

出國報告（出國類別：其他-參加國際生技大會及論壇）

參加「北美生物科技國際會議展
(2017 US BIO)」及「台灣生技產業
策略諮議委員會-海外委員座談會」
出國報告

服務機關：衛生福利部、食品藥物管理署

姓名職稱：何啟功次長、李顯揚博士、何承穎博士、黃小文博士

派赴國家：美國聖地牙哥

出國期間：105年6月17日至6月25日

報告日期：105年8月

摘要

US BIO International Convention 是全球最具規模的生技會議與展覽，每年都吸引超過 60 個國家及 15,000 名生技醫藥的產官學研專家共同參與，今年於 6 月 19 至 22 日在加州聖地牙哥登場舉辦。同時我國為發展生醫產業，本次亦併同參加 US BIO 會議期間，赴美邀請國外科技顧問諮詢委員，於 6 月 18 日辦理 preBTC 海外諮議會，就我國發展生醫產業策略提供指導建言。

我國由行政院政務委員吳政忠率領台灣代表團赴美聖地牙哥參加 US BIO International Convention，今年代表團整合產官學研約 130 人，包含科顧組、科技部、衛福部、經濟部、農委會、中央研究院、生醫方案執行中心、竹科管理局等政府部會代表；以及工研院、生技中心、藥技中心、醫藥品查驗中心、國研院、國衛院、農科院、外貿協會等單位機構及台微體、展旺、太景、杏國、永昕、亞果、台灣浩鼎、豬博士等 30 多家生技廠商及媒體機構共同參與。相關行程及大會參與人員資料請見表一。

Pre BTC 會議

此行於 6 月 18 日舉辦台灣生技產業策略諮議委員會-海外委員座談會(pre BTC)，大會由吳政委主持，針對我國發展創新生醫產業策略，由部會代表報告重點議題與執行進度，並與海外 BTC 諮議委員進行策略討論，作為 2017 年 9 月舉辦之行政院生技產業策略諮議委員會(BTC)之議題共識。本次出席諮議委員有楊育民、陳紹深、林秋雄、蘇新森、唐南珊、閻雲、孔繁建、顧曼芹。本次會議有三大議題：(1)友善生技投資環境、接軌國際市場 (2)強化轉譯醫學、完善產業聚落(3)發展精準醫學，促進健康福祉產業。其中衛福部負責的議題三，分別就發展精準醫學：1)發展癌症精準醫學之創新服務產業策略及目標 2)再生醫學及細胞治療面臨法規規範及加速臨床試驗的需求，有關之措施具體規劃 3)推動特色醫療機構進駐生醫園區之具體措施 4)防疫新南向：建構疫情區域聯合防制網絡；以及促進健康福祉產業：1)如何建構國產國用的環境體系，建立智慧健康生活圈 2)有關健康服務產業的產業化措施之具體規劃等面向進行策略報告。相關簡報資料詳如附錄。

Pre BTC 會中諮議委員建議我國發展精準醫療相關之法規環境應參酌美國經驗，如 LDT (Laboratory Developed Test);CDE 行政法人化應予高度重視；發展細胞治療等創新生醫領域，PI (Principle Investigator) Initiated 的臨床試驗案應有機制；對於美國國會最新通過的 21st Century Cures Act 以及中國大陸發展醫藥的最新進展應予重視。台灣在鼓勵創新，提供產學界資源上，應有更好地做

法，是提供 availability，以使產業珍惜每一分資源。對於業界外銷出口的 GMP 管制應予考慮鬆綁。

台美生技醫藥產業圓桌會議

代表團於 6 月 20 日舉辦台美生技醫藥產業圓桌會議，美國有 AIT 代表、BIO 協會副執行長 Joseph Damond、美國製藥協會、生物協會及 Merck、MSD、J&J、Eli Lilly、Pfizer、Amgen 等知名大藥廠代表出席。

會中吳政委說明近年台灣在醫藥衛生與建置醫療體系有很大的進步，去年政府將「生醫產業創新推動方案」列為重要政策，規劃台灣成為亞太生技醫藥產業重鎮，包括建構有利的生態環境、人才培育與資源投入、北中南生醫園區廊帶的建設、特色醫療機構進駐生醫園區、產業鏈結國際的策略作為，以及推動創新產業，包括精準醫療、特色醫療與福祉產業。

衛福部何啟功次長亦分別就我國在鼓勵新藥之專利連結制度、創新醫療器材優先審查措施、以及 CDE 行政法人化的進展提出說明。衛福部及 CDE 同仁並就我國在 ICH，尤其是銜接性試驗規範(ICH E5)方面的積極參與情形，進行進一步的解說。

美方代表簡報說明台灣在醫藥法規之國際化努力成果，在亞洲乃至全球區域均屬極為進步且名列前茅的國家，尤其美方對於台灣長年積極參與藥品國際法規協會(ICH)方面的努力，極為稱許。但美方提醒中國大陸目前亦積極參與 ICH，鼓勵跨國藥廠在中國境內執行早期多國多中心的臨床試驗，建議我方應就此一大趨勢對跨國藥廠之影響，及台灣如何尋求利基，進行發展醫藥產業之策略規劃。

US BIO 展覽及研討會

US BIO 展覽於 6 月 20 日揭幕，為期 4 天。我國今年首次以國家隊的形式整合法人可移轉技術能量共同參與，有中研院、工研院、生技中心、藥技中心、國研院、農科院、國衛院等七個單位參與，透過 One-on-One Partnering 平台強化學研單位與國際接軌，以吸引國際生技廠商及創業者。我國共計有 463 場媒合會議，成果相當豐富。

在生技創新的投資上，仍以美國為首，2016 年歐美創新投資達 263 億美金中，美國佔了高達 81%，持續扮演引世界生技創新的火龍頭。

BIO 大會指出 2016 年歐美生技併購案衰退了 17%，但 2016 年歐美生技產業研發投入了 457 億美金，年比成長 12%，這也顯示產業對未來健康持續支持研發的重

要指標。今年生技公司洽談活動比往年都熱絡，產業上下游策略聯盟合作也將成為世界生技發展的重要趨勢。

今年大會同時舉辦近 15 個不同主題分論下約 160 場論壇。包括精準醫療的「腦科學」、「數位醫療」、「全球新興市場商機」、「轉譯醫學」、「腫瘤醫療」個體醫療與診斷」、「孤兒藥開發」、「感染疾病與疫苗」、「現代農業革命」，「次世代新醫療」、「大數據與醫療革命」、「新能源」等。

大會安排有多場次平台討論與演講，尤其在精準醫療的議題上呈現及快速地成長。舉其重要者，美國 NIH 在 21st Century Cures Act 支持下，大力推動精準醫學 (Precision Medicine)，NIH 將以” All of US” 計畫進行百萬人的全基因體研究。美國於 2016 年 12 月國會通過「21 世紀醫療法案」(21st Century Cures Act)，預計投入 48 億美元於包含精準醫療(14 億美元)、癌症登月計畫(Cancer Moonshot，18 億美元)及 FDA 創新法規行動方案(5 億美元)在內的相關領域。國際大廠如 Illumina 亦於會中報告相關技術的進展，未來 NGS (Next Generation Sequence) 的檢測將由現階段的 1000 美元大幅降至 100 美元，其影響普及性不可小覷。另一方面精準醫療檢測結果在醫界的採用性亦為大會討論的重點，相關之保險給付制度及認定方式，現階段在美國仍處於相當不一致的情形，美國國會議員亦於大會中報告將在保險制度方面上努力。美國 FDA 亦發表對於精準醫療與細胞治療相關的法規進展，如 DDT、Biomarker Qualification Program 等，預期將建立創新的法規思維與環境。

此外「全球創新聚落」共有 40 個國家/地區參與簡報，我國由行政院科技會報辦公室副執行秘書丁詩同擔綱台灣簡報主講。他指出，台灣位在東亞樞紐位置，離日本、韓國、上海、香港、新加坡等亞洲的重要國家/城市，皆相距不遠。台灣以高鐵沿線打造的生醫產業廊帶為例，自南港的國家生技研究園區、新竹生醫園區、中部科學園區、南部科學園區，到屏東的農業生技園區，每個園區都有各自聚焦的領域，比如新藥、高階醫材等等。同時 2007 年通過的「生技新藥產業發展條例」，也讓台灣成為美國之後，第二個能讓尚未有營收的公司進入資本市場的國家，藉此讓十分需要研發資金的生技公司增加募資管道。台灣場次的演講在我國出席同仁的熱情協助下，吸引相當多的國際友人出席。

表一 Pre BTC 及 US BIO 行程

起迄日期	時間	行程說明
6/18	10:30-16:00	preBTC 會議 (Hilton San Diego Bayfront Cobalt 500, 5F)
6/18	12:00-16:00 (?)	生技論壇
6/19	9:30-10:30	展館準備開幕

6/19	14:00-15:00	AIT/USTR 會談 大會會場 Room 23 (C)
6/20	7:30-11:00	Biopharma industry roundtable 大會會場 Room 23 (A+B+C) , up level
6/20	11:00-15:00	US BIO forum
6/20	15:00-17:00	台灣館開幕
6/20	18:00-20:30	致謝晚宴 San Diego the New Children's Museum
6/21	09:00-12:00	US BIO forum
6/21	13:45-14:00	Taiwan spot
6/21	17:30-19:00	台美日韓泰交流活動 San Diego Wine and Culinary Center (200 Harbor Dr #120, San Diego, CA 92101)
6/22	09:00-16:30	US BIO Forum
6/23	08:00-11:00	參訪 Illumina (by Taxi)

公司名稱(Company)	參團名單(Name)
行政院科技會報辦公室 (Board of Science & Technology. The Executive Yuan, Republic of China)	1.吳政忠政委 2.丁詩同副執行秘書 3.劉祖惠主任 4 徐雅芬研究員 5.王建朗副研究員 6.林溢泓 7.邱玉婷研究員
科技部 (Ministry of Science and Technology)	蘇芳慶次長
生醫產業創新方案執行中心	林治華 營運長(COO) LIN, CHIH-HWA
科技部生科司 (Department of Life Sciences, Ministry of Science and Technology)	1. 蔡少正 司長 (TSAI,SHAW-JENQ, Director General) 2. 余玟萱 YU,WEN-HSUAN

行政院衛生福利部	1. 何啟功次長 (Chi-Kung Ho, Deputy Minister) 2. 李顯揚研究員 3. 何承穎
衛福部食品藥物管理署 (Food and Drug Administration, Ministry of Health and Welfare)	黃小文 博士 Hsiau-Wen Huang, Ph.D., Senior Researcher
技術處	戴建丞科長
經濟部工業局(Industrial Development Bureau, MOEA)	陳昭蓉副組長(Chao-Jung Chen) 黃元品技正 Yuan-Pin Huang
中研院 (Academia Sinica)	1.廖俊智院長 2.吳漢忠處長 3.陳弘章 智財技轉處智財經理 4.蘇秉堉博士
行政院農委會科技處(Council of Agriculture, Executive Yuan)	1.張致盛處長 2.湯惟真
科技部新竹科學工業園區管理局 (Hsinchu Science Park Bureau)	1. 王永壯 局長 Wayne Wang, Director General 2. 夏慕梅 投資組 副研究員 May Hsia, Research Associate, Investment Division
南部科學工業園區管理局 (Southern Taiwan Science Park Bureau)	不參加
外交部駐洛杉磯台北經濟文化辦事處	1.夏季昌處長
駐洛杉磯台北經濟文化辦事處 The Taipei Economic and Cultural Office (TECO) in San Francisco	林若蘭 駐洛杉磯辦事處副組長 (Wendy Lin, Deputy Director, TECO in Los Angeles)

