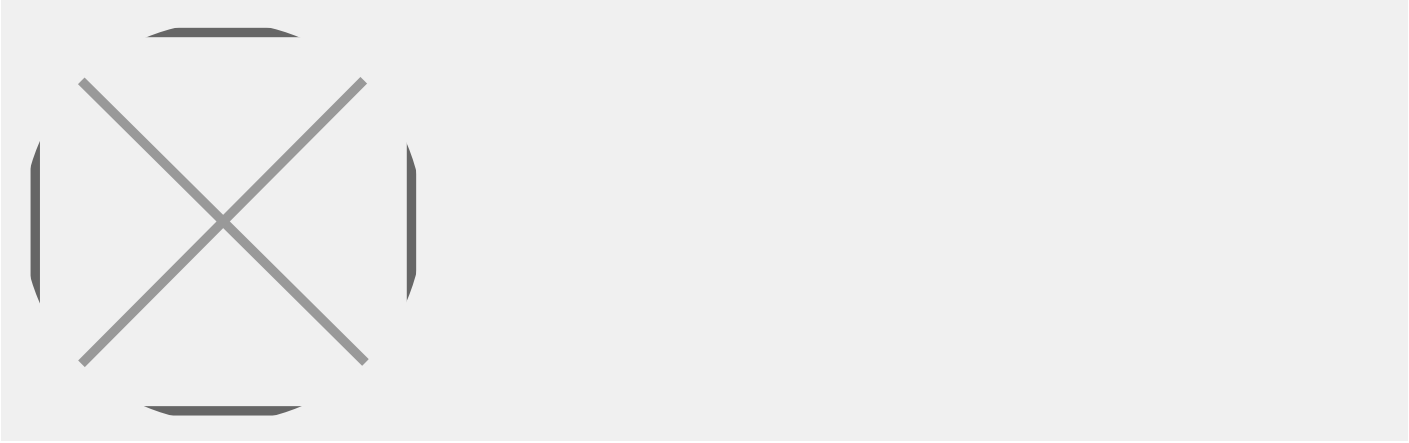
Interview with Dr. David Yang, President, MicroConstants China



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Although MicroConstants traces its history back to 1998 in San Diego, you co-founded the China operations in 2007. What's the story behind how that came about?

It all began when I met Gilbert Lam, the President of MicroConstants San Diego, at a CRO open house in San Diego ten years ago. At that time I was working as a biotech investment manager in Singapore, with the idea of in-licensing novel technology from the U.S. and conducting product development in China to take advantage of a lower cost base. Unfortunately, the quality systems at that time in China were not up to the level what a U.S. pharmaceutical company would demand. In 2006, I got back in touch with Gilbert when I began looking into the possibility of starting a CRO in China with U.S. GLP/GCP quality system because I knew that it was essential to partner with a CRO with U.S. FDA compliance history.

Gilbert had a lot of personal interest in China since he was born in Shanghai. After extensive market research and discussioni with major Pharmas, including several trips to China to explore different options, we finally decide to set up MicroConstants China in Beijing where has most clinical trials in China.

Microconstants is unique in that we began our operations in the U.S. in 1998 with a long track record for GLP and GCP compliance. Our vision was to set up the same quality system in China with local talent and local recruits and duplicate our success in the U.S. As proof of this approach, Microconstants China is the first Chinese bioanalytical lab to receive OECD GLP certification, which is a very strong branding.

On top of setting up a GLP compliant bioanalytical lab, we went great length to work very closely with the clinical pharmacology unit of the Number 307 hospital, the affiliated hospital of the Academy of Medical Science, to bring in new SOPs, GCP/QA training, and project management system. Their quality system has improved dramatically, from being SFDA GCP compliant to ICH GCP compliance. That's a huge milestone for both of us, because we did it all in less than two years. And several Big Pharmas have qualified them to do early stage trials in China. Not only can Microconstants do it in our own facilities, but we can partner with others to have their facilities internationally recognized. Now we working with eight clinical pharmacology units in China to implement ICH GCP quality system. The end result is good for clinical research in China, and ensure that clinical trials conducted in China meet a global standard. It's something we're very proud of.

Would you consider MicroConstants more a of a service provider to domestic pharmaceutical companies or global pharma ?

At this stage, international pharmaceutical companies, including Big Pharma and biotech companies, are our major customer in terms of contract service because they are the ones that demand high quality. Domestic pharmaceutical companies, especially those developing novel drugs, want to ensure their data can be accepted by global regulatory agencies and also by major pharma companies down the line, so they need to conduct their studies according to global standards – and Microconstants can help them there.

