



Advanced Immunology for your Health.

**ADIMMUNE CORPORATION**



Advanced Immunology for your Health.

**ADIMMUNE CORPORATION**

Asia's **ONLY** both **EU EMA & US FDA**  
GMP-certified influenza vaccine manufacturer

**Taiwan's ONLY ONE** manufacturer of influenza  
vaccine

Partners :



北里第一三共ワクチン株式会社



**Sumitomo Corporation**

Enriching lives and the world



**Johnson & Johnson**



# Adimmune Group Core Competence



PICs/GMP certified human vaccine manufacturing site & advanced aseptic Fill/Finish line

New drug R&D team

Global PICs/GMP Quality system

Cross-border clinical trial & RA experience



No.1  
Pharmaceutical  
Partner in Asia

# Adimmune Group Core Technology



## Embryo Egg

- QIV
- TIV
- H1N1 Pandemic Monovalent Vaccine

## Recombinant Protein

- COVID-19 Vaccine
- H7N9 Pandemic Vaccine Technology Platform

Embryo Egg

Recombinant Protein

Cell Culture-Based

GMP Quality

PFS Sterile Filling

## Cell Culture-Based

- EV71 Vaccine
- Japanese Encephalitis Vaccine
- Influenza Vaccine

## PFS Sterile Filling

- US Sanofi
- Protein-Based Vaccine
- EU Tech Dow Enoxaparin Sodium

## GMP Quality

- E.U. EMA PIC/S GMP
- U.S. FDA GMP



# Global GMP Certification

## US FDA GMP Certification



March 8, 2019

UPS EXPRESS MAIL

Mr. Chung Chen Liu  
President  
Adimmune Corporation  
No. 3, Sec. 1, Tansing Rd., Taini District  
Taichung City 42743 Taiwan

Dear Mr. Chen Liu,

The Food and Drug Administration (FDA) received your letter dated August 20, 2008, responding to the Form FDA 483 issued at the end of the July 19 through 30, 2008, FDA inspection of Adimmune Corporation, located in Taichung City, Taiwan.

Your response and proposed corrective actions were reviewed by FDA and appear adequate. Your response was put in your firm's permanent file, and corrective actions will be reviewed and assessed during the next inspection at your facility.

Sincerely,

Robert A. Saville  
Director  
Division of Case Management  
Office of Compliance and Biologics Quality  
Center for Biologics Evaluation and Research

## EU EMA GMP Certification

Agenzia Italiana del Farmaco

CERTIFICATE NUMBER: ZDCGMP/E-05-2019

### CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

#### Part 1

Issued following an inspection in accordance with:  
Art. 111(5) of Directive 2003/85/EC as amended

The competent authority of Italy confirms the following:

The manufacturer: **Adimmune Corporation**

Site address: **No.3, Sec.1, Tansing Rd., Taini Dist., Taichung City, 42743, Taiwan**

Has been inspected in connection with marketing authorization(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 8(2) of Regulation (EC) 726/2004.

Other:

Distast Assessment

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2020-08-07**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC<sup>1</sup>

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EnduroGMP. If it does not appear, please contact the issuing authority.

## Certification of Halal Process & Product

**DAKWAH HALAL FOUNDATION**

السلامة

Certification No: HP210128

**Adimmune Corporation**

No. 3, Sec. 1, Tansing Rd., Taini Dist., Taichung City 42743, Taiwan (R.O.C.)

For items independently assessed and compliant with the requirements of Islamic Law, MS 1500:2009 & Halal Standard 5:12:2008/2 in Indonesia

This certificate is applicable to the following products or services range:

Various Vaccine Products  
(Other products, please refer to attachment)

Page 1 of 2  
Ref No: HP210128-01  
Date of Issue: Jan 20, 2021  
Valid Until: Jan 20, 2022

DAKWAH Halal Foundation  
No. 40-0-017-017, Tel: 08-5173205007, www.dakwah.org  
JAL. 10, No. 1, Sec. 1, Taini Dist., Taichung City 42743, Taiwan

