza	13价肺炎 13-valent pneumonia	HPV
2016	16	0	0	0
2017	34	0	5	9
2018	59	6	27	58
2019	33	12	33	99



# 解决方案

Solutions

02

CONTENTS



# 人用疫苗解决方案 Solutions for Human Vaccines

## 基本路线

Basic Line



### 生产工艺

Production Process



### 安全设计

Safety Design

#### 人物流设计

Personnel flow/material flow design

#### 工艺流设计

Process flow design

#### 工艺分区

Biological safety  
Fire safety

人流

Personnel flow

原辅料

Raw material

成品流

Final product flow

污物流

Waste flow

有毒区

Toxic zone

无毒区

Non-toxic zone

公用设施

Utility

疏散楼梯

Exit stair

逃生走廊

Exit corridor

疫苗车间设计中，生产工艺与安全设计共同影响车间的工艺设计：一方面遵从工艺流程的合理性、布局的合规性；另一方面从安全层面通盘考虑车间的工艺平面设计。

In the design of vaccine workshop, the production process and safety design jointly affect the process design of the workshop: on the one hand, the rationality of process flow line and the compliance of layout should be followed; On the other hand, the process plane design of the workshop under the safety level must be considered.

## 疫苗生产主线路 Main Line of Vaccine Production



## 疫苗生产主线路 Main Line of Vaccine Production

产物的大量生产：通过给微生物营造最适的生长环境，不断提供营养，严格监控pH、溶氧、温度等参数，使其大量的繁殖，不断的产出我们所需的菌体或次级代谢产物，疫苗的生产主要系统为菌苗发酵、细胞培养和病毒培养。

Mass production of products: through the creation of the optimal growth environment for microorganisms, continuous provision of nutrients, strict monitoring of pH, dissolved oxygen, temperature and other parameters, make them reproduce in large quantities, and constantly produce the bacteria or secondary metabolites needed. The main production system of vaccines is the fermentation of vaccine, cell culture and virus culture.

产物的初步分离：通过离心、过滤、破碎等方式，将目的产物与杂质初步分离，根据产物的不同，可以选择收集沉淀（菌体或细胞），也可选择收集上清液（细菌或细胞的次级代谢产物、病毒）。

Preliminary separation of products: preliminary separation of the target products and impurities is conducted by centrifugation, filtration, crushing and other methods. According to different products, sediments (bacteria or cells) can be collected or supernatant (secondary metabolites and viruses of bacteria or cells) can be collected.

产物的毒性处理：灭活疫苗需要对产物进行脱毒或灭活处理。通过添加灭活剂、调节温度等措施使其失去繁殖能力，保留其抗原特性；减活苗则不需要此步

Toxicity treatment of products: Inactivated vaccines need to detoxify or inactivate the products. By adding inactivating agent and adjusting temperature, it lost its reproduction ability and retained its antigenic characteristics. This step is not required for attenuated vaccines.



# 人用疫苗解决方案 Solutions for Human Vaccines

## 疫苗生产主线路 Main Line of Vaccine Production

产物的提纯：通过一系列的纯化方式，将目的产物进行提纯，去除杂蛋白、金属离子、盐等杂质，纯化的主要系统有超滤系统、层析系统、盐析系统、吸附系统等

Purification of products: Through a series of purification methods, the target products are purified to remove impurity proteins, metal ions, salts and other impurities. The main purification systems include ultrafiltration system, chromatography system, salting-out system, adsorption system, etc..

产物的后处理：对提纯后的产物进一步进行处理，可以通过添加佐剂增强疫苗的抗原特性，也可通过配苗进行合批或制成联合疫苗、多价疫苗等

Post-treatment of products: the purified products can be further treated by adding adjuvants to enhance the antigen characteristics of vaccines, or bleeding by combining vaccines, or by making combined vaccines or polyvalent vaccines, etc..

辅助系统 Auxiliary system:

培养基配制系统：为菌苗发酵/细胞培养提供各类的营养液

Media preparation system: provide various nutrient solution for the fermentation of vaccine/cell culture

配液系统：为产物的灭活/脱毒提供灭活剂、阻断剂等

Liquid preparation system: provide inactivating agent, blocking agent and so on for product inactivation/detoxification

为产物的提纯提供各类缓冲液

Provide all kinds of buffer solution for the purification of product

为产品的乳化/配苗提供各类佐剂

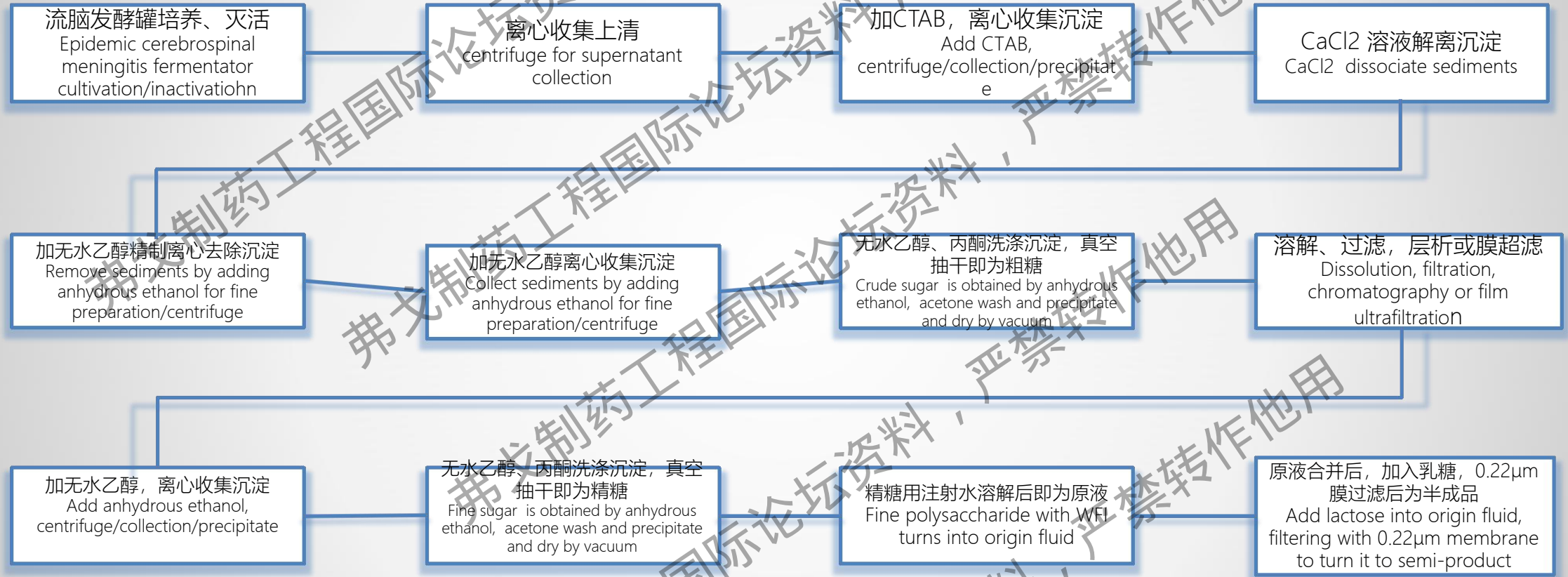
Provide various adjuvants for emulsion/preparation of product

CIP系统：为所有的生产罐、辅助罐以及相应的物料管路提供清洗液，完成在线清洗、在线检测等

CIP system: Provide cleaning fluid for all production tanks, auxiliary tanks and corresponding material pipelines to complete on-line cleaning, on-line inspection, etc..

