出國報告（出國類別：其他）

參加 2018 年北美生技展（2018 BIO International Convention）及行政院生技產業策略諮議委員會（Bio Taiwan Committee, BTC）海外委員會議（pre-BTC）出國報告

服務機關：衛生福利部

姓名職稱：何啟功 政務次長

‘ 黃小文 高級研究員

李顯揚 研究員

吳毅凱 研發替代役

派赴國家：美國

出國期間：107 年 6 月 2 日至 6 月 10 日

報告日期：107 年 8 月

公務出國報告提要

參加 2018 年北美生技展出國報告

頁數： 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

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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：2018 年 8 月

摘要

第 25 屆 BIO International Convention（北美生技展） 於 107 年 6 月 4 日至 6 月 7 日假美國波士頓舉辦，共計來自全世界 67 個國家代表團，18,289 位生技產業人士出席，超過 7,000 家公司參展，並促成 46,916 場次的合作商談（partnering meetings），是全球生技界每年最大的產業活動平台，大會並於 107.6.6 宣布正式成為金氏世界紀錄（GUINNESS WORLD RECORDS，title for the Largest Business Partnering Event），今年大會的議題重點包括次世代生物療法藥物、轉譯醫學研究、基因編輯、投資趨勢、數位健康、智慧財產、孤兒藥與罕病、個人化醫療/診斷等。

本年度於舉辦 BIO 2018 時，同時於 6 月 4 日舉辦 pre-BTC 海外委員會議。本年度『臺灣形象館』展區由財團法人中華民國對外貿易發展協會主辦，由吳政忠政務委員擔任團長，率領臺灣代表團參加本次展覽，計有 27 家生技醫藥相關廠商參加，政府及法人單位則包含衛福部、科技部、經濟部、農委會、中央研究院、櫃買中心、證卷交易所、本院、生技中心、工研院生醫所、農科院、藥技中心、國研院等，代表團共計 268 位成員，並促成了 578 場次的商機會議，大幅提升臺灣在生技產業發展的機會。為將臺灣優質的臨床試驗環境推向國際舞

台，本部本次參展以『臺灣卓越臨床中心-優質臨床試驗環境』為主題，目的在吸引並創造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。臺灣今年寫下不少紀錄，無論代表團人數和參展單位皆刷新歷史新高，來自產官學組成的臺灣代表團這次陣容高達 250 餘人，今年以『精準醫療』為主題參展的臺灣館，堪稱是今年北美生技展最大的國家形象館。

目次

壹、簡介及目的

第 25 屆 BIO International Convention(北美生技展) 於 107 年 6 月 3 日 6 月 7 日假美國波士頓舉辦,共計來自全世界 67 個國家代表團，18,289 位生技產業人士出席，超過 7,000 家公司參展，並促成 46,916 場次的合作商談(partnering meetings)，是全球生技界每年最大的產業活動平台，大會並於 107.6.6 宣布正式成為金氏世界紀錄(GUINNESS WORLD RECORDS，title for the Largest Business Partnering Event)。

今年大會的議題重點包括次世代生物療法藥物、轉譯醫學研究、基因編輯、中國監管變化、 投資趨勢、數位健康、智慧財產、孤兒要與罕病、個人化醫療/診斷等。

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，同時舉辦近十餘個不同主題討論共 180 場以上的論壇,並有超過 200 個生技公司的發表會，總共超過 1,000 演講者參與。

我國於此次BIO 2018的參加單位包括科技會報辦公室、科技部、經濟部、衛福部、中研院；法人包括生技中心、工研院、藥技中心、國衛院、國研院、農科院；由科技部協助成立之國際產學聯盟（Global Research and Industry Alliances，GLORIA）則有國立成功大學、臺北醫

學大學、國立中央大學、國立陽明大學等四所大學參加。

參展廠商包括新藥開發：台灣微脂體、藥華、台灣浩鼎、健永、善笙、永昕、德英、群泰（經皮吸收）、康霈（減重新藥）、資元堂（糖尿病新藥）、竟天生技（藥物傳輸）；CMO：台康生技；精準醫療&智慧醫療：昱星（AI 藥物篩選）、新穎生醫（IVD）；協會：台灣研發型生技新藥發展協會、台灣生物產業發展協會；現場展示區：華碩健康（臨床資料庫）、Funique（VR）、Medical AI（VR）；台北市政府廠商：台灣東洋、遠東生技、彥臣生技、唯醫生技、茂英基因；以及農委會廠商：亞果、京冠、寰宇。

臺灣今年寫下不少紀錄，無論代表團人數和參展單位皆刷新歷史新高，來自產官學組成的臺灣代表團這次陣容高達 250 餘人，今年以『精準醫療』為主題參展的臺灣館，堪稱是今年北美生技展最大的國家形象館。

貳、過程

行程表

6/2 （週六）	**（出發至美國 波士頓）**
於同日上午抵達甘迺迪國際機場，並搭乘主辦單位安排之接駁車至波士頓之下榻飯店。	
6/3（週日）	**（上午-參加波士頓臺灣人生物科技協會及台灣生技論壇；下午-會場佈置）**
1. 上午參加波士頓臺灣人生物科技協會(BTBA)年會座談會 2. 上午 09:00 至 Joseph B. Martin Conference Center （Harvard Medical School）參加臺灣生技論壇（Taiwan Bio Forum）。 3. 下午 1 點整至 5 點 30 分至 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。	
6/4（週一）	**（上下午-會場佈置）**
協助經濟部生醫小組進行會場佈置。	
6/5（週二）	**（上下午-會場攤位諮詢服務；晚上-台灣團長致謝晚宴）**
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。 3. 晚上 6 點至參加台灣團團長致謝晚宴。	
6/6（週三）	**（上下午-會場攤位諮詢服務）**
上午至下午進行攤位諮詢服務。	
6/7（週四）	**（上下午-會場攤位諮詢服務；晚上-撤展）**
1. 上午至下午進行攤位諮詢服務。 2. 下午 5 點半撤展。	
6/8（週五）	**（上午-Woodbury 參觀；下午-紐約市街道參觀）**
1. 8 點半集合前往 Woodbury 進行參訪。 2. 下午 3 點半前往紐約市進行參訪。	
6/9（週六）	**（凌晨-搭機返臺）**
搭乘凌晨 1:25 班機返回臺灣	
6/10（週六）	**（清晨-抵達臺灣）**
於清晨 5:15 抵達臺灣	

一、 波士頓臺灣人生物科技協會（BTBA）年會座談會

衛福部在何啟功次長率領下，於 6 月 3 日隨同吳政忠政委、科技部、經濟部等代表一同出席波士頓臺灣人生物科技協會（Boston Taiwan Biotechnology Association, BTBA）年會。波士頓臺灣人生物科

技協會是由一群年輕學者及生技業界旅美專家組成，此次代表團出席年會並舉辦座談會，出席人數近百人，會中由各部會代表介紹台灣生醫產業現況與政府作為，讓海外學人實際了解台灣生醫產業環境，報告內容包括:

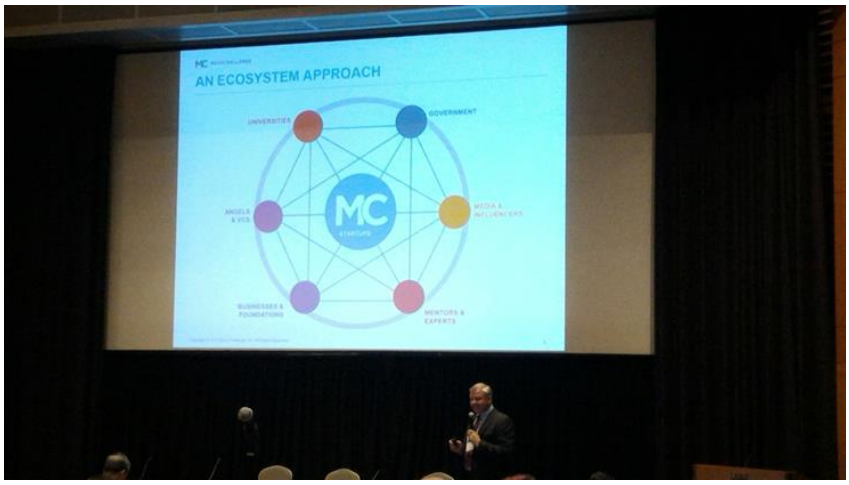
1. 臺灣生醫產業現況綜覽（科技會報辦公室劉祖惠主任）
2. 促進生醫產業發展，開拓全球市場（經濟部李佳峯副組長）
3. 完善法規環境，促進新興科技產業化（衛福部黃小文博士，簡報詳見附件）
4. 強化產學研醫鏈結，提升生醫產業動能（科技部莊偉哲司長）

報告結束後，並由吳政忠政務委員主持、衛福部何啟功次長、科技部莊偉哲司長、農委會張致盛處長、經濟部工業局李佳峯副組長等與 BTBA 成員討論交流。與會人員對於如何回國服務、生技產業投資、以及跨國合作研究等議題相當關切且發言踴躍，尤其是 Boston 地區，

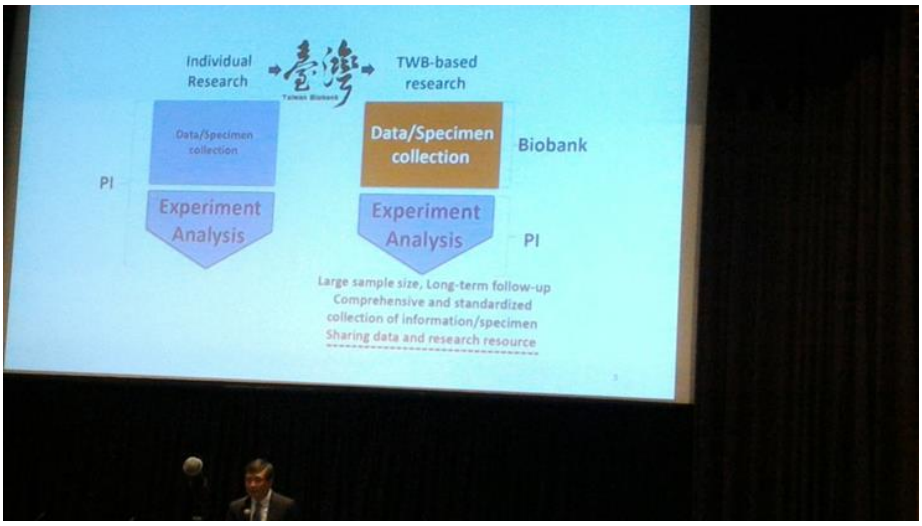
執全球生醫領域之牛耳，我國在此地之生技醫藥領域之人才輩出，創新動能預期將有更積極之作為與投入。

二、2018 臺灣生技商機論壇（Taiwan Biotech Forum）

隨後，衛福部同仁繼續出席參與台灣生技商機論壇，本論壇由財團法人生物技術開發中心及新英格蘭玉山科技協會共同於6月3日假波士頓哈佛醫學院舉辦，為北美生技展開展的前一天，此論壇可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。今年論壇聚焦議題包括我國生技創新公司介紹、國際創投策略、數位轉型及精準醫療、醫療保健與生醫創業創新等。



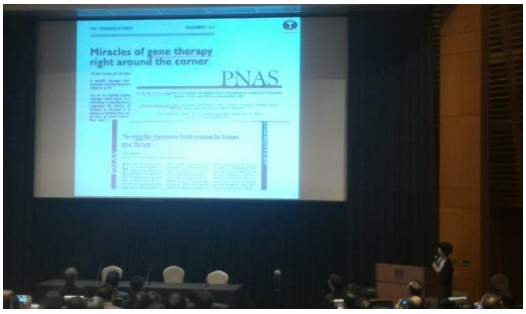
論壇邀請科技部蘇次長芳慶開場致詞，介紹我國政府推動生醫產業的重要策略及整體布局，並期許我國與國際建立良好互動及於生技醫藥、數位健康等領域促成創新生態圈。麻薩諸塞州創業生態系推手 MassChallenge 總裁 Michael LaRhette 於專題演講中，分享該組織如何與麻州及波士頓政府及產業領袖合作推動數位健康產業發展；臺灣人體資料庫（Taiwan BioBank）執行長沈志陽博士於專題演講中，說明臺灣人體資料庫對未來藥物開發及醫療創新之價值，並分享多項研究成果及簡述生物樣本庫之目前使用狀況。



論壇接下來則由臺灣生物產業發展協會理事長李鍾熙及麻州生物科技顧問主席（Chairman of Massachusetts Biotechnology Council）David Lucchino，在產業領袖對話論壇中，針對建立新創生態圈、促進產業研發創新等議題進行深度討論。

主辦單位並於論壇中安排台灣參展廠商進行 5 分鐘自我介紹，包括行動基因、茂英基因科技、華碩健康、肯迪科研、睿科影像、新穎

生醫、昱星生物科技、基因體先驅、安立璽榮等 9 家國內廠商進行簡介，展現臺灣在生技新藥及醫材上的研發能量及實力，不僅能使與會者對本次台灣團展出內容的輪廓有初步的描繪，更能幫助國外廠商可快速準確地從需求面找到洽談對象，對增加我國國際合作機會有加分的效果。



