國際之光．免疫先鋒

國光生物科技股份有限公司

國際之光．免疫先鋒

國光生物科技股份有限公司

亞洲唯一

歐盟EMA&美國FDA認證之流感疫苗製造公司

台灣唯一國產自製流感疫苗生物科技公司

合作夥伴：

SANOFI PASTEUR

Techdow

Daiichi-Sankyo 北里第一三共ワクチン株式会社

Sumitomo Corporation
Enriching lives and the world

Crucell
Johnson&Johnson

國光生物科技技團核心競爭力

符合PIC/s GMP 人用疫苗生產廠房及設施和先進無菌針劑充填產線及產能

研發團隊開發新藥技術及能量

國際認證PIC/s GMP品質系統

經驗豐富的跨國臨床試驗管理能力及全球法規支援能力

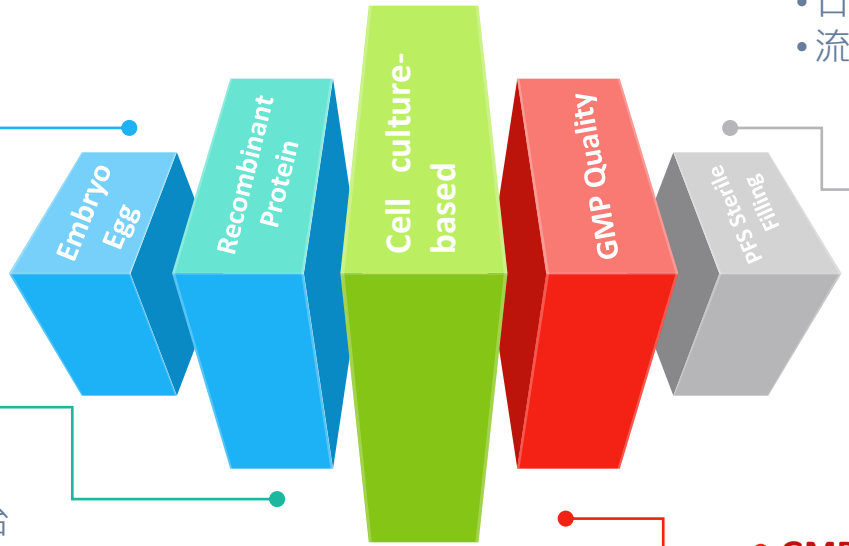
國光生物科技集團核心技術

雞胚胎蛋

- 四價流感疫苗
- 三價流感疫苗
- H1N1 大流行單價疫苗

細胞培養

- 腸病毒71型疫苗
- 日本腦炎疫苗
- 流感疫苗



無菌充填線

- US Sanofi
- 蛋白質疫苗
- EU Tech Dow Enoxaparin Sodium

重組蛋白

- 新冠疫苗
- H7N9 大流行生產疫苗技術平台

GMP 品質系統

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

國際GMP認證

美國 FDA GMP 認證

U.S. FOOD & DRUG ADMINISTRATION

March 8, 2019

UPS EXPRESS MAIL

Mr. Chang Chen Liu
President
Adimmune Corporation
No. 3, Sec. 1, Tanxing Rd., Tanzi District
Taichung City 42743 Taiwan

Dear Mr. Chen Liu,

The Food and Drug Administration (FDA) received your letter dated August 20, 2018, responding to the Form FDA 483 issued at the end of the July 19 through 30, 2018, 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. Sausville
Director
Division of Case Management
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

歐盟 EMA GMP 認證

Agenzia Italiana del Farmaco

CERTIFICATE NUMBER: IT/GMP/E/05-2020

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with:
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Italy confirms the following:
The manufacturer: ***Adimmune Corporation***
Site address: ***No.3, Sec.1, Tanxing Rd., Tanzi Dist., Taichung City, 42743, Taiwan***

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

Other:
Distant 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

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 EudraGMDP. If it does not appear, please contact the issuing authority.

