



國光生技 元大金控創富論壇

國光生物科技股份有限公司
詹啟賢 董事長



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生技產業



R&D
研發

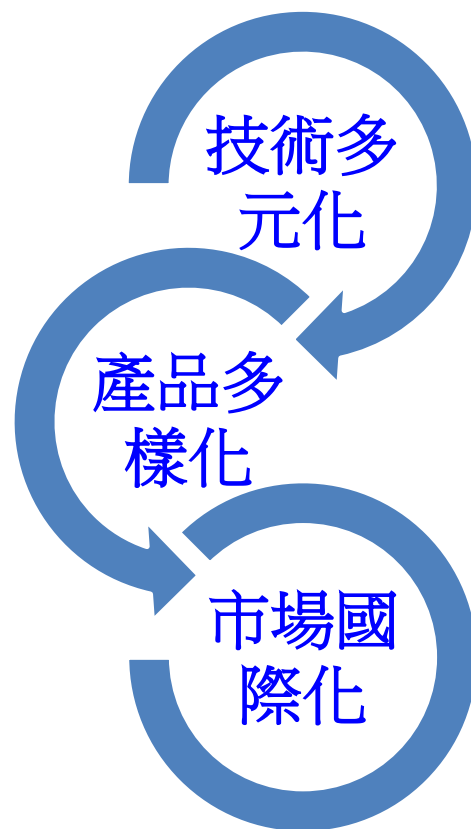
Clinical Trial
臨床試驗

Production
商業量產

G.C.P / G.M.P



生技產業價值鏈



I 機會

- 醫學教育及其他相關學術機構
- 全民健保 / 醫療網
- 法規制度 / 世界接軌/CDE
- 智慧財產 IP Right
- 技術人才-高教育 / 工作倫理 / QA / 海外經驗
- 語言能力



I 挑戰



市場小

- 資源有限
- 政府政策不明—
分散或集中
保護國內市場政策或尋求國外協助

社會觀念分歧



- Domestic/Import
- 產業vs.金融市場操作
- 研發、臨床、生產一貫作業
- Anti Vaccine Movement



關鍵領域人才不足

- 法規、QA、生產
- 國際市場—商業談判、商業模式
- 合約能力

國際競爭激烈



- 國際大廠資源雄厚
- 通路、市場保護策略
- M&A · Consolidation





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認證&美國FDA認證
流感疫苗製造公司(每2年re-certify)
- 合作夥伴

SANOFI PASTEUR 

 Techdow



北里第一三共ワクチン株式会社



Sumitomo Corporation

Enriching lives and the world

 Crucell

Johnson+Johnson



ADIMMUNE CORPORATION

多國GMP查廠認證



- 2010/8/22~27
- **EMA** audit for Flu vaccine



- 2016/11/3
- **US FDA** Inspection for Flublok[®] QIV filling process



- 2012/11/27~27
- **Pharmathen** audit for Enoxaparin Sodium Injection filling process



- 2017/5/1~5
- **Brazil ANVISA** inspection for Flublok[®] QIV filling process



- 2013/4/23~25
- **EMA** Routine inspection



- 2019/5/15~17
- **TFDA** Routine inspection for PIC/S GMP compliance



- 2013/10/2~4
- **TFDA** inspection for H7N9 vaccine



- 2020/5
- **EMA** Remote inspection for Enoxaparin Sodium Injection filling process



- 2014/6/30~7/3
- **KFDA** inspection for Flu vaccine



- 2020/7/16
- **Health Canada** inspection for Quadrivalent Flu vaccine

國光生技榮獲歐盟GMP認證

<i>Italian Medicines Agency</i>	
CERTIFICATE NUMBER: <i>IT/GMP/E/3-2018</i>	
CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER ^{1, 2}	
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: <i>Adimmune Corporation</i>	
Site address: <i>No.3, Sec.1, Tanxing Rd., Tanzi Dist., Taichung City, 42743, Taiwan</i>	
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 .	
From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2017-11-23 , it is considered that it complies with :	
• The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC ³	
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.	