三、2018 行政院生技產業策略諮議委員會議海外座談會

6 月 4 日本部何次長率同仁出席行政院生技產業策略諮議委員會議海外座談會，會議由生醫產業創新推動方案執行中心副執行長莊偉哲報告 2017BTC 會議決議事項以及生醫方案進度成果。有關衛福部之相關準備資料，主要包括我國法規進展，含細胞治療、精準醫療 LDTS（Laboratory Developed Test and Service）指引、醫材專法、CDE 行政法人化、通訊診察治療辦法、衛生福利資料應管理要點等，相關準備

資料請見附件。

今年出席 BTC 海外會議委員包括蘇新森、陳紹琛、林秋雄、張幼翔、顧曼芹、廖俊智等委員。海外委員除就簡報內容進行詢問外，對於我國近來生技法規之進展給予肯定，同時關切以下議題：

1. 生技法規策略諮議會委員組成之產業代表比例。
2. 醫療器材專法，策略上究以歐洲或美國制度為借鏡依據，應提至諮議會討論。
3. 台灣發展數位醫療，軟體審查人才不易尋得，建議政府應考慮如何引進人才。
4. 台灣發展精準醫療，利用數據資料，在研發階段即應納入 biomarker 之研發，在不同族群中找到適當的藥物目標。
5. 國際數據資料庫極缺亞洲華人資料，台灣有健保資料庫優勢，應可善用。
6. 美國 NIH 正發展百萬人基因數據，台灣應加入合作。
7. 分子檢測實驗室，台灣可參考 LDTS 美國最新發展。
8. TFDA 及 CDE 的審查時效，以及健保藥價的核價機制，都是產業最關切的重點。

會議結束後並安排媒體採訪，由吳政委主持，出席媒體包括非凡、世界日報、大紀元及當地記者等。政委說明我國生技結合 ICT 的創新

思維與策略，數位科技和人工智慧發展數位醫療，是必然的趨勢。臺

灣沒有大型藥廠變革不易的包袱，新創反而很有機會，媒體對於臺灣發展精準醫療及數位醫療極為關注，尤其想了解 Boston 地區的產業或其他國際數位資通訊大廠（如 Microsoft, Google 等）與臺灣合作的狀況，此外媒體對於浩鼎案對台灣股市的衝擊影響，以及臺灣對智慧財產的保護也有所關切，政委及部會次長分別就媒體關注事項說明。

四、攤位展示

本次參展我國攤位以水綠色系為主視覺，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，7 個法人單位並且有背靠背型式的小展示台，提供展示解說空間。參展廠商並以三角形背板隔出展示空間，計有 27 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。

另外日本、韓國攤位亦可作為我未來參展之參考，日本館攤位布局採較方正之風格，洽談區則以霧化之隔板圍出半開放空間，此種方式除能讓參觀者清楚區隔各家廠商展示之內容，洽談空間也較封閉式設計更加舒適，對洽談意願及交談氛圍應有加分效果。韓國館將政府展示牆置於展區正中心，並結合諮詢服務台及茶點招待處，吸引觀展

人員上前並順勢介紹展示內容，廠商攤位則布於四圍，環繞政府展示區，方便引導參觀者諮詢後立即於相關攤位進行更深入了解。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『臺灣卓越臨床中心-優質臨床試驗環境』為展覽主題，成功吸引各方人士在我國攤位前駐足，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。

五、參訪精準醫療 CLIA 實驗室

為推動精準醫療分子檢測實驗室管理指引(LDTS，Laboratory Developed Test and Service)，了解美國在 CLIA (Clinical Laboratory Improvement Act)管理架構下臨床實驗室的運作狀況，衛福部何啟功次長、黃小文博士及精策會李伯皇教授、張珩理事長、黃燕姝副秘書長、辜琮祐研究員、吳泓泰總經理、張偉嶠副院長、以及食藥署林春月、王淑慧兩位審查員於 6 月 4 日一同前往拜訪 Brigham and Women's

Hospital, CAMD (center of advanced molecular diagnostics) of Pathology。

BWH 醫院歷史悠久，是附屬於哈佛大學醫學院的第二大臨床教學醫院，醫院擁有 777 床，下設有癌症中心、心血管中心、神經外科中心、骨關節中心、婦產科中心、腎病中心、移植中心、整形外科中心、乳腺癌中心、婦科癌症中心、淋巴瘤中心、黑色素瘤中心、胃腸癌中心、肉瘤中心等科室機構。其中，移植中心是美國最好的移植中心之一。 CAMD 下有 Clinical Cytogenetics 以及 Molecular Diagnostics Laboratory，共約 100 名研究人員，檢測項目包括 Digital PCR、OncoPanel、Liquid Biopsy、HPV、KRAS mutation、EGFR mutation 等等，每年處理的樣本約 23000 件。CAMD 蕭晟副主任現場介紹病理實驗室的設備，並說明美國的專業人員，包括醫師及博士，均需進一步接受專業學會認可的訓練後，才能簽署分子檢測試驗報告。

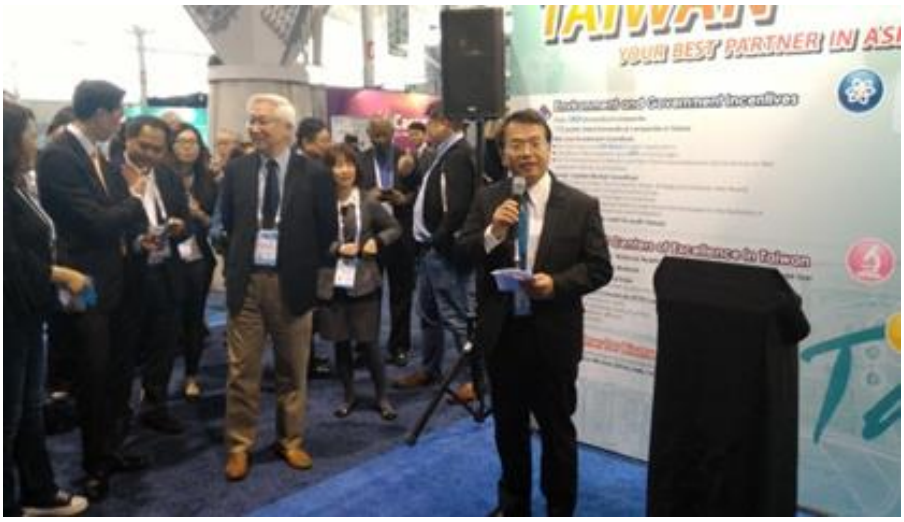
六、赴 Sanofi 藥廠參訪 Genzyme Clinical Specialty Laboratory

6 月 5 日代表團赴美國藥廠 Sanofi 參訪 Genzyme Clinical Specialty Laboratory。由 Dr. Crystal Sung （宋晶晶）, Head of BCB-Clinical Diagnostics 簡介。Sanofi 總部位於法國巴黎，是世界上第四大的製藥企業，產品主要包括七個領域：心血管疾病，血栓形成，腫瘤學，糖尿病，中樞神經系統，內科疾病和疫苗。此次參訪實驗室是該公司進行藥品上市後評估實驗室，實驗設備依據 CLIA 操作複雜度（Complexicity），包括最低複雜度的自動化取樣設備、中度複雜度的 ELISA 自動活性測試設備、以及高度複雜度的質譜儀與分析軟體。由於這些檢測報告涉及藥品的上市後品質評估，並可提供醫院醫師診斷及保險之用，實驗室同時也是美國 CMS （Centers for Medicare & Medicaid Services）認可的實驗室。

七、臺灣國家形象館開幕

6 月 5 日 BIO 2018 臺灣國家形象館開幕儀式，由經濟部生醫推動小組主任，生物技術開發中心副執行長吳忠勳擔任主持人，並邀請行政院吳政務委員政忠及我國駐波士頓臺北經濟文化辦事處處長徐佑典代表致詞，麻州商務廳副廳長 Mr. Nam Pham 也到場致意，在衛福部何次長啟功、科技部蘇次長芳慶、中研院廖院長俊智、農委會、經濟部工業局及技術處等部會官員，及法人、協會及參展廠商的陪同下，

共同揭開以國家形象呈現的臺灣生技展館。



今年開幕活動除提供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，另提供精緻餐點供參觀人員享用，此開幕活動吸引廣大人潮，走道擠滿駐足來賓，我方更藉此機會大力廣宣我國生技產業及政策，期能對參觀人員留下深刻印象。

吳政務委員政忠致詞時表示，今年臺灣各相關部會包括科技部、

經濟部、衛福部及農委會所屬之法人機構，都帶著重大生醫研發技術及成果參展，其中中研院展示之臺灣生物資料庫（Taiwan BioBank）以及（Taiwan Clinical Trial Consortium），充分展現臺灣政府積極建設臺灣成為亞太生醫研發基地之效率，以及鏈結國際合作之決心。去年知名大廠如 Google、Microsoft、Navida 及 Merck 都紛紛到臺灣建立研發中心或合作專案，加上政府『五加二創新產業計畫』的國外拓展政策，將是各國生醫產業合作的最佳夥伴。

此開幕活動不僅展現臺灣特色，並吸引各國參展人員前來，廣大人潮，活動場面熱絡，為臺灣生醫產業增加不少國際曝光度，據統計為歷年來 BIO 臺灣館開幕來賓最多的一次。

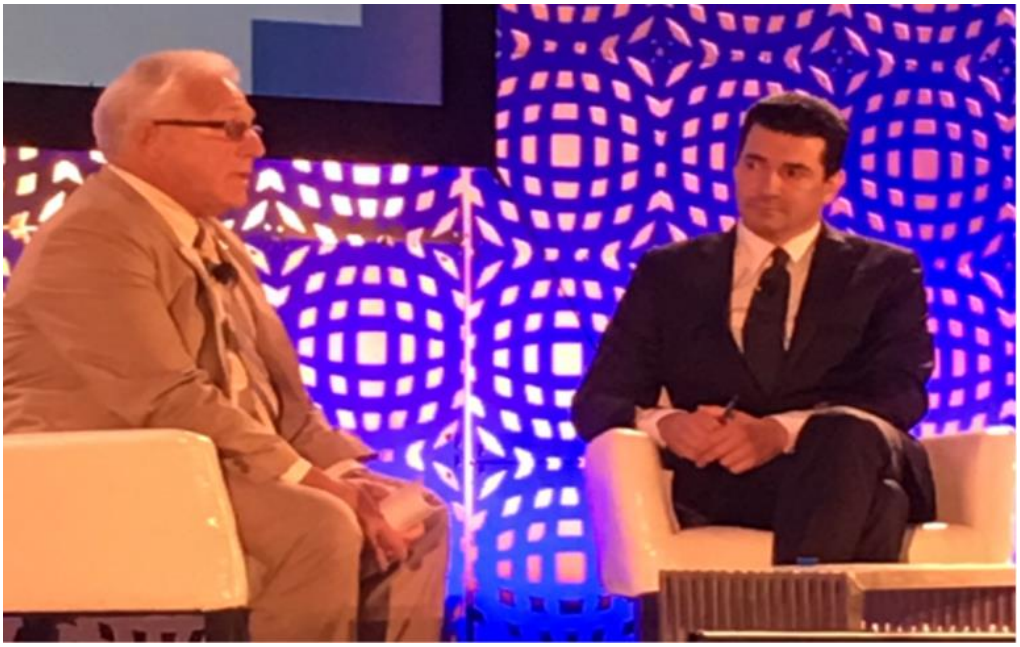
八、臺灣團長致謝晚宴

臺灣團致謝晚宴於 Aloft Boston Seaport Hotel 舉辦，由團長吳政忠政委設宴感謝我國參展人員對此次展覽之用心規劃與執行，並藉此活動凝聚台灣團的成員的向心力，每位團員平時皆處不同崗位為我國生

技產業奮鬥，鮮少有齊聚一堂相互砥礪的機會，此晚宴無疑提供一個最好的平台，使產、官、學各界能於其中交流心得、交換資訊，更為跨界合作的可能埋下希望的種子。

九、精準醫療法規重要進展

此次大會頗受矚目的議程，首推 US FDA Commissioner Dr. Scott Gottlieb 訪談。由大會主席 Mr. James Greenwood 親自提問， Dr. Scott Gottlieb 自上任後，積極提出 US FDA Action Plan for 21st Century Cures Act，將就再生醫療、數位醫療、精進人體試驗、利用 Real World Data 創新審查模式、成立 Center of Excellence 等。尤其他上任後核准 23&Me 以及 CART 等創新生物技術開發的檢測與細胞療法，舉世矚目。Dr. Scott Gottlieb 表示未來在再生醫療技術上，細胞及其衍生物的製程將是審核的重要關鍵事項。



同時，美國為推動精準醫療，兼顧檢測品質與保險的一致性，正由國會草擬 Diagnostic Accuracy and Innovation Act （DAIA）法案，法案係由美國兩位眾議員（Larry Bucshon 及 Diana DeGette）於 2017 年 3 月 20 日發表之討論草案（discussion draft），擬修訂現行之 Federal Food, Drug, and Cosmetics Act （FD&C Act）及 Public Health Service Act (PHS Act)兩法案，建立 In Vitro Clinical Test（IVCT）之管理架構，IVCT 包括最終產品（Finished Products IVD，In vitro diagnostic device）及實驗室測試程序（Laboratory Test Protocols），亦即 IVCT = IVD + LDT。DAIA 法案各章節內容包括：IVCT 定義、IVCT 分級、IVCT 上市前審查要求、IVCT 品質系統要求、IVCT 上市後監控要求、IVCT 實驗室認證及 DAIA 法案過渡期等。

