

## BIOTECHNOLOGY INDUSTRY OVERVIEW

# Taiwan

**PREPARED BY:** DCB Taiwan  
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### CORE CAPABILITIES

- A. The biotechnology industry is the only prioritized industry whose development is promoted through careful legislation by the government.
- B. Domestic upstream biotech R&D energy is sufficient.
- C. The government assigns a dedicated unit, e.g. the Center for Drug Evaluation, which has 10 years of experience, to engage in the establishment of the regulatory environment on par with international counterparts and provide counseling and consultation services.
- D. Compared with other countries in the Asia Pacific region, our country is capable of conducting clinical trials for Chinese and Western drugs whose quality and quantity are both leading in Asia, and hence suitable for development of sponsored-clinical trial industries.
- E. The cGMP international validation standards have been carried out comprehensively in our country. Our domestic pharmaceutical manufacturers are experienced in developing generic drugs.
- F. Abundant Chinese talents in biotech and medicine technology in our nation and overseas.
- G. Taiwan's sub-tropical climate is its advantage to develop subtropical agricultural biotechnology and segment the market from that for temperate products from advanced countries.
- H. Rich accumulation of related health insurance information and patient data.
- I. The traditional agricultural technology is quite advanced, which is a niche in the development of the agricultural biotechnology industry.

### Opportunities:

- A. Living standards in Asia Pacific are enhanced and economy is growing quickly with promising market prospects.
- B. There are more and more cross-national strategic alliances and technical transfers among biomedicine companies.
- C. Under the trend of international division of labor, there is room for developing the R&D industry

and the high value-added precision processing industry.

- D. Decoding of human genome has brought about tremendous business opportunities. Entrance at the right time is full of development potential.
- E. Biotech products are high value-added with a long product lifespan and a long value chain. There are segments that can be pitched in from R&D to product marketing.
- F. Biomedicine R&D service industries (R&D strategy consultation, technology evaluation, design and R&D, intellectual properties and technical transfer services, contract research organizations, and start-up incubation service) are flourishing.
- G. The cross-strait political relationship has been greatly improved on the consensus of “putting aside disputes for joint creation of a win-win situation”. The dense Chinese population is advantageous in the development of related biotech industries for Chinese-exclusive diseases.
- H. As the economy develops, modern diseases are increasing on a daily basis, bringing business opportunities in the development of drugs and disease screening technology platforms.
- I. The global society is aging and the demand for drugs and health maintaining products will increase relatively.

## **REGULATORY FRAMEWORK**

A well-developed legal framework and protection of intellectual property rights is the prerequisite for building an ideal environment where the biotechnology and pharmaceutical industries can flourish. In order to improve the environment for these industries, in recent years the government has approved the amendment and execution of related laws and regulations. In 1999 the Bureau of Standards, Metrology and Inspection was reorganized into the Intellectual Property Office, which demonstrates the importance the government attaches to intellectual property rights. Moreover, amendments have been made to related tax benefit and incentive measures of investment. Other amendments have been made which have allowed R&D results to be more easily transferred to academia and industry. Laws governing Taiwan's biotechnology industry include related laws and regulations for biotechnology and pharmaceuticals; agricultural-related regulations, intellectual property; and tax benefits and incentives. To promote the development of the local biotech industry, the government has included many incentive and aid programs including the biotech and pharmaceutical industry development statute, the Statute for Promoting Industries, rules for encouraging pharmaceutical technology research and development, and incentive measures for emergent and important strategic industries belonging to the manufacturing and technology sectors.

## **GOVERNMENT PROGRAMS AND POLICIES**

To ensure that Taiwan's biotechnology industry becomes the star industry of the 21<sup>st</sup> century, recent years have seen the government implement several major life-breathing measures into the industry. Below is the chronology of events which have taken Taiwan one step closer to having a world-class biotechnology industry.