駐洛杉磯台北經濟文化辦事處科技組 Science and Technology Division, Taipei Economic and Cultural Office in Los Angeles	1. 張組長 Yang Chan Chang, Director 2. 許若儀 秘書 Jo Yi Hsu, Officer
經濟部生技醫藥產業發展推動小組 Biotechnology and Pharmaceutical Industries Promotion Office (BPIPO) Ministry of Economic Affairs (MOEA)	1. 李照斌博士 Chao-Pin Lee Ph.D 主任 Director 2. 林季玫 Chi-Mei Lin 組長 Senior Manager 3. 陳旭麗 Shiu-Li Chen 組長 Senior Manager 4. 林芸帆 Susan Yun Fan Lin 經理 Manager
洛杉磯台貿中心 Taiwan Trade Center, Los Angeles	1. 李惠玲 主任 Hui-ling Lee, Director 2. Daniel Godwin, Manager
外貿協會 (TAITRA)	1. 吳榮隆專案經理 (Eric Wu) 2. 王俞婷專員 (Tina Wang)
醫藥品查驗中心 (Center for Drug Evaluation, Taiwan)	1. 林志六副執行長
財團法人醫藥工業技術發展中心 (Medical and Pharmaceutical Industry Technology and Development Center)	黃千岳處長
財團法人農業科技研究院 Agricultural Technology Research Institute (ATRI)	1. 林俊宏 Chun-Hung Lin 副院長 Vice President 2. 許仁弘 Jen-Hung Hsu 研究員 Researcher 3. 彭子庭 Tzu-Ting Peng 副研究員 Associated Researcher
工業技術研究院生醫與醫材研究所 Biomedical Technology and Device Research Laboratories Industrial Technology Research Institute (ITRI)	1. 林啟萬 Chii-Wann Lin 生醫所所長 Vice President and Director 2. 歐慈惠 Amy Ou 經理 Manager

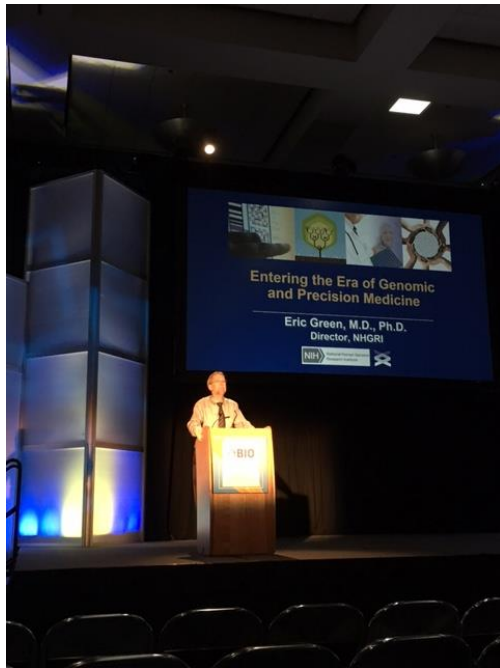
財團法人生物技術開發中心 Development Center for Biotechnology (DCB)	1. 甘良生博士 Lawerance L. Gan, Ph.D. 執行長 President 2. 吳忠勳博士 Chung-Hsun Wu, Ph.D. 副執行長 Vice President 3. 張嘉銘博士 Jia-Ming Chang, Ph.D. 藥物平台所所長 Executive Director of Institute for Drug Platform Technology 4. 孫亦俊 Eric Sun 公共事務組 Public Affairs 5. 王勝鋒 6. 周芳如 7. 陳怡蓁
國研院	1. 陳惠民博士 2. 張漢釗博士
國衛院	1. 葉忠祐主任
亞果生醫股份有限公司 ACRO Biomedical Co., Ltd.	1. 謝達仁 DJ 執行長 CEO 2. 謝明琴 Grace 董事 Director 3. 吳佩純 Patricia 執行長秘書 Secretary to CEO 4. 吳佳郁 Chloe 採購課課長 Procurement Section Supervisor
台康生技股份有限公司 EirGenix, Inc.	1. 劉理成 Lee-Cheng Liu 總經理 President and CEO 2. 張志榮 Chih-Jung Chang 副總 Vice President 3. Thomas Schulze Vice President 4. 高興波 Paul Kao 顧問 Sales consultant 5. 孫惠蒂 Patty Kiang 顧問 Sales consultant 6. 陳胤叡 Yin-Jui Chen 主任 Specialist of Business Development

<p>逸達生物科技股份有限公司 Foresee Pharmaceuticals Co., Ltd.</p>	<ol style="list-style-type: none"> 1. 簡銘達博士 Ben Chien, Ph.D. 創辦人、董事長暨總經理 Founder, Chairman and CEO 2. 周珮芬 Patricia Chou 財務長 CFO 3. Mathieu Boudreau, Ph.D. 業務開發副總經理 VP of Business Development 4. 顏昌芬 Jennifer Yen 營運副總經理 VP of Operations
<p>健永生技股份有限公司 Health Ever Bio-Tech Co., Ltd.</p>	<ol style="list-style-type: none"> 1. 郭富鳳 Fu Feng Kuo 董事長 CEO 2. 何志煌 Chih Huang Ho 事業處總經理 General Manager, Business Development 3. 陳儒廷 Ju-Ting Chen 產業開發專員 Business Development Coordinator 4. 鄭仁芳 Jen-Fang Cheng 臨床試驗專員 Clinical Research Associate
<p>順天醫藥生技(股)有限公司 Lumosa Therapeutics Co., Ltd.</p>	<ol style="list-style-type: none"> 1. 黃文英 Dr. Wendy Huang 總經理 President and CEO 2. 葉聖文 Dr. Mimi Yeh 經理 臨床前研發處 Manager of Preclinical Development 3. 羅小惠 Joanne Lo 經理 事業發展處 Manager of Business Development
<p>金樺生物醫學股份有限公司 TPG Biologics, Inc.</p>	<ol style="list-style-type: none"> 1. 陳佩君 Pei-Jiun Chen 總經理 General Manager
<p>永昕生物醫藥股份有限公司 Mycenax Biotech Inc.</p>	<ol style="list-style-type: none"> 1. 林雲漢 Raven Lin 業務開發處處長 Head of business development 2. 溫國蘭 Karen Wen 總經理 President
<p>台灣浩鼎生技股份有限公司 OBI Pharma, Inc.</p>	<ol style="list-style-type: none"> 1. Kevin Poulos 商務長 Chief Commercial Officer 2. 俞效鋒 Xiaofeng Yu 亞太區資深事業發展處處長 Senior Director of Business Development, Asia Pacific 3. Mitch Che Chief Operation Officer, OBI USA 4. Patricia Ha Associate Director Regulatory Affairs, OBI USA 5. Dee Warren Associate Director of Administration and Human Resources, OBI USA


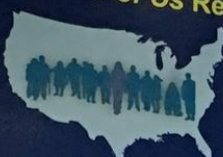
<p>藥華醫藥股份有限公司 PharmaEssentia Corporation</p>	<ol style="list-style-type: none"> 1. 林國鐘 Ko-Chung Lin 執行長 CEO 2. 詹青柳 Ching-Leou Teng 董事長 Chairperson 3. 林俐伶 Lih-Ling Lin 科學長 CSO 4. 李淑芬 Shu-Fen Li 資深處長 Senior Director 5. 高宜君 Jenny Kao 專員 Specialist
<p>豬博士動物科技股份有限公司 Pigmodel Animal Technology Co., Ltd.</p>	<ol style="list-style-type: none"> 1. 王耀宏 Yao-Horng Wang 董事長 President 2. 張乃云 Nai-Yun Chang 助理 Assistant
<p>展旺生命科技股份有限公司 Savior Lifetec Corporation</p>	<ol style="list-style-type: none"> 1. 顧曼芹 M. Sherry Ku 董事長暨執行長 Chairman & CEO 2. 潘世賢 Shih-Hsie Pan 總經理暨技術長 President & CTO 3. 劉佳雯 Amy Liu 經理 Manager 4. 許家豪 Jia-Hau Shiu 高級研究員 Senior Scientist
<p>善笙生物科技股份有限公司 Simpson Biotech Co., Ltd.</p>	<ol style="list-style-type: none"> 1. 許嘉欽 Chia-Chin Sheu 總經理 President 2. 陳長志 Chang-Chih Chen 專案經理 Project Manager 3. 傅則凱 Tse-Kai Fu 研究員 Research Scientist 4. Eric Rentschler 顧問 Consultant
<p>杏國新藥股份有限公司 SynCore Biotechnology Co., Ltd.</p>	<p>班韜 羅廷米 蘇慕寰總經理</p>
<p>太景生物科技股份有限公司 TaiGen Biotechnology Co., Ltd.</p>	<ol style="list-style-type: none"> 1. 邵榮凱博士 Peter W. Tsao, Ph.D. 事業發 展部資深副總經理 Senior Vice President of Business Development ptsao@taigenbiotech.com 2. 蔣佳穎博士 Chiayn Chiang, Ph.D. 體外藥 理副研究員 Associate Investigator, In Vitro Pharmacology cchiang@taigenbiotech.com

<p>台灣微脂體股份有限公司 Taiwan Liposome Company Ltd.</p>	<p>1. 洪基隆 Keelung Hong, Ph.D. 創辦人、董事長暨執行長 Founder, Chairman & CEO 2. 葉志鴻 George Yeh 總經理 President 3. 陳文姬 Wenji Chen, Ph.D. 企業發展處副總經理 Vice President, Corporate Development Division 4. 廖文暉 Wayne Liao, Ph.D. Director, US Operation</p>
<p>臺灣動藥國際股份有限公司 VETCO Pharmaceuticals Inc.</p>	<p>1. 張明義 Ming-Yi Chang 幕僚長 Senior Advisor 2. 鄭雪玲 Suet-Ling Teh 國際發展部經理 International Business Development Manager</p>
<p>台灣研發型生技新藥發展協會(TRPMA)</p>	<p>1. 程馨秘書長 2. 葉映君專案經理</p>
<p>台灣生物產業發展協會 Taiwan Bio Industry Organization</p>	<p>1. 李鍾熙 理事長 (Dr. Johnsee Lee, Chairman) 2. 黃博輝 秘書長 (Apo Huang, Chief-Secretary)</p>
<p>全福生技</p>	<p>張蕾 資深處長(Lilly Zhang, M.S., M.B.A. , Senior Director, R&D)</p>
<p>台灣奈米</p>	
<p>台灣基因</p>	<p>郭東源總經理</p>
<p>景凱生物科技</p>	<p>1. 石英珠 總經理 Ying-Chu Shih 2. 吳森洲博士 Edwin Shen-Chou Wu</p>
<p>基因體先驅生物科技股份有限公司</p>	<p>吳瓊媛執行長</p>
<p>統一國際</p>	<p>邱肇誠 科長</p>
<p>遠見雜誌</p>	<p>林讓均副主編 賴永祥攝影記者</p>

萬國法律事務所	呂紹凡經理
環球生技月刊	林明定社長/總編 蔡立勳記者
基亞生技	1.賴冠郎 副總 K. Conrad Lai 2.王宥人 處長 Lillian Wang 3.陳立威 副處長 Wayne Chen
仁新醫藥股份有限公司	林文堯監察人
聯合生物製藥	湯士毅經理
竟天生技	王藹君 Ae-June Wang 董事長暨總經理 President and CEO



All of Us Research Cohort





- >1 million U.S. volunteers
- Participants to share genomic data, lifestyle information, biological samples – all linked to their electronic health records
- Open, responsible data sharing with strong privacy protections

Three Decades of Genomics

- Human Genome Sequenced for First Time by the Human Genome Project
- Cost of Sequencing a Human Genome Reduced Nearly ~1 Million-Fold
- Many Tens of Thousands of Human Genomes Sequenced
- Profound Advances in Understanding How the Human Genome Functions
- Significant Advances in Unraveling the Genomic Bases of Human Disease
- Vivid Examples of Genomic Medicine in Action Now Emerging


Sequencing a Human Genome

Human Genome Project (1st Sequence)	Today
	
~\$1B	~\$1-2K
~6-8 years	~1-3 days

one

Turning Molecular Data into Clinically Actionable Data

June 2017

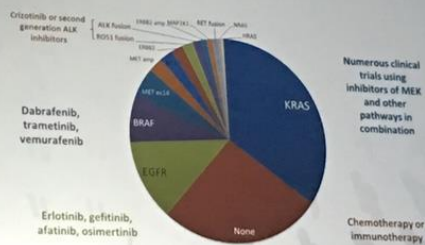


State of Molecular Testing in 2017: What is the Right Test?

2009	2010	2017
<ul style="list-style-type: none"> • FISH • IHC • PCR 		<ul style="list-style-type: none"> • NGS <ul style="list-style-type: none"> • 15 gene • 50 gene • >100 gene • WES • Liquid Biopsy • IHC • Fusion Panel • CNA

When is the right time to test?
Should the physician test for predictive biomarkers for targeted therapy? Immunotherapy? Combination therapies?

