

MAYNE PHARMA ANNOUNCES OFFICIAL OPENING OF NEW SOLID ORAL-DOSE MANUFACTURING FACILITY IN THE US

- The 126,000-square-foot, state-of-the-art facility was custom-designed and built from the ground up to meet or exceed the standards of major drug regulatory authorities.
 - The new facility quadruples Mayne Pharma's capacity to manufacture oral solid-dose pharmaceuticals in the United States and introduces significant capacity to manufacture potent compounds and new capability to manufacture modified-release bead/pellet products.
 - Metrics Contract Services is now able to offer clients a comprehensive 'concept to commercialisation' solution under one FDA site registration.
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18 Apr 2018, Adelaide Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce its new US\$80million, oral solid-dose commercial manufacturing facility in Greenville, North Carolina, USA, is officially open. Custom-designed from the ground up and under construction for two years, Mayne Pharma's new 11,700 square metre (126,000 square foot) facility leverages best-in-class containment design to meet or exceed the quality and safety standards of major drug regulatory authorities.

The new facility more than quadruples the company's capacity to manufacture oral solid-dose pharmaceutical products in the US to well over 1 billion doses and introduces significant capacity to manufacture potent compounds and new capability to manufacture modified-release bead/pellet products.

Mayne Pharma's CEO Scott Richards said, "This new Greenville facility will greatly enhance our internal capacity and capability to support the mid to long term growth potential we see for our business and allows us to manufacture in the United States advanced drug delivery technologies that until today were only available in our Australian facility. The new plant will enable us to better control our supply chain, serve our customers better and reduce product costs. Over the next few years, Mayne Pharma expects to introduce more than 20 products and double its manufacturing volumes in the Greenville site driven by the pipeline of products under development, the transfer in house of several products currently manufactured by third parties and by providing our Metrics Contract Services clients with commercial contract manufacturing services."

"Mayne Pharma has a proven track record of success with technology transfers and product launches. This year, Mayne Pharma completed the technology transfer of disopyramide capsules from a Teva site to Greenville and launched two new products manufactured at Greenville — amiodarone tablets and doxycycline hyclate immediate-release capsules."

With this new facility Mayne Pharma introduces commercial scale, solvent-capable, fluid-bed processing and film coating — a first for its operations in the United States. Fluid-bed processing (also called multi-particulate or bead coating) applies polymers to an active pharmaceutical ingredient. Using this advanced drug-delivery technology, scientists can modify how a drug is

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released after ingestion, such as delaying or sustaining the release to reduce side effects or make the drug more effective.

Specifically designed for containment, the new facility can readily manage the commercial scale manufacturing of potent compounds — a key growth area for pharma companies today as they develop increasingly complex drugs for the treatment of cancer and chronic diseases. Each of the 13 production suites in the new facility was engineered to meet today's stringent manufacturing demands with a best-in-class approach to mitigating cross contamination — while also offering flexible space and delivering a broad range of capabilities and services.

The facility enables Metrics Contract Services — Mayne Pharma's contract development division — to offer clients a comprehensive “concept to commercialisation” solution under one FDA site registration. Metrics Contract Services provides formulation development and analytical chemistry testing services to more than 100 third-party clients.

Now that commercial manufacturing has been consolidated within the new facility, Mayne Pharma's former manufacturing facility in Greenville is being repurposed over the next two years to expand pre-commercial product development capacity to serve both internal research and development and Metrics Contract Services clients. The repurposing includes the creation of 10+ new processing rooms and expanded laboratories.

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About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on applying its drug delivery expertise to commercialise branded and generic pharmaceuticals. Mayne Pharma also provides contract development and manufacturing services to more than 100 clients worldwide.

Mayne Pharma has a 30-year track record of innovation and success in developing new oral drug delivery systems and these technologies have been successfully commercialised in numerous products that have been marketed around the world.

Mayne Pharma has two product development and manufacturing facilities based in Salisbury, Australia and Greenville, USA with expertise in formulation complex oral dose forms including highly potent compounds, controlled substances, modified release products and inherently unstable compounds.

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