DAIA 將分子檢測管理所轄，明確分別歸屬三個管轄領域：

1. FDA：對於可運用於其他單位以及第三方的 IVCT，由 FDA 獨立管理，包括 IVCT 的設計、研發、製造及確效。FDA 需新增主管 IVCT 的組織。

2. CMS：對於在單一實驗室運作的 IVCT，包括試劑與樣品的準備、分析前處理，由 CMS/CLIA 具獨立管轄權。

3. State：由醫事專業人員進行的臨床應用與解釋諮詢，仍屬美國各州政府管轄。

參、心得及建議

一、 北美生技展係國際生技產業重要的商業交流及媒合平台，參與此展覽除可了解生技產業在國際間最新之趨勢及脈動，同仁亦有機會與我國參展之其他政府與民間單位進行交流，對於未來在生技發展規劃中跨部會/單位整合與配搭有良好助益，且可藉由此展向國際間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、 本次展覽中，本部以推廣『臺灣卓越臨床中心-優質臨床試驗環境』為展覽主題，財團法人國家衛生研究院亦展出其傑出的研究成果，展現我國傑出的研究量能及友善的研究環境，吸引許多參觀人員的詢問及討論。惟礙於攤位空間有限，日後若能展出本部及所屬機關如食品藥物管理署、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之豐碩研究成果，相信定能更加凸顯我國在生技產業上的投入與重視，藉以增加國際間合作意願。

三、 本次會展布置，我方係將視覺設計及裝飾以大圖輸出，在另黏貼於背板上，且為配合美國當地法規，我國展館係委託當地承包公司進行架設及布置，惟數處宣傳牆及海報背板上皆有不明

突起物，研判應是進行黏貼工作時未注意空氣的排除而導致，我方雖立刻進行溝通並要求承包公司處理，但考量此類型展覽規模盛大且為全球各國交流之重要平台，建議往後應慎選承包公司或與較具經驗之承包商合作，才能於國際舞台上呈現我國最完美的形象。此種低階缺失不應該發生，希望外貿協會（此次主責展館裝潢）能多注意承包商的選擇，避免此種絕對可以

避免的低階缺失再度發生，而進一步影響國家整體形象的宣傳。

四、 我國在生技產業發展上深具潛力，參展公司及學校技術多元且具創意，結合 ICT 技術將可創造新興生醫醫療領域。

五、 我國發展精準醫療，應考慮IVD及LDT的發展策略，美國DAIA的思維與進展可提供參考。

六、 細胞治療，目前在美國 FDA 已有 200 多件 IND 進行中，目前價錢昂貴且製程高度專業，我國應有切入的機會。

七、 BIO 生技展規模盛大，囿於預算無法安排其他相關單位及人員參與展示，呈現我國更完整豐富的研究成果與亮點，雖備齊相

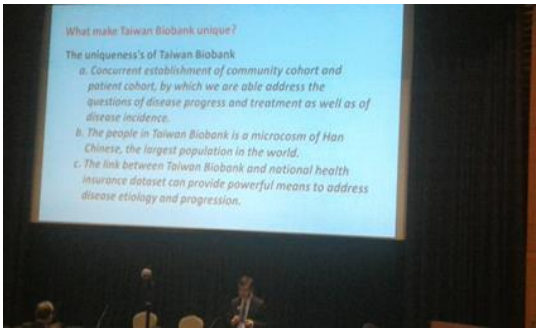
關單位之簡介宣傳品供參觀者參考，以彌補此缺口，但對於具備實際需求並尋求合作的參觀者而言，仍難以取得具體且實用的資訊，爰建議日後無法參與展示之相關單位除提供宣傳品外，亦能提供國際合作事宜窗口之相關聯絡資訊，相信定能促成更多跨國合作機會。

八、各國有關癌症相關研究展出的觀察：

臺灣生技商機論壇（Taiwan Biotech Forum）為BIO 2018北美生技展臺灣代表團一系列相關的活動之一，在本次的活動中，特別請到中研院臺灣人體資料庫（Taiwan BioBank）執行長沈志陽博士，就臺灣人體資料庫的發展現況，進行專題演講。目前臺灣人體資料庫已達成計畫中正常族群檢體約二分之一的數量（90,000+例），並於今年起開始收集多種疾病的檢體，包括多種癌症在內。要進行醫學及生技醫藥研究，大數量且收案嚴謹確實的人體資料庫是不可或缺的，在癌症的精準醫療研究上也是如此。在衛福部的第三期癌症研究計畫中，國衛院正與台北醫學大學合作，進行『第三期癌症研究跨機構合作平台及其整合應用計畫』，其中即包含推動各癌症研究中心配合各類癌症檢體收集程序的標準化，癌症檢體收集資料庫之建立維護，以及臨床資料的整合應用研究等多項重要議題。在臺灣的癌症研究上，如能促成各癌症研究中心、國衛院、及中研院等各單位之合作，建構之各類癌

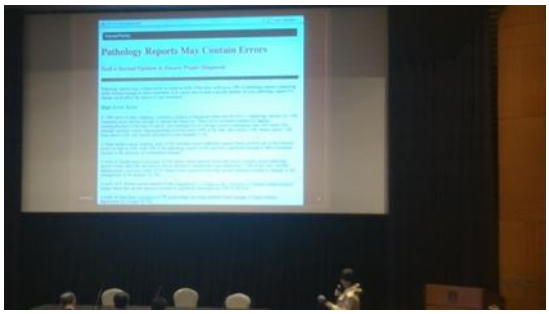
症檢體統一標準化收集、運輸、儲存程序及檢體質量驗證機制，並同時建構完整的檢體資料庫及檢體合作互享機制，配合健保資料及癌登資料庫，將對我國的癌症研究有極大的幫助，並極大程度的提升我國在癌症生技醫療上的發展，朝向癌症精準醫療的目標上大步前進。

論壇也安排包括行動基因、茂英基因科技、華碩健康、肯迪科研、睿科影像、新穎生醫、昱星生物科技、基因體先驅、安立璽榮等9家國內廠商進行簡介，以展現臺灣在生技新藥及醫材上的研發能量及實力，其中有多家廠商的產品，都與癌症之診斷及治療有關。如行動基因（ACT Genomics）提供癌症基因檢測，依據基因特性評估標靶、免疫、荷爾蒙以及化學治療，將複雜的基因資訊轉化為可實行的癌症治療方案。



茂英基因科技（Mao Ying Genetech）開發出世界第一套利用基因表達圖像（Gene Expression Portrait）來偵測癌症惡性程度及癌轉移原發位置的檢測系統。基因體先驅（GenomeFronter Therapeutics, Inc.）的研發焦點，在研發革命性的新世代嵌合性抗原T（CAR-T）細胞免疫療法以對抗實體腫瘤。藉由這些臺灣廠商的報告，可以大致了解目前

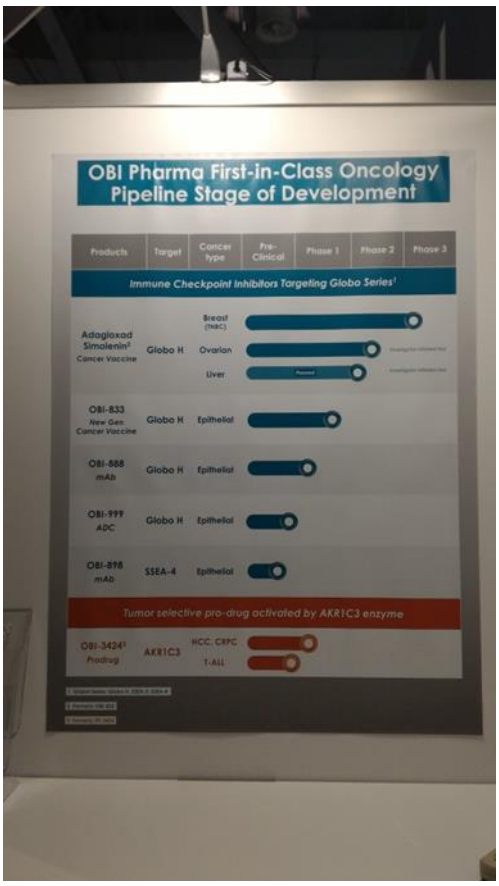
臺灣生技醫療廠商在癌症診斷及治療上的最新進展，同時此種與國際性大型生技展結合的徵才及集資之複合宣傳模式，值得推廣作為國內廠商或研究單位作為推展業務及徵才之國際化實務模式。



今年BIO 2018 北美生技展，我國參展的20餘家優良廠商中，亦有多家廠商的產品跨足於癌症的診斷及治療。如於去年引發關注的浩鼎生技公司（OBI Pharma, Inc），今年仍積極參與北美生技展，並宣傳多種治癌藥物，如Adagloxad Simolenin[2]，其為一種可應用於乳癌、卵巢癌、肝癌等之治療性疫苗，OBI-833則為新開發用在表皮細胞癌的治療性疫苗，OBI-888及OBI-898為新開發用在表皮細胞癌的單株抗體（mAb），OBI-999為新開發用在表皮細胞癌的抗體耦合藥物（antibody drug conjugates；ADC）。

除了浩鼎之外，國內參加BIO 2018的國內廠商，亦有多家投注於

與癌症治療相關的研發中。除了先前提過的茂英基因科技及昱星生物



科技外，如臺灣微脂體（TLC：Taiwan Liposome Company, Ltd.）宣傳其新發展的TLC178，為一款脂質包裹長春花鹼類的化療藥物，透過劑型設計來降低原先此類藥物在用於治療實質固態瘤（如肉瘤 ，Sarcomas）藥物時的毒性問題。藥華醫藥（PharmaEssentia Corp.）於腫瘤醫療方面的發展，包含以Oraxol合併Ramucirumab治療胃癌、胃食道癌或食道癌患者、以及Oraxol於乳癌患者藥物動力學之臨床試驗。健永生技（HEB：Health Ever Bio-Tech Co., Ltd.）開發的MCS-8，為預防攝護腺癌的藥物。竟天生技（Andros Pharmaceuticals Co., Ltd.）開發的非病毒基因載體，是使用具專利的『標的脂質傳輸系統』，利用

具癌細胞標的特性之ligands 結合脂質的配方設計，選擇性的標的至

含有特定 receptors 的癌細胞（如肺癌、頭頸癌、乳癌與腫瘤新生血管），利用 receptor- mediated endocytosis 的方式將siRNA/anti-sense oligonucleotides 送入細胞，增加上述抗癌藥物的效率。台康生技則研發EG12014，其為市售 Herceptin（Trastuzumab，作用於HER2受體）之生物相似藥（Biosimilar），並有多項生物相似藥於臨床前研發（Preclinical）階段。臺灣東洋（TTY Biopharm Company Ltd.）則有多

項針對卵巢癌、卡波西氏瘤、多發性骨髓瘤、乳癌、胰臟癌、前列腺癌紓解治療等之藥物研發中。彥臣生技（NatureWise Biotech & Medicals Corporation，NBM）研發中的NBM-BMX，是對第八型組蛋白去乙醯化酶（HDAC8）具有專一抑制性的新化學物質，可用來抑制腫瘤生長。德英生技（G&E Biotechnology Co., Ltd.）正研發可減緩非小

細胞肺癌（non-small cell lung cancer, NSCLC）腫瘤生長之SR-T100口服

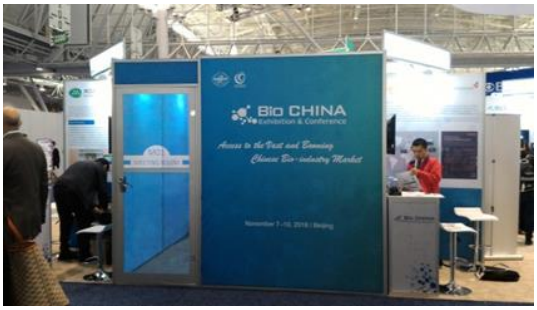
膠囊（合併Cisplatin使用），及用於婦癌及頭頸癌治療之Solarise針劑。

在法人展示區方面，國衛院展出由生技與藥物研究所研發之抗癌候選的新EGFR標靶藥物DBPR112，此藥物已於2016年獲得美國食品藥

物管理局（US-FDA）及臺灣食品藥物管理署（TFDA）試驗中新藥（Investigational New Drug, IND）申請，並完成臨床前試驗，將進行人體第一期臨床試驗。中央研究院則展出新型anti-HER2抗體偶合於載體的技術。

對岸中國的展覽攤位一如去年，占地甚廣，約有近40家廠商參展，布置規劃方面與去年類似，展場採半開放式設計，與臺灣館相似。某些攤位仍是在進行類似『推銷生技園區』的招商活動，不過仍有一些廠商的展出產品與癌症有關，如未名集團（SinoBioway Group Co., Ltd.）

研發用於慢性淋巴性白血病（Chronic Lymphocytic Leukemia，CLL）及非小細胞肺癌（Anti-PD-1）的單株抗體。無錫北大博雅控股集團（Boyalife Group Co.）發展嵌合抗原受體T細胞技術（CAR-T）的細胞開發及製備平台。成都先導藥物（HitGen Ltd.）開發針對HDAC I/II、Trk、HDAC6等之藥物。廣東香雪制精準醫療（Guangdong Xiangxue Life Science）則研發T細胞受體（TCR）嵌合型T細胞（TCR-T）的服務平台。北京凡知醫學科技（Beijing Firegene Medical Technology Co., Ltd.）則提供乳癌BRCA1/2及其他腫瘤之檢測。