清真製程及產品認證


DAKWAH HALAL FOUNDATION

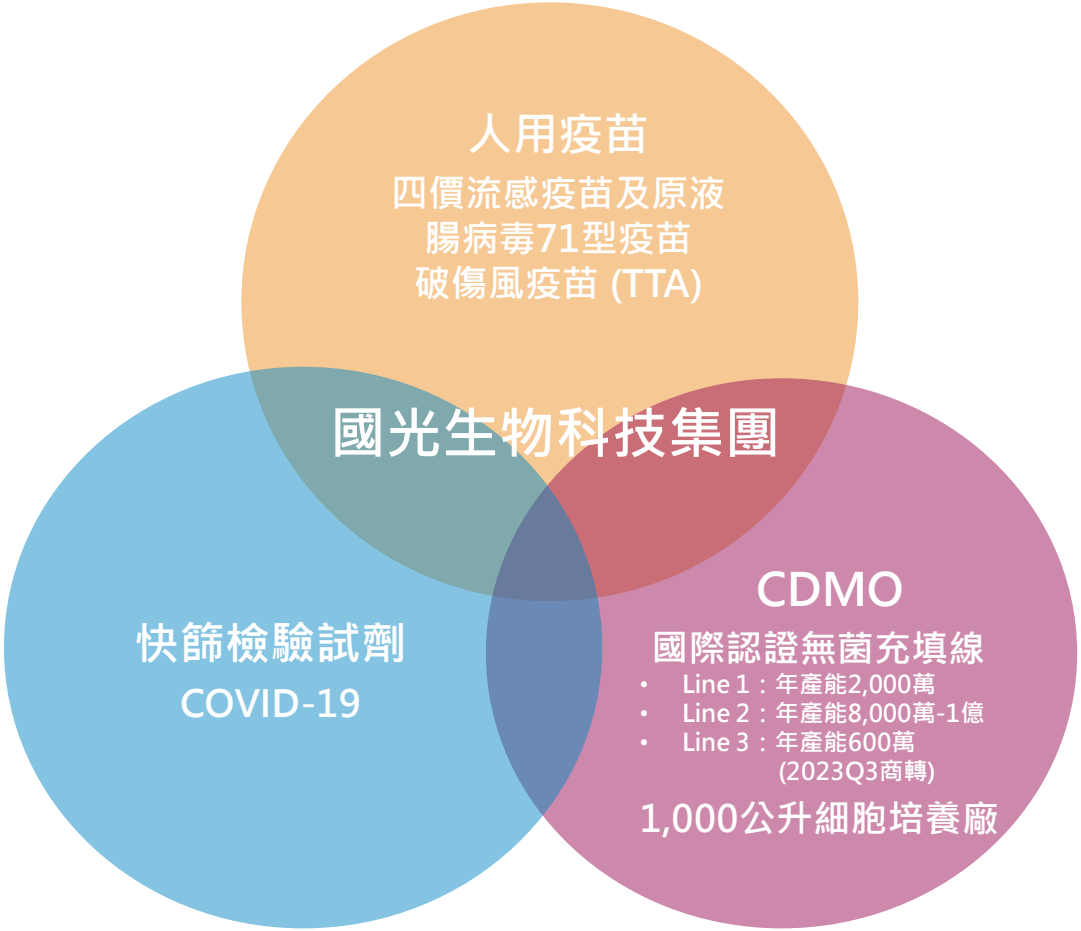
Certification No: HP210128

Adimmune Corporation


DAKWAH HALAL FOUNDATION

Serial No.	Product Name	Capacity
1		
1		
1		
1		
1		