**DAKWAH HALAL FOUNDATION**

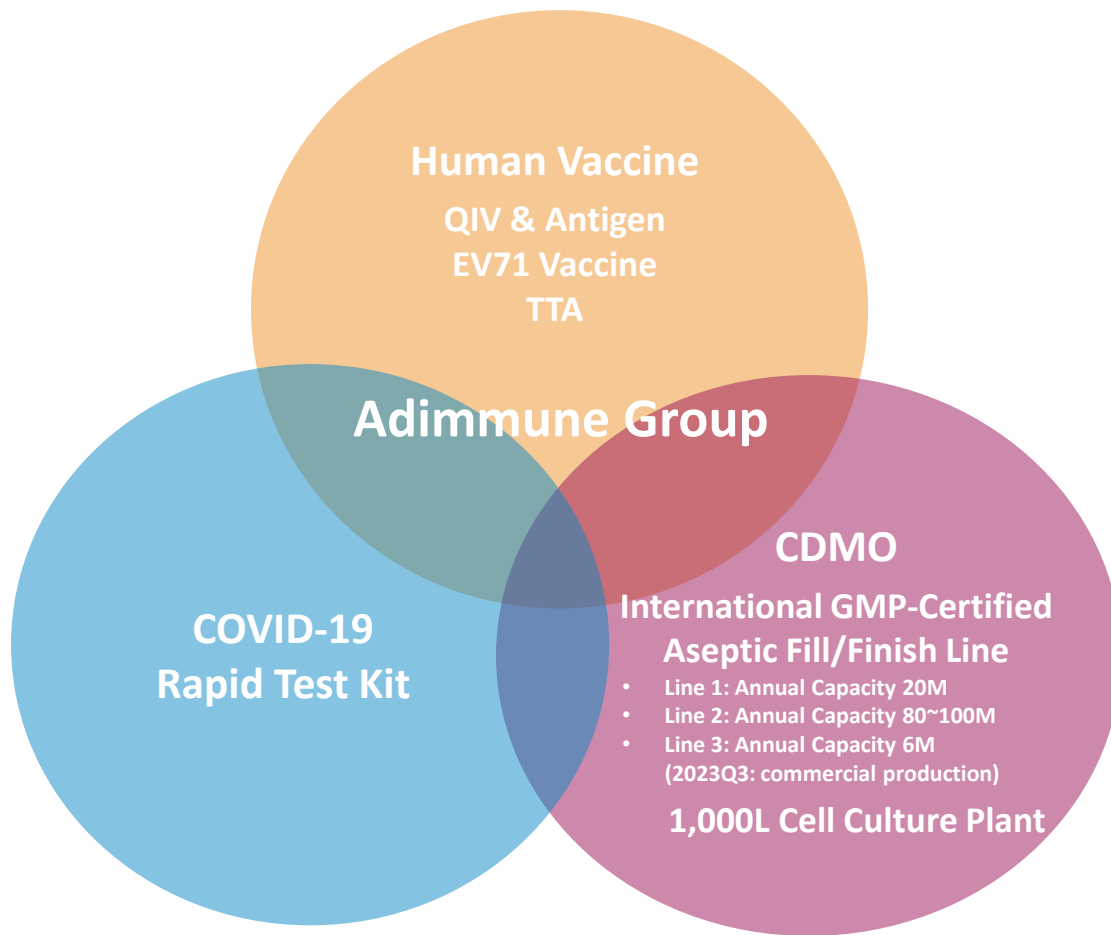
السلامة

| Serial No. | Product Name                                                         | Capacity                            |
|------------|----------------------------------------------------------------------|-------------------------------------|
| 1          | Adimmune Corporation<br>Adimmune Corporation<br>Adimmune Corporation | 1000/1000<br>1000/1000<br>1000/1000 |
| 2          | Adimmune Corporation<br>Adimmune Corporation                         | 1000/1000<br>1000/1000              |
| 3          | Adimmune Corporation<br>Adimmune Corporation                         | 1000/1000<br>1000/1000              |
| 4          | Adimmune Corporation<br>Adimmune Corporation                         | 1000/1000<br>1000/1000              |
| 5          | Adimmune Corporation<br>Adimmune Corporation                         | 1000/1000<br>1000/1000              |
| 6          | Adimmune Corporation<br>Adimmune Corporation                         | 1000/1000<br>1000/1000              |
| 7          | Adimmune Corporation<br>Adimmune Corporation                         | 1000/1000<br>1000/1000              |
| 8          | Adimmune Corporation<br>Adimmune Corporation                         | 1000/1000<br>1000/1000              |
| 9          | Adimmune Corporation<br>Adimmune Corporation                         | 1000/1000<br>1000/1000              |
| 10         | Adimmune Corporation<br>Adimmune Corporation                         | 1000/1000<br>1000/1000              |

Page 2 of 2  
Certification No: HP210128

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No. 40-0-017-017, Tel: 08-5173205007, www.dakwah.org  
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# Adimmune's Integrated Vaccine & CDMO Service