Increasing Number of Genes and Drug Options for NSCLC



Numerous clinical trials using inhibitors of MEK and other pathways in combination

Chemotherapy or immunotherapy

Global Resource for Advancing Cancer Education (GRACE)

Requirements for transforming molecular data to clinically actionable data:

- Test results with clearly identified actionable genes to target, and evidence of the patient's specific variants
- Multi-platform, Multi-variant analysis
- Evidence on the most relevant therapies including clinical trials
- Evidence to support decision-making on immunotherapy such as checkpoint inhibitors and others coming down the line.
- Sophisticated matching to clinical trials targeting the patient's disease and biomarkers; Combination therapy protocols

附錄



2017 pre-BTC 議程

開會時間：2017年6月18日(星期日)上午10:30(美國聖地牙哥時間)

開會地點：Hilton San Diego Bayfront, Cobalt 500(5F)

主 持 人：吳政務委員政忠

時間	議題	報告人
壹、報告		
10:30 - 10:40	1.主席致詞	
10:40 - 11:00	2.盤點我國重大生技政策 / 措施及產業發展報告	科技會報辦公室
11:00 - 11:20	3.「生醫產業創新推動方案執行中心」運作報告	執行中心
11:20 - 11:45	綜合討論	
11:45 - 13:30	餐敘	
貳、議題討論		
13:30 - 13:45	1.友善生技投資環境，接軌國際市場	經濟部
13:45 - 14:00	2.強化轉譯醫學，完善產業聚落	科技部
14:00 - 14:15	3.發展精準醫學，促進健康福祉產業	衛生福利部
14:15 - 14:30	Coffee Break	
14:30 - 15:55	綜合討論	
15:55 - 16:00	主席總結	



議題三：發展精準醫學，促進健康福祉產業

衛福部
106年6月18日



議題三：發展精準醫學，促進健康福祉產業

➤發展精準醫學

- 1)發展癌症精準醫學之創新服務產業策略及目標
- 2)再生醫學及細胞治療面臨法規規範及加速臨床試驗的需求，有關之措施具體規劃
- 3)推動特色醫療機構進駐生醫園區之具體措施
- 4)防疫新南向：建構疫情區域聯合防制網絡

促進健康福祉產業

- 1)如何建構國產國用的環境體系，建立智慧健康生活圈
- 2)有關健康服務產業的產業化措施之具體規劃



大綱

- 最近一年執行成效重點說明
- 關鍵議題分析
- 解決問題之新策略與措施
- 討論焦點



議題三：發展精準醫學，促進健康福祉產業

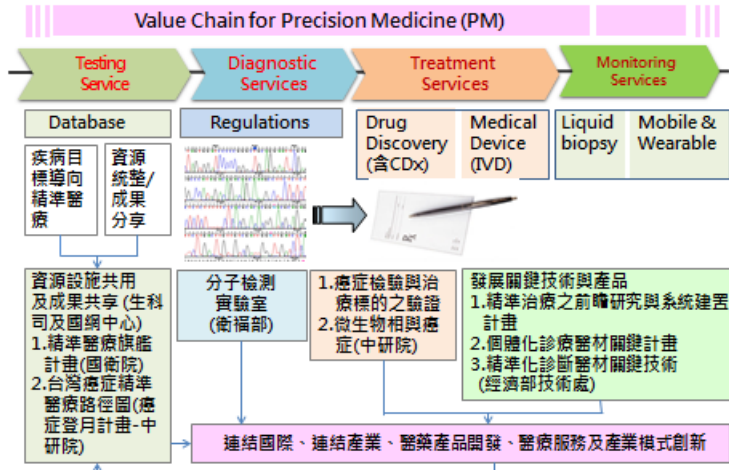
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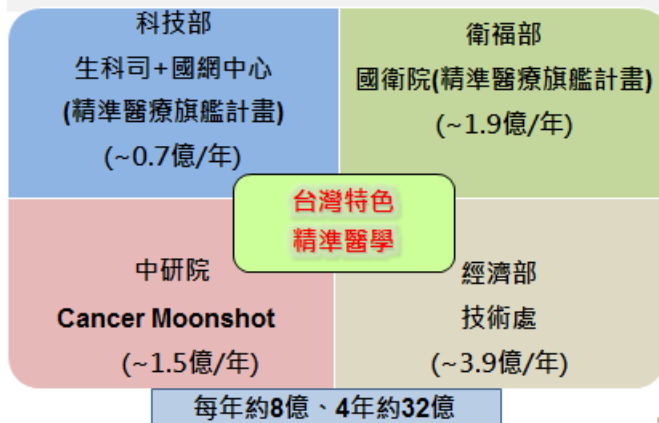
促進健康福祉產業

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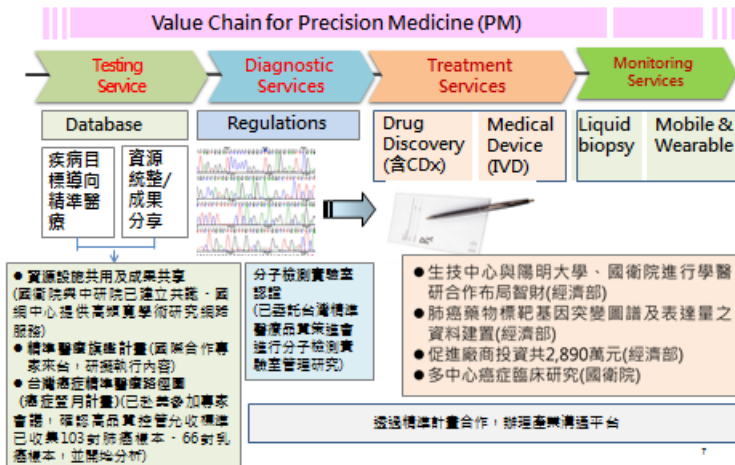
最近一年執行成效重點說明 (1/3)



最近一年執行成效重點說明 (2/3)



最近一年執行成效重點說明 (3/3)



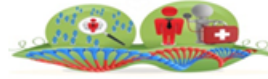
關鍵議題分析

總目標:

統整產學研醫研發量能，完備健康資料運用相關法規，發展利基精準醫學之新興醫療服務模式。

關鍵議題:

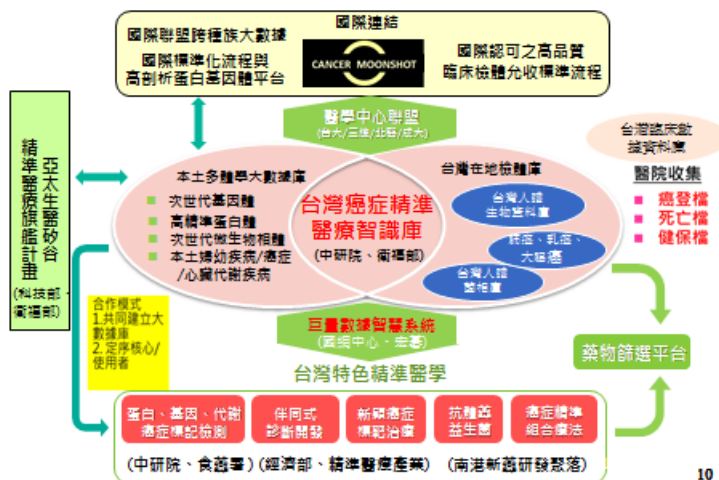
- 疾病目標導向之精準醫療
- 計畫資源共享與資料庫整合倉儲相關系統
- 台灣癌症精準醫療發展路徑圖
- 參考國際趨勢，發展分子檢測實驗室認證



解決問題的新策略與措施(1/4) 疾病目標導向-台灣在地化癌症精準醫療



解決問題的新策略與措施(2/4) 資源共享與資料庫整合倉儲



衛生福利資料庫合理合法的對外提供應用

- 現在產業可與學界研究共同合作
- 依據個人資料保護法第6條第1項第4款:
- 公務機關或學術研究機構基於醫療、衛生或犯罪預防之目的，為統計或學術研究而有必要，且資料經過提供者處理後或經蒐集者依其揭露方式無從識別特定之當事人。



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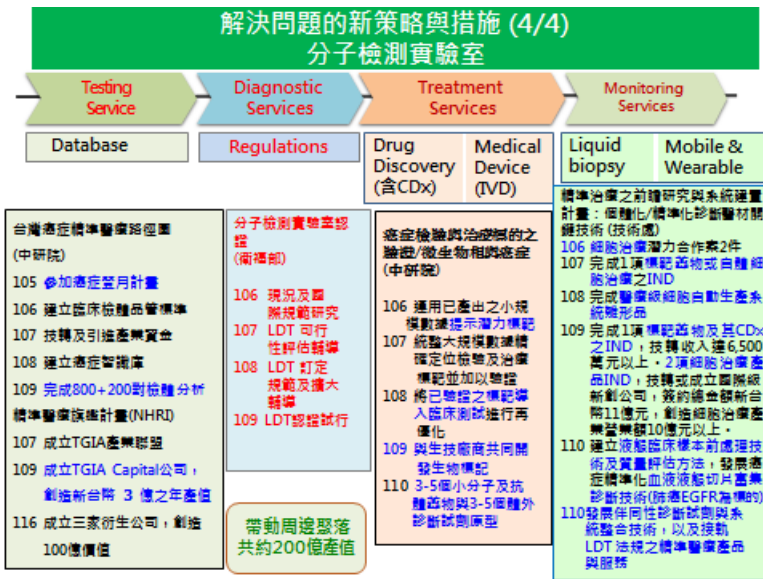
生醫產業應用衛生福利資料法制規劃

工作項目	時程
第一階段 1. 蒐集法務部意見並召開部內會議，彙整意見後提出法制建議雛型。(6月) 2. 進行生醫產業資料應用需求訪談，蒐集需求資料種類、可能的應用方式、運用目的等。(6-8月) 3. 由第1-2點結果修正法制建議雛形，並於國發會「公共政策網路參與平台」蒐集各方意見，訪談相關利益團體(人權團體)意見，藉公開透明作業及程序降低外界疑慮，達成促進個人資料合理利用及支援生醫產業之目的。(8-9月) 4. 提出具體法制建議方案、完成利弊影響分析及規劃立(修)法時程表。(9月)	106年 6-9月
第二階段 1. 完成立(修)法前之過渡期間，辦理生醫產業應用衛生福利資料產學合作先驅試辦計畫，修訂現行申請及審核程序。(10月) 2. 持續與主要團體意見溝通，藉公開透明作業及程序降低外界疑慮。(10-12月) 3. 立(修)法草案提報行政院審議，提出資料管理及應用之配套制度之規劃腹案，以明瞭未來機制運作實況與可能衍生問題。(12月)	106年 10-12月

解決問題的新策略與措施 (3/4) 台灣癌症精準醫療發展路徑圖



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LDT (Laboratory Developed Test)

• US FDA

目前：CLIA分類→ waived、moderate、complexity
 未來：LDT guidance

1. 上市前審查(premarket review)，以確保LDT檢測服務的設計及分析確效、臨床確效符合產品的預期用途。
Class 1, 2, 3
2. 品質系統法規(Quality System Regulation, QSR)，藉由適當的品質管控維持產品設計與製造的穩定性，減少因不良品造成的不良反應事件。
3. 不良反應通報(adverse event reporting)，以利於發現產品功能或品質上的問題。

Current status in Taiwan

	衛環部 食藥署	衛環部 醫事司	TAF 自願性認證 (流程品質)	其他
人類檢體	醫療機構 (臨床醫學實驗室) 如：醫院檢驗部、醫事 檢驗所...	V LDT 檢測服務	ISO 15189	CAP CLIA (強制性)
物理化學、 動植物、 人類檢體	非醫療機構 (測試/校正實驗室) 如：生技公司...	GLP ---非臨床生物製藥 認證 (藥研、生物相關等)	ISO 17025	

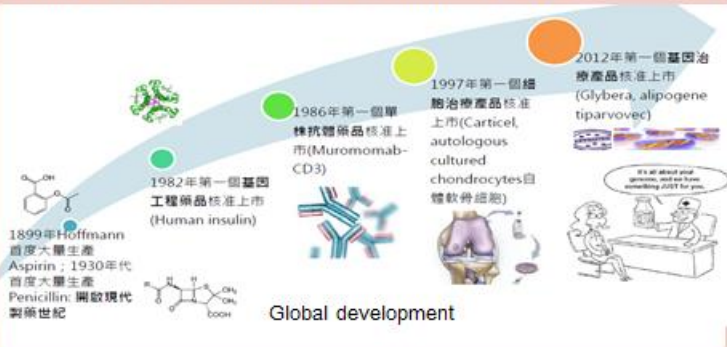
議題三：發展精準醫學，促進健康福祉產業

➤發展精準醫學

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發展再生醫學與細胞治療之具體措施 (1/5)



