Tessie Che – Chairperson & GM, Amaran Biotech, Taiwan

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Tessie Che, chairperson & GM of Amaran Biotech shares the story of how she came to lead the company and set its course to become a leading specialty biopharma CMO that leverages high-quality products and best manufacturing practices above all else. As a veteran in the life sciences and pharma industries, Che also shares her insights on the major trends shaping biopharma in Taiwan and internationally. Finally, Che concludes with a message about Amaran's ambitions to set the gold standard for Taiwanese drug production.

You have had a successful and extensive career, from founding your own company to holding technical and senior positions in companies such as ExxonMobil and Aventis. Can you tell us how your vast experience has helped you in leading Amaran to the next level of excellence?

My educational background is in material science, but I have applied my abilities to operations and manufacturing since the beginning of my "start-up" career when I co-founded Optimer Pharmaceuticals Inc. in San Diego. Optimer started in 2001 as a small company of twelve staff and eventually grew to over 280 employees before being acquired by Cubist Pharmaceuticals and ultimately by Merck Sharp and Dohme Corp. During this time, I gained invaluable experience from building the Company and personally leading the CMC (Chemistry, Manufacturing and Control) team. In fact, Optimer has the reputation for bringing the antibiotic drug, DIFICID®, through early-stage development to its successful registration and commercialization in the US, Canada, and

Europe and only spending about USD 175 million – versus Pfizer's USD multi-billion approach to drug development.

My husband, Michael Chang, was a key founder of Optimer and is currently the chairman of OBI Pharma, which was originally a subsidiary of Optimer USA. Because Michael is very dedicated to the development of Taiwan's pharmaceutical industry, he spends extensive time working here. In late 2012, on a visit to Taiwan, I was asked to help manage Amaran because, at that time, the company's GM had unfortunately fallen ill. I then became Amaran's "interim" general manager in 2013 and have remained so ever since. I continue to dedicate my time to the company because I can perceive the long-term positive impact it will have on the Taiwan biotech industry.

In 2013, the primary business focus of Amaran was to manufacture a botulinum toxin- similar product. However, after a year of rigorous engineering evaluation and risk assessment, we made the critical decision to move away from a botulinum toxin-similar production facility because of cost, business and operational considerations. The construction of a dedicated fully-contained botulinum toxin plant would have proven to be very costly and only a very small amount of the controlled substance would be needed for the clinical trial phases, meaning that the plant would sit idle for years while waiting for the next order.

For these reasons in 2014, I made the decision to go down the path of manufacturing specialty pharmaceuticals. Today, I lead a diverse and talented team and manage Amaran under international standards to follow and fulfil our motto of "Work locally. Think and act globally." Amaran's primary goal is to set the gold standard of excellence in Taiwan for manufacturing safe and quality pharmaceuticals which adhere to global pharmaceutical regulatory requirements.

Can you please tell us more about Amaran's positioning as a CMO and your full-service manufacturing offering?

Amaran is uniquely positioned to serve clients in the early development phases of their biopharmaceutical pipelines. We specialize in the isolation and purification of natural products, protein, and complex molecules which are very difficult to manufacture under GMP standards for the biopharma industry. We provide process development expertise in customer projects and produce substances in PIC/S GMP production areas. Additionally, Amaran offers analytical services and stability studies for biopharmaceuticals and complex APIs in order to provide a full solution for the drug development process.

Our current facility was designed and constructed over a two-year period from 2013 to 2015 and obtained PIC/S GMP certification from the TFDA in June 2017. We have recently been GMP recertified in 2019 and have also been audited and fully qualified by numerous regulatory agencies and third-party auditors from the USA and EU. Our positioning is to be very compliant and transparent – we write and record what we do, and we do what we record. Several years ago, in 2016 a few potential customers decided not to engage with us due to cost considerations since our estimated manufacturing cost seemed higher than other providers. In fact, these “additional” costs were associated with the work required to adhere to our rigid quality protocol. However, in a majority of cases, the cheap route often led into unresolvable manufacturing roadblocks. A number of those companies have since come back and now ask us to fix the situation that they have found themselves in.

Amaran is growing at a controlled pace which is linked to the rise in health market demand. We work on specialized small-scale manufacturing projects focused on drug candidates that are difficult to formulate and are high in value in the sense that only small amounts are needed to treat a life-threatening disease, for example, cancer vaccines.

What else do you have in terms of new growth strategies for the company?

Amaran’s planned expansion project includes a state-of-the-art automated facility for aseptic filling and lyophilization with capabilities to manufacture liquid and freeze-dried proteins and complex molecules in vials or pre-filled syringes for clinical trial and commercial supply. This expansion is now in its engineering design phase and we expect to complete construction in 2020 with plans to offer sterile fill-finish services by the end of 2021.

Tae-Han Kim, President and CEO of Samsung Biologics, described the biopharma industry having an advanced R&D market with a high growth rate yet lacking innovation in plant construction and operation. How are you ensuring that process innovation is continuously happening in Amaran?

Since we are focused on small-batch, specialty products we have decided to explore the emerging areas of automated robotic asceptic drug fill lines. This is a major innovation in our production process which will allow our manufacturing machines to change between product formulations without the need for direct intervention from an operator which will help reduce potential issues

such as contamination. There are currently no such smart manufacturing systems in Taiwan so in a sense, this is a major leap in the industry, however, I am confident in our capabilities to succeed in being a first mover for the sector.