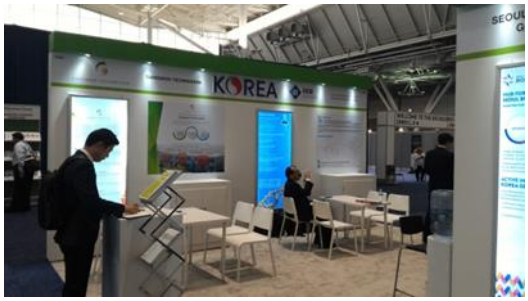


香港的攤位雖小，參展廠商及學研單位不多，但亦有廠商投入抗

癌藥物研發及個人化癌症精準醫療的諮詢服務。

南韓的攤位具相當規模，除了廠商展區之外，官方法人單位如隸屬於韓國科技部的韓國生命工學研究院（Korea Research Institute of Bioscience and Biotechnology，KRIBB），以及韓國自由經濟區（Korea Free Economic Zones，KFEZ）、韓國三星集團（SAMSUNG）均有獨立展場參展。如同往年，三星集團有專屬攤位，投入相當龐大，甚至今年設置夾娃娃機來吸引參展人潮。不過其攤位仍以VR模擬、手機附加健康資訊類之應用研發等作為宣傳主軸，與癌症研究較無相關。

南韓國家館今年採『ㄇ』字型攤位設計，廠商攤位以『ㄇ』字型排列，安排在外側，中央則為服務台及休息區，備有各參展廠商的綜合參展資訊。服務人員態度還可算是親切及專業。南韓這次有10餘家廠商參展，其中有多家廠商有投入抗癌藥物之研發。如SN BioScience Inc. 研發double-core shell micelle（DUCS® Technology），可製造出穩定的奈米大小的微胞（micelle）攜帶難以溶解的抗癌藥物如



SN-38（Irinotecan之活性代謝產物）、paclitaxel（Taxol）或docetaxel（Taxotere）。 Alteogen Inc.則研發治療乳癌/胃癌及卵巢癌之抗體藥

物複合體（antibody-drug conjugate，ADC）及治療乳癌之Herceptin（Trastuzumab）的生物相似藥。

此外，由韓國衛生福利部選定之T2B（Technology to Business）Infrastructure Center 亦擺設攤位展出，其下有7個聯盟（consortium），包含癌症、心血管疾病、代謝疾病、消化道疾病、呼吸系統疾病、眼部疾病及關節炎/免疫系病等領域，其功能相似於臺灣的特定疾病臨床試驗合作聯盟（Taiwan Clinical Trial Consortium，TCTC）。

韓國展館有一點值得我國學習之處，在於其致力及提早宣傳本國的生技展覽，例如說今年的韓國展館中，設有專區介紹推廣將於2019年舉辦的韓國生技展2019 BIO Korea（4/17-4/19，2019），而反觀臺灣亦於會場宣傳於我國舉辦之生技展，但均為今年將舉辦的生技展，包括年底生策會主辦的2018臺灣醫療科技展（2018 Healthcare Expo Taiwan，11/29-12/02），及2018台灣生技月－生物科技大展（BioTaiwan

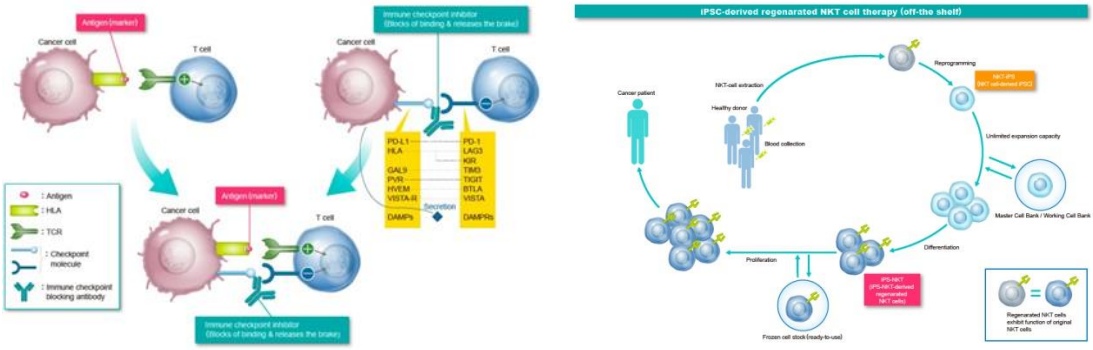
2018，7/18-7/22），以時程來說相對緊迫，國外參展者極可能在會場知道台灣生技展覽訊息後，無法及時規劃行程來臺參與，殊為可惜。這一點希望日後規劃北美生技展時能加以注意。

韓國自由經濟區（Korea Free Economic Zones，KFEZ）此次有獨立的參展攤位，在韓國目前有七個區域，其架構應該是類似我國的科學園區，惟我國於北美生技展中雖有科技部所屬之科學園區參與，但歷年來都沒有大力進行宣傳。此次韓國自由經濟區的參展，代表南韓在整合本土生醫產業發展、吸引外商投資設廠之雄心壯志的具體體現，這點十分值得我國注意及參考。

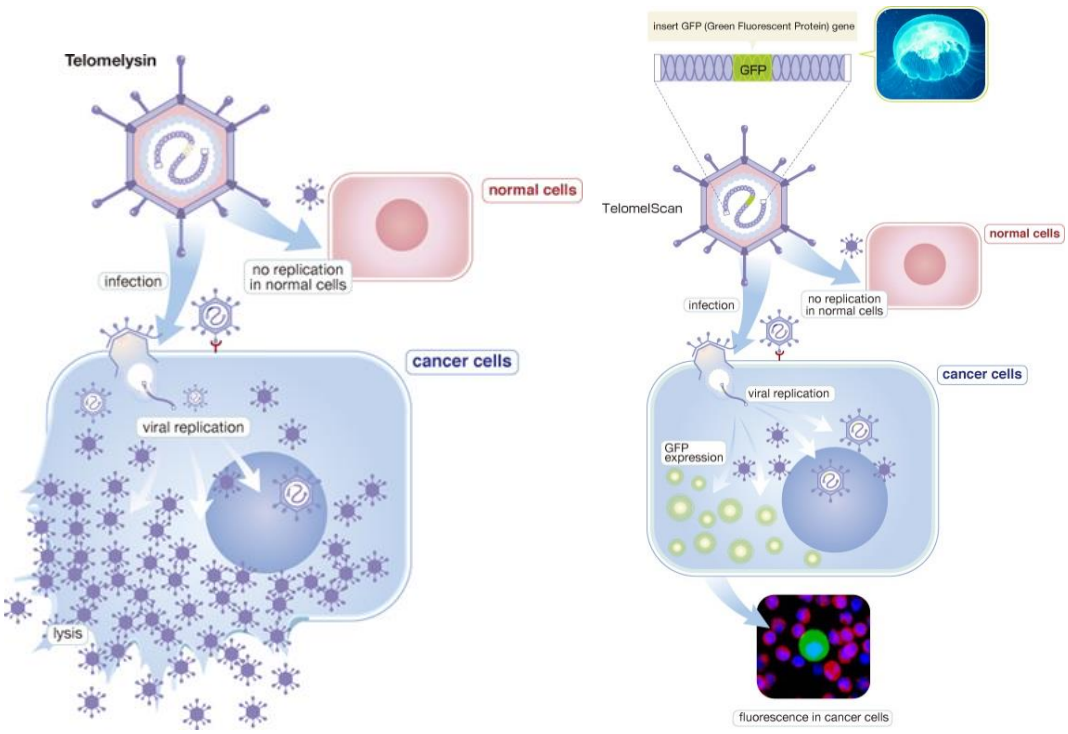
日本的參展攤位，設計仍保持其簡潔明亮的一貫特色，以方形為設計格局，廠商攤位安排在外側，各攤位展示主題標示相當清楚，而展場內部則為洽談區，採開放式設計。服務台工作人員的態度一如往年，非常主動親切，而參展廠商人員也十分樂意回答問題及參與討論，

雖然一般來說英文能力不若南韓人員流利，但是其服務熱心態度則令人印象深刻。

日本今年有20餘家廠商參加BIO 2018 北美生技展，其中有多家廠商的產品涉足於癌症領域。如BioComo Incorporation發展BC-PIV vector（由重組人類副流感病毒2型載體 recombinant human parainfluenza virus 2 (hPIV2) vectors 衍生而來），可用於腫瘤免疫學（Immuno-Oncology）上之應用。BrightPath Biotherapeutics Co., Ltd. 進行癌症免疫治療之研發，目前有3種cancer peptide vaccine於研發階段。NRL Pharma, Inc. 則進行可用於癌症之新藥研發（如Ascochlorin）。Oncolys BioPharma 則發展多種產品，著眼於癌症的



治療與偵測診斷，如oncolytic adenovirus（Telomelysin）、histone deacetylase (HDAC) inhibitor、以及engineered adenovirus type 5 to detect tumor cells（TelomeScan）。Summit Pharmaceuticals International Corp.則與福島醫學大學（Fukushima Medical University）合作，進行patient-derived tumor xenograft （PDX，異種移植）及patient-



Derived tumor organoid （PDO，類器官）（organoid）模式的建置，目前已有96種solid tumor及14種hematopoietic tumor的PDX模式，及79種的PDO模式。

日本在推動生物醫藥產業的發展上，同樣的投注相當大的資源與資金。日本於2015年成立『國家研究開發法人日本醫療研究開發機構』（Japan Agency for Medicine Research and Development；AMED），負責整合原有來自日本政府不同部會之研究經費與資源，並對成功申請研究經費的單位，提供並建立研究環境、降低行政上的繁文縟節及及精確管理計畫之執行，同時推動進行多面向之國際合作。AMAD目前有10個整合性研究計畫，共補助2,300個類研究計畫，與24個國家合作，所有計畫合計有9,000名研究人員參與。10個整合性研究計畫中

包含癌症研究計畫，其補助金額於各項研究計畫中僅次於新藥開發

研究 計畫於2017年的經費為17.2億日元（接近新臺幣4.72億元）。

不過此次日本的參展內容，在抗癌藥物的研發上，沒有去年那麼豐富，而，亦沒有像往年北美生技展那樣有亮點，殊為可惜。個人認為今年日本展館的亮點，為PDX及PDO模式之發展建置，可以用於癌症的研究上。

美國的癌症研究協會（American Association for Cancer Research，AACR）一如往年，在北美生技展中設有攤位，提供各式出版品供參觀人群免費取閱及參觀。

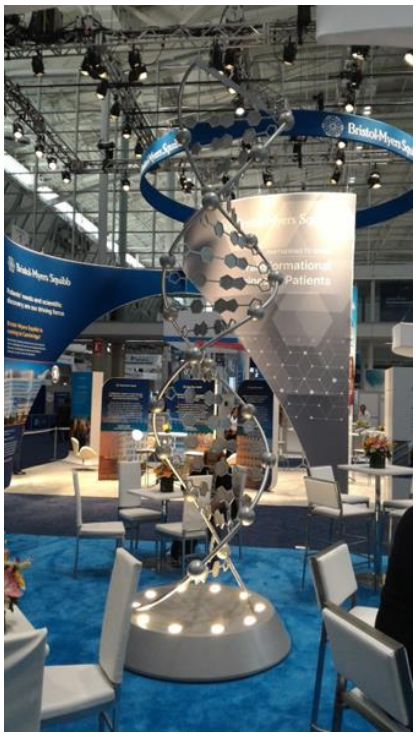
美國身為地主，自然歷年來參展單位眾多，許多州都有獨立展覽的攤位，展館設計也各有特色，惟由於身負協助衛福部展覽解說及協助臺灣館服務接待參觀來賓之職責，參訪其他展覽攤位時間實在有限，在時間有限之情況下，蒐集資料以亞洲各參展國，無法深入這些州的攤位並了解各州之生技業特色及癌症研究之相關產出，十分可惜。

美國NIH的展覽場地與去年相比，縮水甚多，參展攤位也不如去年多。但其展場的規劃仍不脫去年，未對於各類不同展覽主題進行區分，給人欠缺整體規劃之感覺。

參與如BIO這類的大型國際生技展，與學術研討會及學會年會完全不同，是一個增廣見聞、跳出純學術思維，以國家生技醫藥產業發

展的角度，對比國際上發展的一個難得機會與經歷。同時利用有限時

間走訪亞洲各國攤位，收集各國在癌症生醫研發的相關資料，收穫頗豐，並從中學習到不少新知，頗有不虛此行之感。



不過由於參加生技北美展時，因同時有公務任務需要執行，必須與同僚輪流執行本部參展攤位的解說任務及協助臺灣館服務接待參

觀來賓，往往忙於執行公務無法脫身，無法於參展期程間，以全部時間詳細參訪各國參展單位，為美中不足之處。尤其是因時間緊迫，無法保留時間，詳細參訪多家國際大藥廠的參展攤位，實際了解這些國際大廠商於癌症相關藥品及治療上的最新發展及研發思維，此點真的十分可惜，也反映出日後如有類似機會，配合所負任務行程的時間及目的規劃相當重要，才能以有限時間，對需要走訪許多不同攤位的任務，作最有效的規劃及時間運用。