- 106.01.18 總統令公布修正。修正《生技新藥產業發展條例》，以租稅優惠獎勵新興生物科技企業，提高產業創新動力。
- 106.05.12 行政院指定「新興且具策略性發展方向之生技醫藥項目」，包括：精準醫療、基因治療、細胞治療、依據美國《藥品價格競爭及專利期間回復法》規定主張原廠新藥專利無效或未構成侵權之藥品（簡稱paragraph IV藥品），總計4個項目。

發展再生醫學與細胞治療之具體措施 (2/5)

國內目前細胞治療產品上市管理法規



發展再生醫學與細胞治療之具體措施 (3/5)

人類細胞治療產品臨床試驗申請作業與審查基準

申請作業
審查考量

2014.09.17正式公告

-人類細胞治療產品 (Human cell therapy products) 係指使用取自人類自體 (autologous) 或同種異體 (allogeneic) 的細胞，施用於病人，以達到疾病治療或預防的目的。

調整審查流程

經本署認定同時符合以下四個條件之細胞治療產品，本署得調整審查程序。

- 最小操作 (Minimally manipulated)
- 同源使用 (Homologous use)
- 無合併其他物質 (No combination)
- 無全身性作用 (No systemic effects)



科學 倫理 安全

衛生福利部
食品藥物管理署
FDA Food and Drug Administration

發展再生醫學與細胞治療之具體措施 (4/5)

細胞治療產品GTP查核

- 法規
 - 依據「人類細胞治療產品臨床試驗申請作業及審查基準」及「人類細胞治療產品查驗登記審查基準」。
- 運作機制
 - 人類細胞治療產品於**臨床試驗**及**查驗登記**階段，其製造方法、設施及管制措施，皆應符合「**人體細胞組織優良操作規範 (GTP)**」，後者並應符合「**藥物優良製造準則之西藥藥品優良製造規範 (PIC/S GMP)**」。
- 執行現況
 - 自99年1月1日迄今，共執行**67案GTP訪查**，並以**幹細胞類產品最高(37案)**，**免疫細胞次之(17案)**。

衛生福利部
食品藥物管理署
FDA Food and Drug Administration

發展再生醫學與細胞治療之具體措施 (5/5)

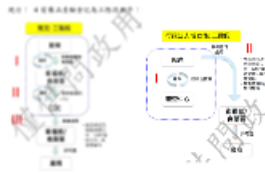
人類細胞治療人體試驗附屬計畫

105年4月14日修正發布「人體試驗管理辦法」第3-1條

- 精神** → 為治療病況已危及生命或嚴重失能，且國內尚無適當醫療方法，亦未能符合我國已核准之人類細胞治療人體試驗參加資格的特定病人，提供參與人類細胞治療人體試驗的機會。
- 參加條件** → 與原人體試驗計畫具有相當適應症，但未能符合原人體試驗受試者資格者。
- 人數限制** → 以不超過原人體試驗計畫受試者人數為限。
- 收費方式** → 和一般人體試驗不同，附屬計畫可向受試者收費的，其收取之費用依據各試驗內容而定。
- 更多資訊** → 相關問答集、審查流程、申請文件檢核表等皆已公告於食藥署官網，並已提供醫院、試驗主持人、各專科醫學會及相關公協(學)會參考。

法規單位之配套措施 - CDE 行政法人化

- 整合審查能量，改善行政效率
- 免除重複審查，且權責相符
- 穩定財源收費，有助徵才留才，聘用足夠審查人力
- 審查人力專注審查，有助提升審查效率與品質
- 建立權責相符的藥物技術審查體系
- 加速藥物研發上市時間，提升產業國際競爭力



- 審查中心依據衛福部與TFDA所定法規審查
- TFDA擁有最後許可證核准駁權力
- 設計並建置完善監督機制，審查中心審查過程中TFDA仍具高度參與決定權



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議題三：發展精準醫學，促進健康福祉產業

➢ 發展精準醫學

- 1) 發展癌症精準醫學之創新服務產業策略及目標
- 2) 再生醫學及細胞治療面臨法規規範及加速臨床試驗的需求，有關之措施具體規劃

3) 推動特色醫療機構進駐生醫園區之具體措施

- 4) 防疫新南向：建構疫情區域聯合防制網絡

➢ 促進健康福祉產業

- 1) 如何建構國產國用的環境體系，建立智慧健康生活圈
- 2) 有關健康服務產業的產業化措施之具體規劃

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推動特色醫療機構進駐生醫園區之具體措施 (1/3)



建立**尖端醫學專業場域**，導引醫療服務與周邊支持性產業共榮發展。以**醫療優勢結合全方位服務模式**，滿足諮詢互動平台、就醫就診、住宿交通、餐飲旅遊等多元化醫療需求，**發揮醫療福祉效益**。

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推動特色醫療機構進駐生醫園區之具體措施 (2/3)



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推動特色醫療機構進駐生醫園區之具體措施 (2/2)



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議題三: 發展精準醫學, 促進健康福祉產業

▶ 發展精準醫學

- 1) 發展癌症精準醫學之創新服務產業策略及目標
- 2) 再生醫學及細胞治療面臨法規規範及加速臨床試驗的需求, 有關之措施具體規劃
- 3) 推動特色醫療機構進駐生醫園區之具體措施
- 4) 防疫新南向: 建構疫情區域聯合防制網絡

▶ 促進健康福祉產業

- 1) 如何建構國產國用的環境體系, 建立智慧健康生活圈
- 2) 有關健康服務產業的產業化措施之具體規劃

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防疫新南向：建構疫情區域聯合防制網絡

防疫成效重點說明

1) 登革熱防治成效

- 105年透過多元化之防治策略，並強化中央與地方溝通協調，同時成立「國家蚊媒傳染病防治研究中心」，以跨領域科學研究支援第一線防治實務，我國本土病例數由104年4萬3,419例減為105年8例。

2) 結核病防治成效

- 自95年推動「結核病十年減半全民動員計畫」，採取多項防治策略，結核病發生率由94年每10萬人口72人減為105年43人；多重抗藥性結核病管理中人數由98年440人減為105年168人，治療成功率高達77%，防治成效獲國際肯定。

關鍵議題分析

東南亞國家登革熱及結核病疫情嚴峻，更多的雙向往來，傳染病跨境傳播風險亦隨之增高

- 1) 登革熱70%病例分布于東南亞國家，以印尼、菲律賓及泰國等疫情最為嚴峻。
- 2) 全球大部份結核病個案分布于東南亞(29%)，結核病高負擔國家包含柬埔寨、中國、印度、印尼、緬甸、菲律賓、泰國及越南。

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防疫新南向：建構疫情區域聯合防制網絡

解決問題之新策略與措施

我國登革熱及結核病防治成功經驗的轉殖，將有助於新南向國家對該二項傳染病之防治，並防範疫情跨境傳播。

1) 成立防疫技術轉殖中心：

- 建立登革熱及結核病防治策略模式
- 舉辦登革熱及結核病防治國際訓練研習營：106年4月25-28日，本署與外交部及AIT合作辦理「登革熱/茲卡/屈公病檢驗診斷國際研習營」，共有18個國家共35名學員參訓，其中包括澳洲、孟加拉、柬埔寨、印度、印尼、馬來西亞、緬甸、紐西蘭、尼泊爾、巴基斯坦、菲律賓、新加坡、斯里蘭卡、泰國及越南等15個新南向國家。
- 建立聯繫網絡平臺，進行技術分享與合作
- 成立防疫深耕隊，實地提供指導與協助，運用檢測、監視、醫療等防疫措施，拓展南向市場。

- 2) 成立新南向人員健康服務中心：以人為中心，提供前往新南向國家之工作人員，出國前、中、後之相關健康服務，降低出國產生之健康危害。未來並將研議雙向服務，擴大南向範圍。

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議題三：發展精準醫學，促進健康福祉產業

發展精準醫學

- 1) 發展癌症精準醫學之創新服務產業策略及目標
- 2) 再生醫學及細胞治療面臨法規規範及加速臨床試驗的需求，有關之措施具體規劃
- 3) 推動特色醫療機構進駐生醫園區之具體措施
- 4) 防疫新南向：建構疫情區域聯合防制網絡

促進健康福祉產業

- 1) 如何建構國產國用的環境體系，建立智慧健康生活圈
- 2) 有關健康服務產業的產業化措施之具體規劃

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關鍵議題分析

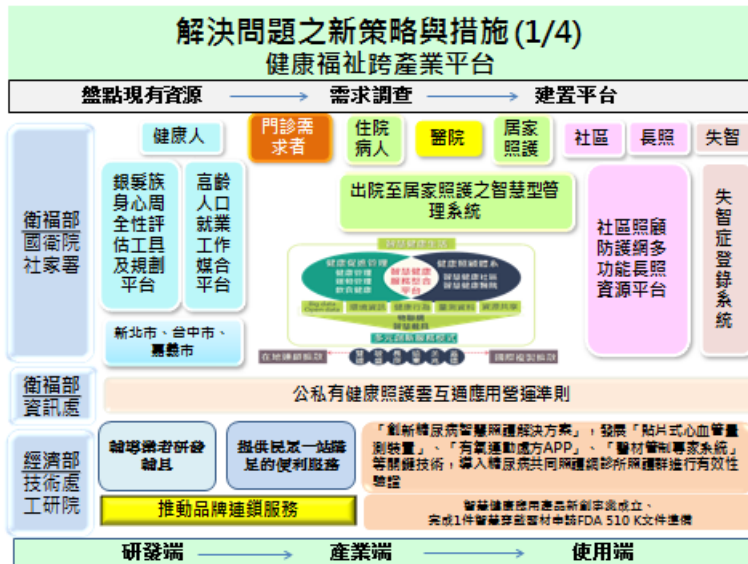
總目標：

藉由調適法規、運用商業服務模式統整醫療體系與運用資通訊技術及異業整合，開發產品與服務，並藉由複製擴散，佈局國內外市場。

關鍵議題：

- 健康福祉跨產業平台
- 建構台灣輔助科技研發示範場域
- 智慧健康服務，運用ICT技術與跨業整合
- 服務產業國際化，行銷全球醫療健康市場

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解決問題之新策略與措施 (2/4)

建構台灣輔助科技研發示範場域

▶ 建構台灣輔助科技研發示範場域，以獲取臨床照護實際需求

▶ 刺激異業跨入，整合異質研發、服務量能

- 提供臺灣輔助科技示範場域：建構國內輔助科技產業場域，進行產品與服務模式的驗證試煉，作為產品開發與精進研究依據。
- 建構輔具跨部會整合單位：將臨床端的輔具中心與學協會、研發端的學校、法人研發單位以及國內廠商進行整合與連結。



資料來源：工研院IEK

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解決問題之新策略與措施 (3/4)

智慧健康城市計畫



解決問題之新策略與措施 (4/4)

行銷全球醫療健康市場

- ▶ 人口老化及慢性病盛行，健康照護支出重心由**疾病治療**朝向**健康促進及預防服務**。
- ▶ 全球健身和保健市場2014年高達**1.49兆美元**。
- ▶ 推動亮點計畫，聚焦強化服務與照護端的照護模式，提供照護者可通用之系統與平台，滿足長照體系需求。期建立完善的照顧示範模式，進而擴散複製，預計可**補足健康福祉產業產的缺口產值達200億元以上**。



討論焦點

1. 台灣發展精準醫療之利基
2. 建構福祉產業之環境

出國報告（出國類別：其他）

參加 2017 年北美生技展
（2017 BIO International
Convention）出國報告

服務機關：衛生福利部

姓名職稱：何啟功 政務次長

何承穎 研發替代役助理研究員

食品藥物管理署 黃小文博士

派赴國家：美國

出國期間：106 年 6 月 18 日至 6 月 25 日

報告日期：106 年 9 月

公務出國報告提要

參加 2017 年北美生技展出國報告

頁數：29 頁 含附件：是 否

出國計畫主辦機關 / 聯絡人 / 電話

衛生福利部科技發展組/李顯揚研究員/02-85907567

出國人員姓名 / 服務機關 / 單位 / 職稱 / 電話

何啟功/衛生福利部/部長室/政務次長/02-85907710

何承穎/衛生福利部 /科技發展組/研發替代役助理研究員/02-85907564

黃小文/衛生福利部食品藥物管理署/生醫產業創新推動方案執行中心

出國類別：1 考察 2 進修 3 研究 4 實習 5 其他

出國地區：美國

報告日期：2017 年 9 月

摘要

BIO International Convention(北美生技展) 本次於 106 年 6 月 19 日 6 月 22 日假美國加州聖地牙哥的 San Diego Convention Center 舉辦，共計來自全世界 55 個國家代表團，16,000 位生技產業人士出席，超過 1,800 家公司參展，近千家公司參與媒合洽談，是全球生技界每年最大的產業活動平台。

