

Grace Yang - General Manager, TSH Biopharm, Taiwan



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Grace Yang, general manager of TSH Biopharm, discusses how the company is uniquely positioned to deliver end-to-end healthcare solutions to the APAC region in the areas of cardiovascular, gastrointestinal, autoimmune, central nervous system, and why TSH step in to cancer diagnosis business area. Yang goes on to explain how TSH can play a role as an experienced & strategic licensing partner for industry players looking to tap into the complex Southeast Asian markets.

Ms Yang, you joined TSH Biopharm as general manager at the beginning of the year with about 20 years of leadership in TTY Biopharm's oncology Business unit. Can you please introduce yourself and your experience to our readers?

I have worked for TTY for about 20 years. I started in primary care but eventually became focused in the area of oncology. During my time in the business, I rotated through several different positions starting on the medical team conducting clinical trials. Later on, I transferred to the marketing team as a product manager, launching new products, developing and executing marketing strategy, and managing product life cycle. Then, I was more focused on Product Portfolio management after promoted as Marketing Manager, and that is when I had a chance to devote myself to Business Development, including Exporting and Licensing-in.

At first, moving from primary care to oncology was a major change for me. However, I realized that with the contemporary medical advancements in treatment and improving the survival rates,

cancer will be regarded as a chronic disease in the near future. This was a major factor to help ease my transition into the oncology field.

What priorities did you identify upon taking on the role of general manager for TSH Biopharm?

Initially, TSH was focused only on chronic disease, which is where TTY had its early beginnings 30 years ago. A special team, TTH, was established as a new business unit in TTY in 2003 dedicated to cardiovascular, gastrointestinal, and central nervous system diseases. TTH spun-off from TTY as TSH Biopharm in September 2010 after seven years of successful operation.

To strengthen the business, my priority has been incorporating more innovation into the TSH model. We are focused on cardiovascular, gastrointestinal, and autoimmune areas, and we understand the patients' demand. However, there is relatively less highly innovative products being brought to market, particularly in cardiovascular and gastrointestinal. As a consequence, we are aiming to bring new business to TSH such as through our collaboration with CellMax to tap into cancer risk assessment, diagnosis, treatment selection, and remission prediction.

The most recent news for TSH Biopharm has been the acquisition of commercialization rights for all CellMax Life liquid-biopsy diagnosis products. What is the significance of this expansion in TSH's portfolio?

TSH has invested in CellMax, acquiring its commercial business in Taiwan, Southeast Asia, and South Korea in order to offer personal diagnosis service for cancer risk assessment, cancer diagnosis, and progression monitoring. We chose CellMax as a partner because of the high level of quality in their innovative products. TSH was well positioned in the high-level health check space. Our business scope is aiming 80 percent at early-stage cancer patients with the remaining 20 percent being to late stage. Expansion into multi-analyte oncology diagnostics is one of the top strategic priorities for our company, driven by demand from oncologists, patients and consumers. Our aim is to provide a complete solution starting from diagnosis to monitoring and create a market synergetic effect with TTY Biopharm, who is leading in Taiwan oncology market.

How will this new business area be balanced with TSH Biopharm's existing CNS, cardiovascular, and gastrointestinal portfolio?

Organizationally, I have set up a dedicated team of sales experts in particular for this new business. This area is booming currently in terms of considering the FDA approvals for new oncology treatment with specific targets in the past few years. Precision and personalized genetic testing will completely change the traditional concept of treatment and oncology is just the first step. More and more research results have been published in areas like cardiovascular, immunotherapies, and even weight loss. Therefore, now is a very unique moment for TTY and TSH to anticipate the wave of precision medicine as a first mover.

In addition to TSH Biopharm's diverse portfolio, you also have a promising R&D pipeline with two compounds at different stages of development. Can you tell us more about these two assets and the company's R&D focus?

RNTA06 is used to treat angina – a cardiovascular disorder. We are currently conducting clinical trials to be approved in Taiwan, and recent unblinded clinical trial results indicate that primary end-point achieved and optimistic in terms of regulatory aspects. Considering the high entry barrier of development in this area, we believe R06 can create significant value from the market.

