

ITRI biomed lab working with China on guidelines

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Taiwan's Industrial Technology Research Institute (ITRI) has one of the largest medical technology and device research labs in the country. The lab works on both medical devices and pharmaceutical drug development. Some of the typical medical devices and technology that it focuses on are medical electronics, orthopedics, and combination devices. In pharmaceutical drug development, they focus on small molecule drugs and herbal medicine.

In an interview, Dr Yio-Wha Shau, vice president and general director of the BioMedical Technology and Research Laboratories at the Industrial Technology Research Institute (ITRI), Hsinchu, Taiwan, tells *BioSpectrum* about the work ITRI is doing to aid Taiwanese companies as well as international companies interested in doing business in the region. ITRI's role is to come out with industry alliances and fill in the gaps. They form an alliance with the companies and suggest government support for them to speed up product development and bring in the regulatory party in the very beginning. ITRI transfers technology to the industries, because that is what it is required to do, research and develop technologies, and transfer to them to taiwanese companies or the industry.

Mr Shau, whose research interests vary from clinical biomechanics, diagnostic ultrasound hypersonic aerodynamics, fluid mechanics, thermal sciences and angiogenesis research, has over 10 patents in Taiwan and the US to his credit. He also serves as professor at the Institute of Applied Mechanics at National Taiwan University and forensic science consultant at the Ministry of Justice. Excerpts from the interview:

How does ITRI engage with companies, both local and international, in the medical devices segment?

Our function basically is as an incubator for advanced technology in biomedical application. We have a very strong linkage with Taiwanese physicians or most of hospitals and medical centers are ITRI's allies. So, we will link the scientist to the industry and help them come up with patents of their intellectual property. Most of the companies work with us under the support of the government (Ministry of Economic Affairs). But ITRI is not entirely funded by the government. We are also raise funds from contracts.

What is the source of funding for ITRI biomed labs?

Typically, 60 percent of the funding for the bio labs at ITRI comes from government projects. Another 30 to 35 percent revenue for the bio labs is generated from the industrial services that we provide. And around five percent of the revenue comes from the IP or the spin-off companies.

For the new pharmaceutical companies, ITRI offers its GMP manufacturing procedure and does the proof-of-concept. We also offer the testing equipment to do clinical trials. In medical devices, we do offer the product IP and help in finding the key components from the Taiwanese industry. So, product IP is not our only role, we have to have the linkage to all the suppliers to come up with low cost products or solutions. We link the local industry to suppliers.

Also, we come up with some amount of devices for the clinical trials. We don't do mass production.

What is the trend in the medical devices segment right now and what kind of devices is ITRI working on?

Most of the Taiwanese companies work on medical electronics for home use, especially instruments such as blood pressure monitors, thermometers and glucose monitors. ITRI plays a role in trying to do more in diagnostic equipment and therapeutics. For example, one of the devices is to treat sleep apnea. Also, we have some surgical procedure products or prototypes. The biomaterial team comes out with solutions for growth factors and dental implants. We also do instruments for orthopedic surgery and minimal-invasive surgery. What do you do in diagnostics?

In diagnostics, we have medical electronics. Also, there is the ultrasound system and the OCT (optical computed tomography). Also, we have an in vitro diagnostics team focused on the point-of-care.

Tell us about the start-ups spun-off from ITRI and companies it engages with?

With respect to the biomedical field, we have about six companies and departments. That should be three companies and three divisions in large companies. By June 2012, there will be five companies as two new ones are coming up. One of the companies will be in December.

Then we have around three departments in ICT companies. Most of the ICT companies in Taiwan are looking to invest in medical devices. So, a whole new department is formed with ITRI's employees or our core team.

We also provide service to international companies, especially because Taiwan is far from these continents. We provide industrial service to about two to three major companies in the US and Europe. For the Taiwanese industry, we provide industrial service to more than a 100 companies every year.

Does the ITRI also provide registration services and help with the regulatory process work to companies?

That is one of the services that we can provide. We can prepare the documents for FDA. ITRI also does the testing for Taiwanese FDA. For example, some of the devices or tests cannot be performed in the industry. We will come out with the testing for it and regulated by the TFDA.

By doing that we also become a party of the State Food and Drug Administration in China. They are looking for somebody who can test some of the innovative devices and come out with testing strategies as well as the regulatory guidelines of Taiwan. So, in Taiwan we are working with China on how to set up the regulatory guidelines specifically for the Chinese market. Most of the approved drug or device are tested on Caucasians, and some of these medical devices come to China which is a cause of concern.

Also, there is a lack of guidelines for Class II, Class II B and class III high risk devices because some of the new technologies, such as nanotechnology, are pretty new to the regulatory parties all over the world.

The Taiwan government has identified some focus areas in medical devices?

They are looking at devices for renal function repair equipment. This is a key area in the Chinese group because it consumes a lot of national government insurance coverage. The second key area is lung diseases or the COPD. The third focus area is the minimally-invasive surgical tools and procedure. Then, there are dental devices or equipment, such as implants and a lot of dental service-related biomaterials. The last one is IVD or point-of-care in vitro diagnostics.

Are the focus areas in line with the China market?

China is one of the target areas. However, in between we do see the far east countries too. In Mainland China, we still have to deal with technology transfer. This is going to be approved very soon because cross-straits negotiations have come to a stage where both sides want more collaborations. But the IP should be brought into discussion at the very beginning before any real action is employed.

What according to you will be the big trends in medical devices in 2013?

In Taiwan a lot of companies will work on mobile healthcare, self-care or personalized care for self-alerting. These types of devices will have a good growth in 2013 because the technology is already there. They may not be called medical devices but they are self-alerting medical accessories or assistive devices.

What do you think is the biggest challenge for the industry?

The government support is there. However, the difficulty or hurdle has been in going to the physician. Physicians have to be convinced that some of the devices can provide early surveillance. The doctors can then take decisions without any questions asked. This reduces the effort a doctor spends on each patient. The government is supposed to support a good data system or a cloud service, something like a health cloud or a wellness cloud. These will come up very soon because a lot of these ICT companies already have the capability.