國光生技美國FDA GMP認證

	DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Silver Spring MD 20993
November 3, 2016	
Adimmune Corporation Attention: Dr. Chungchen Liu President 3, Tanxing Rd., Sec. 1, Tanzi Dist. Taichung City Tanzi District 42743 TAIWAN	
Dear Dr. Liu:	
We are enclosing a copy of the Establishment Inspection Report (EIR) as a result of the inspection conducted at your premises located at 3, Tanxing Rd., Sec. 1, Tanzi Dist. Taichung City, Tanzi District 42743, Taiwan on March 24 through April 01, 2016 by the U.S. Food and Drug Administration (FDA). This pre-approval inspection was performed regarding your manufacturing activity as a contractor of Protein Sciences Corporation (PSC) for their purified recombinant influenza hemagglutinin (Influenza Vaccine), Flublock® Quadrivalent. When the Agency concludes that an inspection is "closed," under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.	
The Agency continually works to make its regulatory processes and activities more transparent for regulated industry. Releasing this EIR to you is part of that effort. The copy we are providing to you contains the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the FOIA and 21 CFR Part 20. This, however, does not preclude you from requesting additional information available under FOIA.	
Sincerely yours,	
 Carrie M. Mampilly Director, Division of Inspections & Surveillance Office of Compliance & Biologics Quality	



ADIMMUNE CORPORATION

清真認證證書



DAKWAH HALAL FOUNDATION

الشهادة

Certification No: HP210128

Adimmune Corporation

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

has been independently assessed and is compliant with the requirements of Islamic Law, MS 1500:2009 in Malaysia and HAS 23000:1 in Indonesia

This certificate is applicable to the following products or service ranges:

Various Vaccine Products

(Total 7 products, please refer to attachment)

Page: 1 of 2

Ref No.: IPT9316-TCT-0128/2021

Date of Issue: Jan 28, 2021

Valid Until: Jan 27, 2022

(Signature) Director General



Dakwah Halal Foundation

Tel 886-2-6617-8817, Fax. 886-2-2722-5922 www.halalorg.tw

A26, 5F., No. 5, Sec. 5, Xinyi Rd., Xinyi Dist., Taipei City 110, Taiwan

Dakwah Halal Foundation is in cooperation with SAS Test Certification Ltd. in fields of halal testing and assessment. This certificate is the property of Dakwah Halal Foundation, the rightful certification body to issue and suspend Halal certificates. Every certificate issued from this Foundation requires an annual audit in order to remain its validity. Any unauthorized alteration, forgery or falsification of the content for illegal use if strictly prohibited, offenders may be prosecuted to the extent of the Law.



DAKWAH HALAL FOUNDATION

الشهادة

Serial No.	Product Name	Capacity
1	AdimrSC-2f Recombinant Corona Virus Vaccine-Baculovirus System	0.5mL/Syringe · 20 Syringe /Box 0.5mL/Syringe · 1 Syringe /Box
2	AdimFlu-S (QIS) Quadrivalent influenza vaccine	0.5mL/Syringe · 20 Syringe /Box 0.5mL/Syringe · 10 Syringe /Box 0.5mL/Syringe · 1 Syringe /Box
3	TetraFlu Quadrivalent influenza vaccine	0.5mL/Syringe · 10 Syringe /Box 0.5mL/Syringe · 1 Syringe /Box
4	Influenza Vaccine (Split Vision), Inactivated	0.5mL/Syringe · 20 Syringe /Box 0.5mL/Syringe · 1 Syringe /Box
5	Quadrivalent Influenza Vaccine (Split Vision), Inactivated	0.5mL/Syringe · 20 Syringe /Box 0.5mL/Syringe · 1 Syringe /Box
6	Tetanus Toxoid Alum Precipitated "Kuo Kwang"	0.5mL/Syringe · 20 Syringe /Box 0.5mL/ vial · 10 vial / box 1mL/ vial · 10 vial/box 3mL/ vial · 10 vial/box 5mL/ vial · 10vial/box 20mL/ vial · 10 vial / box
7	EnVAX-A71 Enterovax Enterovirus 71 Vaccine	0.5mL/Syringe · 20 Syringe /Box 0.5mL/Syringe · 10 Syringe /Box 0.5mL/Syringe · 1 Syringe /Box
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Page: 2 of 2