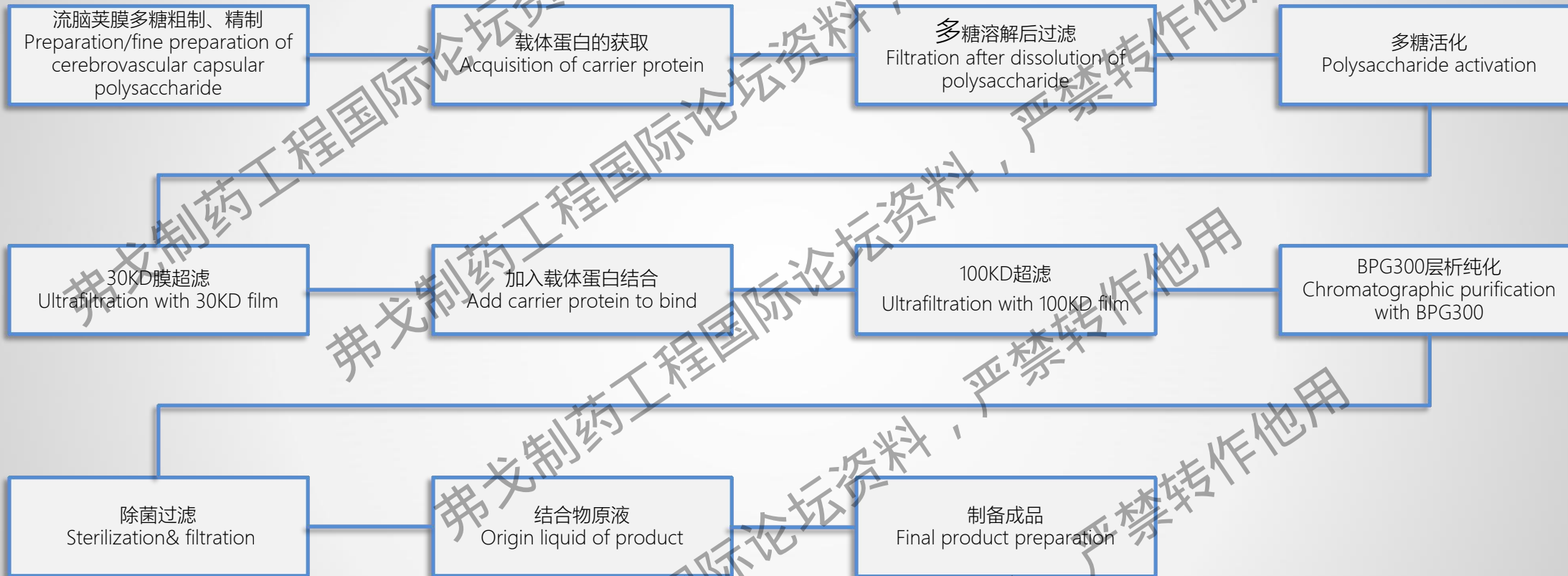
# 人用疫苗解决方案—工艺 Solutions for Human Vaccines-Process

