

# pharma

**TECH OUTLOOK**



**Drug  
Discovery  
APAC**  
Edition



Stefan Cross,  
President, International Operations

**Mayne  
Contract  
Services**

Supporting Drug  
Development—  
From Concept to  
Commercialization



COVER STORY

# Mayne

## Contract Services

a division of Mayne Pharma Group Limited (ASX: MYX)

By Stacey Smith

**H**eadquartered in Salisbury South, Australia, Mayne Pharma (ASX: MYX) is driven by the simple yet powerful mission of improving patient access to life-enhancing prescription medications. The technology-driven specialty pharmaceutical company applies its drug delivery expertise to commercialize branded and generic pharmaceuticals and equip patients with better and more accessible medicines. Mayne Pharma has a team of over 900 staff including more than 200 scientists who invent, develop, and manufacture pharmaceuticals for specialty, niche target markets.

While the world today recognizes Mayne Pharma for an array of services and its unparalleled expertise, one must ponder over the company's history that dates back to 1845. It began when Francis Hardy Faulding, a surgeon-superintendent from Liverpool, arrived at the shores of Adelaide to lay the foundation stone for F. H. Faulding & Co.—a wholesale druggist and manufacturing chemist. Since then, Faulding operated independently as one of the largest and most prominent public companies in South Australia until

Supporting Drug  
Development—  
From Concept to  
Commercialization



Stefan Cross,  
President, International Operations

it was acquired by Mayne Group Limited—an Australian healthcare and logistics company—in 2001.

In November 2005, Mayne Group Limited demerged the business and Mayne Pharma Limited was formed—a global pharmaceutical company focused on research and development, manufacture, marketing and distribution of injectable and oral pharmaceuticals. Nearly two years later, Hospira Inc, a global pharmaceutical and medical device company acquired Mayne Pharma Limited as it tied in with the firm's skills in specialty generic injectable pharmaceuticals. By 2009, the Australian biotechnology firm, Halcyon Pharmaceuticals, purchased the oral pharmaceutical division of Mayne Pharma from Hospira and rebranded itself to Mayne Pharma Group Limited.

At present, Mayne Pharma's single focus is on making medicines better. "Paired with technology on the edge of convention, we breed an attractive and progressive-thinking culture. This is evident in our approach to fresh ideas, and then a speedy implementation to market," says Stefan Cross, President, International Operations at Mayne Pharma. The company has developed several oral drug delivery systems that have been successfully commercialized in numerous products like ASTRIX® to treat cardiovascular disease, DORYX® for acne and certain bacterial infections or as an anti-malarial, ERYC® that is used in the treatment of bacterial infections, KAPANOL® for the management of chronic breathlessness and chronic pain, and LOZANOC®/TOLSURA®, super-bioavailable itraconazole used to treat fungal infections. "When applied appropriately, our technology can reduce dosing frequency, increase patient compliance, improve side effect profile, and ensure consistent therapeutic effect," Cross mentions.

Mayne Pharma also realized the wider industry's need for rapid innovation and quick drug delivery while handling the growing complexity of drug substances. As such, they built a full-service contract development



**Even though the business is deeply rooted with Australian heritage, our engagement across the APAC region has been active for over two decades**



and manufacturing organization (CDMO)—Mayne Contract Services—to help clients seamlessly develop and deliver pharmaceutical products. Together with its sister-company in the US, Metrics Contract Services, Mayne Pharma supports more than 100 biotech and pharmaceutical companies be more agile and flexible by offering comprehensive services with reliable and impeccable quality across the drug life cycle. Mayne Contract Services holds scientific expertise in developing complex oral and topical dose forms, including modified-release products and poorly soluble compounds. "We support clients to bring their pharmaceutical programs to life with our extensive knowledge and FDA, TGA and European experience. We are the first Australian company to receive New Drug Application (NDA) approval by the FDA back in the 1970s. This enables us to support clients seeking access to global markets from within the APAC region," Cross continues.

