

## **MAYNE PHARMA OPENS NEW \$80-MILLION ORAL SOLID-DOSE COMMERCIAL MANUFACTURING FACILITY IN GREENVILLE, NORTH CAROLINA**

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- **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 regulatory authorities.**
  - **The new facility quadruples Mayne Pharma’s capacity to manufacture oral solid-dose pharmaceuticals in the United States.**
  - **A key highlight of this expansion is Mayne Pharma’s commercial-scale, solvent-based, fluid-bed processing and film coating — a first for its operations in the United States. With this facility, Mayne Pharma triples its fluid-bed processing capacity globally.**
  - **Metrics Contract Services is now able to offer clients a comprehensive ‘concept to commercialization’ solution under one FDA site registration.**
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**April 17, 2018, Greenville, N.C.:** Mayne Pharma Group Limited (ASX: MYX) proudly announces that its new \$80-million, oral solid-dose commercial manufacturing facility in Greenville, N.C., is officially open.

Custom-designed from the ground up and under construction for two years, Mayne Pharma’s new 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 United States 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. In 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.





## News Release

“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 (API). Using this advanced drug-delivery technology, scientists can modify how a drug is released after ingestion, such as delaying or sustaining its 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 for mitigating cross contamination — while also offering flexible space and delivering a broad range of capabilities and services. Key features include:

- Single-pass air and multiple distinct and strategically placed airlocks for gowning, material and equipment.
- Segregated product corridors.
- 100-percent HEPA-in and HEPA-out filtered air.
- Dedicated quality control laboratories.
- Commercial scale up to 450kg per batch.

The facility enables Metrics Contract Services — Mayne Pharma’s contract development division — to offer clients a comprehensive “concept to commercialization” solution under one FDA site registration. Metrics Contract Services provides formulation development and analytical chemistry testing services to more than 100 third-party clients. With the ability to offer those clients downstream commercial manufacturing services, Metrics Contract Services can deliver larger scale and increased capabilities for seamless scale-up, and reduce or eliminate the need for site transfers.

While commercial manufacturing is a new offering for clients of Metrics Contract Services, it is not a new capability for the Mayne Pharma team at the Greenville site. The Greenville site has successfully tested, manufactured and packaged commercial products for more than 10 years. Space constraints in the former manufacturing facility precluded Metrics Contract Services from broadly offering commercial manufacturing services to its clients.

Now that commercial manufacturing has been consolidated within the new facility, Mayne Pharma’s former manufacturing facility in Greenville will be repurposed during 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 a specialty pharmaceutical company listed on the Australian Securities Exchange and focused on applying its drug-delivery expertise to commercialize 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 commercialized 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, N.C., USA, with expertise in formulating complex oral dose forms including highly potent compounds, modified-release products and inherently unstable compounds. Learn more at [www.maynepharma.com](http://www.maynepharma.com)

## **About Metrics Contract Services**

Metrics Contract Services is a full-service pharmaceutical development and manufacturing organization serving more than 100 clients worldwide. We deliver proven scientific and operational excellence for oral dosage forms. Metrics' areas of expertise include: Quality pharmaceutical formulation development; first-time-in-man formulations; Phase I-III clinical trial materials manufacturing; and analytical method development and validation services leading to commercial scale manufacturing. Technical capabilities include highly potent, cytotoxic and unstable compounds; Schedule II-V controlled substances; and products with poor bioequivalence, for which we offer an impressive proprietary portfolio of advanced delivery methods. Located in Greenville, N.C., Metrics is a proud member of Mayne Pharma. Learn more at [www.metricscontractservices.com](http://www.metricscontractservices.com)