本年度「台灣館」展區由財團法人中華民國對外貿易發展協會主辦，並依循過往的模式，由吳政忠政務委員組成台灣代表團參加本次展覽，計有 27 個相關單位參加，代表團共計 139 位成員，並促成了 463 場次的商機會議，大幅提升台灣在生技產業發展的機會。

本部於今年度的參展主題為「台灣卓越臨床中心-優質臨床試驗環境」，經由在這國際舞台推廣台灣優質的臨床試驗環境，以吸引國際廠商至我國進行臨床試驗的機會，藉此強化「提升台灣醫療研究的量能」、「幫助國人優先獲得新藥之機會」及「強化我國在國際新藥發展路程的實力」等優勢。

目次

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<u>貳、過程</u>	36
<u>參、心得及建議</u>	18
<u>肆、附件</u>	20

壹、簡介及目的

美國生技展 (USA BIO) 在美國三大生技產業聚落之一的聖地牙哥盛大舉行。總計來自全世界 55 個國家代表團，超過 1,800 家公司參展，近千家公司參與媒合洽談。今年首次報名參加人數達 6,000 人，較去年成長 37%，估計將有 16,000 位生技產業人士出席，是全球生技界每年最大的產業活動平台，可促進搭起產、官、學界橫向合作的橋梁，故我國多年來皆組團參加這一年一度的盛事。

每年大會的議題、活動事件與論壇發表，往往扮演了國際生技產業各領域發展動向與趨勢的風向球，今年大會在 4 天之內，同時舉辦近 15 個不同主題討論共約 160 場論壇。包括「腦科學」、「數位醫療」、「全球新興市場商機」、「轉譯醫學」、「腫瘤醫療」、「個體醫療與診斷」、「孤兒藥開發」、「感染疾病與疫苗」、「現代農業革命」、「次世代新醫療」、「大數據與醫療革命」、「新能源」等。其中因應近兩年大數據引發醫療變革，以及氣候變遷下農業必須新科技解決等當下國際共同難題，今年特別設立大數據與農業論壇，據大會統計每天吸引約 7,000 人穿梭在各個論壇。

今年參展廠商包括台灣微脂體、太景生技、藥華醫藥、善笙生技、台灣浩鼎、逸達生技、杏國生技、健永生技、順天醫藥生技、永昕生

技、金樺生物醫學、展旺生技、台康生技以及台灣動藥、亞果、豬博士動物科技；政府與法人單位則有本部、中研院、科技部生科司、新竹科學工業園區管理局、南部科學工業園區管理局、農委會、生技中心、工研院生醫所、農業科技研究院、藥技中心、國家衛生研究院、國家實驗研究院、外貿協會、台灣生物產業發展協會、台灣研發型生技新藥發展協會等。每個研究單位及廠商皆努力爭取與國際廠商技轉或合作開發的機會，本部及其他政府單位亦積極招募有興趣來台投資的國家或機構及推廣台灣極佳的研究環境，以提升台灣在生技產業發展的軟、硬實力為共同目標。

貳、過程

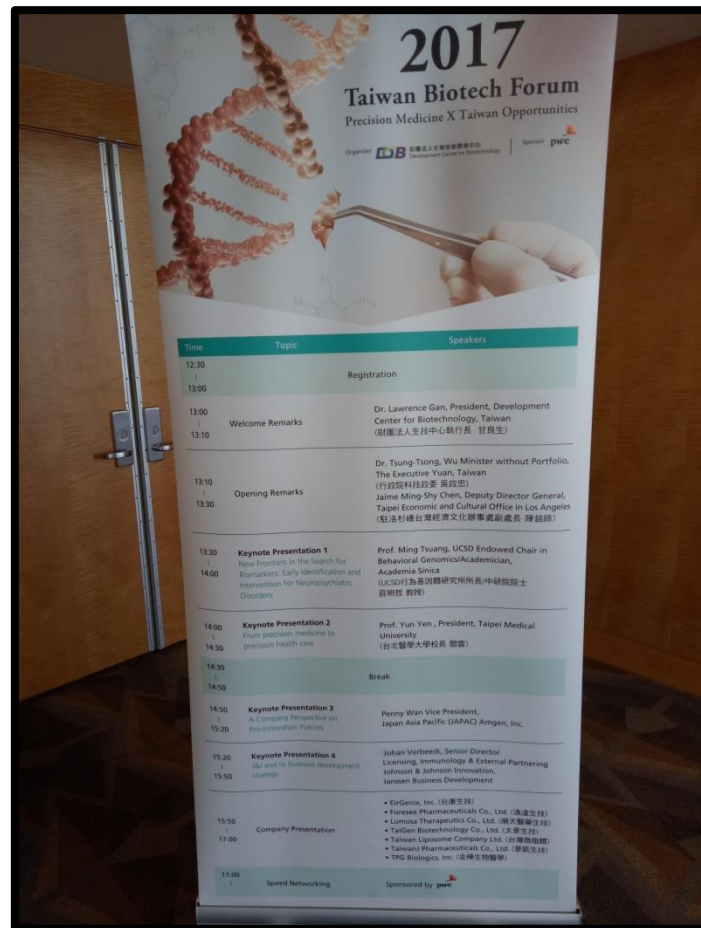
一、行程表

6/17(週六)	(出發至美國 聖地牙哥)
於同日晚間抵達洛杉磯國際機場，並搭乘主辦單位安排之接駁車至聖地牙哥之下榻飯店。	
6/18(週日)	(上午-會場佈置；下午-參加臺灣生技商機論壇)
<ol style="list-style-type: none">1. 上午 9:00 至 San Diego Convention Center 報到並索取參展吊牌及相關文件，再至台灣館確認會場佈置情形。2. 下午 1 點整至 5 點 30 分至 Bayfront 飯店參加臺灣生技商機論壇 (Taiwan Biotech Forum)。	
6/19(週一)	(會場佈置及攤位諮詢服務；下午-與美國貿易代表署代表晤談)
<ol style="list-style-type: none">1. 上午至下午進行攤位諮詢服務。2. 下午 2 點於 San Diego Convention Center Room 23C 與美國貿易代表署代表會面晤談。	
6/20(週二)	(上下午-會場攤位諮詢服務；晚上-台灣團長致謝晚宴)
<ol style="list-style-type: none">1. 上午至下午進行攤位諮詢服務。2. 下午 4 點於台灣館參加開幕儀式。	

<p>3. 晚上 6 點至 San Diego the New Children's Museum 參加台灣團團長致謝晚宴。</p>	
<p>6/21(週三)</p>	<p>(上下午-會場攤位諮詢服務；晚上-台美日韓泰交流晚會)</p>
<p>1. 上午至下午進行攤位諮詢服務。</p> <p>2. 晚上 5 點半於 San Diego Wine and Culinary Center 參加台美日韓泰交流晚會。</p>	
<p>6/22(週四)</p>	<p>(上下午-會場攤位諮詢服務；晚上-撤展)</p>
<p>1. 上午至下午進行攤位諮詢服務。</p> <p>2. 下午 5 點半撤展。</p>	
<p>6/23(週五)</p>	<p>(上午-Illumina 參觀；中午-由)聖地牙哥坐車至洛杉磯，再由洛杉磯搭機返臺。</p>
<p>1. 8 點半集合前往 Illumina 進行參訪。</p> <p>2. 自聖地牙哥啟程，經洛杉磯返臺，於 6/25 清晨抵臺。</p>	

二、 內容

(一) 2017 臺灣生技論壇



Time	Topic	Speakers
12:30 13:00	Registration	
13:00 13:10	Welcome Remarks	Dr. Lawrence Gan, President, Development Center for Biotechnology, Taiwan (財團法人生技中心執行長 莊俊生)
13:10 13:30	Opening Remarks	Dr. Tsung Tsong, Wu Minister without Portfolio, The Executive Yuan, Taiwan (行政院科技政委 吳政忠) Jaime Ming Shy Chen, Deputy Director General, Taipei Economic and Cultural Office in Los Angeles (駐洛杉磯台灣經濟文化辦事處副處長 陳鈺麟)
13:30 14:00	Keynote Presentation 1 New Frontiers in the Search for Biomarkers: Early Identification and Intervention for Neuropsychiatric Disorders	Prof. Ming Tsuang, UCSD Endowed Chair in Behavioral Genomics/Academician, Academia Sinica (UCSD行為基因體研究所所長, 中研院院士 莊明哲 教授)
14:00 14:30	Keynote Presentation 2 From precision medicine to precision health care	Prof. Yun Yen, President, Taipei Medical University (台北醫學院校長 嚴震)
14:30 14:50	Break	
14:50 15:20	Keynote Presentation 3 A Company Requirement on Pharmaceutical Policies	Penny Wan Vice President, Japan Asia Pacific (JAPAC) Amgen, Inc.
15:20 15:50	Keynote Presentation 4 Keynote in Biotech Development outside	Johann Verbeek, Senior Director Licensing, Immunology & External Partnering Johnson & Johnson Innovation, Janssen Business Development • Eisai, Inc. (藥生技) • Kinase Pharmaceuticals Co., Ltd. (藥生技) • Lumosa Therapeutics Co., Ltd. (藥生技) • Taiwan Biotechnology Co., Ltd. (藥生技) • Taiwan Liposome Company Ltd. (藥生技) • Taiwan Pharmaceuticals Co., Ltd. (藥生技) • TPG Biologicals, Inc. (藥生技)
15:50 17:00	Company Presentation	
17:00	Speed Networking	Sponsored by pwc

本次會議於6月18日假聖地牙哥 Bayfront 飯店舉辦，為北美生技展開展的前一天，會上邀請吳政忠政務委員為大會開場致詞，讓代表團成員先初步了解國內外發展的現況，藉此確立本次台灣代表團出訪的目標。論壇中來自世界各地的重量級專家學者，與150位以上的生技專業人才，共同探討多項當紅主題包括精準醫療、生技醫藥發展、台灣生技創新和藥物的發展機會、全球夥伴和合作策略。更邀請聖地牙哥加大 (UCSD) 行為基因體研究所所長、中央研究院院士莊明哲

教授，由基因體定序的觀點來談精神分裂症的研究，以及試圖找出關鍵生物指標的重要性。

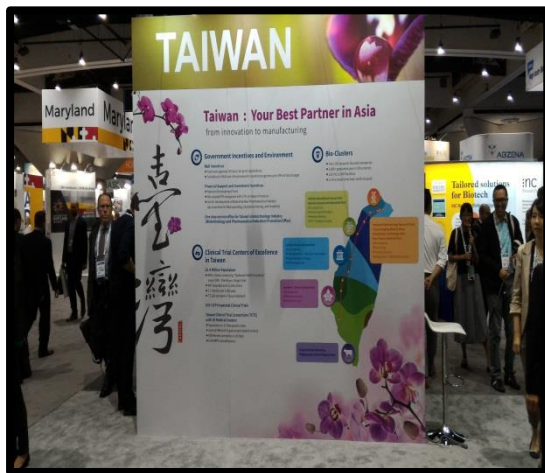


另，台北醫學大學閻雲校長亦受邀擔任本次論壇之演講貴賓，從學研角度探討台灣精準醫療現況，從前端精準預防、精準治療到後端精準醫療照護，配合大數據，未來將可從行為模式、飲食習慣預測疾