To accomplish this evolution, we are working with the Canadian company who has already distributed over 30 of their robotic units to companies around the world. In fact, some have already passed FDA inspection, so we are excited to be the first manufacturer to establish this emerging technology in Taiwan.

With well-established international players such as Samsung Biologics and Lonza and local players such as Formosa and EirGenix, how are you maintaining a competitive edge?

In reality, I consider the main growth drivers of Amaran to be its employees. Our human resources department identifies individuals who are not only technologically adept and experienced in the field but also risk-takers with strong, creative problem-solving skills. Once onboard, we nurture independent thinking tempered with a strong quality-committed attitude through continuous training and career development programs.

We provide our staff with a self-management environment and encourage people to accomplish their tasks independently through creative thinking. We encourage a bottom-up approach to let people express their opinions or suggestions related to their work. At the same time, an essential sense of team spirit is strongly encouraged with many operation decisions made through team discussion and majority consensus. Additionally, we are very conscious of promoting a work-life balance career model for our talent because we believe a happy employee is an effective employee.

What are the major trends you have observed in the global and Taiwanese CMO market?

Indeed, the CDMO market has been steadily growing in recent years. More and more companies are bringing their products into the clinical trials phase and are choosing to out-source to a full-service CDMO rather than several niche providers. This simplifies the supply chain and can help to reduce time to market by streamlining regulatory management. In general, many pharmaceutical companies work with contract service providers to reduce costs and take advantage of the new technologies that manufacturers like Amaran are developing which they might not have access to

otherwise.

In terms of CMO vendors, many of Taiwan’s established drug manufacturers are now also opening up their current production capacity to provide paid production services to keep their operations afloat. Therefore, it seems that the competitive landscape of the sector is beginning to gradually increase.

In recent years, several biotech and CMO companies have chosen to raise funds from the capital market, for example, our neighbour EirGenix has already had an IPO to support the construction of their new facility. Meanwhile, Amaran currently depends on the very strong support of its private investors. Of course, we do plan to go public in the future after establishing a healthy revenue stream. At the moment, we are in a “healthy lake” state with steady cash flow both in and out of the company.

How is Taiwan’s biopharma landscape positioned today?

Taiwan’s domestic market is small, but the country has the highest quality medical system and clinical environment in Asia. This includes 19 medical centres and 124 clinical trial hospitals. In addition, the implementation of the National Health Insurance (NHI) over twenty years ago paired with all English medical records give Taiwan a strong international competitive advantage with regards to conducting global trials. A greater number of clinical studies carried out in Taiwan can be predicted which will only increase the need for quality CDMOs like Amaran.

What do you expect as the potential impact of biologic and biosimilar adoption will be for the Taiwan pharmaceutical and biotech sectors as a whole?

Taiwan’s biotech industry has its special advantages such as strong R&D talent, but basic research is not enough. Strong capabilities in GMP is critical in bringing a drug from the discovery bench to patients. The skills and experience required for GMP manufacturing are very different from those of early development. I believe that bridging the gap and ensuring the smooth transition from R&D processes to GMP is one of the key challenges being faced by Taiwan’s biotech industry. The major roadblocks for a smooth technology transfer from the bench the manufacturing are poor communication and a lack of compromise between the parties involved.

Being on the pharma customer side with Optimer, I do understand the priorities of our customers and what they care about the most. In drug development, it can be very hard to pass on your technology to a third party and in a way give up some control. This is why I am highly committed to creating strong relationships with our clients where they can trust that each decision we make will have their company and product's best interest in mind. Sometimes, CDMOs can overspend and create large project budgets, then just walk away – this is not how Amaran operates. Especially in Taiwan's biopharma market, which is saturated with CMOs, we are a true partner that fully understands and is committed to the needs of the local industry.

I believe that Taiwan is in the right place at the right time, however political stability and government support will be a key factor in the growth of Taiwan's biopharma sector.

How has Amaran forged partnerships and collaboration within the local market and internationally?

We currently have several very important CMO projects with a leading Taiwanese biotech company and a joint collaboration with a large European company. One thing the differentiates Amaran from other Taiwanese CDMOs is our strong dedication to quality and our commitment to fostering trusted long-term partnerships. We are a manufacturing partner who embraces our client's every challenge as our own and fully travels the long journey from clinical studies to commercial success with our customers.

What future ambitions do you have for Amaran's development as a CMO of choice?

My personal goal is to set Amaran up with strong management and operating teams and establish a long-lasting company characterized by a legacy of excellence and quality in manufacturing critical life-prolonging drugs. I also hope that Amaran will be a service provider known for its good Taiwanese citizenship by supporting volunteer community activities. For example, Amaran stands on the point of green not only in reducing the pollution but also supporting local initiatives like "Travel with A Tree."

What final message would you like to deliver on behalf of Amaran Biotech?

Amaran takes a lot of pride in our staff as everyone is self-driven and takes ownership of the company and its long-term goals – some often giving over 100 percent of their energy to that end. Amaran's staff is well trained and highly motivated to provide top tier results and service to our clients in Taiwan and the rest of the world.

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