## 流脑疫苗生产流程 Production Flow of Meningitis Vaccine

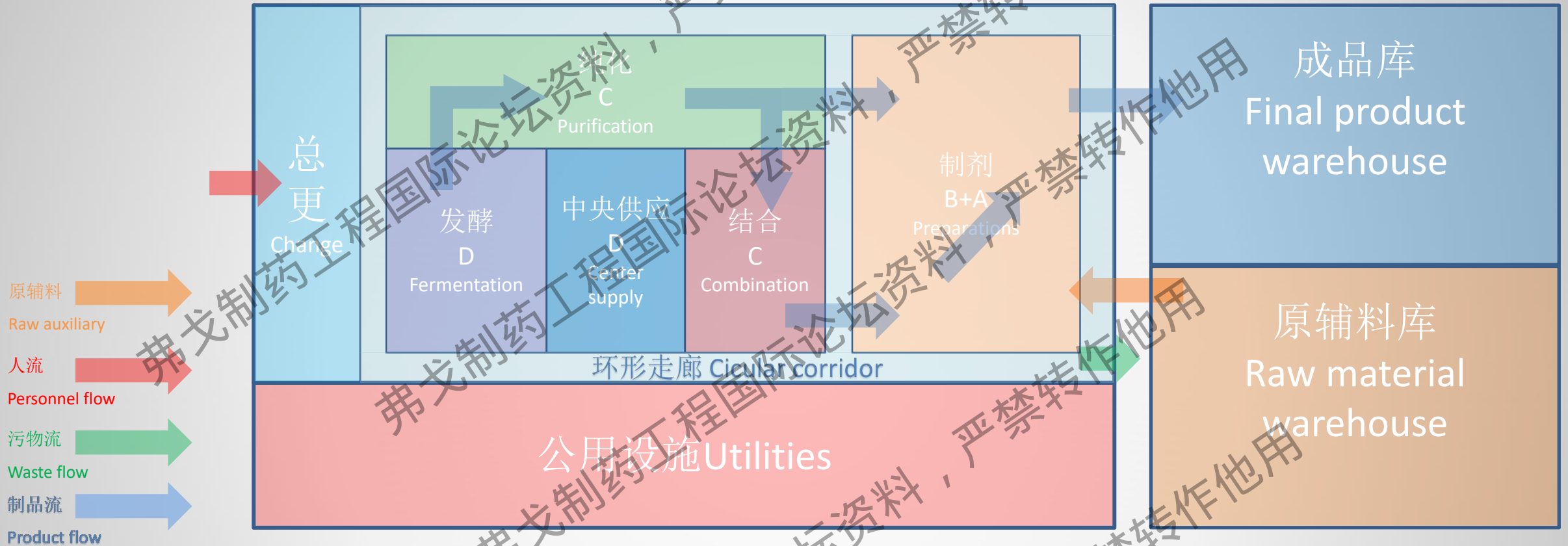


# 人用疫苗解决方案—工艺 Solutions for Human Vaccines-Process

## 流脑疫苗生产流程 Production Flow of Meningitis Vaccine



# 概念分区1-工艺流设计 Conceptual Zoning 1- Process Flow Design

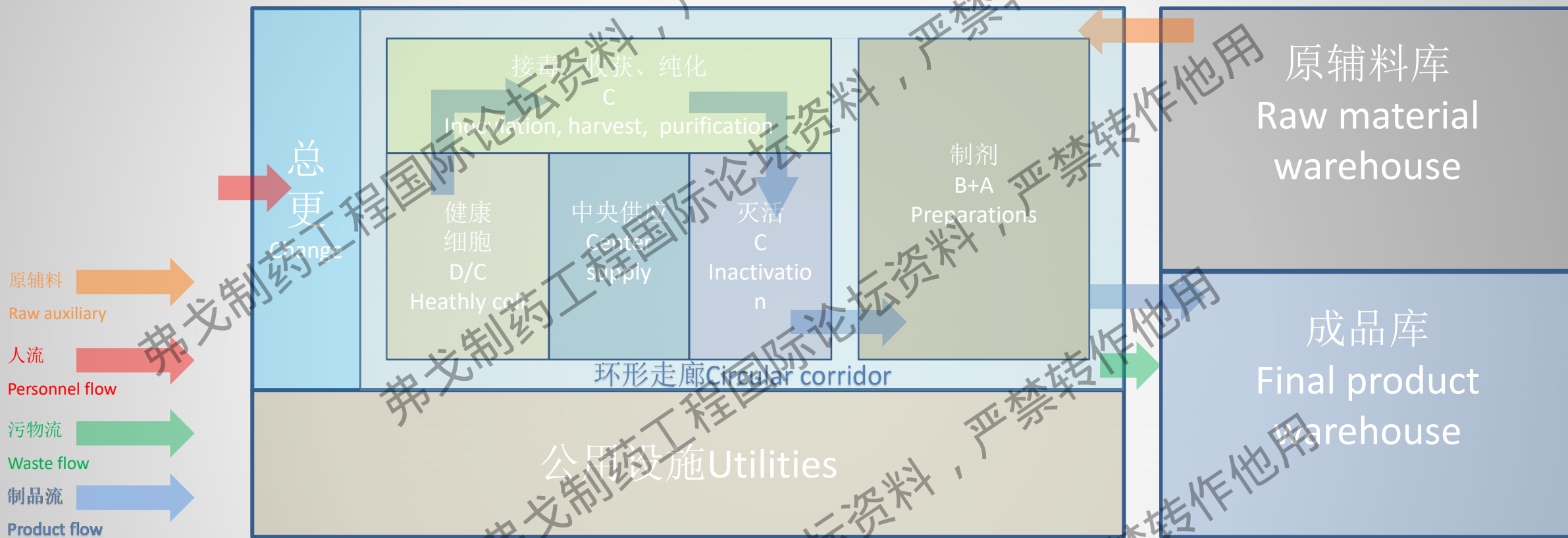


菌苗类概念工艺分区 Conceptual zoning of bacterial seeds

- 1、严格按照工艺流向布置平面； Arrange the plane in strict accordance with the flow direction of the process；
- 2、不同的产品采用不同的布局工艺； Different products adopt different layout technology
- 3、纯化工艺决定是否需要防爆； Whether explosion protection is needed for purification process
- 4、原液车间规模在1000-2500平米之间，制剂车间500-800平米之间。

The size of the raw liquid workshop is between 1000-2500 square meters, and the preparation workshop is between 500-800 square meters

# 概念分区1-工艺流设计 Conceptual Zoning 1- Process Flow Design



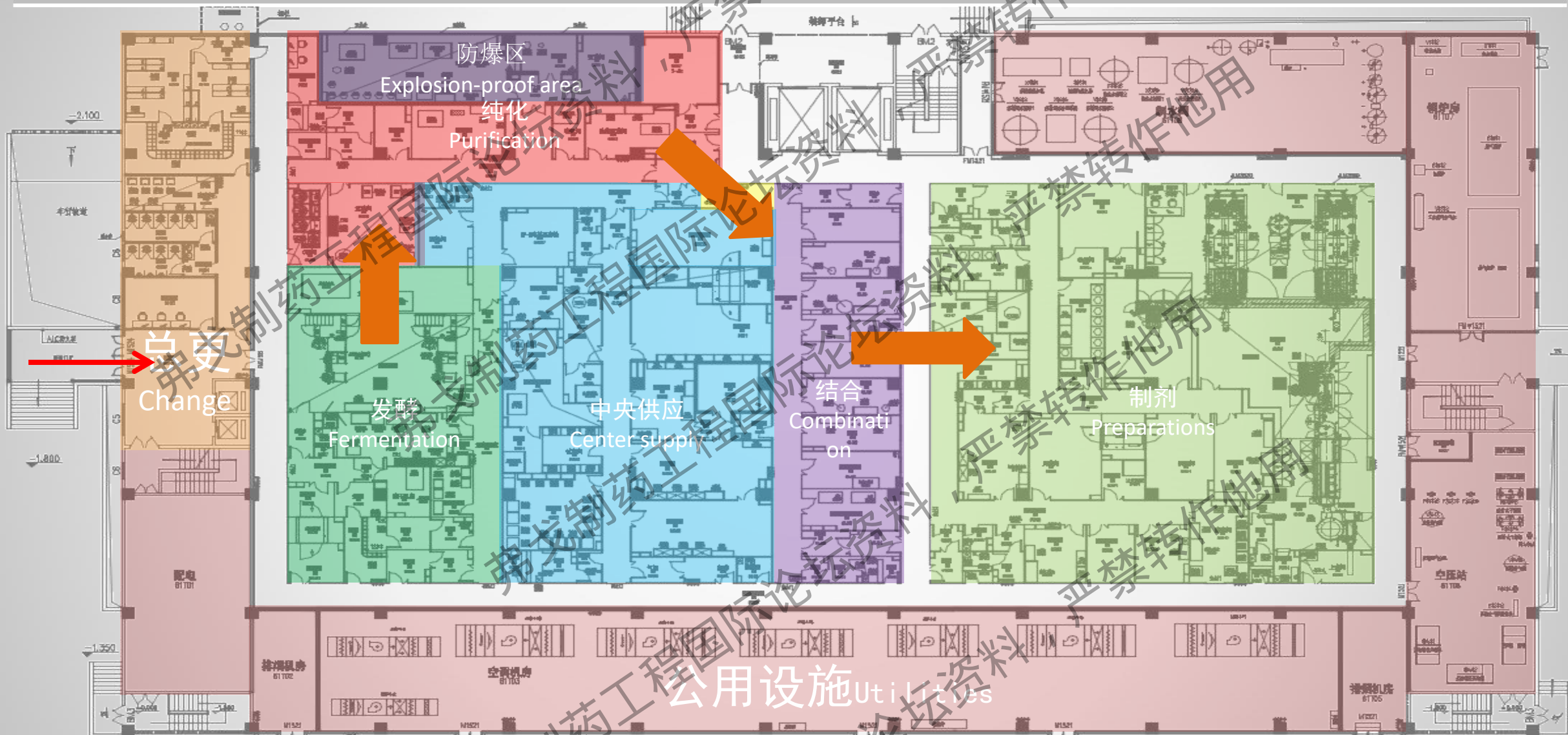
毒苗类概念工艺分区 Conceptual zoning of viral seeds:

- 1、严格按照工艺流向布置平面; Arrange the plane in strict accordance with the flow direction of the process;
- 2、不同的产品采用不同的布局工艺; Different products adopt different layout technology
- 3、纯化工艺决定是否需要防爆; Whether explosion protection is needed for purification process
- 4、原液车间规模在1000-2500平方之间, 制剂车间500-800平米之间。

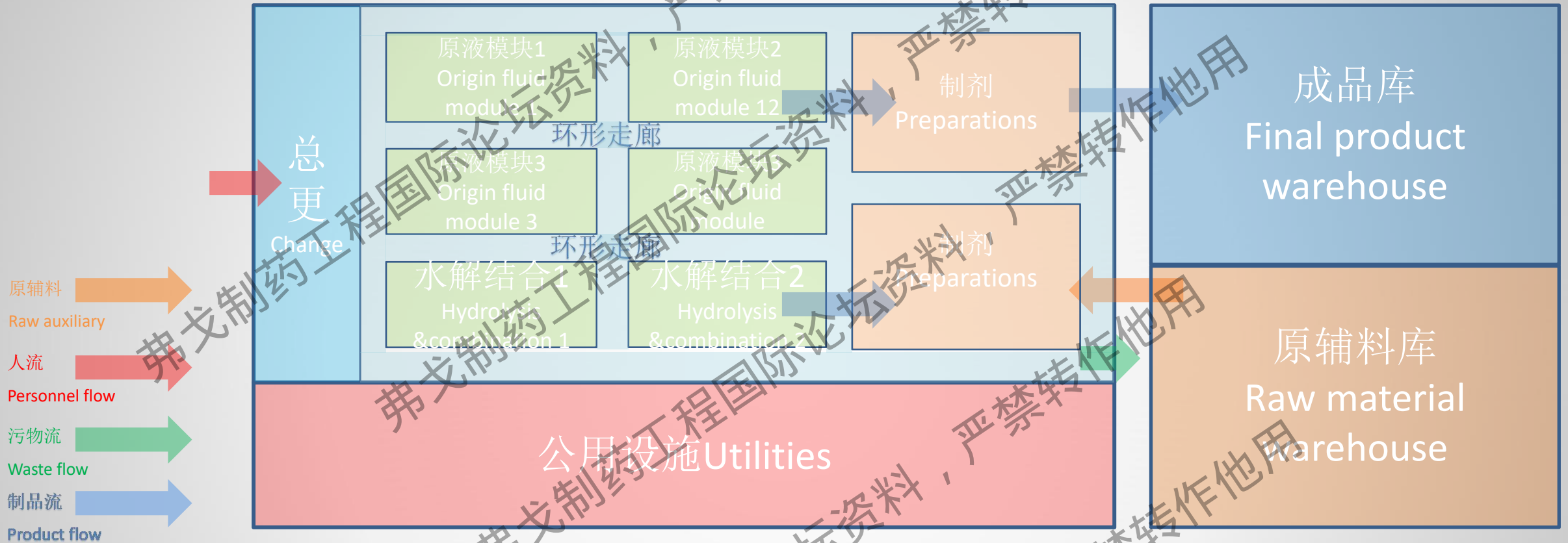
The size of the raw liquid workshop is between 1000-2500 square meters, and the preparation workshop is between 500-800 square meters.

# 中国医学科学院昆明所流脑车间平面

Layout of Epidemic Cerebrospinal Meningitis Workshop for Chinese Academy of Medical Sciences-Kunming Institute



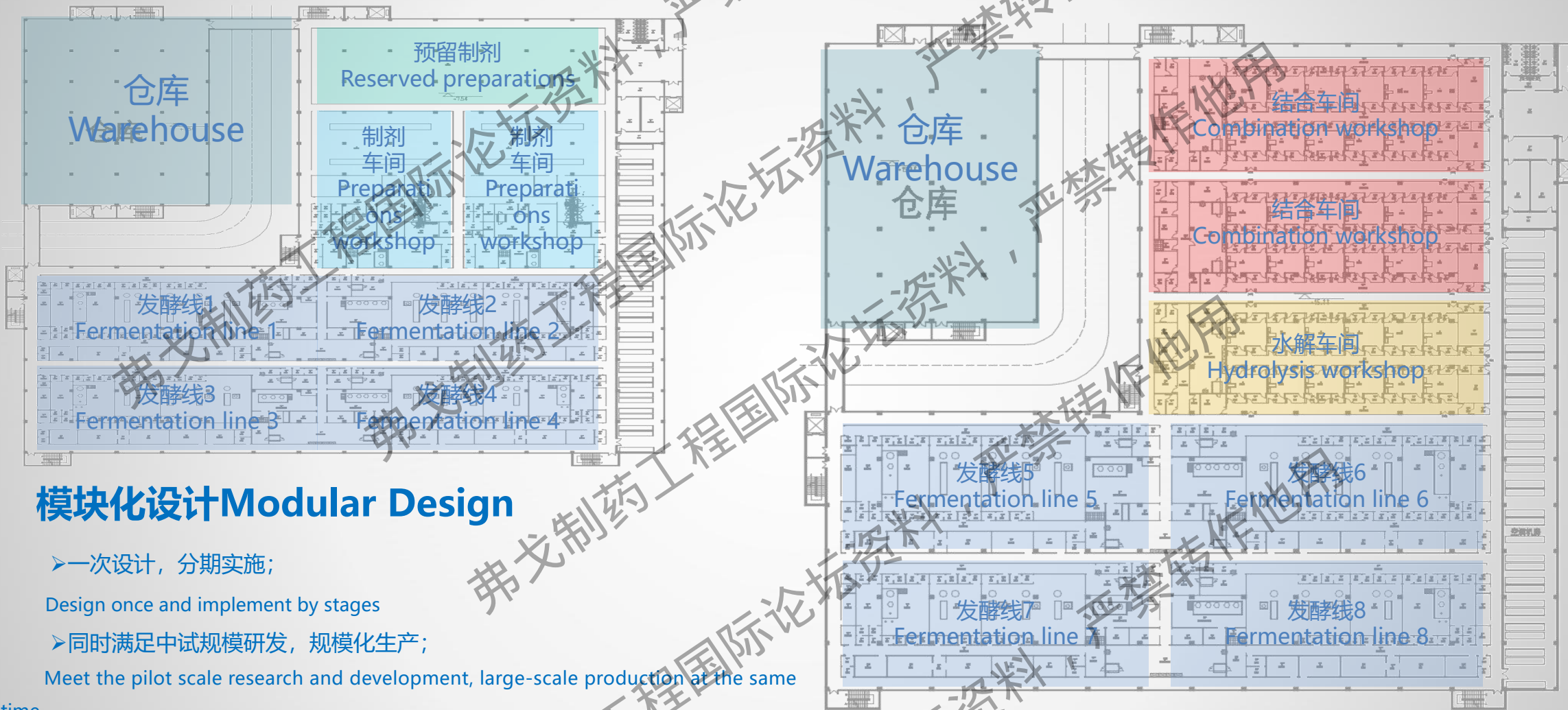
# 概念分区2-模块化设计 Conceptual Zoning 2- Modular Design



## 模块化设计 Modular Design:

- 功能设计模块化 Modular of function design
- 车间物流闭环 Closed loop for workshop material flow

# 肺炎车间项目 Pneumonia Workshop Project



## 模块化设计 Modular Design

➤ 一次设计，分期实施；

Design once and implement by stages

➤ 同时满足中试规模研发，规模化生产；

Meet the pilot scale research and development, large-scale production at the same time.