Certification No: HP210128



Dakwah Halal Foundation

Tel 886-2-6617-8817, Fax. 886-2-2722-5922 www.halalorg.tw

A26, 5F., No. 5, Sec. 5, Xinyi Rd., Xinyi Dist., Taipei City 110, Taiwan

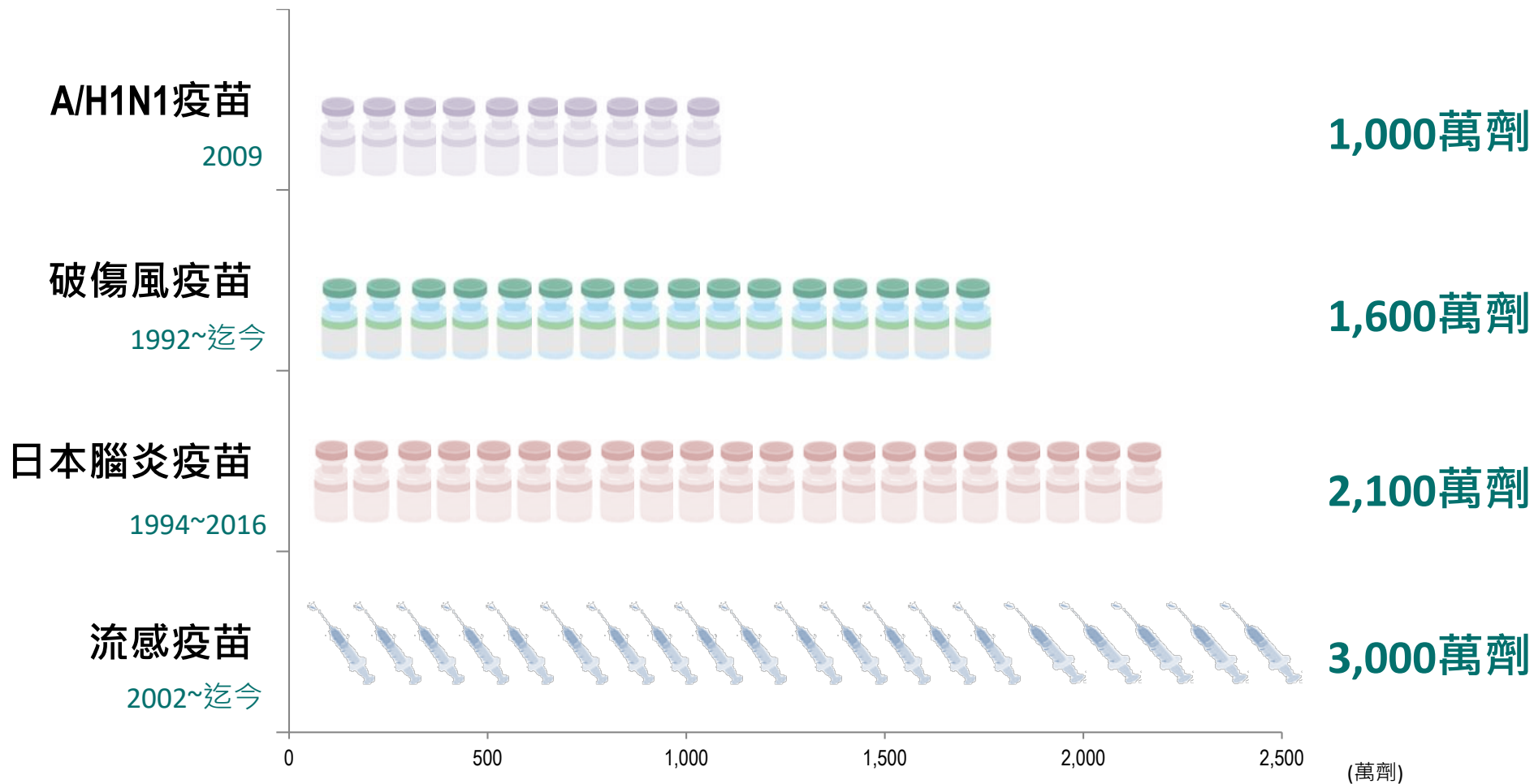
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清真認證疫苗

