

Interview with Jeff Wang, President, Development Center for Biotechnology

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The Development Centre for Biotechnology was founded in 1984 as a tool for connecting biotechnological academia to the Taiwanese industry and promoting the strengths of Taiwan's biopharmaceutical sector to the global audience. The centre was established by both government and private industry as a non-profit organization. How do you think those were the best choices, establishing a public and private as well as a non-profit organization?

Taiwan biotech and pharmaceutical companies are small- to medium-sized and they have only very limited resources for R&D. For this reason, government set up those non-profit R&D institutes to conduct the research activities for them. This was also the main purpose for the foundation of DCB. After we have done the research and development, we transfer potential product candidates to the local biotech companies so that they can do further studies such as clinical trials and then commercialization.

Since then what have been the most important milestones for the DCB? What have been some of the most exciting projects you have done in the last few years?

The first project DCB undertook was to introduce hepatitis B vaccine to Taiwan. DCB screened the places where the vaccine was available and identified the technology of Sanofi-Pasteur in France and eventually licensed the technology into Taiwan and founded the first biotech company in Hsinchu Science Park. In 1986, Taiwan started the vaccine immunization program to all new born infants. The program has reduced perinatal transmission rates from 86-96% to 12-14% in babies born to highly infectious HBsAg carrier mothers. This was a success story.

For the last 3 years, DCB has filed 4 INDs and got approval from Taiwan DOH or the US FDA. Among these four, two are botanical drugs, one is new formulation, and one is biologic product. Also, we built up the first GLP Tox Center to conduct tox studies for Taiwan biotech communities and the first cGMP mammalian cell bioreactors (300 & 500 L) for production of biologic drugs for phase I and II clinical trial studies.

Your first project was to bring a specific technology to Taiwan. Does the organization still operate in the same way or did you change your strategy?

We would like to do that but it is not always easy to have such a successful story. We have developed several proprietary technologies and products by ourselves. For example, We spun off a diagnostic company, Taiwan Advanced Biopharm Inc., by out-licensing our own developed proprietary technologies. Recently, we developed a botanical drug, WH-1, for diabetic wound

healing. The IP rights were out-licensed from the DCB to Microbio. This product is in Phase II clinical trials in Taiwan. Microbio founded a spin-off company called Oneness by raising 550 million NT for developing WH-1 and related products.

How much was invested by the government when DCB was established?

The total capital for the initial investment was 35 million NT.

There seems to be a lot of investments into the DCB, initially in 1984 and you created some top quality facilities. But these facilities have not been used by the industry for a long time. How was that a challenge and how is the situation today? How did you overcome this problem? How well are the facilities used today?

Our facilities are fully occupied and utilized today. Each year the government grants DCB about 700 million NT for R&D and the total budget for the DCB is around 900 million NT. We do have open laboratory space for the private companies, either locally or internationally. There are 3 companies renting our Shijr facilities now.

How would you describe the current priorities of the DCB? What kind of strategic sectors are you looking at?

In the beginning, we essentially did everything, pharmaceuticals, all kinds of biotech, including agricultural and environmental biotech. In these days we only focus on biopharmaceuticals which include biologics, small molecule and botanical drugs. For the diseases areas, we focus on 4 main areas, oncology, diabetes, infectious diseases, and rheumatoid arthritis. We are conducting translational research mainly. We get the lead compounds either from universities or domestic or foreign biotech companies. Before we get those leads, we have to do due diligence studies like patent analysis, market analysis, technology competitiveness, etc. Therefore, we need to have a very strong business development group to do these kinds of analysis. After this process, if we think the lead is good, we need to in-license it or partner with those universities or companies to conduct R&D. After the R&D stage has been completed, we transfer those products candidate compounds to the local companies for conducting clinical trials and commercialization. The technology transfer process is always transparent and reviewed by a committee.

This is a very interesting model for a research organization. You have also done international collaborations with Merck, Crucell and Boehringer Ingelheim amongst others. How important do you think it is for the Taiwanese biotech sector to help these international collaborations in terms of research to promote itself internationally?

We have to collaborate with international biotech communities because we lack of good lead compounds and enough resources here in Taiwan. For example, AbGenomics is an antibody company spun off from the medical school of National Taiwan University. They developed the Antibody 168 and out-licensed it to Boehringer Ingelheim so that they can get some funding to conduct other R&D works. Panion & BF Biotech is another success story. They in-licensed a compound from the University of Michigan, conducted preclinical studies and phase I clinical trials and then out-licensed it to Keryx. Keryx is now conducting the phase III clinical trials in the US.