TRIA11 is a biosimilar indicated for osteoporosis. We are working with several Taiwan-based CDMOs who have high international standards of quality for the development of TRIA11, making it a purely "Made-in-Taiwan product". Moving forward, we are expecting to begin phase I clinical trials in Australia by the end of 2019.

We are focused on future growth throughout new business territory primarily in the Asia Pacific market. In emerging markets like Latin America and Southeast Asia, the patient population with cardiovascular conditions is still increasing year-to-year. This creates a favourable opportunity to continue expanding our network in Asia, especially considering we have already forged distribution agreements in countries like Philippine, Thailand, Malaysia, Singapore, Hong Kong, and Indonesia. Based on my previous experience in TTY, I am working to establish the same business development and export capabilities within TSH.

Starting from 2016 figures, the regional burden of cancer is projected to increase by 41 percent in incidence and 44 percent in mortality by 2025. What is the role of regional

pharmaceutical players like TSH to provide treatments to Asian patients?

We must understand that no matter the therapeutic area, each population could have different pharmacokinetics, different efficacy, and different safety profile which are Authority's concerns, especially in oncology. For example, the efficacy of EGFR Tyrosine Kinase Inhibitors are observed in Asia populations and less so in Western populations, due to the percentage of specific cancer mutation. One of my strategies is to incorporate partners' global phase II or III trials, and this means not just only to bring the product on the market faster, and expedite the marketing penetration rate by offering medical doctors hands-on experience for the treatment. Not every pharmaceutical company is willing to invest or has the capability to join a global study in the region of our interest. Secondly, we continue to closely monitor regulation policies, and prepare for the change in advance. Many countries have varying regulations and different levels of healthcare development, and how to meet registration criteria without redundant work in the markets of interest.

The major role of companies that are the size of TSH and TTY is to offer a flexible, total solution which can meet the unique needs of each market we serve. The vast differences that exist among Asian markets can be a challenge for mid-sized players, therefore, TSH and TTY can be a regional licensing partner who can manage all the nuances that go into serving the Asia Pacific region. Another advantage for us to expand in the business is we have our own PIC/S GMP manufacturing plant with many capabilities including oral formulation, and injection, which allow us being more flexible between license-in or in-house development.

Through self-development and co-development products, TSH Biopharm will keep providing an economic treatment plan to gain more welfare for chronic patients.

TSH has already secured a number of international collaborations with industry players like Abbott, Menarini, and Mycenax to name a few. What makes TSH Biopharm a partner of choice for industry collaboration?

One of our key competencies is the highly experienced talent coaching scheme implanted in TSH. We have strong expertise in Southeast Asia starting from more than ten years ago when we established our first office in Thailand in 2003. In any business, I believe that having the right team is crucial. TSH and its people have particular know-how about the region and we are working step by step to build our presence and capabilities. Coming from a small market like Taiwan, we have a deep understanding of balancing risks and leveraging our core strengths as we expanding outward.

What goals have you set for yourself and TSH Biopharm for your first five years as general manager?

I have already established TSH's business development department which I will use to bolster our collaborations with regional and international industry players. Like our investment in cancer diagnosis business, we will continue to explore opportunities to enhance our pipeline. We are also interested in expanding our solution offering to include high value-added medical devices.

Personally, I am also intrigued by the idea of perhaps including cell therapy as a new business area for TSH. I ever led a cell therapy license-in and registration operation when I was in TTY, and TTY holds the marketing rights for in six Asian markets. I am confident to replicate this experience in TSH when we identify an attractive asset. From the beginning, TSH's portfolio is medicines oriented but we believe we could do more in different treatment other than just pills.

What advice can you offer to a young professional looking to replicate your career development?

Having worked in TTY for 20 years, I have been very striving to work with many different divisions. I enjoy being challenged professionally and I believe that trying new experiences is crucial to having a successful career. I motivate my colleague to look back and evaluate what they learn on a year-by-year basis in order to offer impact on their knowledge and capabilities in their field!

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