**1982** - The government identified biotechnology as one of the eight key technologies. The Ministry of Economic Affairs assisted Food Industry Research and Development Institute to set up “Culture Collection and Research Center”, and was renamed as “Bioresources Collection and Research Center” in 2002.

**1984** - The National Science Council started promoting large-scale biotechnology programs. “Pig Research Institute Taiwan” had converted to non-profit system.

**1984 April** - The Ministry of Economic Affairs established the “non-profit Development Center for Biotechnology (DCB)” to assist in the promotion of biotech R&D.

**1984** - Taiwan's first biotech company - Paoshen Pharmaceutical (Dismissed in 1995) was set up in Hsinchu Science-based Industrial Park, producing hepatitis B vaccines.

**1988** - The Council of Agriculture, Executive Yuan included biotechnology as national level experimental research program.

**1989 November** - The “ROC Biotechnology Industry Development Association” was established.

**1993** - Academia Sinica set up “Institute of Molecular Biology” and “Institute of Biomedical Sciences”. The Ministry of Economic Affairs and domestic pharmaceutical enterprises co-established the “Pharmaceutical Industry Technology and Development Center”.

**1995 January** - The non-profit “National Health Research Institute (NHRI)” was established by the Department of Health, Executive Yuan.

**1995 July** - The Executive Yuan approved the “Technology Professional Training and Application Program”, include strategies to enhance the education of college technology personnel, to strengthen the training of industrial technology personnel, to bring back oversea technology professionals, to propel professional interflows and application, and to construct superior environment.

**1995 August** - The Executive Yuan approved the “Promotion Plan for the Biotechnology Industry”, aggressively promoting the industry. The Executive Yuan passed the first amendment at August 1997. It subsequently passed the second amendment in March 1999, a third amendment in October 2001, and a fourth in March 2003.

**1996 January** - The National Science Council established the Tainan Science-Based Industrial Park, and set up the “Agricultural Biotechnology Special Zone”. The “Frontier Program of Medical Gene Research” was also promoted in the same year.

**1996 February** - The Ministry of Economic Affairs established the “Biotechnology and Pharmaceutical Industries Program Office”, to assist with the promotion of setting Taiwan as an Asia-Pacific bio-manufacturing center.

**1996 November** - The Department of Health announced the “Good Clinical Practice (GCP)”.

**1997~2001** - The Executive Yuan convened annual Strategic Conference of Biotechnology Industry. From 2002 to 2004, the Executive Yuan continuously included biotechnology in the agenda of Strategic Review Board (SRB) conferences.

**1997 March** - The National Science Council launched the “National Science and Technology Program for Agricultural Biotechnology”, with phase II of the project continued in 2002. Phase III of the project was started in 2005, and estimated to proceed for four years.

**1997 December** - The Executive Yuan's Development Fund management committee promulgated the “Five Year Development Fund Investment Plan for the Biotechnology Industry”. From 1998 to 2002, the fund invested a total of NT\$20 billion into the industry. At 2005, the plan was extended to 2010.

**1998 January** - The Ministry of Education promoted the “Improvement Plan of Biotechnological Science Education”, emphasized on the integration of basic courses and the establishment of biotechnology subject

education. The second phase was launched in 2002, the third phase was started in 2006 and renamed as the "Training Program of Frontier Biotechnology Professionals". Academia Sinica established "Preparatory Office of the Institute of BioAgricultural Sciences", and transformed to "Agricultural Biotechnology Research Center" in August 2006.

**1998 July** - The "Center for Drug Evaluation (CDE)" was established by the Department of Health, to provide technical examination, consultation and to draw up regulation drafts. In same year, Good clinical practice (GCP) was implemented and on-site inspections were carried out.

**1999** - The "Foundation Law for Technology Development" was approved, the Ministry of Economic Affairs set up "Measures for Promoting Industrial Technology Development", to encourage industries to invest in R&D. In the same year, the biotechnology industry was considered as one of the ten major emerging industries in Taiwan. The Industrial Technology Research Institute (ITRI) established the "Biomedical Engineering Center (BMEC)" and was renamed as "Biomedical Engineering Research Laboratories (BEL)" in 2006.