1		
1		
	Blank	

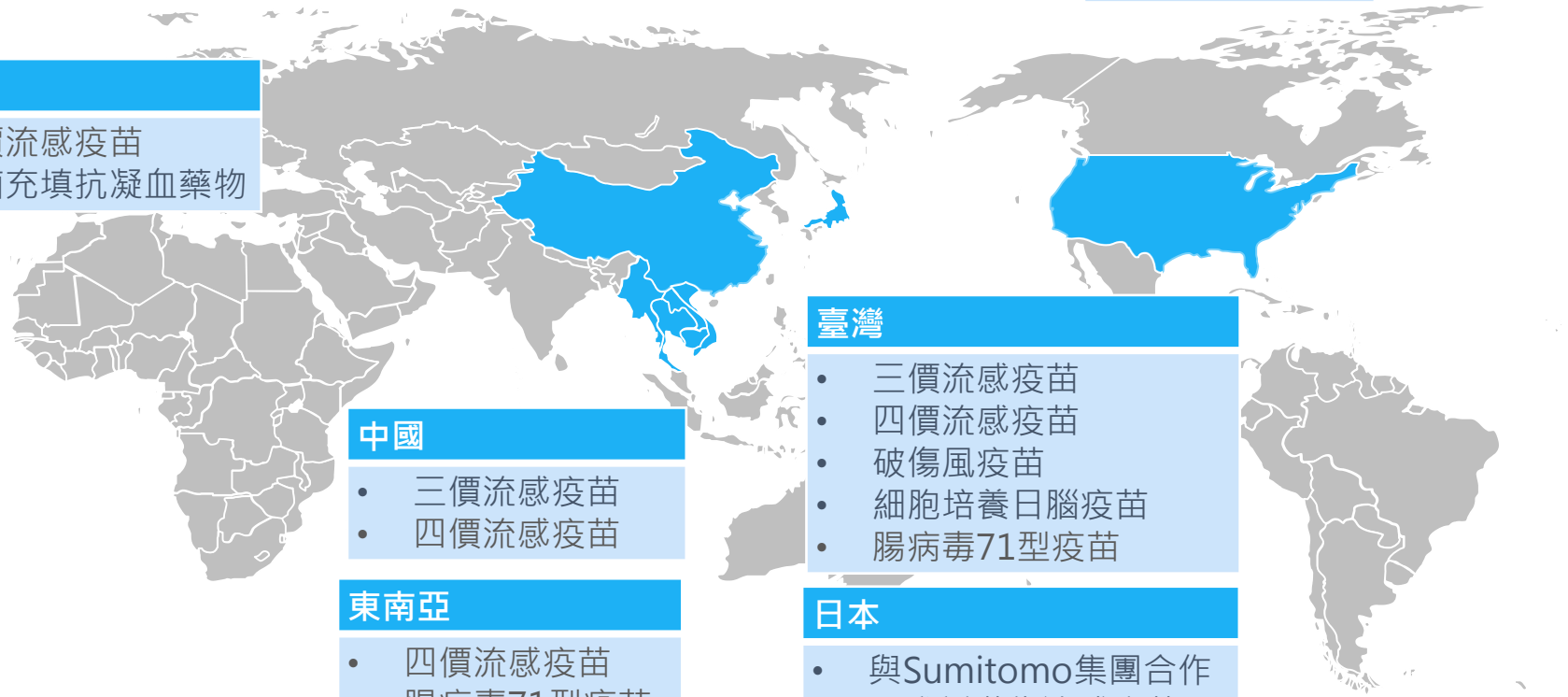
國光生物集團全方位專業疫苗及CDMO專業服務



國光生技集團成長動能

	CDMO 專業服務		四價流感疫苗成品
	Sanofi (Portein Sciences Corporation)	天道醫藥	北京首惠医药
產品/服務標的	CDMO 充填服務	CDMO 充填服務	四價流感疫苗