病的發生，訂定個人基因序列表，以有效協助醫師能更精準診斷病因。

(二) 攤位展示



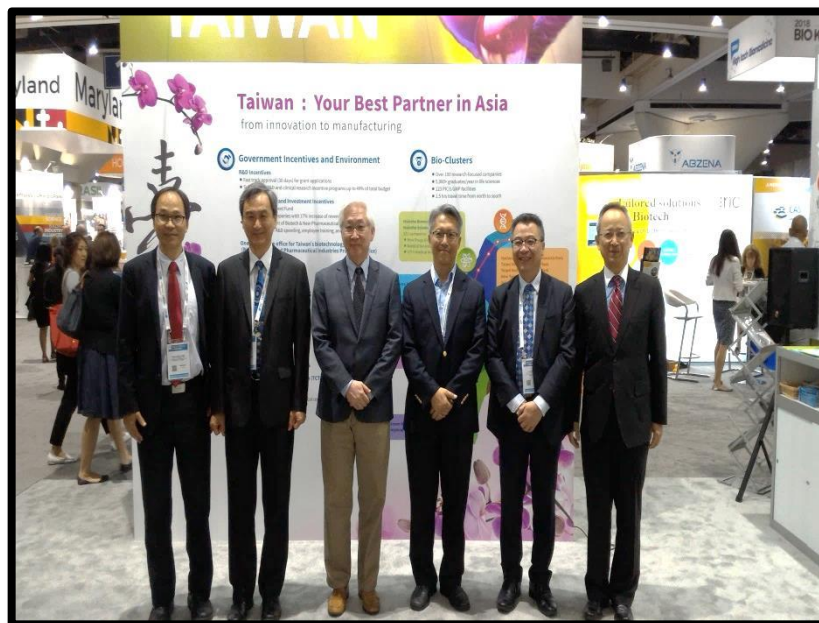


我國攤位本次以綠色系及蘭花圖騰為主，政府及法人單位各以一面獨立之背板做展示牆，形成開放式設計攤位；法人單位之展示牆另有裝設 iPad 及電視，以循環撥放各單位之簡介及研發亮點，政府及法人單位共計有 11 家。參展廠商並以三角形背板隔出展示空間，計有 15 個廠商攤位展出，每 2 個攤位配有 1 個供洽商使用的會議室，雖受限場地大小而略顯擁擠，但整體設計空間運用得宜且溫馨舒適。

而亞洲地區列舉日本、香港及韓國三星攤位亦可作為我未來參展之參考，日本館採較為嚴謹方正之風格，使用大片外牆包覆內部洽談區，有利於展示眾多成果但偏於封閉。香港館將展示看板自攤位中心以放射狀排列，方便觀展人員進出，並於展示海報前設置接待座位就近討論相關事宜。韓國三星館以藍與白代表色設計展館，於該展館設有服務台，以燈箱及電視展示研發成果，不僅給人簡約明亮的視覺概念，更透過觸控式螢幕進行細部介紹及互動，有利提升商機媒合。未來我國參展可因應不同需求及性質，調整攤位之設計及功能，以期能提升我國生醫產業於國際之行銷及推廣，帶動國內相關產業發展。

另，本部推廣「台灣卓越臨床中心-優質臨床試驗環境」為展覽主題，成功吸引各方人士在雙方攤位前駐足，並由本部帶領諮詢者了解我國優質的臨床試驗及生技研究環境，以增加各界藥廠至我國進行臨床試驗的機會。

(三) 台灣館開幕會





台灣代表團由吳政忠政務委員進行台灣館開場致詞，本部何啟功次長、科技部蘇芳慶次長、中研院廖俊智院長、農委會、經濟部工業局及技術處、竹科管理局等部會官員，及生技醫藥相關法人、協會及參展廠商陪同下，共同揭開以國家形象呈現的台灣生技展館。今年開幕活動特別提供準備台灣金車噶瑪蘭威士忌做為台灣特色禮品，並舉辦現場抽獎，此開幕活動吸引廣大人潮，走道擠滿駐足來賓，據統計為近年來台灣生技館來賓最多的一次。吳政忠政委致詞時亦表示，從

研發環境面，台灣在臨床醫學與華人特有疾病研究具有國際優勢，並且建置了屬於台灣的人體生物資料庫(Taiwan Biobank)，加上臺灣醫療技術與環境已享譽國際，台灣擁有充分條件可以成為亞太生技醫藥產業的先期市場和試驗基地。此外，台灣中研院與台大、長庚等機構已參與美國癌症登月計畫(Cancer Moonshot) 初期階段，進入國際醫藥研發價值鏈，因此台灣具有極佳優勢條件成為各國發展生技醫藥的亞洲首選夥伴。此開幕活動成功凸顯出我國具有深厚的研發量能、卓越的生技人才及優良的生技環境，以吸引國際廠商來台投資及合作的機會。

(四) 台灣團長致謝晚宴





台灣致謝晚宴設於 San Diego the New Children's Museum 舉辦，
並由團長吳政忠政委率領我國所有參展人員共同與會，除感謝我國參
展人員對此次展覽之用心規劃與執行，並藉此活動聚本次出訪生技團
的成員的向心力，也期望能進一步交織出產、官、學合作的無限可能。

參、心得及建議

- 一、經由參加北美生技展的機會除可提升同仁的國際觀，進一步了解國際間在生技產業的作為及脈動，亦可使同仁認識其他生技參訪團的成員，有助於未來在生技發展規劃中增加跨部會/單位的整合機會，並可藉由傳達本部的宗旨及任務，加強各國政府單位對我國的信任及認識。
- 二、我國相較其他國家在生技產業發展上深具潛力，另因國土狹小反而具產業高度整合性之機會，然而政府單位在此其中更扮演極重要的角色，而「生技醫藥產業」亦為政府重要發展策略，若經由參考他國的作為再結合我國的優勢，必定能進一步提升我國生技產業的發展環境。
- 三、本次展覽中，本部以推廣「台灣卓越臨床中心-優質臨床試驗環境」為展覽主題，吸引許多參觀人員的詢問及討論，惟可惜礙於攤位空間有限，展出資訊亦受限制。日後若能爭取更大的展示空間，應整合本部補助多年之傑出研究計畫與「財團法人國家衛生研究院」、「食品藥物管理署」、「疾病管制署」、「國民健康署」及「衛生福利部國家中醫藥研究所」等單位，由本部科技發展組代替未能參展之單位展出其豐碩的研究成果，藉以展現我國傑出的

研究量能及友善的研究環境。

四、因應國際資訊技術之進步，我國於本次參觀展會時，以掃描會員證上QR code之方式以收集參訪人員資料，可藉其收集資訊並建立相關資料庫，亦便於後續以mail發送相關訊息等，極具便利性且富科技元素。另，各國參展單位之宣導品亦各有其巧思，其中以VR眼鏡搭配手機下載宣導影片之方式，最為吸引參訪目光。我國未來於參展時，亦可考量各式新興或符合我國特色之宣傳品，或於相關宣傳品或宣導單張上印製諮詢網址及專線電話，以及製作展會諮詢專屬名片，讓所有有興趣之參觀者即使未能在現場充份了解，亦能找到諮詢的窗口以及所需資訊。

五、本次台灣團代表成員皆委託同一旅行社代為預訂飯店，故多數成員（尤其是部會代表）均能在早餐時溝通交流各部會及相關單位對藥物臨床試驗及法規管理的經驗。此一安排有助於在會場時互相幫忙，在與國外相關領域的人士交流時，能更有效率的將對我們有興趣的廠商與業務單位進行媒合。彰顯政府對生技產業的完善分工與規劃，並有效提升我國生技產業之能見度與國際觀。

肆、附件

Bio-Clusters

- Over 100 research-focused companies
- 5,000+ graduates/year in life sciences
- 132 PIC/s GMP facilities
- 1.5 hrs travel time from north to south

2017 BIO International Convention, Jun 19-22, 2017
Taiwan Pavilion - Booth: 1437, 1537

Taiwan

Program

Taiwan Biotech Forum
Precision Medicine X Taiwan Opportunities
Time & Date: 12:30-18:00, June 18th (Sunday) 2017
Venue: C. Hilton Bayfront San Diego

Taiwan Pavilion Opening Ceremony
Join us for award winning whiskey and signature food of Taiwan
Time & Date: 16:00-17:00, June 20th (Tuesday) 2017
Venue: Taiwan Pavilion (Booth no. 1437 & 1537)

Bio Global Innovation Hub - Taiwan
Time & Date: 13:45-14:00, June 21st (Wednesday) 2017
Venue: Spotlight Theatre, Salls Pavilion

121 companies

- ✓ New Drugs & Biologics
- ✓ Medical Devices
- ✓ ICT + Medical Imaging

295 companies

- ✓ Rehabilitation + Precision Instruments
- ✓ Applied Biotechnology
- ✓ Pharmaceuticals

468 companies

- ✓ New Drugs
- ✓ Medical Devices
- ✓ Diagnostics + Medical Electronics

205 companies

- ✓ Pharmaceuticals
- ✓ Medical Devices

Map of Taiwan: Keelung, Taipei, Hsinchu, Taoyuan, Miaoli, Taichung, Nantou, Hualien, Yilan, Keelung, Pingtung, Tainan, Chiayi, Taitung, Pingtung, Kaohsiung.

Key Locations:

- Hsinchu Biomedical Science Park
- Hsinchu Science and Industrial Park
- National Biotechnology Research Park
- Taipei Nangang Biotech Plaza
- Taipei Neihu Technology Park
- New Taipei Industrial Park
- Central Taiwan Science Park
- Southern Taiwan Science Park
- Taiwan Orchid Plantation
- Pingtung Agricultural Biotech Park

Taiwan: Your Best Partner in Asia
from innovation to manufacturing

Taiwan Exhibitors Information
One stop service office
Biotechnology and Pharmaceutical Industries Promotion Office (BPIPO)

R&D Subsidies

- Fast track approval (30 days) for grant applications
- Subsidies for R&D and clinical research incentive programs up to 49% of total budget

Tax Benefits

- Act for Development of Biotech and New Pharmaceutical Industry
 - Tax Reduction for R&D (up to 35% of R&D spending)
 - Tax Reduction for Personnel Training (up to 35% of personnel training spending)
 - Tax Credit for Shareholder's Investment (up to 30% of original cost of shares)
 - Statute for Industrial Innovation
- Tax Deferral for Technology Shares
- Tax Deferral for Stock Options

IP Protection

- Intellectual Property Office set up since 1999 (patent, trademark, copyright, IC layout, and trade secret)

Fund

- National Development Fund

IPO Recommendation

- Bio-related IPO companies with 17% increase of revenue

Incentives

New Drug / Product Development **Preclinical Study** **Clinical Study** **Production and Marketing**

Infrastructures & Resources

Academic and Research Institutes

- Leads
- Drug Screening
- Platform

5,000+ graduates/year

99% citizens covered by "National Health Insurance" since 1995

77,200 samples in Taiwan Biobank

Research Institutes

- Lead Optimization
- Pharmacology
- Toxicology
- Preclinical Service Platform

Taiwan FDA (set up since 2010)

Clinical Trial Centers of Excellence

- Taiwan Clinical Trial Consortium (TCTC) specializes in 13 therapeutic areas
- Central-IRB with 9 authorized medical centers
- IRB Review completes in 20 days
- 6 AAHRPP

Clinical Trial CRO
BA/BE
Biologics CMO

100+ research-focused companies

Facility	cGMP	PIC/s GMP
Pilot Plant	8	10
API	21	22
Chinese Medicine	97 (IGMP)	96 (IGMP) (Apr/13/2016)
Finished Product	140	132 (May/2017)

台灣館文宣資料—本屆台灣形象館以「台灣生技創新加值夥伴」及「共創生技醫藥大未來」做為展出主題。

Taiwan Food and Drug Administration
Ministry of Health and Welfare

Service
Profession
Innovation
Quality

To ensure the
QUALITY
and
SAFETY of food and
medical products.

To safeguard national health and lead the nation into
a new era of food and drug management.

Food and Drug Administration, Ministry of Health
and Welfare
TEL: +886-2-2787-8000
ADD: No.161-2, Kunyang St, Nangang District,
Taipei City 115-61, Taiwan (R.O.C)
Website: <http://www.fda.gov.tw/EN/Index.aspx>

食藥署文宣資料—簡介有關藥品、醫材、食品、化粧品之管理。



The Ministry of Health and Welfare of the Republic of China

www.mohw.gov.tw/EN/Ministry/Index.aspx

Company Description

The Ministry of Health and Welfare of the Republic of China (MOHW) is the ministry of the Republic of China and the highest authority responsible for the administration of the public health system, social welfare, affordable and universal health care, health policy-making, hospitals, pharmaceutical, immunization programs, disease prevention, supervision and coordination of local health agencies in Taiwan.

The Ministry of Health and Welfare's responsibilities include health planning and promotion, prevention and control of disease, food safety, drug management, social insurance, and welfare, relief and protective services. MOHW's mandate also includes biotechnology R&D, international health cooperation, and diverse other areas affecting public health and well-being far beyond Taiwan.