與臺灣同處東亞地區的日本及南韓，在研發癌症新藥及治療方法上均不遺餘力，除投注可觀資金外，並由政策面、法規面及行政管理

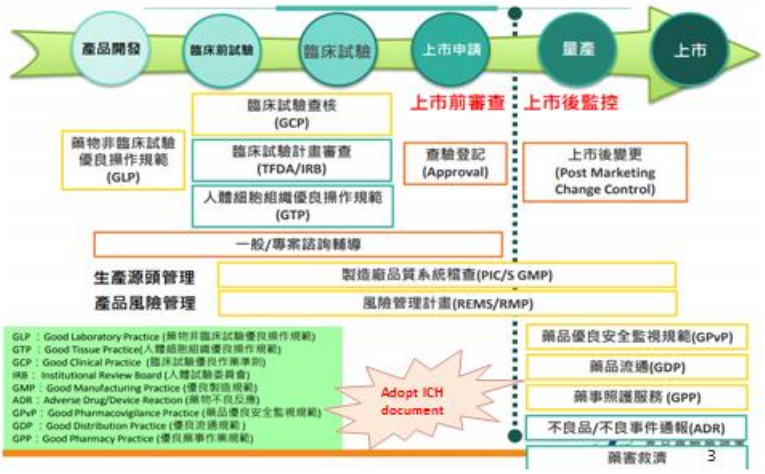
上進行變革與改良，以進一步扶助本土研發團隊的研發產出及廠商的拓展商機，並以各種優惠措施吸引外資投資設廠。這一點確實是值得我們深思參考的。政府大力投資經費推動生醫科技，如何能依實際需要擬定有效政策、修改鬆綁法規、扶助我國生醫產業發展，使得我國的生技醫療產業能於國際上打出一片天地，實在是我國未來不可忽視的問題。

肆、附件

1. 臺灣人生物科技協會(BTBA)年會簡報

衛生福利部 MINISTRY OF HEALTH AND WELFARE

藥品生命週期管理



衛生福利部 MINISTRY OF HEALTH AND WELFARE

歷年新藥核准件數

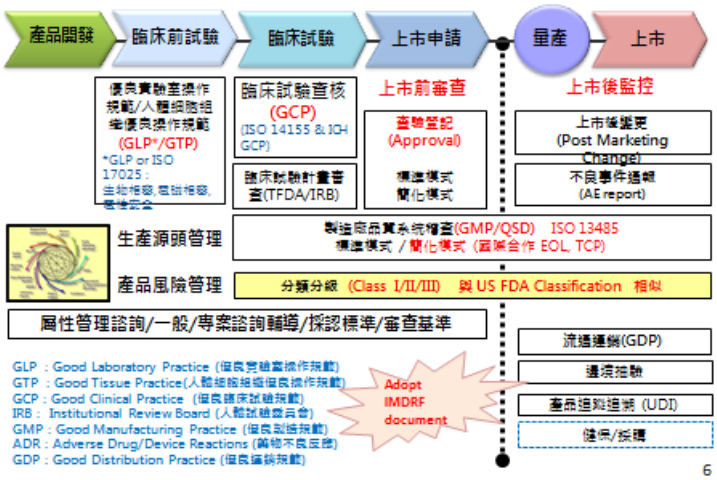
總件數	166							
案件類型	國產				輸入			
案件數	19(11.4%)				147(88.6%)			
百分比	化學製劑		生物製劑		化學製劑		生物製劑	
案件類型	16		3		117		30	
案件數	新成分	4	疫苗	2	新成分	54	疫苗	0
	新複方	1	血液製劑	0	新複方	21	血液製劑	3
	新適應症	0	預唐素製劑	0	新適應症	12	預唐素製劑	0
	新使用途徑	0	基因工程製劑	1	新使用途徑	0	基因工程製劑	27
	新劑型	2			新劑型	13		
	新使用劑量	1			新使用劑量	6		4
	新單位含量	8			新單位含量	11		

衛生福利部 MINISTRY OF HEALTH AND WELFARE

我國與美歐日新成分新藥核准數比較

衛生福利部 MINISTRY OF HEALTH AND WELFARE

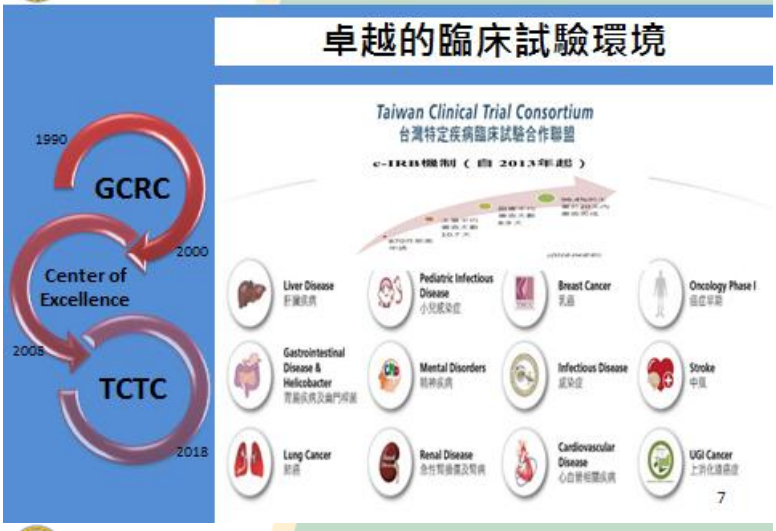
醫療器材生命週期管理



6

衛生福利部 MINISTRY OF HEALTH AND WELFARE

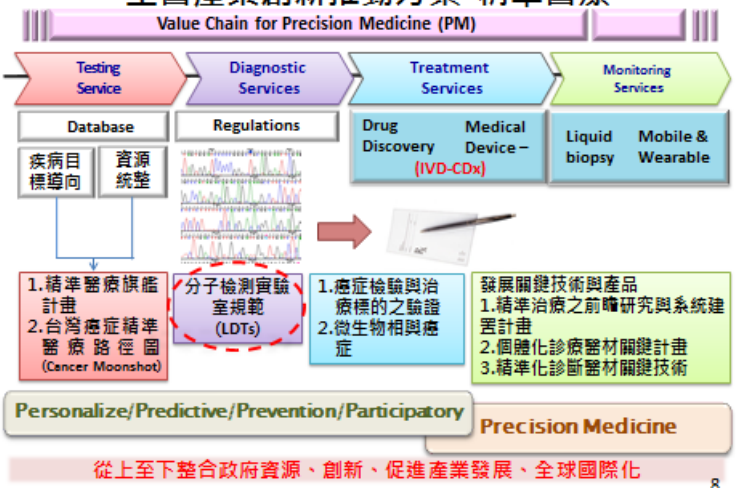
卓越的臨床試驗環境



7

衛生福利部 MINISTRY OF HEALTH AND WELFARE

生醫產業創新推動方案-精準醫療

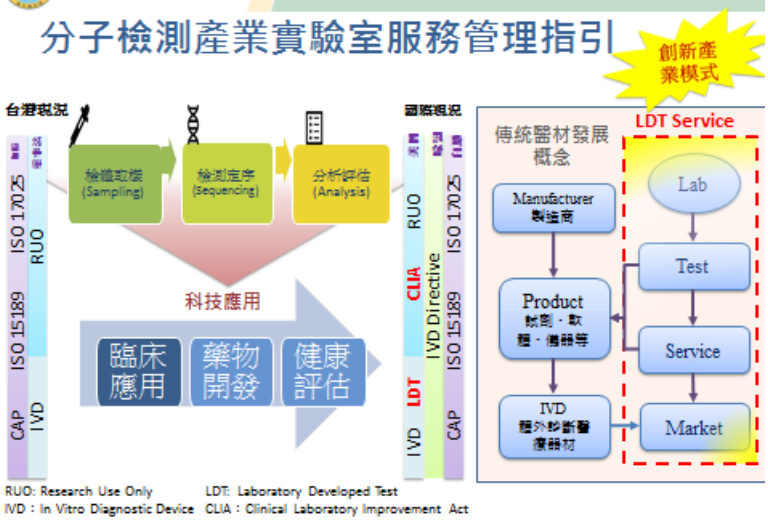


從上至下整合政府資源、創新、促進產業發展、全球國際化

8

衛生福利部 MINISTRY OF HEALTH AND WELFARE

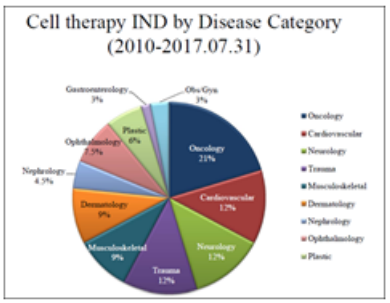
分子檢測產業實驗室服務管理指引



RUO: Research Use Only　　LDT: Laboratory Developed Test
IVD：In Vitro Diagnostic Device　CLIA：Clinical Laboratory Improvement Act

衛生福利部 MINISTRY OF HEALTH AND WELFARE

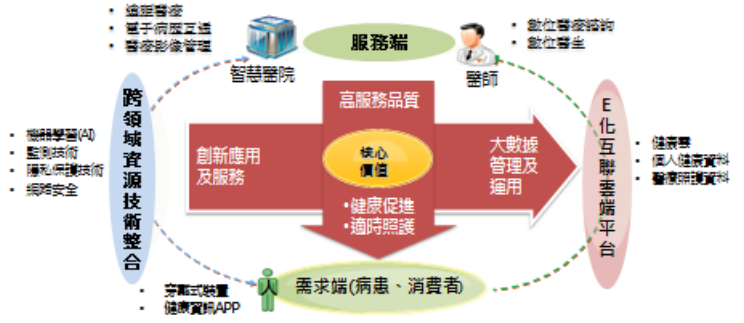
研擬「再生醫療製劑管理條例」草案



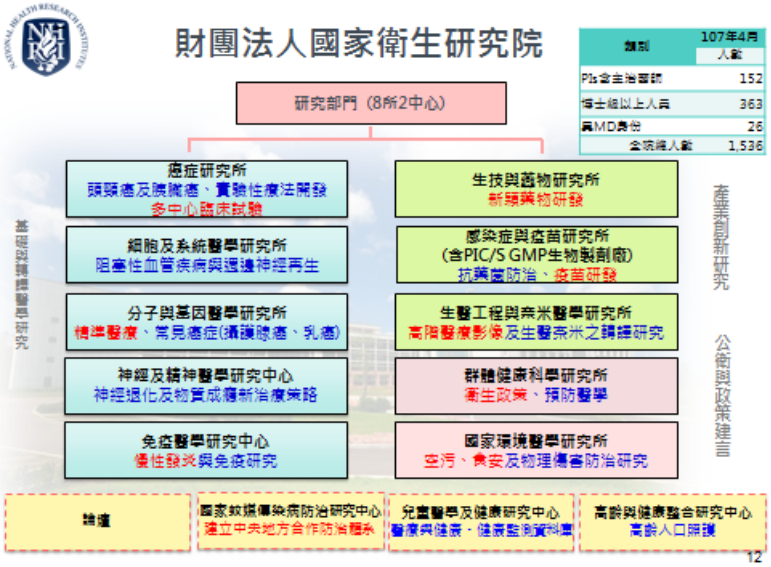
1. 「細胞及基因治療產品管理法」草案，將修正為「再生醫療製劑管理條例」草案。
2. 新法與日本法規架構相似，可核發Conditional approval.
3. 修訂衛福部「特定醫療技術檢查檢驗醫療儀器施行或使用管理辦法」。

衛生福利部 MINISTRY OF HEALTH AND WELFARE

數位醫療照護與應用服務



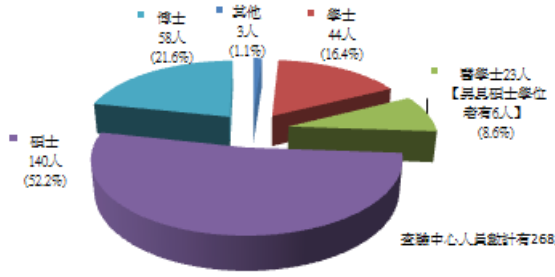
1. 「通訊診療治療辦法」，放寬遠距診療適用範圍，包括住宿式長照及非本國籍之境外病人
2. 「衛生福利資料應用管理要點」，取得當事人同意之產業得申請使用衛生福利資料，創造商業價值。
3. 於蒐集、儲存、分析、顯示、轉換人體健康狀態、生理參數、醫療相關紀錄等處理軟體稱為醫用軟體，其中部分涉及疾病診斷、預防及治療功能之醫用軟體，將以醫療器材列管，須符合醫療器材相關管理規範。
4. 比照 US FDA 21st Century Cures Act，5類低風險的醫用軟體在一定條件下不以醫材管理。



衛生福利部 MINISTRY OF HEALTH AND WELFARE

醫藥品查驗中心

- 財團法人醫藥品查驗中心由行政院衛生署（衛生福利部前身）於 1998 年 7 月 13 日捐助成立。
- 成立目的是提昇台灣醫藥品審查之品質與效率，藉此保障民眾用藥安全及使疾病患者及早獲得所需醫藥品，以達成增進國人健康與福祉。
- 查驗中心結合具醫學、藥學、化學、生物、統計、法律、醫工、醫檢、公共衛生、藥物經濟學、食品科學、食品營養及相關生命科學等專長之專業專職人才。



查驗中心人員數計有268人 (2018.4.30)

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衛生福利部 MINISTRY OF HEALTH AND WELFARE

Thank You for Your Attention!