Serial No.	Product Name	Capacity
1	AdimrSC-2f Recombinant Corona Virus Vaccine-Baculovirus System	新冠 0.5mL/Syringe , 20 Syringe /Box 0.5mL/Syringe , 1 Syringe /Box
2	AdimFlu-S (QIS) Quadrivalent influenza vaccine	流感 0.5mL/Syringe , 20 Syringe /Box 0.5mL/Syringe , 10 Syringe /Box 0.5mL/Syringe , 1 Syringe /Box
3	TetraFlu Quadrivalent influenza vaccine	0.5mL/Syringe , 10 Syringe /Box 0.5mL/Syringe , 1 Syringe /Box
4	Influenza Vaccine (Split Vision), Inactivated	0.5mL/Syringe , 20 Syringe /Box 0.5mL/Syringe , 1 Syringe /Box
5	Quadrivalent Influenza Vaccine (Split Vision), Inactivated	0.5mL/Syringe , 20 Syringe /Box 0.5mL/Syringe , 1 Syringe /Box
6	Tetanus Toxoid Alum Precipitated "Kuo Kwang"	破傷風 0.5mL /Syringe , 20 Syringe /Box 1mL / vial , 10 vial / box 1mL/vial , 10 vial/box 3mL/vial , 10 vial/box 5mL/ vial , 10vial/box 20mL/ vial , 10 vial / box
7	EnVAX-A71 Enterovax Enterovirus 71 Vaccine	腸病毒 0.5mL/Syringe , 20 Syringe /Box 0.5mL/Syringe , 10 Syringe /Box 0.5mL/Syringe , 1 Syringe /Box
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I 防疫尖兵



經營團隊 打造全新國光

- COVID-19 變種病毒株研發
- 執行COVID-19海外臨床試驗
- 取得腸病毒71型藥證
- 取得中國四價流感藥證
- 取得清真認證
- 進入中亞及中東市場