拓展全球市場



美國

- 四價流感疫苗無菌充填針劑

歐洲

- 四價流感疫苗
- 無菌充填抗凝血藥物

臺灣

- 三價流感疫苗
- 四價流感疫苗
- 破傷風疫苗
- 細胞培養日腦疫苗
- 腸病毒71型疫苗

中國

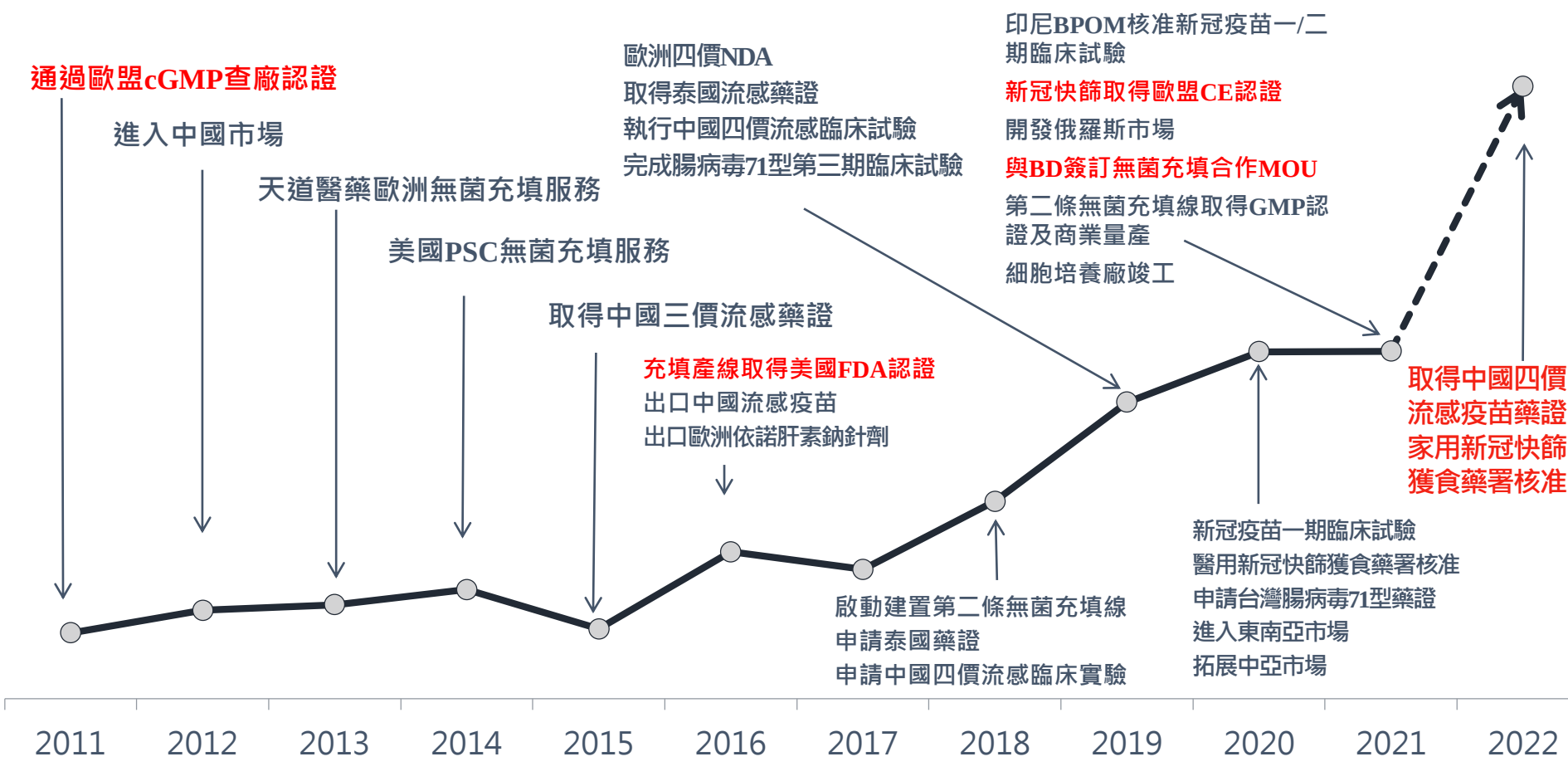
- 三價流感疫苗
- 四價流感疫苗

東南亞

- 四價流感疫苗
- 腸病毒71型疫苗

日本

- 與Sumitomo集團合作開發新世代流感疫苗


通過歐盟cGMP查廠認證
進入中國市場
天道醫藥歐洲無菌充填服務
美國PSC無菌充填服務
取得中國三價流感藥證
充填產線取得美國FDA認證
出口中國流感疫苗
出口歐洲依諾肝素鈉針劑
歐洲四價NDA
取得泰國流感藥證
執行中國四價流感臨床試驗
完成腸病毒71型第三期臨床試驗
印尼BPOM核准新冠疫苗一/二期臨床試驗
新冠快篩取得歐盟CE認證
開發俄羅斯市場
與BD簽訂無菌充填合作MOU
第二條無菌充填線取得GMP認證及商業量產
細胞培養廠竣工
啟動建置第二條無菌充填線
申請泰國藥證
申請中國四價流感臨床實驗
新冠疫苗一期臨床試驗
醫用新冠快篩獲食藥署核准
申請台灣腸病毒71型藥證
進入東南亞市場
拓展中亞市場
取得中國四價流感疫苗藥證
家用新冠快篩獲食藥署核准
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022

Thank You