**1999** - The Department of Health implemented the drug relief system and established a national and regional Drug Adverse-Reaction Reporting System; GMP and reclassification for medical devices were also implemented. Drug cGMP system was propelled and executed at the same time.

**1999** - The National Science Council promoted the implementation of the "National Program for Pharmaceuticals and Biotechnology", which was continuously promoted and renamed as the "National Science and Technology Program in Pharmaceutical and Biotechnology" in 2003.

**2000** - The Legislative Yuan approved the "Rare Disease and Orphan Drug Act" and the "Drug Injury Relief Act" proposed by the Health Department.

**2001** - The "Biotechnology & Pharmaceutical Investment Program Office" of the Ministry of Economic Affairs was renamed the "Biotechnology & Pharmaceutical Industries Program Office". The Ministry of Economic Affairs also launched the "Five Year Plan of Chinese Medicinal Industrial Technology Development".

**2001** - The Taiwan Pharmaceutical Product Quality Research Institute was set up, and the Pharmaceutical Technology Research & Development Award and the Rare Disease & Orphan Drug Award were established by the Health Department. In the same year, "Pig Research Institute Taiwan" had renamed as "Animal Technology Institute".

**2001 December** - Based on a consensus opinion of the "Economic Development Advisory Conference", Industrial Sector established the "Executive Yuan's One-Stop Service Office for the Biotechnology Industry".

**2002 May** - The Executive Yuan reviewed and approves the "Challenge 2008, six-year National Development Plan" (2002 to 2007), identifying the biotechnology industry as one of the Two Trillion, Twin Stars industries.

**2002** - The second phase of the "Nankang Software Park" called for the creation of a biotechnology special zone.

**2002** - The National Science Council launched the "National Science and Technology Program for Genomic Medical Science".

**2003** - In January, Academia Sinica founded the "Genomics Research Centre". At the same time, the Health Department, Executive Yuan commenced implementation of the "Medium-Term Outline Plan for Pharmaceutical Technology Development Programme (2003-2006)", and the "Integrated Plan for the Modernisation and Internationalisation of Traditional Chinese Medicine" was executed by the Department's Traditional Chinese Medicine Committee.

**2003 February** - The Executive Yuan approved and passed plans for the establishment of the central "Agricultural Biotechnology Park" as well as the local Changhwa "National Floral Park", the Tainan "Orchid Biotech Park", the Chiayi "Spices and Medicinal Herb Biotech Park" and Ilan "Marine Biotech Park".

**2003 March** - The Executive Yuan reviewed and approved the "Hsinchu Biomedical Park Plan" and the park had come into use in March, 2008.

**2003** - Based on the "Program Report on Enhancing the Competitiveness of the Northern Central and Southern Cities", the Executive Yuan's Council of Economic Planning and Development arrived at a consensus to rapidly build the biotechnology special zone of the "Tainan Science-based Industrial Park".

**2003 October** - The Council of Agriculture completed the report of "Strategic program of Taiwan agriculture technology development", and had sent to the Executive Yuan for approval and execution.

**2004 January** - Academia Sinica set up "Biotech Research Center" in Tainan Science Park.

**2004 March** - The Legislative Yuan passed the "Act of Establishment and Administration of Agricultural Technology Parks", and revised "Plant Seed Act" to "The Plant Variety and Plant Seed Act". Besides, Department of Health, the Executive Yuan published "Chinese Medicinal Yearbook" and renamed as "Taiwan Traditional Medicine Yearbook" in August 2005.

**2004 August** - MOEA established "Nankang Biotech Incubation Center".

**2004 November** - The 5th National Industrial Development Conference was held and item 5 on the agenda were the development strategies for the biotechnological new pharmaceutical industries.

**2004 November** - To broaden the scope of development, to include Western medicine, new traditional medicine, and medical equipments, the "Pharmaceutical Industry Technology and Development Center" was renamed "Medicinal and Pharmaceutical Industry Technology and Development Center".