- 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型第三期臨床實驗

- 出口美國PSC四價流感疫苗
- 取得台灣四價流感藥證
- 完成歐洲四價流感臨床試驗

- 美國Protein Sciences無菌充填服務

- 證交所核准掛牌上市
- 進入中國市場

供貨1,000萬劑
A/H1N1疫苗

新管理團隊
啟動國光
轉型與改革

通過歐盟cGMP查
廠認證

- 充填產線取得美國FDA cGMP 認證
- 出口中國流感疫苗
- 出口歐洲依諾肝素鈉針劑

- 天道醫藥歐洲無菌充填服務

- 取得中國
流感藥證

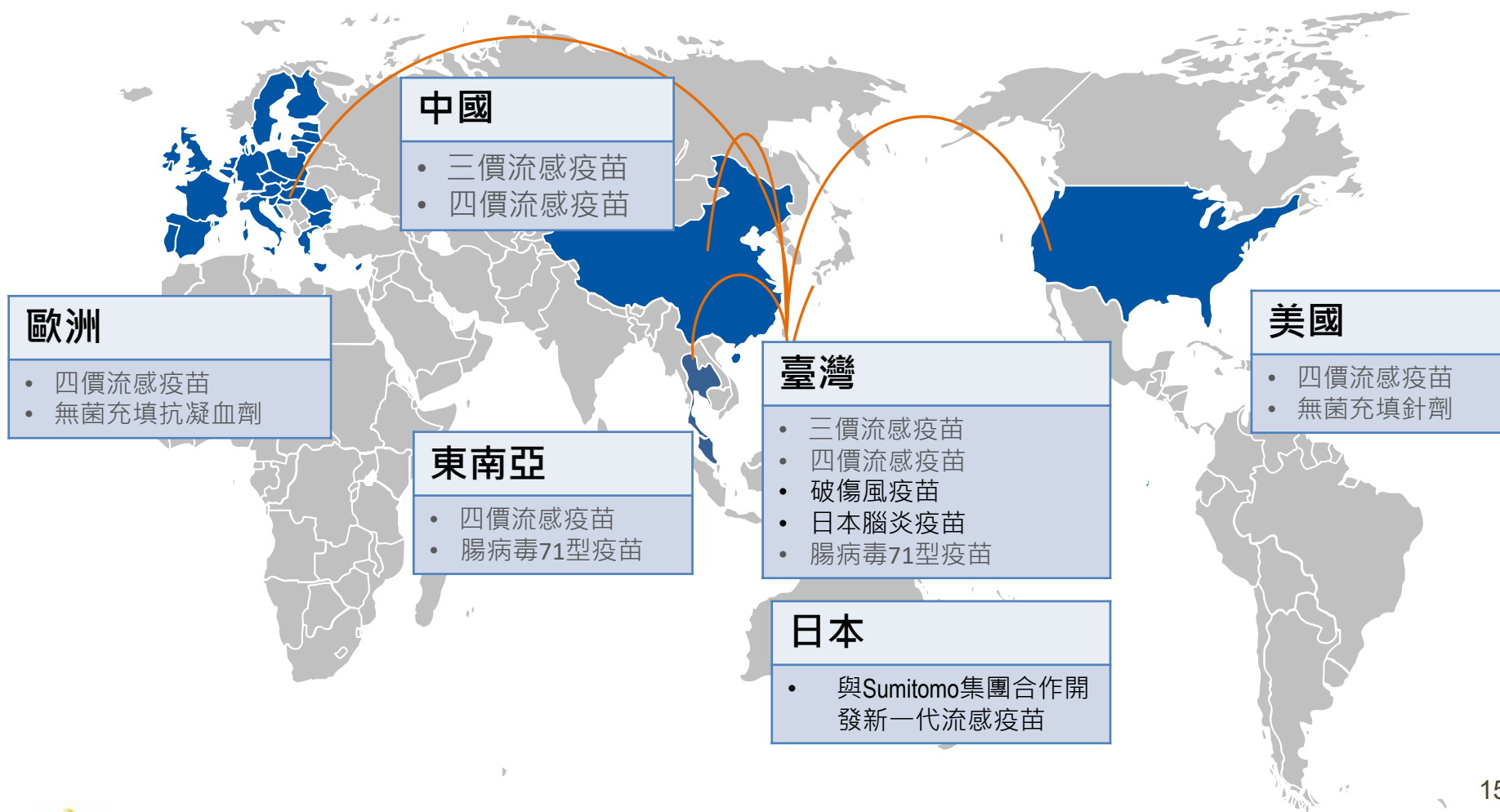
- COVID-19研發
- COVID-19檢驗試劑
- 進入東南亞市場

- 啟動建置第二條無菌充填線
- 申請泰國藥證



2008 CORPORATION

I 市場國際化



I 國光生技既有產能

- 流感廠

- ✓ 年產 1,400 萬劑

- 充填一線

- ✓ 年產 1,800~2,000 萬劑

- 國衛院細胞培養廠

- ✓ 200L



國光生技新建廠區

- 細胞培養廠 1,000L

生物反應器

✓ 年產 1,200 萬劑

✓ 2021下半年投產

- PFS 充填二線

✓ 年產1億劑

✓ 2021下半年投產

- 破傷風疫苗原液廠

✓ 2023/ 7月商業量產

- 行政後勤棟 (專業倉儲)



研究開發中疫苗



Completed

In Progress

Up coming

Discovery

Pre-clinical

Phase I

Phase II

Phase III

NDA

Adim Flu-A

H7N9 Avian Flu Vaccine

EV71 Vaccine

台灣

Cell Cultured JEV

Recombinant Flu

Vaccine

Cell Culture

Coxsackie Virus Vaccine

COVID-19 Vaccine

ASEAN

完成研發階段 即將商業銷售疫苗



Completed

In Progress

Up coming

Discovery Pre-clinical Phase I Phase II Phase III NDA

AdimFlu-S (QIS)

Age 6M to 35M



EV71 Vaccine



AdimFlu-S (QIS)

Age > 3 yrs old (China)

中國

**COVID-19 Ag
Rapid Test Kit**
(ASEAN)

ASEAN

Thank You

Q & A