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Sectors Promoting the Health and Well-Being of All Citizens in Taiwan.

2



Council of Agriculture Executive Yuan

www.coa.gov.tw/show_index.php

Company Description

Agriculture enhanced and contributed development of Taiwan. The Council of Agriculture (COA), Executive Yuan is the competent authority on the agricultural, forestry, fishery, animal husbandry and food affairs in Taiwan. The Council is committed to promoting the diversified value of agriculture, ensuring food security, preserving agro-ecological environment and cultural landscape, and creating a competitive LOHAS agriculture. The COA is leading the policies toward expediting agricultural structure adjustment, promoting agro-business management, boosting agricultural industry internationalization, activating agricultural resources, in order to ensure the sustainable development of agriculture in Taiwan.

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Sectors Promoting Sustainable Agriculture in Taiwan.

3



Hsinchu Biomedical Science Park

www.sipa.gov.tw/english/index.jsp

Company Description

Hsinchu Biomedical Science Park supports the development of new drugs R&D for diseases that are common in Asia, and of high-end medical devices. It integrates the nearby Hsinchu Science Park's ICT value chain with open lab and core facilities served by the National Laboratory to provide services fulfilling all possible demands of innovation entrepreneurs. The hospital under construction is expected to provide over 728 beds for medical treatments and clinical trials when it is completed. In addition, the Park will also develop featured clinics and medical services.

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Sectors New Drugs, High-end Medical Devices, Featured Clinics

4



Southern Taiwan Science Park Bureau, Ministry of Science and Technology

www.stsp.gov.tw

Company Description

The biotechnology industry at the Southern Taiwan Science Park (STSP) has been actively developing the visionary biomedical devices, has become one of Taiwan's most important development and manufacturing areas of the medical device industry.

The STSP has taken a proactive role in facilitating the development of medical device industry by integrating medical, industrial, academic, and research resources and providing resident businesses with a holistic service platform.

By demonstrating that high technology industry clusters can also be an environmentally-friendly and high-quality living environment, the STSP has now developed into a bastion of high-tech industry and talented people.

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Sectors One-stop Service, Research Ecosystem, Innovative Consultation Platform for Industrial Development, Platform to Boost Clinic Reliability, International Marketing Services Platform

5



Academia Sinica

www.sinica.edu.tw/en

Company Description

Since its inception in 1928 in China and then in Taiwan after 1949, Academia Sinica has been at the forefront of advanced research activities and has established outstanding track records in the domains of physical sciences, life sciences, and social sciences and the humanities. In recent decades, the excellence of Academia Sinica has been widely recognized through the success of many international research projects and memberships within the world's most prestigious academic organizations.

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Sectors Academia/Research Institution, Tech Transfer

6



Agricultural Technology Research Institute

www.atri.org.tw

Company Description

Agricultural Technology Research Institute (ATRI) was established on January 1, 2014 supported by Council of Agriculture (COA) with the mission of turning agricultural techno-innovation into techno-entrepreneurship through technology business incubation.

The ATRI possesses diverse agricultural technologies and professional experts, and will combine creative thinking and technical advantages with the R&D energy of the up and middle stream of domestic agricultural research institution(s), to add value to the applications of Taiwan's agricultural technology R&D results, promote industry integration, and with the objectives of enhancing international competitiveness of agricultural products and accelerate Taiwan's agricultural transformation.

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Sectors Agriculture

7



Development Center for Biotechnology

www.dcb.org.tw

Company Description

The Development Center for Biotechnology (DCB) of Taiwan is a not-for-profit organization founded in 1984, based on government grants and private donations. DCB's mission is to accelerate the development of Taiwan's biotech industry, by way of building infrastructures, developing key technologies, promoting cooperation and industrialization, and training talented workforces, in coordination with governmental, industrial, and academic institutions.

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Sectors Non-Profit > Research Institution
Primary Technologies > Drug Development
Primary Technologies > Plant-made Pharmaceuticals

8



Industrial Technology Research Institute

www.itri.org.tw

Company Description

Industrial Technology Research Institute (ITRI) is the leading non-profit R&D organization engaging in applied research and technical services, aiming to innovate a better future. ITRI's Biomedical Technology and Device Research Laboratories (BDL) works to bring about a future of health and happiness. At ITRI BDL, we focus on five core areas of research including **botanical drugs, targeted drug and delivery technology, regeneration medicine, Bio-IT and diagnostics and precision medicine**. We have access to cutting-edge technologies, and provide technology transfer, licensing and other industry services. We would like to extend a hearty welcome to domestic and overseas businesses to file their applications for technology transfer or licensing, prototyping, or other industry services. ISO 13485, GMP, EU/FDA certified.

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Sectors Bio-materials and cell therapy; New drugs; Botanical drugs; Drug delivery systems; Cosmetic product R&D; Medical devices for minimally invasive surgery, diagnostics, and imaging; Biomarkers; Services in regulatory, IP, clinical trials

9

NAR Labs National Applied Research Laboratories/
National Nano Device Laboratories

www.narlabs.org.tw

Company Description

National Nano Device Laboratories (NDL), founded in 1988, has two branches in Hsinchu Science Park and Southern Taiwan Science Park. NDL has been recognized internationally for the achievement of research and development (R&D) and provided service platforms for the R&D of semiconductor manufacturing and chip-based biomedical technologies. It also supports academia and industries on the R&D of nano-device technologies that involve new materials, structures, and applications, mostly in Taiwan. In addition, NDL has developed a cross-disciplinary research platform for numerous novel research topics of microelectronics, physics, chemistry, optoelectronics, micro-electromechanical systems, mechanical engineering, bio-medical devices and chip-based new drug screening and development.

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Sectors Non-profit Research Institute (Technology Development and Service)

10



National Health Research Institutes (NHRI)

english.nhri.org.tw/NHRI_WEB/nhriw001Action.do

Company Description

The National Health Research Institutes (NHRI) was formally established in 1996 in Taiwan as a government-supported non-profit research organization with the purpose to promote and develop medical and health-related research in order to enhance social welfare for the people. As the only public research institute to focus entirely on human health and a think tank for the Ministry of Health and Welfare in Taiwan, the NHRI's mission is to (a) advance biomedical sciences, (b) promote population and individual health, (c) forge biotechnology and pharmaceutical development, and (d) train and cultivate biomedical researchers. Since December 2004, the NHRI has relocated to its state-of-the-art main campus at Zhunan, which is close to the High-Tech cluster near Hsinchu Area, Taiwan. Currently, the NHRI, as a whole, comprises a community of more than 1,500 employees, including 130+ Principal Investigators, 170+ post-doctoral fellows, 750+ research assistants and 350+ supporting staff.

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11



Taiwan Bio Industry Organization
(BioTaiwan 2017)

www.taiwanbio.org.tw, www.bio-taiwan.com

Company Description

Taiwan Bio Industry Organization (TBIO) is the largest and the most influential biotechnology organization in Taiwan. TBIO represents over 300 members ranging from private companies and academic institutes to government bodies involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology. We are a strong arm to foster the development of biotechnology in Taiwan. Our mission is to provide advocacy, business development, international partnership, training and communication service for our members. TBIO organizes the annual BioTaiwan conferences and exhibition, the largest gathering of biotechnology industry in Taiwan.

BioTaiwan 2017, its 15th annual event will be held June 28 - July 2 in Taipei, Taiwan. website: <http://www.bio-taiwan.com>

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Address 7F-1, No. 3-2, Yuan-Qu St., Nangang Dist., Taipei City 115, Taiwan (R.O.C.)
Sectors BioTaiwan 2017 (6/28-7/2): opportunities await in Asia's most under-explored biotech location! www.bio-taiwan.com

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Taiwan Research-based Biopharmaceutical
Manufacturers Association (TRPMA)

www.trpma.org.tw

Company Description

Taiwan Research-based Biopharmaceutical Manufacturers Association (TRPMA), composed of 30 Taiwanese innovative biopharmaceutical companies, plays a pivotal role in coordinating the resources, strengthening the alliances among the industry, the academic and the government in Taiwan. Our ambition is to create a competitive value chain of biopharmaceutical industry to boost nation's economy and promote the Asian along with global cooperation in biopharmaceutical innovation.

TRPMA Mission:

1. Motivate Open Innovation
2. Establish Academia-Industry-Government Platform
3. Promote International Collaboration
4. Build Business Partnership

Contact Information

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Sectors Biopharma

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Company Description

ACRO Biomedical is in the leading position of the field of collagen derived medical devices that expertizes in tissue engineering and regenerative medicine of human tissues and organs. The high end medical devices were process by using supercritical carbon dioxide extraction technology to remove lipids, cells, and non-collagenous proteins from tissues and organs to create natural collagen scaffolds suitable as xenograft biomaterials for tissue engineering and regenerative medicine applications. The products can be applied to various fields including Wound Care, Dentistry, Orthopedic, Ophthalmology, Aesthetic Microsurgery, Cardiology, and Neurosurgery.

Contact Information

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Address 3rd Fl., No. 57, Luke 2nd Rd., Lujhu Dist., Kaohsiung City 82151, Taiwan (R.O.C.)
Sectors Collagen Matrix, Bone Graft, Collagen Membrane, Collagen Ophthalmic Matrix, Dermal Filler, and Skin Care Products

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Company Description

EirGenix, Inc. is a new Asia Development & Manufacturing Hub for Biologics and offers high quality and cost-effective services to support clients from around the world. The firm owns and operates two cGMP compliant plants, producing microbial and mammalian based biologics all the way from cell line development to final product bulk filling. Additionally it provides assistance in product and process development and analytical testing for all stages starting from pre-clinical stages to commercial manufacturing. EirGenix aims to become the vanguard of Taiwan's antibody drug conjugates (ADC) drug development and hope that not only will it provide quality service and economic solutions to its clients, it will further stimulate the global demand for the drugs.

Contact Information

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Address No. 101, Lane 169, Kang Ning Street, Xizhi District, New Taipei City 22180, Taiwan (R.O.C.)
Sectors CDMO, ADC, Biosimilar, Biologics

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Company Description

Foresee is a Taiwan and US-based pharma company listed on the Taipei Exchange. Foresee's R&D efforts are focused on its unique SIF depot delivery platform & derived drug products targeting specialty markets, and its transformative early stage preclinical and clinical NCE programs targeting inflammatory & fibrotic diseases with highly unmet needs. Foresee's product portfolio includes (1) FP-001, a stable, premixed, pre-filled version of leuprolide depot for prostate cancer, whose 97% of phase 3 subjects achieved primary efficacy endpoints; (2) FP-025, a highly selective oral MMP-12 inhibitor targeting inflammatory and fibrotic diseases, which is currently completing a phase 1 study; and (3) FP-045, an oral small molecule ALDH2 agonist, targeting NAFLD/NASH and cardiovascular diseases.

Contact Information

Name ① **Mathieu Boudreau, Ph.D.** **Position** ① Vice President, Business Development ② **Patricia PEIFEN Chou, M.S.** CFO
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E-mail ① **Mathieu.Boudreau@foreseepharma.com**
 ② **Patricia.Chou@foreseepharma.com**
Address 3F., No. 19-3, Sanchong Rd., Nangang Dist., Taipei City 115, Taiwan (R.O.C.)
Sectors Two core technologies: (1) Drug Delivery Technology: stabilized injectable formulation (SIF); (2) Rational Drug Design: novel new drug (New Chemical Entity, NCE) development

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Company Description

Health Ever Bio-Tech Co., Ltd. (HEB) was established to focus on the research and development of innovative botanical drugs backed with scientific and medical evidences for today's great unmet medical needs. With in-house ISO/IEC 17025 certified laboratory and PIC/S GMP manufacturing facility, HEB has been actively involved in the preclinical and clinical development of botanical new drugs that have been verified effective and safe on animal, cellular and human studies. HEB has built a network of domestic and international scientific advisors and consultants who are top-notch in the industry to maximize the success and quality of our pipeline. HEB endeavors to provide botanical new drugs of the best quality and makes strenuous efforts to improve the health of our compatriots.

Contact Information

Name **Alex Chen** **Position** Business Development Coordinator
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Sectors Research and Development of Botanical New Drugs

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Lumosa Therapeutics Co., Ltd.

www.lumosa.com.tw

Company Description

Lumosa Therapeutics is dedicated to the development of innovative new drugs for the treatment of neurological and inflammatory diseases with unmet medical needs. The company is actively engaged in scientific licensing and new drug development under the "reSEARCH and DEVELOPMENT" model. We select drug candidates with strong scientific rationale and high feasibility of technical success, and transform them into highly differentiated products. Several novel new drug products with global market potential under development by Lumosa are available for collaborations in clinical trials, product development and for commercialization.