14

2. pre-BTC 海外諮議會（衛福部相關簡報資料）

行政院 2018 生技產業策略諮議委員會預備會議 (pre-BTC)
Bio Taiwan Committee

2017 總體建議推動成果報告

衛生福利部

2018年 6月4日

2018 pre-BTC

壹、 2017 總體建議推動重點

2017總體建議推動重點 (衛福部)

1. 我國生醫產業切入全球市場之機會與挑戰
   (1)智慧醫療與遠程醫療
   (2)應用健保資料庫創造商業價值
   (3)促成藥品醫材跨境電子商務服務
2. 促進生醫產業發展之醫藥法規環境
   (1)研擬「再生醫療產品管理條例」草案
   (2)研擬精準醫療分子檢測實驗室服務(LDTs)管理指引草案
   (3)成立「生技法規策略諮議委員會」

2018 pre-BTC

智慧醫療與遠程醫療-放寬適用範圍

「長期照顧服務機構法人條例」公告 107.1.31

- 擴大公民營長照服務機構照服員資格認列範圍

「通訊診療辦法」預告 107.1.10 (預計 107.4公告)

- 因應網路時代來臨、科技產品之進步，以及高齡化社會在宅醫療之需求，放寬醫師以通訊方式進行診療
- 醫師法第十一條第二項授權中央主管機關訂定
- 適用情形:

一、急性住院病人，依既定之出院準備計畫，於出院後三個月內之追蹤治療。

二、住宿式長照機構與醫療機構訂有醫療服務契約，其住民之病情需該醫療機構醫師診療。

三、「全民健康保險家庭醫師整合性照護計畫」之會員，其病情需該家庭醫師診療。

四、主管機關認可之遠距照護或居家照護相關計畫之收案對象，執行該計畫之醫療團隊醫師曾於三個月內親自診療。

五、擬接受或已接受本國醫療機構治療之非本國籍，且未具健保身分之境外病人。

我國生醫產業切入全球市場之機會與挑戰

應用健保資料庫創造商業價值

「衛生福利資料應用管理要點」修訂（106.9.10）

- 公告明列取得當事人同意之產業得申請使用衛生福利資料之相關規定。
- 106年12月20日針對生技醫療產業及TRPMA會員舉辦「衛生福利資料加值應用產業說明會」，介紹衛生福利資料庫、使用辦法及規範等，以促進相關產業研發創新，計26個單位與會討論。

2018 pre-BTC

促成藥品醫材跨境電子商務服務

醫療器材

衛福部自101年起陸續公告開放得於網路販售之醫療器材品項，累計至今共計開放低風險第1等級醫療器材721品項及18品項之第2等級醫療器材。

目前符合「居家使用、非侵入性、非植入性、無須專業人員指示操作」四大原則而適合於網路販賣之醫療器材品項均已完成開放，已促成醫材產業於電子商務服務平台行銷。

藥品

針對Business-to-Business，藥品許可證持有藥商倘欲國際行銷其自身藥品，可依相關規定於該公司網站刊登產品資訊。

針對Business-to-Consumer，衛福部已開放藥商、藥局或符合規定之百貨店、雜貨店及餐旅服務商得依相關規定透過網路平台業者網路零售乙類成藥。

我國生醫產業切入全球市場之機會與挑戰

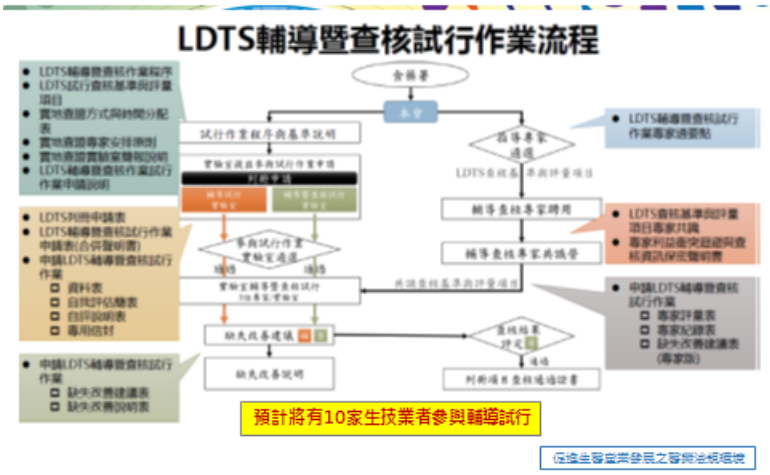
2018 pre-BTC

研擬「再生醫療產品管理條例」草案

1. 「細胞及基因治療產品管理法」草案，將修正為「再生醫療製劑管理條例」草案。
2. 食藥署於107.3.1及107.4.18召開法律專家會議，就「再生醫療產品條例(草案)」之徵詢衛福部法規會委員建議，與會者對本法以專章或專法方式制定持有不同立場，惟尊重衛生福利部之立法政策，建議若為專法，應於總說明詳細載明制定專法之考量，並說明與現行藥事法管理差異以及醫療技術之處。
3. 衛福部醫療技術特管辦法預計於107.7.31完成。

2018 pre-BTC

精準醫療分子檢測實驗室服務(LDTs)管理指引草案(1/2)



2018 pre-BTC

精準醫療分子檢測實驗室服務(LDTs)管理指引草案(2/2)

2018 pre-BTC

成立「生技法規策略諮議委員會」

衛生福利部生技法規策略諮議會設置要點　2018.1.15

(一)生技法規策略之諮詢建議事項。

(二)創新科技研究與技術發展趨勢之諮詢建議事項。

(三)生技醫藥產業發展及其創新服務模式之諮詢建議事項。

(四)其他與生技法規策略相關之諮詢建議事項。

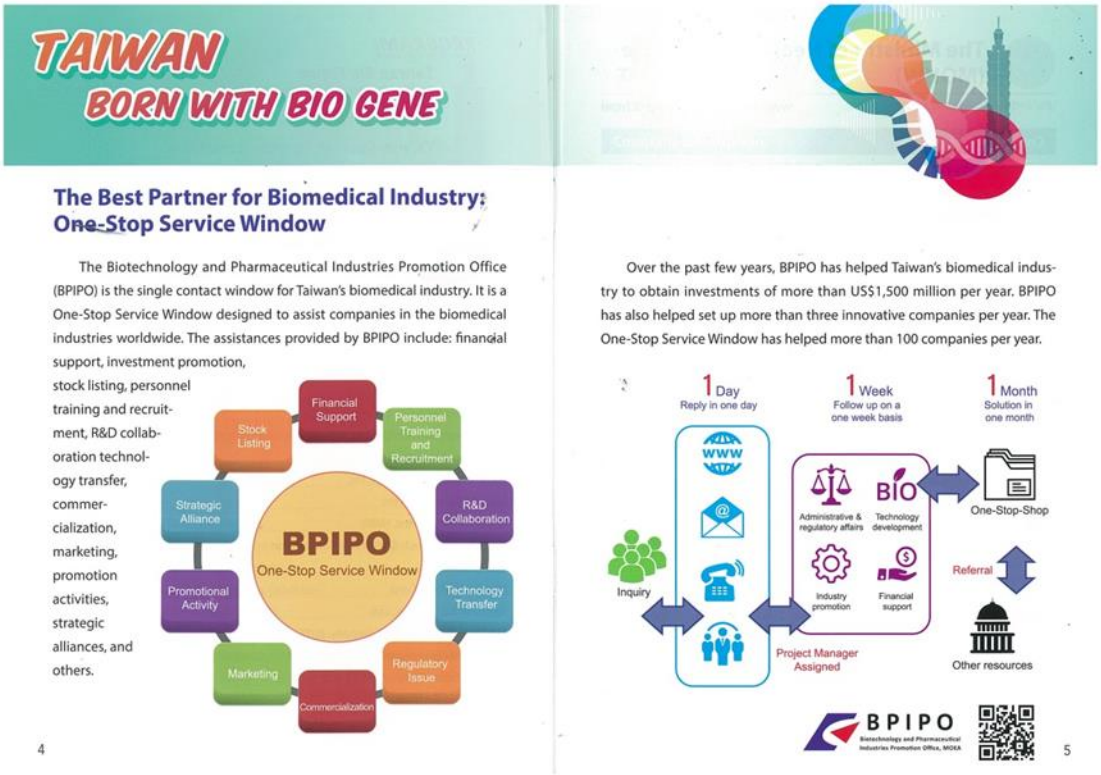
2018.5月初 將召開第一次諮議會

Date	6/2(六)	6/3(日)	6/4(一)	6/5(二)	6/6(三)	6/7(四)	6/8(五)	6/9(六)
上午	搭乘長榮(BR030) 08:00直飛紐約 A.專車前往波士頓 B.紐約轉機 17:30抵達	8:30-10:00 波士頓臺灣人生物科技協會(BTBA)年會 9:00-18:00 Taiwan Bio Forum(DCB & MJNE)	8:00-19:00 佈展 08:00-17:00 RFSI conference 09:30-13:00 Pre-BTC meeting	7:00-17:30 Business forum區洽商 10:30-17:00 展館洽商 10:00~11:00 Mass challenge	參訪Merck KGaA LifeScience總部、M Lab、Healthcare研發中心	07:00 Gloria Breakfast meeting 參訪J&J Innovation Center和LabCentral		A+B. 長榮01:25紐約返台05:15(+1) C. 國泰CX-811 01:50由波士頓飛香港
下午	C.搭乘國泰(CX523) 13:45香港轉機18:15抵波士頓	8:00-19:00 Registration open & 佈展 16:00 BIO 2019 Priority Pavilion	14:00-14:30 華文記者會	16:00-17:00 台灣館開幕(BPIPO)	參訪Merck & Co.(MSD默沙東) 16:30-16:45 Global Innovation Hub Taiwan		A.下午專車前往紐約 B. 波士頓18:30飛紐約 20:04	6/10 C. 國泰CX564 08:10香港10:00抵台北
晚上	19:00-21:00 駐波士頓辦事處徐佑典處長晚宴	18:00-20:00 海外科技人士及社團交流座談會	18:30-21:30 Taipei Night	18:00 致謝晚宴 (BOST)	17:30-21:00 US Taiwan Night-AI in Healthcare (MJNE)	16:30 撤展		

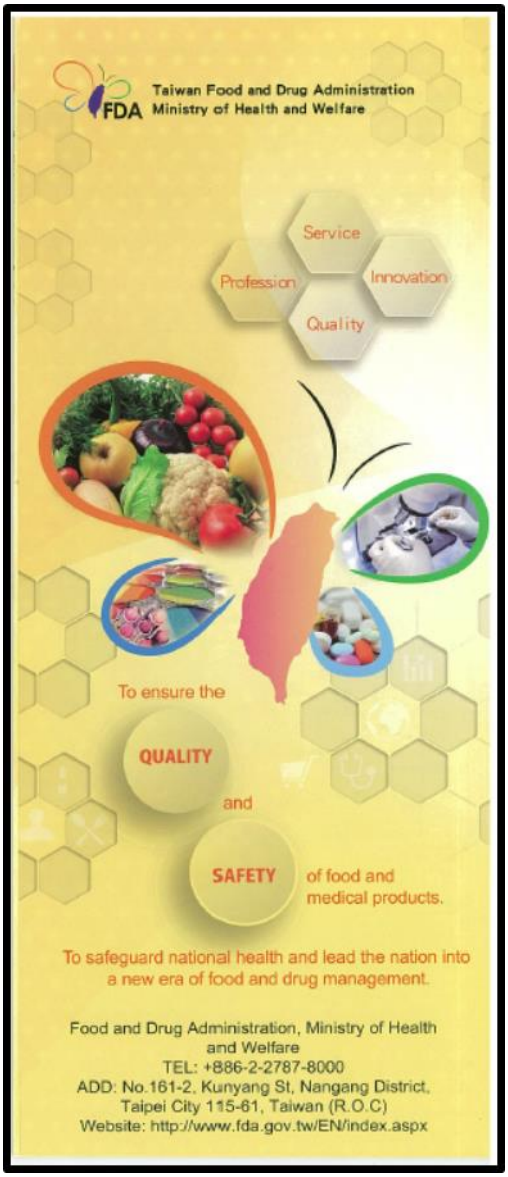
*藍字為台灣代表團相關活動，黑字為大會活動，紅字為官方團活動，綠字為交流活動(自行註冊/繳費)

5

3. 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」做為展出主題。



4. 食藥署文宣資料–簡介有關藥品、醫材、食品、化粧品之管理。



5. 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。

The Ministry of Health and Welfare (MOHW)

www.mohw.gov.tw/mp-2.html

Company Description

The Ministry of Health and Welfare of the Republic of China (MOHW) is the Executive Yuan ministry responsible and the highest authority for the administration of the public health system, social welfare, affordable and universal health care, hospitals, pharmaceutical, immunization programs, disease prevention, supervision and coordination of local health agencies in Taiwan. The mission of MOHW is to promote the health and well-being of all Taiwan citizens.

The MOHW's diversified responsibilities include health policy 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. The MOHW will continue to pursue the goals of effective teamwork and coordinated planning for health and welfare services that meet changed needs of Taiwan citizens.