We welcome Big Pharma to come even though the initial intent was not to set up MicroConstants for that target. In fact, in the U.S. operations we are mainly focused on smaller and medium-sized biotech. Even though we may be smaller compared to other CROs, bigger pharma come to us because they are most concerned about quality.

There seems to be a consensus that while Chinese scientists have come a long way, for now, U.S. trained scientists still retain an edge in creative problem-solving. To what degree to you agree with this assessment?

I agree – Chinese scientists trained overseas have a much more thorough understanding of the problem they're facing, and can come up with systemic solutions to address issues one by one. Chinese-trained PhDs have a narrower view of the field, because the educational system is very different. For example, in my own experience, I took an undergraduate degree from Fudan University. I didn't study my curriculum in my last half year; instead, I spent my time in the lab. I loved to work in the lab, and I skipped class to do experiments, but ended up getting a D in some classes! My overall GPA was just good enough to be accepted to graduate school in the U.S. In the my first year in graduate school, my professor had no problem to let me leave for 6 weeks to visit my family in another city. The difference is that in the U.S., the professors don't care how much

time you spend in class. What they care about is your capability to conduct work, and to be able to learn by yourself. Since I worked in the lab before , the first day in graduate school, I could start to conduct experiment with minimum supervision. So I finished my PhD in four years, with four publications as first author in good journals. And I didn't work in the evening at all. I played tennis, basketball, volleyball, squash, went skiing, and participated in activities other than wasting time finishing graduate homework. In China it's different. Everyone studies so hard, but sometimes, the students lose the opportunity to learn other things in life. Education-wise, being trained in the U.S. is more around how to address the issue of finding the crucial point, and letting the other minor issues resolve themselves over time. In China, most students focus on the small issues and forget the big picture, and no matter how much time they spend working, they are still working to solve the small issues..

We've met a number of "sea-turtles," yourself included. How would you differentiate the American Dream from the Chinese Dream?

If American Dream is to own a house and cars, and have a family, most of the sea-turtles have realized American dream. They return to China for something big, ambition to do something more than is allowed or expected by their position in the U.S. They want to be leaders and contribute more to the society or industry. For me, the satisfaction is already there because I've already achieved OECD GLP compliance, and made our partners ICH GCP compliant, AAALAC–accredited.

We had some tough times in the first few years, because there are so many academic bioanalytical labs in China not up to global standards. But the sponsors, especially domestic sponsors don't care, and use them anyway. Fortunately, the SFDA published two guidelines last year. The first is for phase 1 clinical trials centre operations, and the second is for bioanalytical lab operations. As a result, most of the academic bioanalytical labs will have difficulty to keep up with GLP/GCP compliance requriement, which gives MicroConstants a competitive advantage. Another opportunity came when the Chinese government further limited clinical sample shipping into and out of the country.

Now, a big biopharmaceutical company signed up with MicroConstants China to undertake their first early-stage project in China. They have been extremely happy with the way MicroConstants works. They'll have four or five more projects in 2013, and even more in the future. Being a small CRO, we really care about the details; we make sure everything goes the way we promised – and we're delivering the results in timely fashion. That's the MicroConstants difference, between making a promise and being able to deliver.

China is fond of the Five Year Plan. Now that MicroConstants is entering its second five years, what would you like to achieve?

In the first three years, our goal was very clear: to duplicate the quality systems of MicroConstants San Diego. We did that very well, and the last two years were more on business development and marketing. Historically we haven't been very good at marketing, and in the first ten years of MicroConstants' history, we didn't need to market at all and still enjoyed 10-15% growth every year. But as of 2010 we have hired our first marketing specialist during a tough time for the industry. And we rebounded very strong and are expect to grow over the next five years in China with a focus on marketing based on word-of-mouth, which has been key to our success. This will involve properly building our reputation. For instance, because we didn't publicize our collaboration with a very successful clinical partner, the industry took note of their quality improvement but didn't know MicroConstants was behind it! We will do better in this respect in the future, and continue to work closely with our partners by tapping into our current customer resources.

The old concept of coming to China was based on cost savings. Now it's no longer the case. Just coming to China you'll save money, but don't expect to save a lot if you're doing regulatory-related work, because setting up a quality system is expensive anywhere. All the equipment and reagents MicroConstants uses are imported from the U.S. Our goal is to save customers 30% – but also provide added value at the same time by reducing the need for sample shipping, shortening product development timelines, and by making their PM's life easier.

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