

Advantages and Challenges in Australian Biomanufacturing

It is well known fact that the technology used to support medicines, particularly those derived from biotechnology, is complicated. A lesser known fact however was more widely proclaimed in 2012, by Mark Metherell, health correspondent of the Sydney Morning Herald. On a per capita basis, the overall value of Australia's publically traded biomedical companies was higher than for companies in the United States. Chairman of pharmaceutical industry association Medicines Australia, Mark Masterson, has revealed an ambitious agenda as a result of such promising value-added developments. *"The vision is to double our manufacturing output from AUD7 billion (USD7.34 billion) in 2012 to AUD14 billion (USD14.68 billion) over the next decade and to establish a number of highly specialised bio-manufacturing plants,"* Masterson said in December 2012. *"Double our exports from AUD4 billion (USD4.19 billion) to AUD8 billion (USD8.39 billion); double our R&D investment from AUD1 billion (USD1.05 billion) to AUD2 billion (USD2.1 billion); creating many more high-skilled jobs and increasing the number of Australians accessing clinical trials to 30,000."*

There are many other reasons to manufacture biologics in Australia. Another is that the large number of mutual recognition arrangements that exist with Australia and key international regulatory authorities. For example, the US Food and Drug Administration (FDA) has signed a Memorandum of Understanding (MOU) with the Australian Therapeutics Goods Administration (TGA) which allows the two organizations to exchange information on Good Manufacturing Practice (GMP) inspections of pharmaceuticals facilities. This represents a streamlined approval process for Australian-based pharmaceutical companies seeking to market their products in the US.

Over the past decade Australia has developed robust clinical trial infrastructure that in general reduces the overall cost of biotherapeutic product development. This is because Australia has a favourable regulatory environment, world renowned hospitals and a medical system with a strong reputation for high quality clinical development. Australia has also holds a leading international position in robotics research and in automated process control which can be leveraged to streamline bioprocessing cost within a manufacturing setting.

Australia's robust and internationally compatible intellectual property regime is recognised as being one of the most effective and modern systems in the world in terms of patents and copyright enforcement. In fact, Australia's intellectual property system is ranked above countries such as the UK, Japan, Hong Kong and Singapore

All this is augmented by Australia's unique R&D tax situation. The Australian Taxation Office allows up to a 45% tax deduction, which under some circumstances can be in the form of a cash refund, on eligible R&D expenditure that can include the manufacture of materials for clinical testing. This makes Australia a very attractive location not only for manufacturing and clinical trials, but also as a base for establishing R&D operations.



Typical pharmaceutical manufacturing facilities are R&D intensive and require skilled employees, two attributes that make Australia attractive for pharmaceutical investment. There are two distinct stages to pharmaceutical manufacturing: primary and secondary manufacture. Primary manufacture involves the production of active chemical and biopharmaceutical ingredients. Secondary manufacturing involves formulation and packaging of the end product and usually occurs in smaller factories that are geographically proximate to their market. The fact that international pharmaceutical giant GlaxoSmithKline (GSK) has increased its Australian investment in both types of manufacturing by roughly \$60 million over the past five years is a testament to the favourable Australian conditions. GSK now operates two significant manufacturing operations, one at Port Fairy and another at Boronia. The Port Fairy plant specialises in producing active pharmaceutical products while the Boronia plant is a secondary manufacturing facility, which formulates and packages a range of prescribed pharmaceuticals and is the largest GSK sterile facility globally.

There are approximately 120 locally and foreign owned companies participating in the Australian pharmaceutical industry, which comprises both local and multinational subsidiary organisations. The majority of industry players in Australia are subsidiary organisations. The multinational manufacturers with subsidiaries in Australia include GSK, Merck, Pfizer, Bristol-Myers Squibb and Novartis. Local manufacturers include CSL Limited, Australia's largest biotechnology company, and small-molecule producers Mayne Pharma, Institute for Drug Technology (IDT), Sigma Pharmaceuticals and Alphapharm. Some of these firms have significant secondary manufacturing infrastructure in Australia, while others specialise in clinical trials R&D.

Activity in Australia's large-molecule biologics space is increasing. In October of 2013, DSM Biologics opened up a contract manufacturing facility in Brisbane specialising in the production of mammalian cell culture based biopharmaceuticals. This new mammalian cell facility perfectly complements LuinaBio's existing microbial-based manufacturing operations. Also located in Brisbane, LuinaBio has been conducting all phases of contract cGMP manufacturing in microbial systems for over fifteen, strengthening Brisbane's position as a regional hub for biotherapeutic development.

Briefly, in the biopharmaceuticals space, LuinaBio can undertake:

- Master and working cell bank preparation, validation and storage
- Upstream fermentation
- Downstream biopharmaceuticals purification
- Up and downscale fermentation optimisation
- Downstream process optimisation and development

Please contact us and you will be happy to find that the scientific team that we have in place in LuinaBio's Brisbane, Australia facility has the expertise, training and experience to ensure a successful outcome for your biopharmaceuticals production project.

Contact Us

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