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Sectors To Promote the Health and Well-Being of all Taiwan Citizens

6

Taipei City

www.biodriven.taipei/en/

Company Description

Taipei is the national hub for biotechnology and medical research. There are nearly 400 biotech companies in the city. The annual revenue of these companies is around 6 billion USD, accounting for 50% of that of Taiwan's biotechnology industry. Academia Sinica and eight major medical centers are located in Taipei, while more than 20 universities and vocational colleges in the city have biotech departments.

Taipei city is implementing the Nangang Biotech cluster BOT project which is scheduled to be completed in May 2021. Taipei City Government also provides one-stop services to incoming businesses that assist them in investment consultation and finding office space, subsidies and funding.

Contact Information

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Address No. 1, City Hall Rd., Xinyi Dist., Taipei City 11008, Taiwan (R.O.C.)

Sectors Invest Taipei Office, Taipei City Government

7

National Biotechnology Research Park (NBRP)

nbrp.sinica.edu.tw

Company Description

NBRP located near the world-class research campus of Academia Sinica and the Nangang Biotech Plaza in Taipei city is a research-oriented biopark for clustering and promoting Taiwan biotech industry. NBRP provides state-of-the art platform technologies for research-driven discovery and drug development, as well as fosters biotech entrepreneurship. With the support from Academia Sinica, Ministry of Science and Technology, Development Center for Biotechnology, and Taiwan Food and Drug Administration, NBRP serves as a single enterprise to provide cutting-edge talents and interactive environment for facilitating growth and expansion of collaborations with innovative biotech companies and international Pharma.

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Sectors Incubation center for Biotech Corp. and Pharma; Technical service and regulatory consultation for drug development

8

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 348 beds for medical treatments and clinical trials when phase 1 is completed in 2020. In addition, the Park will also develop featured clinics and medical services, and to provide craniofacial reconstruction, cardiovascular treatment, joint replacement and other exquisite medical treatments. The Biomedical Science Park is expected to pilot global biomedical industry technology development and turns out to be the model of biomedical science park in Asia.

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Sectors New drugs, High-end medical devices, Featured Clinics

9

Central Taiwan Science Park

www.ctsp.gov.tw/english/00home/home.aspx?v=20

Company Description

Central Taiwan Science Park (CTSP), as an emerging technology hub for innovation-driven industries, has formed an effective biotechnology cluster with high-tech companies focusing on medical & assistive devices, vaccines & drugs, dietary supplements, advanced agricultural products, etc.

CTSP endeavors to facilitate the development of the biotech industry by fostering an environment where industrial, academic and medical resources are integrated. In response to the sustainable development in an ageing world, CTSP is fully committed to developing new solutions that better support public needs, such as minimally invasive surgical devices and intelligent assistive technologies.

Contact Information

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Sectors Medical & Assistive Devices, Vaccines & Drugs, Dietary Supplements, Advanced Agricultural Products

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.

Contact Information

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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

Taiwan Stock Exchange

www.twse.com.tw/en/

Company Description

The Taiwan Stock Exchange (TWSE) started operation on Feb. 1962. With the objective of creating a fair, efficient and safe trading environment, the TWSE operates in line with government policy to develop a healthy securities market.

Products listed on the TWSE include Taiwan Depository Receipts (TDRs), Warrants, Stocks and Exchange Traded Funds (ETFs). As of 2017, there were 924 listed companies (including TDRs) with a total market capitalization of US$ 1.07 trillion, and ranked No. 18 in the world.

TWSE, through its listing advisory guidance and market oversight functions, actively promotes sustainable operation of listed companies with a special focus on economic development, social responsibility, and environment sustainability.

Contact Information

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Sectors Responsible for operating and developing Taiwan securities market.

Taipei Exchange

www.tpex.org.tw/web/index.php?l=en-us

Company Description

Taipei Exchange (TPEx) is an integrated and multifunctional exchange founded in 1994. TPEx has been an official member of the World Federation of Exchanges (WFE) since 2011. TPEx has built an efficient fund-raising platform that supports the growth of small and medium-sized enterprises and helps mid-sized corporations become stronger. Our market provides a tiered structure, which ranges from the micro-enterprise supporting Go Incubation Board for Startup and Acceleration Firms (GISA), to the Emerging Stock Board (ESB) for negotiated-price trading of pre-IPO companies, and on to the Mainboard (MB) for trading more established companies. This GISA to ESB to MB structure supports enterprises' growth through all their stages of development and has contributed to the strong growth of Taiwan's capital markets.

Contact Information

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Sectors Stock Market, Bond Market and Derivatives Market

Academia Sinica (AS)

www.sinica.edu.tw/en

Company Description

Research Institutes:

Academia Sinica(AS)

In addition to basic research, Academica Sinica takes a leadership role in launching new initiatives in applied areas to meet a broad spectrum of social, medical and technological needs in Taiwan. Among its twenty-four research institutes and seven research centers are the Institute of Cellular and Organismic Biology, Institute of Biological Chemistry, Institute of Molecular Biology, Institute of Biomedical Sciences, Agricultural Biotechnology Research Center and the Genomics Research Center.

Contact Information

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Sectors Research Institution, Technical Transfer

14

Development Center for Biotechnology

www.dcb.org.tw

Company Description

The Development Center for Biotechnology(DCB) was founded in 1984 by Taiwan's Ministry of Economic Affairs, tasked with establishing the biotechnology industry in Taiwan. We strive to act as the industry's partner, coordinating resources among government, academia and private companies. DCB remains a key force in building and upgrading Taiwan's biomedical infrastructure, developing key technologies, and growing Taiwan's professional workforce.

Our ultimate aim is to improve the quality of life for the people of Taiwan and the world. To this end, DCB fosters international partnerships and collaborations with research institutes and global biopharmaceuticals throughout Asia and the world.

Contact Information

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Sectors Research Institution, Protein Drugs, Small Molecule Drugs, Botanical Drugs

15

Industrial Technology Research Institute

www.itri.org.tw/eng/

Company Description

Industrial Technology Research Institute (ITRI) is the leading nonprofit 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.

Contact Information

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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.

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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 institutions, 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.

Contact Information

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Sectors ATRI is a development platform for industrialization of agriculture technology and commercialization of innovative business, provides agri-enterprises, farmer groups and farmers with agriculture technology, commercialized products, industrialization service.

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National Applied Research Laboratories (Narlabs)

www.narlabs.org.tw

Company Description

Narlabs provides R&D platforms and technical services in fields such as "Environmental Monitoring and Hazard Mitigation", "Information and Communication Technology", "Biomedical Science and Technology", and "Science and Technology Policy Research". In the field of biotechnology, we establish a one-stop service platform conforming to ISO 13485 standards for medical devices, and provides high-quality R&D service equipment in biomedical testing. We also provide comprehensive tumor test-related resources and services including specialties of oncology, genetic modifications, animal-related experimentation, 3D medical imaging, and veterinary.

NARLabs offers solutions to future problems that a society may face and prompts innovative research to go beyond laboratories with an aim of becoming a supportive force for human life and a better world in the future.

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

18

National Health Research Institutes (NHRI)

www.nhri.org.tw

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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Sectors

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Taiwan Bio Industry Organization (BioTaiwan 2018)

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

Company Description

The Taiwan Bio Industry Organization (TBIO), established in 1989, is the largest and the most influential biotechnology association in Taiwan. TBIO represents more than 300 members ranging from companies and academic institutes to government bodies, encompassing a wide range of bio-industry sectors including innovative healthcare, agricultural, industrial and environmental biotechnology. Our mission is to foster the development of biotechnology industry especially on the globalization and industrial training, and provide advocacy and communication services for our members.

The 16th annual BioTaiwan Conferences and Exhibition (www.bio-taiwan.com), the largest biotechnology gathering in Taiwan, will be held July 18-22, 2018 in Taipei. BioTaiwan 2018 offers an ideal platform to discover new business and partnering opportunities in one of the most underexplored biotech locations in Asia.

Contact Information

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Sectors Association

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BioIPSeeds TRPMA

www.ipseeds.net, www.trpma.org.tw

Company Description

BioIPSeeds is a global P2P platform utilizing blockchain technology to promote biomedical open innovation. Targeting at academia and industry members, BioIPSeeds speeds up technology transfer and commercialization process of early researches by providing module functions of IP Notary, Online NDA and Confidential Data Exchange. Industry members can easily search early R&D projects and access to researchers on the BioIPSeeds.

Taiwan Research-based Biopharmaceutical Manufacturers Association (TRPMA) is a non-profit organization composed of 28 R&D innovative biopharma companies. TRPMA is a window in Taiwan for promoting biopharma clinical trials, modern regulations, business partnerships and international collaborations.

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Sectors
- Innovation Driver
- International Collaboration
- Academia-Industry-Government Platform
- Business Partnership

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Medical and Pharmaceutical Industry Technology and Development Center

www.pitdc.org.tw

Company Description

Partnership with medical and pharmaceutical industry to promote technology advancement and market development

In order to strengthen Taiwan's medical and pharmaceutical industry to meet the need of development, performance, and globalization, the Medical and Pharmaceutical Industry Technology and Development Center (PITDC) was established jointly by the government and pharmaceutical companies in 1993.

PITDC has integrated resources from government, academia, and industrial partners to serve Taiwan's pharmaceutical and biotech manufacturers, R&D companies, and medical devices and technology industry to enhance core competence and global competitiveness. The mission is to cultivate a key technology platform, upgrade the industry, and promote internationalization.

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Sectors
1. Discovery Research of Botanicals Drugs
2. R&D of Pharmaceuticals
3. R&D of Medical Devices
4. Laboratory Accreditation/validation
5. Regulatory Services
6. Promotion and Market Development Services

ACRO Biomedical Co., Ltd.

www.acrobiomedical.com/index.php?lang=en

Company Description

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

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Sectors Collagen Matrix, Bone Graft, Collagen Membrane, Collagen Ophthalmic Matrix, Scar Care and Skin Care Products, Atelo-collagen, etc.

Andros Pharmaceuticals Co., Ltd.

www.androspharma.com

Company Description

Andros Pharmaceuticals Co., Ltd. (Andros) is a bio-pharmaceutical company engaged in developing novel drug delivery technologies and products, including topical new dosage form, and non-viral gene delivery system.

Andros core technology focuses on lipid-based/polymer-film topical drug delivery system, of which Andros utilizes to generate a pipeline in pain management with a product in Phase II. In addition, the liposomal non-viral gene delivery technology enables siRNA/anti-sense oligonucleotide to be effectively delivered into target cells in cancer therapy.

Combined with platform technologies, in-house development expertise, and a PIC/s GMP certified manufacturing facility, Andros is in a great position to develop novel new dosage form that are both unique and of significant market potential.

Contact Information

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Sectors Drug Delivery System, Topical New Dosage Form, Non-viral Gene Delivery, Pain Management

Aquavan Technology Co., Ltd.

www.aquavan.com.tw

Company Description

The platform developed by Aquavan gives novel and effective new molecular entities for unmet medical needs. For instance, the No.4 Hualien Bitter Melon which cultivated by Taiwan government is organically planted and extracted by Aquavan has been scientifically proven for its efficacy in controlling diabetes. Furthermore, Aquavan found and purified several molecules via this cutting-edge platform shows the awesome anti-cancer results in breast cancer and colon-rectal cancer. The Phase I clinical study will be conducted in December 2018.

Aquavan has More than 500 herbs identities in its database, in the meantime, we're building up a fascinating Functional Herbs API Standard Center. Aquavan expects to gain more NME to meet the unmet medical demand in the near future.

Contact Information

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Sectors NME:
- Oncology
- Cardiovascular disease
- Diabetes
- Depression

Extraction/Purification, Mass Production.

Bio Preventive Medicine Corp.

www.bpmbiotech.com

Company Description

Bio Preventive Medicine Corporation (BPM) is a clinical-staged biotech company, focusing on developing novel biomarker-based diagnostics for chronic diseases and oncology. Our first product, DNlite, is a non-invasive urinary test for predicting/monitoring the progression of Diabetic Kidney Disease (DKD). BPM is a leading company in the novel renal biomarker area. We can help in the development of drugs not only in evaluating renal efficacy but also renal safety. BPM welcomes strategic partnerships in expanding the product pipeline and technology platform for biomarker detection. In addition to co-development, BPM is looking for international partnership for commercialization.

Contact Information

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Sectors Diagnostics

Caliway Biopharmaceuticals Co., Ltd.

www.caliway.com.tw

Company Description

Caliway focuses on exploring novel drugs for obesity and medical aesthetical products. Four products are on our pipeline: (1) CBW-511: an oral form to treat obesity and NAFLD/NASH. Phase II for obesity will finish recruitment by 2018. (2) CBL-514: a lipolytic injection to reduce local fat. It can also be used to treat mid-to-severe obesity (including rare disease: Prader-Willi syndrome) and NASH. CBL-514 already entered Phase I/II clinical trial for non-surgical fat reduction. (3) CBA-539: a skin-whitening and anti-aging injection, and (4) CBO-012: an injection for osteoarthritis therapy. CBA-539 and CBO-012 will enter clinical trial in 2-3 years.