➤ 复制产能，产能快速倍增；

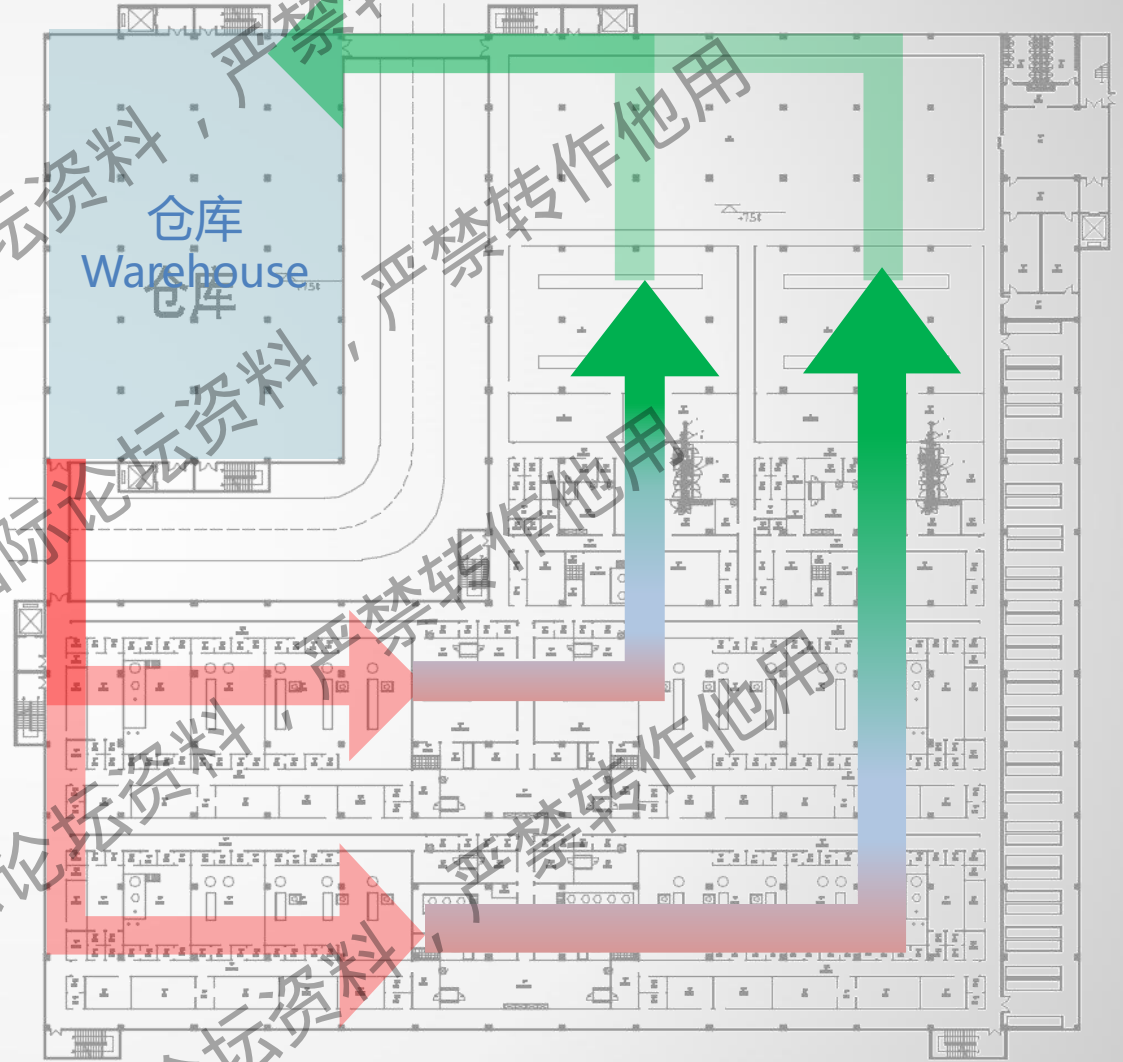
Production capacity replication, production capacity quickly doubled.



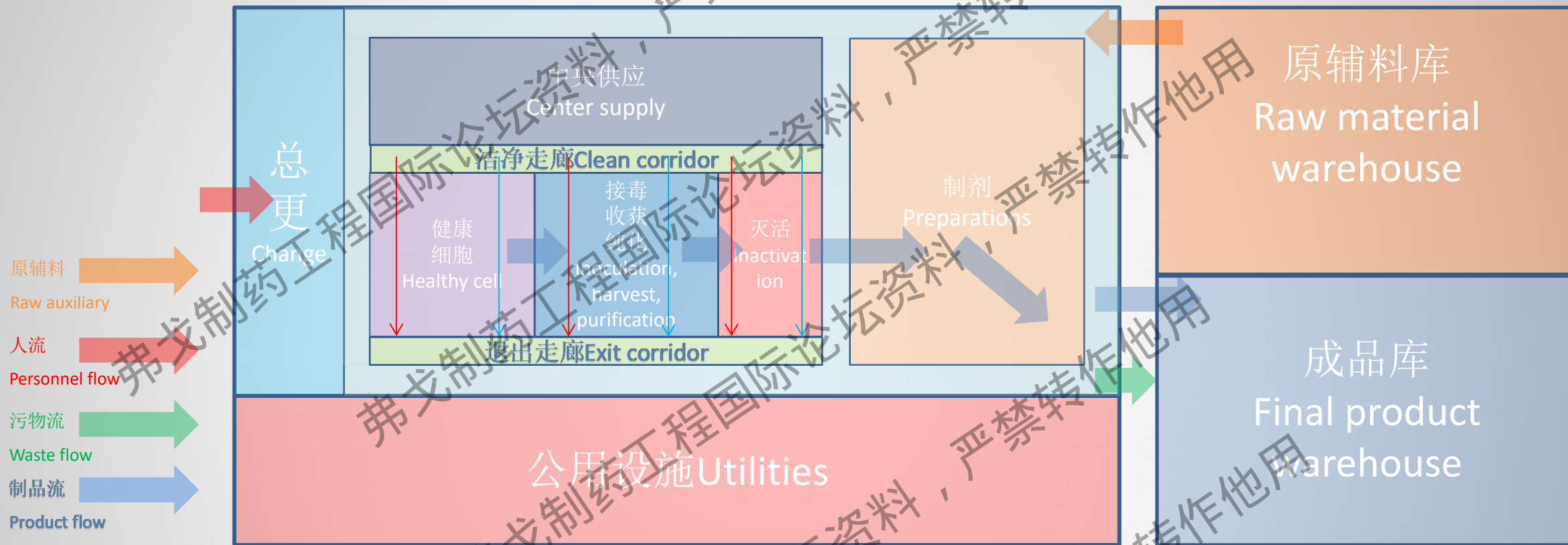
# 肺炎车间项目 Pneumonia Workshop Project

## 闭环物流 Closed loop material flow

- 仓库车间无缝连接，提升周转效率，减少室外周转量；  
Warehouse & workshop seamless connected to improve turnover efficiency, and reduce outdoor turnover.
- 原辅料、成品独立出入口，物流单向循环；  
Independent import and export of raw materials and finished products, one-way material flow cycle.
- 车间内流向清晰，提升车间管理水平；  
Clear flow direction in the workshop, improve the level of workshop management.
- 环形通道兼顾物资转运及参观功能。  
The circular passage can be used for material transfer and visiting.