Contact Information

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Address 4F, No. 3-2, Park St., Nangang Dist., Taipei City 11503, Taiwan (R.O.C.)
Sectors (1) LT1001 – long-acting analgesic IM injection product
(2) LT3001 – dual-acting NCE for acute ischemic stroke

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Illycenax Biotech Inc. Mycenax Biotech Inc.

www.mycenax.com.tw/en/

Company Description

Mycenax Biotech Inc.(MBI), the CMC-based biopharmaceutical company, was established in 2001. MBI featured in utilizing the most advanced single-use technology in its USFDA DMF registered and TFDA PIC/S GMP certified biomanufacturing facility, and conducting microbial fermentation in fermenter up to 50 L, and cell culture in bioreactor up to 2,000L. MBI provides high quality, cost-effective, time-efficient and international quality service for developing and manufacturing cGMP drug substance and finished product.

In addition to offering process development and manufacturing services to clients, we focus on biosimilar and bionovel development. MBI is keen to look for strategic partner or co-developer for regional or global development.

Contact Information

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Sectors (1) CDMO services
(2) Biological product development

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OBI Pharma, Inc.

www.obipharma.com/en

Company Description

We are a Biopharma company focusing on developing innovative cancer therapies. Our pipeline focuses on targeting novel therapeutic targets—Globo Series (e.g. Globo H, SSEA 3 & 4). Globo Series are carbohydrate antigens highly expressed in multiple types of cancers. Our novel cancer pipeline focusing on "Globo Series" (Globo H, SSEA 3 & 4) include: (1) OBI-822 Active Immunotherapy in Metastatic Breast Cancer (P2 completed), Ovarian Cancer Trial (P2 ongoing) and other solid tumors (2) OBI-833 active Immunotherapy in solid tumors (P1 ongoing); (3) OBI-888 Globo H mAb in multiple solid tumors (planned); (4) OBI-999 Antibody-Drug Conjugate (ADC) in multiple solid tumors (planned).

Contact Information

Name Kevin Poulos **Position** Chief Commercial Officer
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Sectors Biotech, Biopharma, Oncology, Immuno-oncology, Immuno Therapy, Cancer Therapy

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PharmaEssentia Corp.

www.pharmaessentia.com

Company Description

PharmaEssentia Corporation is a global, fully integrated biopharmaceutical company publicly traded and based in Taiwan. The company is headquartered at a state-of-the-art facility in Nankang Science Park in Taipei, and its world-class cGMP manufacturing site is located in Central Science Park in Taichung. PharmaEssentia's mission is to discover, develop, manufacture, and bring to market efficacious, safe, and cost-effective therapies for the treatment of MPN disorders. The company is also undertaking drug research and development initiatives in hematology, infectious diseases, oncology, and dermatology.

Contact Information

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Sectors Ropeginterferon alfa-2b (P1101)

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Pigmodel Animal Technology Co., Ltd.

www.pigmodel.asia

Company Description

The mission of Pigmodel is to serve as contract partner of bio-technology industry by using pigs as animal model for pre-clinical trials and bio-medical research. Pigmodel is a complete animal trial facility equipped with professional staff, responsible veterinary care and animal husbandry in accordance with the highest scientific, humane and ethical principles. This is achieved by the development and maintenance of quality animal care program in full compliance with Guide (NRC, 2011) and Taiwan national legislation. Pigmodel provides effective service team for pre-experimental consulting and to accomplish clients' requests and has achieved AAALAC accreditation and National Biotechnology and Medical Care Quality Award in 2016.

Contact Information

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Sectors Pharmacokinetics; R&D Services; Regenerative Medicine; Cosmetics; Devices; Customized experimental designs

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Savior Lifetec Corporation

www.saviorlifetec.com.tw/en/

Company Description

Savior Lifetec Corporation (SLC) is a specialty injectable company based in Chunan, Taiwan. Our state of the art facilities are vertically integrated, capable of producing sterile API and finished dosage formulations. Our facilities comply with the highest quality standards, having passed inspections by authorities from the US, EU, and Japan. SLC also has dedicated state-of-the-art GLP compliant R&D centers for API research and pharmaceutical research. SLC's expertise in sterile crystallization and the aseptic processing of sterile powder serves as the foundation for product innovation.

SLC is targeting high barrier non-penem drug candidates. These non-penem products will leverage SLC's expertise in sterile crystallization and the aseptic processing of sterile powder. Eventual manufacturing will occur in Zhunan, Taiwan.

Contact Information

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Sectors Pharma: API
Pharma: Small Molecular Drug
Pharma: Biologics

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Simpson Biotech Co., Ltd.

www.simpsonbiotech.com

Company Description

Simpson Biotech Co., Ltd.(SBC), established in 1998, is a privately held company located in Taipei, Taiwan focusing on 1> **Bacteria Rapid Detection System** based on magnetic beads coated with its patent pending "SimpTrap™" molecule that can bind almost all bacteria for foodborne pathogen or gut microbiome detection. 2> Fermentation of medicinal fungus and the enzymatic hydrolysis of natural ingredients for dietary supplements and early stage drug discovery. 3> The development and the fermentation of recombinant proteins and industrial enzymes using patented proteins purification platform. Simpson Biotech has won numerous awards and holds more than 39 issued patents with another 21 pending.

Contact Information

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Sectors (1) Bacteria Rapid Detection
(2) Anti-inflammation drug
(3) Natural dietary supplement
(4) Recombinant protein

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SynCore Biotechnology Co., Ltd.

www.syncorebio.com

Company Description

About SynCore

SynCore Biotechnology Co, Ltd (SynCore) (4192:TT) is a biopharmaceutical company with a comprehensive pipeline portfolio of new drugs in the areas of oncology, ophthalmology, dermatology and infectious diseases. Please visit the Company's website at <http://www.syncorebio.com/>

For further information please contact:

Media: Charles Liang, CFO finance@syncorebio.com
Business Development: BD@syncorebio.com

Contact Information

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Sectors SynCoreBio is a public listed company established in 2008, focusing on new drugs R&D. SynCoreBio owns a comprehensive pipeline with 5 new drugs: SB01 (Phase2, Head and Neck Cancer); SB02 (Pre-IND, Solid Tumors); SB03 (FDA approval, External Genital Warts); SB04 (Phase2, dry AMD); SB05(Phase3, Pancreatic Cancer/Triple-Negative Breast Cancer).

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TaiGen Biotechnology

www.taigenbiotech.com.tw

Company Description

TaiGen Biotechnology, a public listed company in Taipei Exchange (4157.TWO), is a leading research-based biotechnology company in Taiwan. TaiGen's pipeline includes in-house discovered and developed new chemical entities: Taigexyn®, a novel antibiotic, is one of the first NCEs developed by a Taiwanese company that received market approval and launched in Taiwan and mainland China. Burixafor, a chemokine receptor antagonist, completed Phase 2 clinical trial for stem cell transplantation in the U.S. Fuparevir, a HCV NS3/4A protease inhibitor, completed Phase 2 clinical trial in HCV genotype 1b patients in Taiwan. In 2016, TaiGen Biotechnology signed an agreement to form a new company with YiChang HEC ChangJiang Pharmaceutical Co., Ltd. in mainland China for the joint development and commercialization of direct-acting antiviral agents (DAAs) for HCV treatment in the Greater China region.

Contact Information

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Sectors TaiGen Biotechnology focuses in the research and development of New Chemical Entities (NCEs). TaiGen's pipeline includes first-in-class and best-in-class treatment for infectious diseases, oncology and diabetes-related complications.

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Taiwan Leader Biotech Corp.

www.twleaderlife.com/en/

Company Description

Taiwan Leader Biotech Corp. is the leader brand of Taiwan unique medicinal fungus- Taiwanofugus camphoratus (Antrodia cinnamomea) industry.

We are devoted to Cinnamomum kanehirae Hayata reforestation and has obtained international Forest Stewardship Council (FSC) certification (FSC-FM/COC) verify by NGO organization - Rainforest Alliance (RA).

We obtained the approval from US FDA to conduct Phase I/IIa clinical trials, for botanical drug, LEAC-102

The leading company obtained the largest number of T. camphoratus raw materials legal permits approved by TFDA.

Taiwan Leader Biotech Corp provides "Safety, quality and expertise" products and services with a variety of ways of cooperation!

Contact Information

Name Darren Lin **Position** Business Development Specialist

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E-mail LESD@twleaderlife.com

Address 13F-1, No. 81, Sec. 2, Chengde Rd., Taipei City 10353, Taiwan (R.O.C.)

Sectors Specialized on T. camphoratus materials/ health supplements/ cosmetics/ general food and beverage, OEM and ODM

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TLC (Taiwan Liposome Company, Ltd.)

Enriching hopes for life

www.tlcbio.com

Company Description

Based in Taipei, TLC is a commercial stage biopharmaceutical company developing novel nanomedicines for cancer, ophthalmic conditions and pain management that maximize the potential of its proprietary lipid-based drug delivery technology. TLC's highly scalable and versatile technology enables the development of sustained release and targeted therapies capable of reducing toxicities and improving effectiveness. Advanced programs include TLC388 in liver cancer, TLC399 for diseases of the eye and TLC599 for osteoarthritis pain. TLC has global commercial partnerships, an experienced drug development and commercialization team and subsidiary offices in the US, the Netherlands, China, Hong Kong, Australia and Japan.

Contact Information

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Sectors Drug Delivery System, Targeted Delivery, Sustained Release, Oncology, Ophthalmology, Pain Management

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TPG Biologics, Inc.

www.tpgbiologics.com

Company Description

TPG Biologics is a biotechnology company that specializes in the early stage research and development of biologics. We are a multifaceted biotech company that provides CRO services and monoclonal and protein biosimilar cell lines. This diversity is made possible by our well-established and state-of-the-art technology platforms, as well as our highly-skilled and dedicated scientists. Our mission is to be the best partner for worldwide pharmaceutical and biotech companies. At TPG, we work to tailor each project to our clients' wishes, communicating individually with them to ensure outstanding results.

Contact Information

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Sectors (1) CRO services for cell line and process development
(2) mAb and protein biosimilar production clones

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 **United BioPharma, Inc.**
www.unitedbiopharma.com/eng/index.html

Company Description

United Biomedical, Inc. Group of Companies

- UBI was established in 1985 with HQ in Long Island, New York, USA
- United BioPharma specializes in biologics development and manufacturing
- UBI Pharma offers both biologics products and small molecule products

CMO/CDMO: Integrated Solution Provider

Biologics Solutions:

- Process Development for Bio-pharmaceuticals

Small Molecules Solutions:

- Formulation Development
- GMP Contract Manufacturing

Track records:

- Global Partners: Pfizer, MSD, GSK, Aspen, Astellas
- USA (FDA): approved sterile injectable line
- Japan (PMDA): approved sterile injectable line
- Australia (TGA): approved ointment line
- Colombian BoH (INVIMA): approved ointment line

Contact Information

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Sectors:

- Cell line development
- cGMP cell bank
- Process development
- cGMP contract manufacturing
- Analytical solutions

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 **VETCO Vetco Pharmaceuticals Inc.**
www.vetcogroup.com

Company Description

Vetco is a Taiwanese veterinary pharmaceutical company, focused on developing novel products to supply the needs of untapped market in the veterinary industry. We are devoted to providing veterinary professionals with innovative therapeutic solutions to improve the well-being of animals and owners.

Vetco has successfully developed the first pet anticancer drug in Asia, Antican®, which will be launched in Taiwan in 2017. Besides Taiwan, Vetco would also work to bring this product to its full potential onto the global stage through the collaboration with international pharmaceutical companies who share the same view with us.

Contact Information

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Address: 20F, No. 97, Sec. 4, Chongxin Rd., Sanchong Dist., New Taipei City 241, Taiwan (R.O.C.)

Sectors: Antican® is a safe, effective, and broad-spectrum drug and can mitigate the issue of undeveloped pet oncology market.

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台灣館參展單位列表—以講求簡單明瞭的方式條列國內各家優秀廠商及研究單位，內容言簡意賅，可提高媒合研究員與其他單位的合作機會，藉以有效的成功拓展國際合作夥伴關係。



2018 北美生技展(2018 Bio International Convention)宣傳資訊，將於麻薩諸塞州波士頓舉辦。