Contact Information

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Sectors Innovative new drugs development, obesity therapy, medical aesthetical

EirGenix, Inc.

www.eirgenix.com

Company Description

EirGenix, Inc., is a contract development and manufacturing organization (CDMO) that offers high quality and cost-effective services to clients around the world. The firm owns and operates two cGMP compliant plants, producing microbial and mammalian biologics starting from cell line development to drug substance release. Additionally, it facilitates product and process development and analytical testing for all stages ranging from pre-clinical to commercial manufacturing. EirGenix is currently building a commercial-scale facility that has the capacity for twelve 2000L-scale single-use bioreactors. The new commercial facility will be operational at the end of 2018. Aside from increasing production capacity, EirGenix has also developed seven product pipelines including mAb biosimilars and niche biologics. Recently, one of EirGenix's mAb biosimilar product has entered the Global Phase 3 Clinical Studies.

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Sectors CDMO, ADC, Biosimilar, Biologics

G&E Biotechnology Co., Ltd.

www.geherbs.com.tw

Company Description

G&E (Taiwan Stock Code 4911) is a biopharmaceutical company since 2002. G&E focused on the development of SR-T100 new drug for the treatments of cancer, genital wart, common wart, actinic keratosis and treatment/prevention of skin aging. The clinical trials of SR-T100 have been approved by FDA in the treatment of genital warts, common warts, and actinic keratosis. SR-T100 also has superior effect to retinoic acid in the treatment of skin aging. The SR-T100 injection (Solarise) contains >99% purity of API for anticancer treatment with the potential of selectively kill cancer cells without damaging the hematopoietic and immunological systems. G&E has gained several talent patents in most countries in the world. G&E also complies with PIC/s GMP and manufactures Hepanamin® which is a high bioavailability silymarin for the treatments of liver diseases.

Contact Information

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Sectors
- **SR-T100 gel and injection**
  - Genital warts, common warts and actinic keratosis treatments
  - Skin cares for anti-aging and anti-inflammation
  - Contains >99% purify of Active Pharmaceutical Ingredient
- **Hepanamin® capsule – high bioavailability silymarin**

Far East Bio-Tech Co., Ltd.

www.febico.com.tw

Company Description

FEBICO (Far East Bio-Tec. Co., Ltd.) was established in 1976 by our founder Mr. C. C. Chiueh. Our current operational targets are classified as four main axes : "Nutrition Health Care", "Biomedical Reagents", "New Drug Development" and "Green Energy Environmental Protection".

We have the following plans and expectations for the future development:

(1) Continuously improve production technology and become a world-class R&D and production center for microalgae.
(2) Global business philosophy for sustainable growth, have been on sale all over 63 contries.
(3) The antiviral technology on influenza virus, enterovirus, hepatitis B virus, and Ebola virus had been further applied on new drugs developments.
(4) Using microalgae for energy conservation and carbon reduction.

Contact Information

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Sectors Nutraceuticals, New Drugs Development, Antiviral Remedy, Green Superfoods, Beauty Skin Care, Color For Life Sciences, Solargen

Health Ever Bio-Tech Co., Ltd.

www.hebiotech.com

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

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Sectors Research and Development of Botanical New Drugs

King's Ground Biotech Co., Ltd.

www.kgbio.com.tw

Company Description

Over the decades, KG Bio has evolved into a pioneer in using the nature resources and agriculture manufacturing by-products as raw materials and a magician in turning the wastes into the valuable assets. KG Bio has dedicated in promoting AGP free feeding practice and becoming the animal NGP leading provider.

One of the company's key products, VIVA, is a certified functional feed additive with the ability to improve the animal's health by decreasing stress induced discomfort, improving liver function and immunity and weakening pathogen infection rate. It is the feed millers and farmers best AGP alternatives with no residues in meat or eggs and no withdrawal period.

Contact Information

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Sectors Animal/Aqua feed additives, functional food for human, Agriculture circular economic research and development

LumiSTAR Biotechnology, Inc.

www.lumistar.com.tw

Company Description

LumiSTAR Biotechnology is an expert in designs of a range of protein-based indicators for cellular dynamics measurements. Our expertise includes photochemistry, induced pluripotent stem cell (iPSC) technology, optogenetic tools and regenerative medicine. All of these technologies are packaged into a high content all-optical platform for phenotypic screening, drug discovery, and toxicity testing; the long-term goal is for precise/personal medicine. This high content platform enables customers to do their drug screening tasks in a more efficient and economical way. We offer a variety of functional assays for different disease modelling; customization service is also available.

Contact Information

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Sectors High Content Drug Screening Assays; Precise Medicine; Auto-luminescent Products; AI-Machine Learning

Mao Ying Genetech Inc.

www.mygenetech.com

Company Description

Mao Ying Genetech Inc., founded in Taipei in 2012, is a research and development oriented company focusing in bioinformatics data mining. We have successfully identified gene markers with potential applications to diagnosis or therapy by mining biomedical data followed by clinical validation including OncoDx and MetaDx for cancer diagnosis and a set of markers for human organ identification.

Contact Information

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Sectors OncoDx- to determine the malignancy of a tumor specimen
MetaDx- to find the primary site for a metastatic cancer
OrganID- to identify the anatomic site of unknown human tissue

Mycenax Biotech Inc. (MBI)

www.mycenax.com.tw/en/

Company Description

Established in 2001, MBI has served our clients from Asia Pacific, Europe and North America for over 15 years to satisfy their business needs from cell line development to commercial manufacture with a data-driven, science-based and result-oriented approach. Equipped with CMC based platform, disposable technology and PIC/S GMP manufacturing system, we dedicate to deliver satisfactory results by providing a high quality, cost-competitive and full-line solution to develop and manufacture biological products. In addition, we are also focused on new biological entities and biosimilars development and looking for strategic partnership from early stage opportunities to product commercialization. Our mission is to be the best trustworthy partner in Asia Pacific to accelerate clients' biopharmaceutical developments. Our vision is to launch value added and affordable products from bench to better human life.

Contact Information

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Sectors Service: Biological CDMO service
Pipeline (prominent):
• TuNEX (anti-TNF medication against Rheumatoid Arthritis)
• LusiNEX (tocilizumab-similar)

Naturewise Biotech & Medicals Corporation

www.naturewise.com.tw

Company Description

NaureWise Biotech & Medicals Corporation, a new drug development company founded in the year of 2000, focuses on the botanical drug and small molecule therapies. By taking advantage of our profound knowledge in herbal medicines, we use systematic approach to study and modify natural compounds to look for candidates to be used in diseases in need of better treatment modalities. The study of isoform-selective HDAC inhibitors is one of the company's important programs, and has received the Gold Award of Innovation twice in Taipei City's Biotech Award Contests. One of our products in the portfolio, NBM-BMX, a specific HDAC8 inhibitor, has superior safety and efficacy profiles to non-selective HDAC inhibitors.

Contact Information

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Sectors Isoform Selective HDAC Inhibitors
Research and Development of Small Molecule & Botanical Drug

OBI Pharma, Inc.

www.obipharma.com/en

Company Description

OBI Pharma, Inc., is a Taiwan biopharmaceutical company that was established in 2002. It is publicly-listed on the Taipei Exchange (TPex ticker: 4174). OBI's mission is to develop and license novel therapeutic agents for unmet medical needs against cancer targets such as Globo Series (including Globo H, SSEA 3, SSEA 4), AKR1C3, and other promising targets. Globo Series and AKR1C are highly expressed in cancers of unmet need including Breast, Ovarian, Gastric, Lung, Liver Prostate and Esophageal.

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Sectors Biopharmaceutical, Biotech, Immuno-oncology, Novel Cancer Treatment

PharmaEssentia Corp.

www.pharmaessentia.com

Company Description

PharmaEssentia Corporation (Taipei Exchange: 6446) is a fully integrated global biopharmaceutical company delivering efficacious, safe and cost-effective therapeutic products for the treatment of human diseases while aiming to bring long lasting value to stakeholders.

PharmaEssentia was founded in 2003 by a group of Taiwanese-American executives and high-ranking scientists from leading U.S. biotechnology and pharmaceutical companies in order to develop treatments for myeloproliferative neoplasms, hepatitis, and other diseases. The company is committed to the improvement of health and quality of life for patients suffering from these diseases.

The Company's world-class cGMP biologics facility in Taichung is certified by the Taiwan Food and Drug Administration (TFDA) and is designed and operated to be compliant with all U.S. FDA and EMA requirements.

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Sectors Ropeginterferon alfa-2b (P1101)

Simpson Biotech Co., Ltd.

www.simpsonbiotech.com

Company Description

Simpson Biotech Co., Ltd. (SBC), established in 1998, is a privately held Co. located in Taiwan focusing on: 1>. Bacteria Rapid Capture & Detection System based on a bacteria-binding molecule (Pat. Pending) mainly for food safety usages. 2>. Fermentation of medicinal fungus and enzymatically hydrolyzed bioactive natural compounds/ingredients used for dietary supplements and/or for drug development. In 2017, SBC launched hydrolyzed seaweed formulations targeting for diabetes GI control and immune regulation. 3>. A Recombinant Proteins & Industrial Enzymes Purification Platform using patented starch-binding protein for OEM services. SBC has won numerous awards and 52 patents issued.

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Sectors (1) Bacteria Rapid Detection
(2) Anti-Inflammation Drug
(3) Natural Dietary Supplement
(4) Recombinant Protein

TLC (Taiwan Liposome Company, Ltd.)

www.tlcbio.com

Company Description

TLC is a clinical-stage specialty pharmaceutical company dedicated to the development and commercialization of best-in-class novel nanomedicines that maximize the potential of its proprietary lipid-based drug delivery platforms. TLC's highly scalable and versatile technologies enable the development of sustained release and targeted therapies capable of reducing toxicities and improving effectiveness. Lead programs include TLC599 for osteoarthritis pain, TLC399 for eye diseases, TLC590 for postsurgical pain and TLC178 for sarcomas. TLC has global commercial partnerships, an experienced management team and offices in 8 locations worldwide.

Contact Information

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Sectors Lipid-based drug delivery, Sustained release, Targeted delivery, Pain management, Ophthalmology, Oncology

TRITECH Biopharmaceuticals Co., Ltd.

www.tritechbiopharm.com

Company Description

TRITECH focuses on developing non-invasive drug delivery system since 2003. We are interested in transforming some ingredients into transdermal and topical forms. Those drugs which are oral dosages but not friendly-used or causing severe side effects will be the first priority to select as the candidates.

Based on Franz Cell technology, we construct a direct high throughput screening platform (DHTSP) for selecting chemical enhancers more efficiently to design our drugs. Through this core technique, we have developed several transdermal formulations.

We aim to provide innovative medical care with low side effects, high patient-compliance, long-lasting treatment for people.

Contact Information

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Sectors Transdermal drugs formulating

TTY Biopharm Company Ltd.

www.tty.com.tw/en-us/

Company Description

TTY is a biotech pharmaceutical company advanced in special formulation drug development, focus on Liposomal products and Microsphere formulation platform and international marketing. On one hand, TTY is continuously improving ability in areas such as international technical documentation formats (CMC, CTD), and manufacturing process which matches EMEA and FDA specifications. On the other hand, TTY continues to select the suitable collaborative partners for new drugs development around the world. Other than continuing operation in Taiwan, TTY is entering the international market through developing high barrier and concept-proved new drugs and special formulation generic products. In the future, TTY will continue its cultivation of target markets to expand geographic coverage and become the best partner with the best drug development and marketing capabilities for international innovation companies in global market.

Contact Information

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Sectors Products Sales and Marketing, Contract Manufacturing Organization, Contract Development and Manufacturing Organization and Contract Research Organization

WeMED Bio-Tech Inc.

www.wemed-biotech.com/

Company Description

WeMED Bio-Tech Inc., funded since April 2015, is an innovative medical device R&D company spin off from the Bio-Image Lab leaded by Prof. Woei-Chyn Chu in the institute of biomedical engineering, National Yang-Ming University, Taiwan, ROC. We started from clinical unmet needs, find the solutions for the problems they encountered, and design state-of-the-art medical devices to become the best assistant for surgeons in the clinical environment. In the past few years, we have had got 11 patents (US, EU, JP, CN and TW), 2 awards in 2017 exhibition of future tech (hosted by MOST, Taiwan), 1 FDA 510k medical device approval and several science articles published on world famous SCI journals. With the assistance of Taiwan Supra Integration and Incubator Center (Si2C) leaded by its former chief consultant Dr. Su Huai-Ren, we moved into Hsinchu biomedical scientific park which was considered to be the most famous biotechnology ecosystem in Taiwan since 2015.

Contact Information

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Sectors Main Products: IntraMedullary Endo-Transilluminating Device (iMET): An innovative medical device that help orthopedic surgeons solving the distal screw hole targeting problem for intramedullary nailing operation.

Zih Yuan Tang Biotechnology Co., Ltd.

www.zih-yuan-tang.com

Company Description

ZIH YUAN TANG Biotechnology Company was founded in 2005 by a group of specialists from various fields. Through the research cooperation with professors in College of Medicine, National Taiwan University, some active principles from herbal medicines were found useful for cancer and metabolic diseases.

After several years of efforts in research, the **small molecule drugs** for therapeutic use in diabetes, **diabetic wound healing** and **diabetic retinopathy** were found. In animal study, a **prominent therapeutic effect** was found at very low administration dose. Patents of the therapeutic uses of these principles are issued in multiple nations recently.

We appreciate the cooperation with other pharmaceutical companies in development of these principles as therapeutic medicines.

Contact Information

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Sectors Small molecular drug for diabetes and Retinopathy

6. 2019 北美生技展（2019 Bio International Convention）宣傳資訊，將於賓夕法尼亞州費城舉辦。