**2005 January** - The "Blood Preparation Articles" were approved. Article 19-2 and 19-3 were amended and added to the "Enforcement Rules of the Statute for Upgrading Industries". Moreover, the Executive Yuan approved the "Program for the Establishment of Kaohsiung Biotechnological Park". Furthermore, the "Communication Platform for the MOEA, the Department of Health and Service Providers" was started.

**2005 April** - The Executive Yuan launched the "Biomedical Technology Island Program," covering three major plans: the development of national health information, the establishment of Taiwan BioBank, and the constitution of clinical trial and research systems.

**2005 September** - According to the "Biomedical Technology Island Program", the constitution of clinical trial and research systems, the Department of Health, the Executive Yuan had set up the "Clinical Trial and Research Program Office".

**2005 October** - The Executive Yuan convened the first Bio Taiwan Commission (BTC). The second commission was hold in October 2006, continue with the main theme of commission 2005, selected three major field e.g. agriculture biotech, medical equipments and biotech pharmaceuticals as the conference issues.

## TOP TEN COMPANIES

Company	Capital (US\$ million)	Business Scope
ScinoPharm Taiwan	170.28	Active pharmaceutical ingredients
China Chemical & Pharmaceutical	90.91	Generic drugs
Yung Shin Pharm. Industry	77.40	Generics, new drug development
VitaGenomics	73.92	Genomics drugs
Taigen Biotechnology	54.19	New drug development
Standard Chem. & Pharm.	46.44	Generic drugs
Taiwan Biotech	37.15	Active pharmaceutical ingredients
Cytopharm	32.51	Interferon
Taiwan Flower Biotech	30.96	Flower production
Sinphar Pharmaceutical	30.03	Chinese herbal medicines, Nutraceuticals

Source: Department of Investment Services, Ministry of Economic Affairs. *Biotechnology Industry Analyses & Investment Opportunities*, 2008

## ECONOMIC CONTRIBUTION & MARKET CAPITALISATION

Taiwan's biotechnology industry includes biotechnology, pharmaceuticals and medical devices. In 2007, the total annual revenue for these industries in Taiwan was approximately NT\$191.2 billion, of which NT\$48.3 billion came from biotechnology by 294 companies, each with average revenue of NT\$164 million. Their business scope covered genomics, drugs, diagnostics, agricultural biotechnology, environmental biotechnology, protein drugs, contract research organizations, biochips and bioinformatics. The island's pharmaceutical industry returned NT\$68 billion, with 321 companies active in this sector, averaging NT\$212 million per company. The medical devices industry returned NT\$74.9 billion, coming from 501 companies, with average revenue of NT\$150 million each. The biotechnology workforce size is 40,794, of which 9,320 are in the biotechnology industry, 11,274 in the pharmaceutical industry and 20,200 working in the medical devices industry.

Industry	Biotechnology		Pharmaceutical		Medical devices		Total	
	2006	2007	2006	2007	2006	2007	2006	2007
Revenue*	43.4	48.3	66.0	68.0	69.7	74.9	179.1	191.2
Number of manufacturers	268	294	368	321	500	501	1,136	1,116
Size of work force(number)	8,570	9,320	12,224	11,274	16,350	20,200	37,144	40,794
Export value*	17.6	19.3	13.7	15.5	29.3	31.7	60.6	66.5
Import value*	18.7	20.5	69.8	70.7	44.7	46.2	133.2	137.4
Domestic sales vs. export	60:40	60:40	79:21	78:22	58:42	58:42	66:34	65:35
Domestic market demand*	44.5	49.5	122.1	123.2	85.1	89.4	251.7	262.1