### **Bringing Innovations to Fruition**

Cross explains that the primary goal of Mayne Contract Services is to help clients right from the beginning of the R&D process to commercialization. This includes outcome-focused early-stage formulation development from fluid bed spray, and rotor granulation, to name a few. After completing this phase of development, the company focuses on analytical method development, validation, and transfer that play a vital role in establishing the identity,



**Our success begins and ends with our people and is centered on a collective passion to make a positive difference in the lives of patients**

purity, physical characteristics, and potency of drugs. This analytical development phase includes raw material testing, product characterization, and stability assessment, bidirectional analytical method transfer, preparation of GMP documentation and reports, compendial verification and qualification, and many others.

When the scientific soundness of a pharmaceutical product is proved during the development phase, Mayne Contract Services moves to commercial-scale production. At this point, the company ensures the proper manufacturing and packaging of solid, semi-solid, liquid, and topical products, serialization (if required), stability storage, and testing. Leveraging Mayne Contract Services' extensive expertise and capabilities in formulation, analytical development, and commercialization, clients are assured of the shortest possible time to registration without compromising quality.

This is how Mayne Contract Services takes away all the heavy lifting from their clients and brings their pharmaceutical programs to life. Cross believes that the key behind this sustained success is the capability to attract, develop, and retain talented employees who bring diverse competencies and expertise to the table. This paves the way for collaboration and innovation with clients. "Our success begins and ends with our people and is centered on a collective passion to make a positive difference in the lives of patients. Our behavior and interactions with our clients are rooted in our core values: Passion, Creativity, Integrity, Accountability, Empowerment and Agility," he mentions.

### **Strong track record of success**

Such a reputation forged with a productive organizational culture has enabled Mayne Contract Services to partner with companies across multiple markets. Many of these partnerships are long-term, spanning more than ten years, with many returning clients and repeat business. In one instance, a pharmaceutical company was struggling as the pellets for encapsulation were not suitable for tablet compression. As such, there were high chances of pellets getting damaged. Mayne Contract Services modified the core granulation processes to allow the manufacture of pellets which could withstand the tableting compression forces. The pellets were redesigned to prevent segregation from excipients required for successful compression and dose uniformity. As a result, the company could formulate a bioequivalent tablet containing modified release pellets to satisfy the customer brief. This led to one of the very first pellet in a tablet modified release formulations approved by the FDA.

Mayne Pharma acquired a second CDMO business in North Carolina— Metrics Contract Services in 2012 to further extend its capabilities. In 2019, its 126,000-square-foot commercial manufacturing facility in Greenville, N.C., completed a Japanese Pharmaceuticals and Medical Devices Agency (PMDA) inspection. The successful audit enabled Metrics Contract Services to commercially manufacture a branded oncology drug to be marketed in Japan. "Over the past 5 years, we have invested extensively in the CDMO businesses spending more than \$200 million in the two operating facilities in Greenville and Salisbury," Cross mentions. Striding ahead, Mayne Pharma envisions turning Mayne Contract Services into an Australian leader in pharmaceutical development and manufacturing by continuously improving its client experience. The company also strives to support the emerging therapeutic segment of cannabinoids with the TGA license, which will open up new opportunities for its clients. Not stopping there, Mayne Contract Services will make a significant investment in site upgrades to enhance its development and manufacturing capabilities. "Even though the business is deeply rooted with Australian heritage, our engagement across the APAC region has been active for over two decades. Mayne Contract Services has supported the APAC region with product supply into South Korea, Thailand, Malaysia, and Singapore. We have also licensed various products into China and Japan over this same period," Cross elucidates.

In a nutshell, the spirit of helping patients that a young surgeon-superintendent instilled almost two centuries back still runs through the veins of Mayne Pharma, and the coming years will witness the continuation of their innovation. 

DECEMBER - 09 - 2020

ISSN 2644-2787

# pharma

**TECH OUTLOOK**

WWW.PHARMATECHOUTLOOK.COM



## Mayne Contract Services



*The annual listing of 10 companies that are at the forefront of providing Drug Discovery and Development solutions and transforming businesses*