# Adimmune's Growth Highlight

|                     |                                          |                     |                 |
|---------------------|------------------------------------------|---------------------|-----------------|
| Product/<br>Service | CDMO Service                             |                     | QIV PFS         |
|                     | Sanofi<br>(Protein Sciences Corporation) | Techdow             | Beijing Shouhui |
|                     | CDMO<br>Fill/Finish                      | CDMO<br>Fill/Finish | QIV             |

# Global Strategic Partner



**Inhixa®**  
Enoxaparin sodium injection  
for EU market

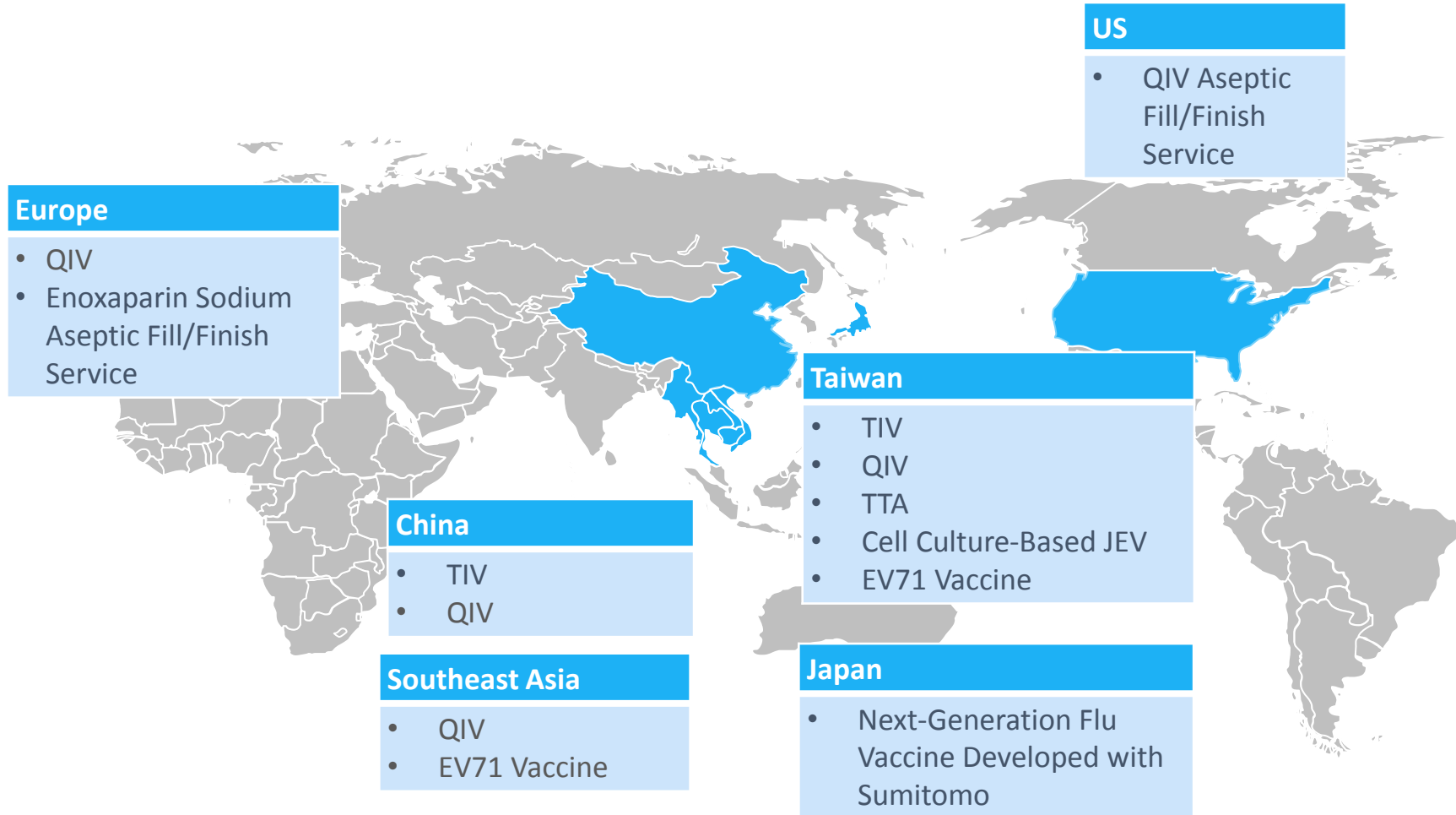