What do you think of the reputation of Taiwan internationally for biotech?

We still need to work hard in order to get recognition. Not a single NCE compound in the global market has been developed entirely by Taiwanese local companies so far. As DCB, we consider ourselves as a value adding partner for academic institutes as well as both domestic and foreign companies.

Now we have seen that Taiwan government has just introduced Diamond Action Plan for biotech takeoff. As an institution that was initially set partly by the government, you must be working very closely with them even today to help them develop any particular plans they will have towards the biotech sector. How did this come about, how did you help to influence this policy? And how much do you think it is going to change the biotech sector in the years to come?

DCB is considered to be the second runner in the whole drug development value chain. The first runner will be academia. They do the discovery research and we do the translational research. For instance, we didn't have a DMPK group for translational research. Because of the inception of Diamond Action Plan for Biotech Takeoff, we started to build up this group from last year. Also, we need to strengthen our toxicology studies capability and build up a microbial cGMP GMP manufacturing group facility. Once the bio-venture capital (60 billion NT), one of the strategies in the Diamond Action Plan, starts operating, I expect that there will be a lot of start-up companies forming with several potential blockbusters in the product pipelines. DCB would like to work closely with the bio-venture capital management teams in terms of conducting due diligence studies and translational research for those start-up companies.

What is your time frame? When do you think this action plan will be a success? How long do you think it's going to take?

4 to 5 years.

Biotech has a longer investment time than the IT sector but it was 1984 when the government started to really push for the first time. We haven't seen still anything. Why do you think it has taken so long for the biotech sector? What do you think is missing in Taiwan?

In 1984, the infrastructure was not ready for biotech. The real government initiative for the development of biotech started in 1995. The government initiated a the Action Plan for Biotech Industry Development and from then we started to build infrastructures such as strengthening R&D, recruiting talents, promoting VC investments, strengthening IP protection, and upgrading the regulatory laws. In 2007, the government initiated Statute for the Development of Biotech New Drug Industry and started to encourage new drug development. Last year the Diamond Action Plan for Biotech Takeoff was announced. This has been the most important boost for the industry so far. Biotech is a highly regulated industry. Even in the US, it took ca. 20 years for developing this industry. Taiwan lacks of innovative drug pipelines and we desperately need a major success story for promoting the biotech industry.

How do you recruit the talent?

Ideally, we would like to bring back talent from the US or Europe, because we like to have experienced people, especially those who have worked in multinational companies or small biotech companies. For the local Ph.D. or M.S. researchers, we do have enough manpower. It is in science and business double majors that Taiwan is really low on human capital, such as people with biotech science background and with experience in licensing negotiations.

In the context of its Asian neighbours, Taiwan doesn't have the manufacturing capabilities of China or India in terms of volume. What is your vision for Taiwan standing up and separating itself from its Asian neighbours and really defining itself within that context?

Our niche is that we have very good teaching hospitals to conduct clinical trials. We also have very strong discovery research. Biologic drugs like MABs will be one of our main focuses and we would like to build a manufacturing plant for preparing commercial products in the near future. Another niche will be in medical devices because we do have very strong ICT industries and it will be easy to

incorporate both biotech and ICT for developing medical device products.

What is your final message to the pharma and biotech communities around the world? Why should they consider Taiwan while planning their investments or partners?

I would like to emphasize that recently we have very good connection with the biotech communities in China. We think this is also one of the niches for Taiwan. Multinational companies and small biotech companies usually have difficulties in doing business with China. In this regard, Taiwan can serve as a stepping-stone to China. We have the same culture, language, and we are trying to create harmonization with them in terms of regulatory aspects. We would like to negotiate with them to follow international standards of either the US FDA's or EMEA's. As you know, China will soon become the 3rd largest pharmaceutical market country and by 2020, China will be ranked 2nd.

What is your message to the Taiwanese nationals who are abroad and perhaps looking at Taiwan and maybe waiting for something to happen to come back in ten years? Why should they come back sooner?

I think all Taiwanese nationals have feelings for Taiwan. We would like to do something for the country. Although the salaries here cannot compete with the those in the US, those who want to achieve something and make major impacts in their lives should come back sooner. Now is definitely the right time because of the Government's initiative "Diamond Action Plan for Biotech Takeoff".

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