\*Units: NT billion

Source: Biotechnology and Pharmaceutical Industries Program Office, MOEA, 2008

## RESEARCH AND DEVELOPMENT

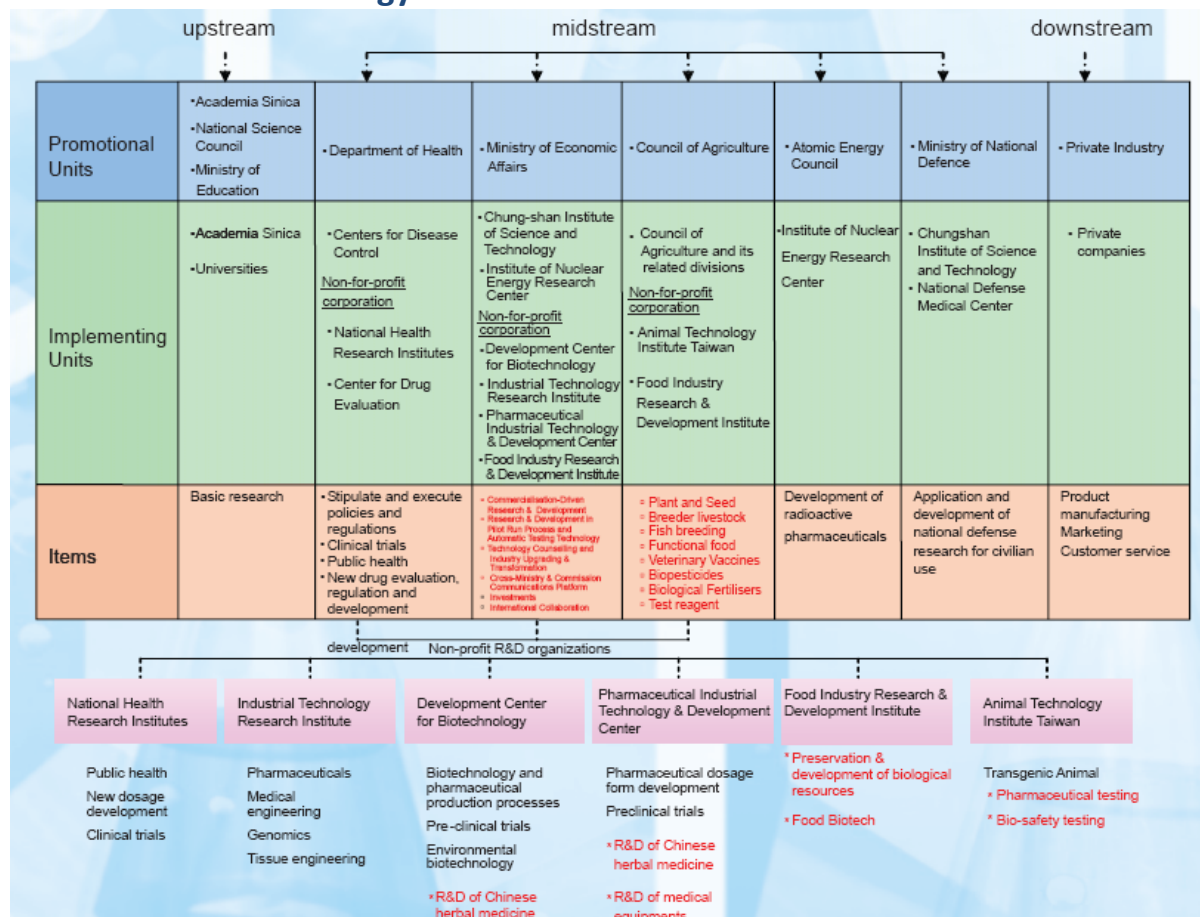
Taiwan has considerable biotechnology research and development expertise. In addition to domestic universities, many national research institutes have been established, including the Institute of Biomedical Science and the Institute of Molecular Biology in Academia Sinica; the Biomedical Engineering Research Laboratories (BMRL), the Industrial Technology Research Institute (ITRI) and the Development Center for Biotechnology (DCB). Sectors such as biochip, medical equipments, bio-medical materials, bio-medical information, pharmaceutical engineering were provided with many transferable technologies. For example, the Animal Technology Institute Taiwan has obtained patent rights in Taiwan and the U.S.A in the “ production of heterologous protein in milk of transgenic non-human mammals”, setting an important milestone in producing medical protein through transgenic livestock in Taiwan. The new plant extract drug, DCB-WHI, developed by the Development Center for Biotechnology for treatment of diabetes wounds, has been approved by the U.S. FDA to be used in a Phase II clinical trial in the U.S. A. and the technology has been transferred to the MicroBio Co., Ltd., which will conduct subsequent clinical trials. Meanwhile, the Center has signed a technical transfer and collaboration agreement with MicroBio Co., Ltd. regarding the plant extract to treat rheumatoid arthritis; a technical transfer and collaboration agreement with the Synmosa Biopharma Corporation, which will take over the “DCB-ADI” technology for treating Alzheimer’s disease. PhytoHealth Corporation will take over BEL-CATC701, the new Chinese medicine used in treating Hepatitis C, from the Industrial Technology Research Institute of Taiwan (ITRI). Medigreen Biotechnology Corporation will take over BMEC-1217B, the new anti-asthma drug developed by ITRI, which was approved by the U.S. IND to go on with Phase I clinical trials. The handheld cancer cell detector developed by Academia Sinica can detect whether cancer has developed in cells within a very short period of time. The Metal Industries Research & Development Center has developed the intelligent and autonomous powerful human transfer auxiliary module and the Precision Machinery Research and Development Center has developed the wireless wearable respiratory monitoring system. These are just some examples.