**Flublok®** Quadrivalent  
Influenza Vaccine  
for US ,UK market

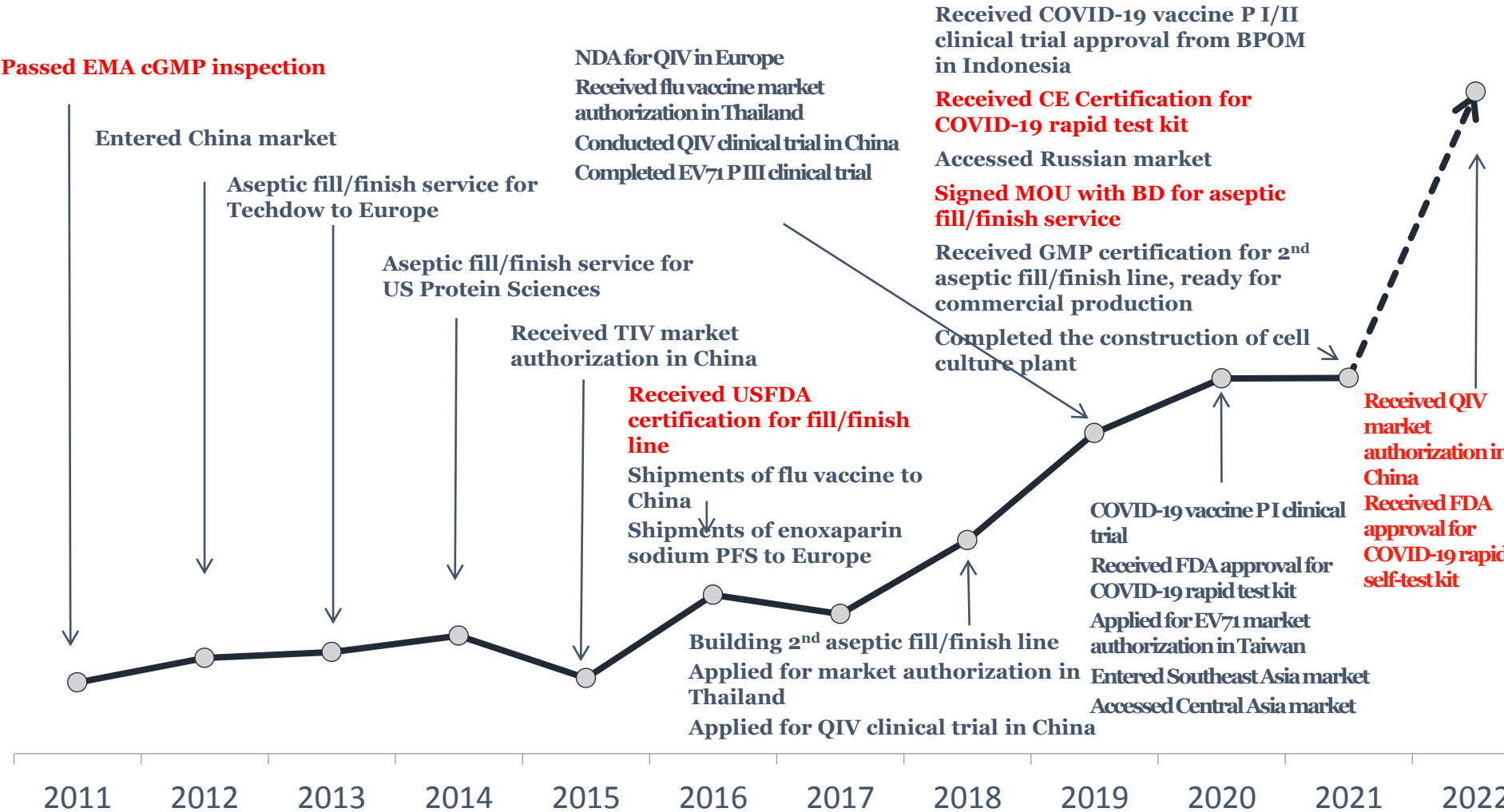


**MOU with BD**  
for Aseptic F/F CDMO service

# Global Market



**Passed EMA cGMP inspection**



NDA for QIV in Europe  
Received flu vaccine market authorization in Thailand  
Conducted QIV clinical trial in China  
Completed EV<sub>71</sub> P III clinical trial

Received COVID-19 vaccine P I/II clinical trial approval from BPOM in Indonesia

**Received CE Certification for COVID-19 rapid test kit**

Accessed Russian market

**Signed MOU with BD for aseptic fill/finish service**

Received GMP certification for 2<sup>nd</sup> aseptic fill/finish line, ready for commercial production