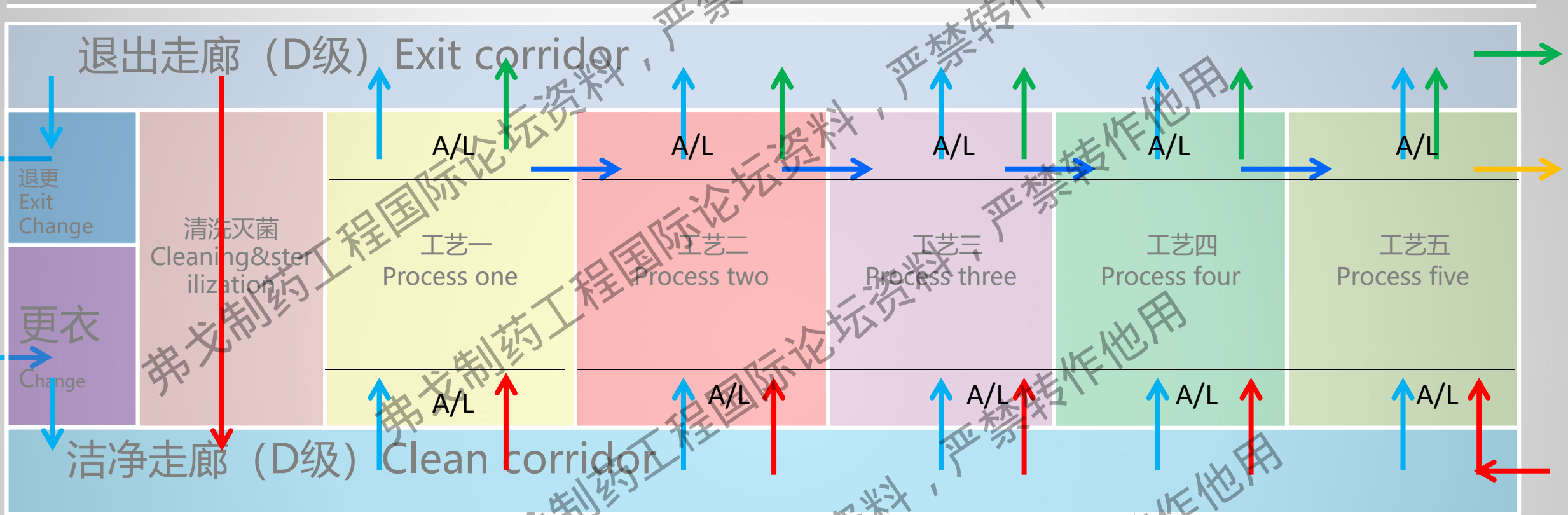
# 概念分区3-单向流设计 Conceptual Zoning 3- One-way Flow Design



毒苗类概念工艺分区-单向流 Conceptual zoning of viral seeds-one way flow:

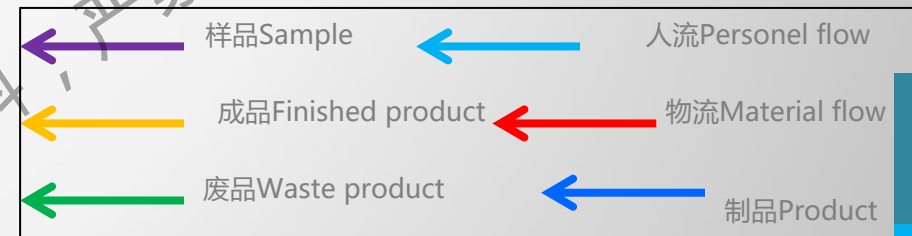
- 1、核心区域人物流单向设计 One-way flow design for personnel flow & material flow in critical zone;

