

Client Support Services Offered by Contract Manufacturers

As a contract manufacturing organisation (CMO) located in the suburb of Darra, Australia's central business district (CBD) south of Brisbane, LuinaBio provides comprehensive manufacturing solutions for both biological and small molecule drugs.

LuinaBio offers manufacturing services including:

- Biopharmaceutical contract manufacturing
- GMP manufacture of recombinant proteins and vaccines
- Microbial products
- Small molecule synthesis for human and veterinary use
- Synthetic organic chemistry
- Production of GMP material for pre-clinical studies and clinical trial material batches for Phase 1, 2 and 3 clinical studies.

Technical expertise is always critical in the decision about which CMO to partner with to provide manufacturing solutions. However other key variables of importance that distinguish the best CMOs are timelines, efficiency, flexibility and related organizational expertise. LuinaBio strives to have a thorough appreciation for the entire scope of what is going on with your project and not just the material that you contract us to make. LuinaBio perspective is not just that of an "order-taker." We have reliable and professional project management capabilities, with individuals who are empowered to make decisions, such as offering suggestions for improving processes. LuinaBio offers a full range of client support services that complement our manufacturing services.

LuinaBio offers client support services such as:

- Project management
- Manufacturing advice
- Process validation
- GMP document preparation
- Regulatory advice
- CMC or dossier package development
- Product labelling
- Product distribution
- Stability studies

Besides manufacturing advice LuinaBio is capable of validating the process. We can not only give regulatory advice but also prepare all necessary GMP documents and help you put





together your CMC or dossier package. When the drug substance that we make for you is turned into drug product, we can do the stability studies and also handle product labelling and distribution.

LuinaBio approach is to be open, honest and up-front when things go wrong. Utilizing our change control system early in the development of a process, we have the ability to change or modify a product and justify that change once production has begun. In the latter phases of GMP manufacturing, we have a corrective and preventive action (CAPA) system in place to solve and address issues concerning any nonconformities that may be encountered and prevent them from happening again in the future.

LuinaBio is a CMO that not only can handle the work, but one that sees you as a partner and supports your needs.

Contact Us

Email: enquiries@luinabio.com.au

Website: <http://www.luinabio.com.au/>