To develop the national clinical center and drugs research system, Taiwan's government established National Clinical Research Centers in several selected Teaching Hospitals and Medical Centers. At the same time, the Taiwanese government provides the Contract Research Organization/ Clinical Research Organization (CRO) and the Site Management Organization (SMO) with industrial supplies, clinical trial-related conferences and meetings. Meanwhile, there are 126 hospitals and several CRO companies that supply clinical research, and their products include medicine, medical device, Chinese herbs, bio-medicine, health food, artificial organs, diagnosis kits, or radical medicine and etc.

Moreover, short-, mid-and long-term plans focusing on potential biotechnology products have been mapped out. Short-term plans focus on clinical trials/bio-equivalence, clinical animal experiments, biotech-related contract manufacturing, cord blood preservation services, bioinformatics, biochips, drug development, herbal medicine, physiological / biochemical monitoring systems. The

mid- to long-term plans will focus on monoclonal antibody drugs, gene diagnostics and gene therapy, stem cell technologies, transgenic plants and animals, technology for developing pharmaceutical dosage forms, genetic engineering, and artificial organs. It is hoped that the development of these key technologies and products will support the successful expansion of the island's biotechnology sector and companies.

## R&D of the Biotechnology and Pharmaceutical Industries:



## BUSINESS CLIMATE

With the “Growth Competitiveness Index” and the “Business Competitiveness Index” as the rating criteria for the “Global Competitiveness Index”, the latest “Global Competitiveness Report 2007 – 2008 of the World Economic Forum” said that the global competitiveness of the U.S.A tops the world. Taiwan ranks 14th in the world and 5th in Asia, second only to Singapore, Japan, Korea, and Hong Kong. The first “Investment Environment Risk Evaluation ” done by Business Environment Risk Intelligence (BERI), the well-known U.S. company in 2008 also points out that the investment environment in Taiwan ranks 6th in the world, following Switzerland, Singapore, the Netherlands, Japan, and Norway, and among the Top 3 in Asia. The results reflect that compared to other Asian countries, Taiwan has a more stable economy, rapidly reactive enterprises, well-developed financial

organizations, and abundant foreign reserves. These factors have made Taiwan an important destination for overseas investors.