# 平面规划-单向流概念 Planing - One - way Flow Concept

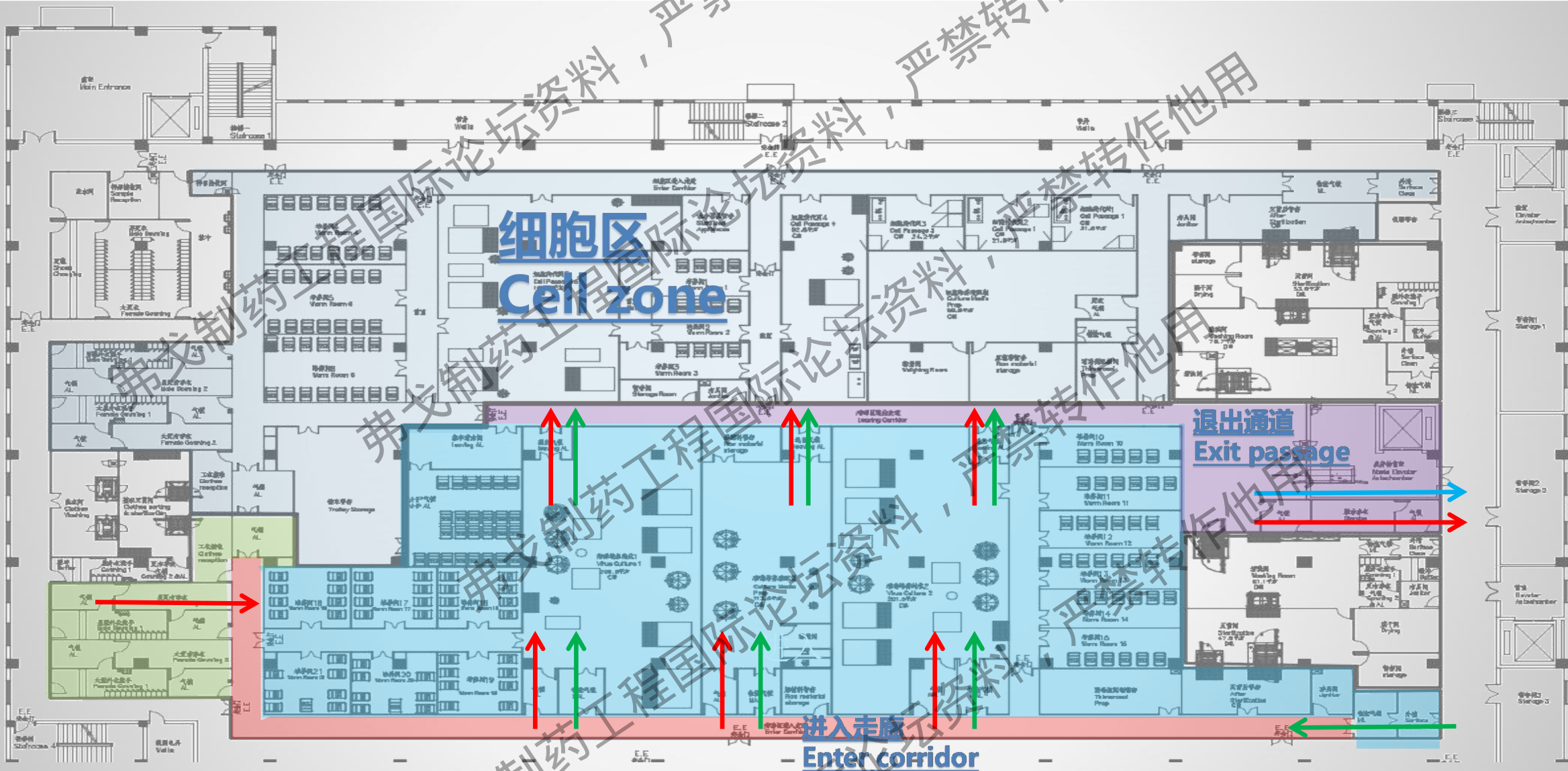


## 概念工艺 Conceptual process

- 各工艺间通过气闸与洁净走道、退出走廊相连，进退均设有气闸；  
Each process room is connected with the clean air lock, clean corridor and exit corridor, and air lock is provided forward and backward.



# 轮状车间平面图 Layout of Rota-virus Workshop



# 工艺设备 Process Equipment

## 标准设备 Standard equipment

脉动真空灭菌柜、VHP传递窗、洗烘联动线、灌装机、轧盖机、冻干机  
Pulsating vacuum sterilization cabinet, VHP transfer window, washing and drying linkage line, filling machine, cap rolling machine, lyophilizer

## 纯化设备

## Purification equipment

超滤、层析

Ultrafiltration, chromatography

## 配液系统

## Liquid preparation system

一次性配液袋、配液罐

Disposable bag, liquid preparation tank

## 生物反应器 Bioreactor

### 反应罐 Reaction tank

细胞工厂、转瓶、一次性反应器  
Cell bank, flask, Disposable reactor

Disposable reactor

## 分离设备 Seperation equipment

深滤器、离心机、匀浆机  
ultrafiltration machine, centrifuge machine, homogenizer

弗戈制药工程国际论坛资料，严禁转作他用



# 公用设施Utilities



## 公用设施

洁净公用工程  
Clean utility

PW、WFI、GA、PS、CO2、O2

暖通工程  
HVAC

新风系统、排风系统、压差控制  
Fresh air system, exhaust air system,  
differential pressure control

电气  
Electronics

照明插座、动力配电、网络通信  
Lighting socket, power distribution, network  
communication

非洁净公用工程  
Black utility

冷冻水、冷却水、工业蒸汽  
Chilled water, chilling water, industrial  
steam

给排水  
water supply  
and drainage

带压排放、冷凝水、活毒废水、碱液、有机  
Discharge with pressure, condensate, l  
waste water, base, organic solvent

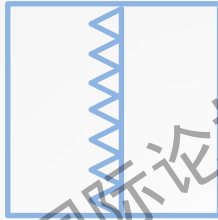


# 暖通系统 Heating Ventilation Air Conditioning

## 新风系统

### Fresh air system

- 三级过滤，末端高效
- Three stage filtration, high end efficiency
- BSL-3设置备用送风机
- BSL-3 Standby blower



## 消毒、排风系统

### Disinfection and exhausting system

- 排风经双级高效过滤器过滤后排放，过滤器进行原位消毒和检漏（P3）
- The air is discharged after being filtered by a two-stage high efficiency filter, which is in-site disinfected and leakage detected (P3)
- 采用臭氧或过氧化氢对系统进行消毒
- Disinfect the system with ozone or hydrogen peroxide

## 有毒区保持负压

Negative pressure in toxic zone:

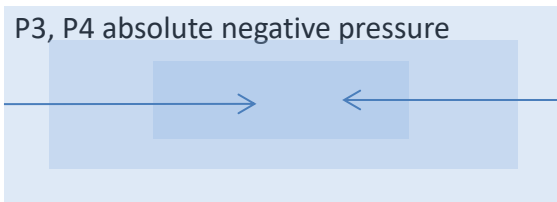
### P1,P2相对负压

P1,P2 relative negative pressure

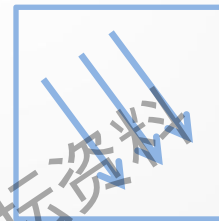
### P3,P4绝对负压

P3, P4 absolute negative pressure

气压



气压



## 室内定向流

### Indoor directional flow

无风险区  
No risk zone

低风险区  
Low risk zone

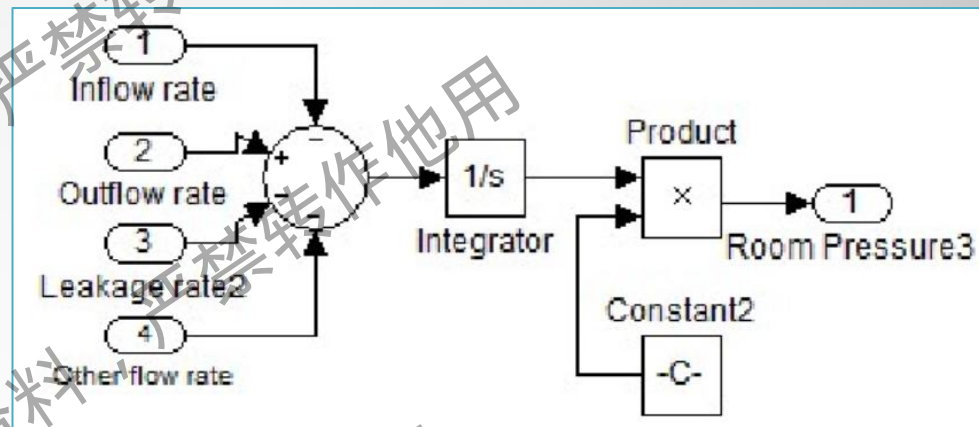
高风险区  
High risk zone

弗戈制药工程国际论坛资料，严禁转作他用

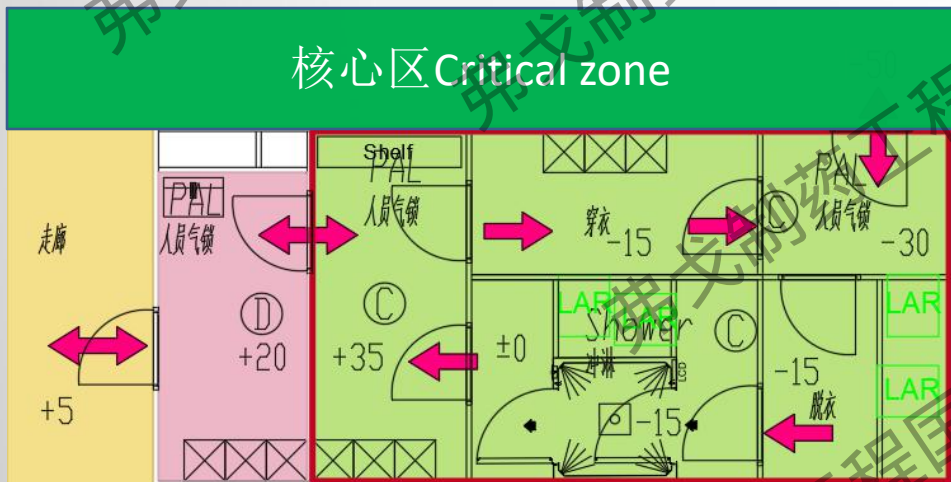
# HVAC系统-压差控制 HVAC System-Differential Pressure Control

采用模拟软件Simulink或Modelica建立实验室压差控制的数学模型，分析定风量阀、变风量阀、压差平衡阀及风机变频PID控制参数对压差控制的控制效果，通过以下控制措施满足本项目系统稳定性要求。

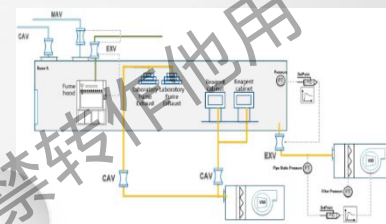
The simulation software Simulink or Modelica is used to establish the mathematical model of the pressure difference control in the laboratory, to analyze the control effect of the constant air flow valve, variable air flow valve, pressure difference balance valve and fan variable frequency PID control parameters on the pressure difference control, and to meet the stability requirements of the project system through the following control measures:



房间压差模型  
Room DP model



压差梯度 DP gradient



高效、稳定的房间压差控制  
Efficient and stable room DP control

定送定回系统  
Constant supply/return system

定送变回系统  
Constant supply/variable return system

变送变回系统  
Variable supply/return system



# 电气系统Electrical System

## 配电箱 Distribution box

专用配电箱且设在防护区之外  
Specified distribution boxes are located outside the protected areas

## 插座 Socket

重要设备单独回路配电且设漏电保护装置  
Separate circuit distribution and leakage protection for important equipment

## 穿墙密封 Penetration seal

采用金属管敷设且穿墙处采用专用穿墙装置  
Metal pipes shall be laid and special wall-penetration devices shall be used

## 应急照明 Emergency lighting

设不少于30min的应急照明及疏散指示系统  
Set up emergency lighting and evacuation indication system for no less than 30 minutes

## 互锁解除 Interlock removal

中控系统或互锁门附近设解除互锁功能或装置  
The central control system or the interlock door vicinity is provided with the interlock removal function or device

## 自控系统报警 Auto-control system alarm

报警信号分类且主实验室内设紧急报警按钮  
Alarm signals are classified and the main laboratory is equipped with an emergency alarm button

## ■ 三废处理Waste Treatment

- 固体废弃物：毒区固体废弃物经各区双扉灭菌柜灭菌后运出生产区，原则上废弃物使用独立废弃物电梯。

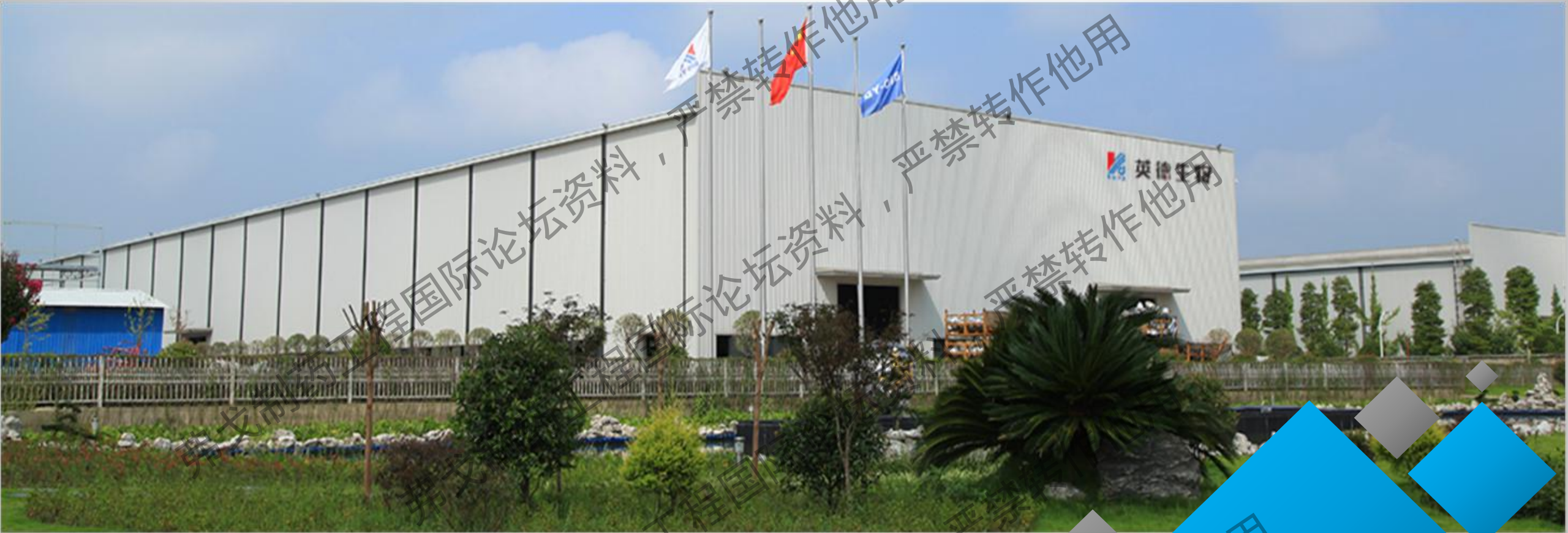
Solid waste: The solid waste in the toxic zone shall be transported out of the production area after sterilization by the double-bucket sterilization cabinets in each district. In principle, the waste shall be used in an independent waste elevator.

- 液体废弃物：带毒废水经灭活系统灭活后排至园区污水处理系统，由污水处理系统处理至政府限定标准后排至市政管网；有机溶剂经专用管道排至收集容器，由专业厂家外运回收处理。

Liquid waste: toxic waste water is inactivated by the inactivated system to the park sewage treatment system, and then treated by the sewage treatment system to the government standards and then to the municipal pipe network; The organic solvent is discharged to the collection container through the special pipe, and is transported and recovered by the professional manufacturer.

- 气体废弃物：发酵过程产生的废气经尾气过滤后排至室外。

Gas waste: the waste gas produced in the fermentation process is filtered and exhausted to the outdoor.



# 谢谢您

Talents come from diligence,  
and knowledge is gained by accumulation.