Completed the construction of cell culture plant

**Received USFDA certification for fill/finish line**

Shipments of flu vaccine to China  
Shipments of enoxaparin sodium PFS to Europe

Building 2<sup>nd</sup> aseptic fill/finish line  
Applied for market authorization in Thailand  
Applied for QIV clinical trial in China

COVID-19 vaccine PI clinical trial  
Received FDA approval for COVID-19 rapid test kit  
Applied for EV<sub>71</sub> market authorization in Taiwan  
Entered Southeast Asia market  
Accessed Central Asia market

Received QIV market authorization in China  
Received FDA approval for COVID-19 rapid self-test kit

# Adimmune Integrated Manufacturing Site

- 1,000L Cell Culture Plant + 200L Bioreactor

- ✓ Annual capacity: >30 million doses

- ✓ **Completed construction. Under inspection.**

- 2<sup>nd</sup> PFS Fill/Finish Line

- ✓ Annual capacity: 100 million doses (PFS)

- ✓ **GMP certified. Commercial production ready.**

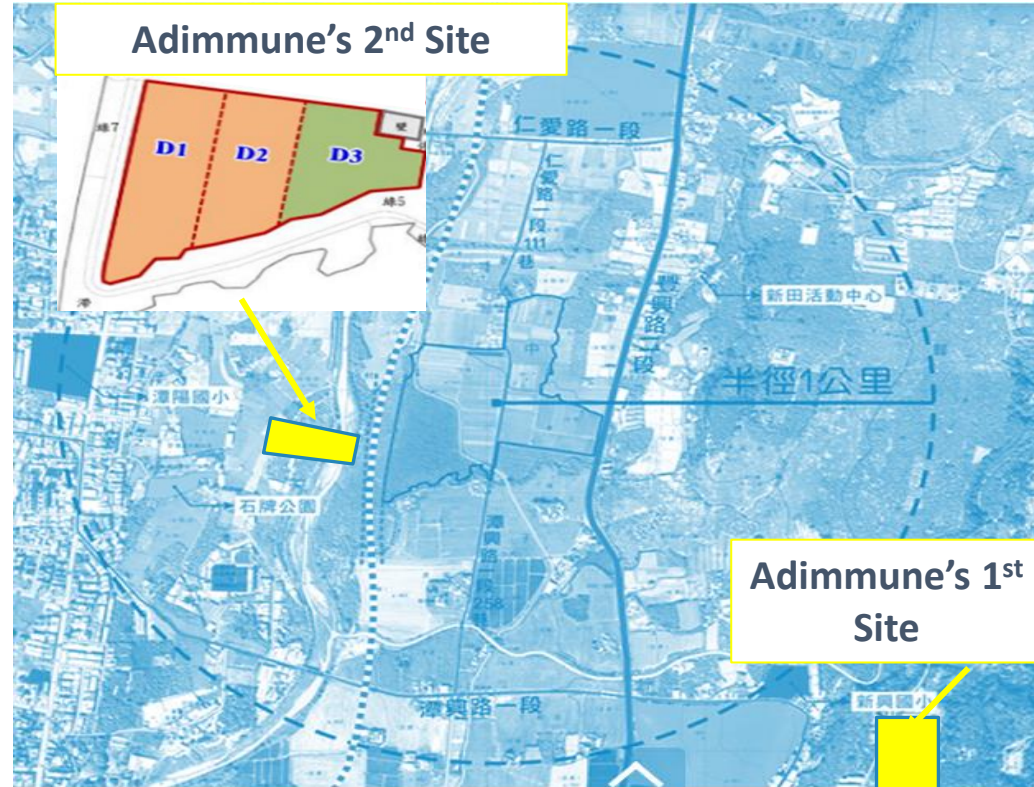
- Tetanus Vaccine Drug Substance Plant

- ✓ **2021: facilities installed**

- ✓ July 2023: commercial production ready

# Global R&D & CDMO Campus Tanzi Juxing Industrial Park

- **R&D Lab**
- **Animal Room & Testing Lab:**
- NDA, preclinical animal testing
- **Microorganism Pilot Plant:**  
Vaccine & biologics for clinical trial  
(protein drug, RNA, DNA)
- **Cell Culture Pilot Plant:**  
Vaccine & biologics for clinical trial  
(protein and antibody drug)
- **Multi-Functional F/F & Automated Packaging Plant:**  
From clinical trial to commercial production  
(PFS, vial, lyophilized powder)
- **Cell Culture Plant:**  
Biologics, i.e., vaccine, mAb
- **F/F & Automated Packaging Plant**





**Thank You**