## **BIO/OVERVIEW OF OUR INDUSTRY ORGANISATION**

The Development Center for Biotechnology (DCB) of Taiwan is a nonprofit organization established in 1984 with the support of the Department of Industrial Technology (DOIT), Ministry of Economic Affairs (MOEA). Our main mission is to help shape and develop Taiwan's biotechnology industry through R&D, infrastructure-building and training programs. We play the crucial role of facilitator to promote synergy of governmental, academic and industrial efforts and serve as a bridge connecting Taiwan's biotech industry to the world.

We currently have about 400 employees (including 59 PhDs) and operate three contract service facilities: the GPCR Drug Screening Facility, the Center of Toxicology and Preclinical Sciences (CTPS), and the cGMP Biopharmaceutical Pilot Plant Facility (BPPF). The main offices and laboratories of DCB are located in a science park in eastern Taipei, in proximity to the Nankang Biopark, the National Genome Research Center, and the main campus of the Academia Sinica.

### **Programs in the Division of R&D**

Guided by Taiwan's established biotech industry policies, we are currently focusing our R&D efforts on (1) environmental biotechnology; (2) herbal medicines; (3) pharmaceuticals: small-molecule drugs and new formulations of existing drugs; and (4) biologics: monoclonal antibodies, recombinant proteins and vaccines. At present, the therapeutic areas selected for drug development at DCB are cancers, diabetes and infectious diseases.

### **Division of Industrial Promotion**

The Division of Industrial Promotion was set up in 2000 with the aim of strengthening DCB's capability to promote synergy between academia and industry and to help Taiwan's biotech industry link up with the world. To this end, a program (since renamed "BioBiz") has been created to screen commercial leads. The BioBiz program has two main emphases: upgrading Taiwan's biotechnology value chain and facilitating partnerships and collaborations. We also provide, for the benefit of domestic biotech companies, the Industrial Technology Information Service (ITIS), which collects, translates, evaluates and disseminates information for market analysis and strategic planning.

### **Biotechnology and Pharmaceutical Industries Program Office (BPIPO)**

The Biotechnology and Pharmaceutical Industries Program Office (BPIPO, [www.biopharm.org.tw](http://www.biopharm.org.tw)) is created by the Executive order for the purpose of coordinating the promotion and implementation of Taiwan's biotech policies. To develop a world-class biotech industry in Taiwan it is essential that we

have a nurturing environment that is conducive to creativity and innovation. BPIPO is set up as a "one-stop window" where companies can seek solutions or explore partnership and collaboration opportunities. We work closely with other governmental agencies on technical and regulatory matters. We can help by streamlining bureaucratic procedures, easing regulatory bottlenecks, or even arranging financing so companies can focus on their core business.

## Nankang Biotech Incubation Center (NBIC)

The Nankang Biotech Incubation Center (NBIC, [www.nbic.org.tw](http://www.nbic.org.tw)), under the Small and Medium Enterprise Administration (SMEA) of MOEA, runs facilities and programs designed to help early-stage biotech companies. We offer assistance, often free of charge, in the following areas: business planning, financing, intellectual property and regulatory affairs, advertising, marketing and sales, human resources and RD resources by arranging from time to time on-site meetings with service providers: law firms, accounting firms and consulting agencies; and by providing free seminars, forums and workshops as well as networking opportunities.

## New Drug Development Value Chain

As a provider of integrated services, DCB has committed major resources to New Drug Development Value Chain. We have set up a series of world-class facilities: the GPCR Drug Discovery Facility for high throughput screening of novel molecules targeting the G-Protein Coupled Receptors (GPCR); the **Center of Toxicology and Preclinical Sciences (CTPS)**, where the animal facility is AAALAC-certified, and the GLP-compliant core facility supports the tests required for IND (Investigative New Drug) applications; the cGMP **Biopharmaceutical Pilot Plant Facility (BPPF)**, which is in full compliance with the U.S. FDA regulations for manufacturing monoclonal antibodies and recombinant proteins for clinical trials. These facilities, in conjunction with other clinical research centers and CROs (Contract Research Organizations) in Taiwan, offer a broad spectrum of services to meet the needs of biotech and pharmaceutical companies.



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