Thermo Fisher Scientific: Brisbane, Australia facility

Biologics manufacturing from preclinical through commercialization

Site address:
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Thermo Fisher Scientific's site in Brisbane, Australia, is a premier biologics production facility specializing in preclinical optimization, scale-up, and commercial manufacturing. The award-winning* site has expertise with commonly used commercial cell lines and CGMP production of recombinant antibodies and proteins. From 2018 to 2024, the Brisbane site completed 159 batches.

The facility includes 118,403 sq. ft./11,000 sq. m. of manufacturing space and 43,055 sq. ft./4,000 sq. m. of warehouse space. Employing over 300 bioprocess experts, the site utilizes single-use technology (S.U.T.), featuring Thermo Scientific and Global Life Sciences (Cytiva) single-use bioreactors (S.U.B.) ranging in size from 50 L up to 2,000 L for preclinical through commercial scale. Both batch-fed and perfusion methods are available for upstream bioprocessing. S.U.T. offers significant advantages over traditional stainless steel bioreactors, including reduced contamination risk, greater flexibility to produce different molecules with quick turnarounds, and improved sustainability by eliminating extensive cleaning and validation requirements. In contrast, traditional bioreactors are less flexible and sustainable since they can only handle one molecule at a time and require large amounts of water and cleaning agents.

We also have robust downstream and analytical capabilities with the flexibility to handle 100 g to 20 kg of product. For purification, we offer several chromatography systems, including Global Life Sciences ÄKTA ready™ single-use systems. The team has extensive experience with all major pre-packed column suppliers, such as Repligen and Global Life Sciences.

We also offer multiple tangential flow filtration systems (TFF), including the Global Life Sciences Uniflux 120 with up to 40 sq. m. membrane capacity. Our purification services are complemented by a wide range of analytical capabilities for characterization, stability, formulation, and method development.

Our company has established a robust framework of compliance and quality assurance across multiple regions. The site is locally regulated by the Australian Therapeutic Goods Administration (TGA). TGA inspections, audits, and licenses of CGMP facilities in Australia are accepted by the FDA and EU authorities through a memorandum of understanding (MoU), eliminating the need for further audits. We are approved by the FDA, TGA, EMEA, MHRA, Anvisa, Saudi Arabia FDA, and Korean MFDS for both clinical and commercial production. Additionally, programs such as the Australian R&D Tax Incentive and the Australian Clinical Trial Notification scheme can help fast-track your Phase I product timelines.

*2014 winner of the ISPE Facility of the Year Award for Process innovation; 2015 winner of the Frost and Sullivan APAC CMO of the Year Award.

Our Brisbane site is fully integrated into Thermo Fisher Scientific's global network, enabling us to seamlessly collaborate with our international affiliates for efficient technology transfers, as well as expanded capabilities. We can offer analytical development (St. Louis, US), bioprocess development (St. Louis, Missouri, US and Lengnau, Switzerland), cell line development and cell banking (St. Louis, Missouri, US) and drug product manufacturing (Monza, Italy; Ferentino, Italy; and Greenville, North Carolina, US), as well as analytical services both onsite and through Thermo Fisher CRG locations.

Core capabilities:

- **Scale-up and CGMP manufacturing:**
  Preclinical through commercial CGMP manufacturing and analytics.
- **Advanced analytical capabilities:**
  Robust in-house analytics for quality control (QC) and quality assurance (QA), ensuring rigorous testing and compliance.
- **Commercialization:**
  - A strong control strategy is developed for every commercial product, including comprehensive process characterization (PC) and process validation (PV) services. These include CMC- and regulatory-supported PC and PV risk assessments, experimental testing design, and data analysis.

Key features and offerings:

Single-use technology:
The site specializes in single-use technology (S.U.T.). We utilize Thermo Scientific S.U.B.s and Global Life Sciences (Cytiva XDR) S.U.B.s, ranging from scales of 50 L to 500 L as seed bioreactors and 500 L to 2,000 L as primary culture bioreactors.

Downstream processing utilizes S.U.T. chromatography skids, tangential flow filtration (TFF), and other flexible systems, eliminating the need for process-specific cleaning validation. The site also has reusable Global Life Sciences ÄKTA chromatography skids.

State-of-the-art equipment:
Capabilities include shake flask expansion and single-use wave-mixed bioreactors (2 L, 10 L, 20 L, and 50 L) for pre-culture expansion. We utilize stirred single-use seed bioreactors ranging from 50 L to 250 L and main culture bioreactors from 500 L to 2,000 L.

Chromatography capabilities include a wide range of pre-packed columns from all major suppliers and bioprocess systems with gradient capacities up to 2,000 L/h. Global Life Sciences ÄKTA ready gradient systems are used with single-use flow paths up to 510 L/h, as well as Global Life Sciences ÄKTA ready XL.

Filtration systems include automated skids: one Pall™ and one Global Life Sciences ÄKTA flux XL with 2.5–10 sq. m. membrane area capacity; a Global Life Sciences Uniflux with up to 40 sq. m. membrane area; and two Global Life Sciences ÄKTA ready small-scale skids with 0.1–2 sq. m. membrane area capacity.

In-process analytical capabilities include monitoring cell viability (Beckman Coulter Vi-CELL™ XR and Vi-CELL BLU) and cell culture conditions (Nova BioProfile® FLEX2). Analytical QC equipment and capabilities include, but are not limited to, CTech™ SoloVPE® (concentration), qPCR (bioburden), ELISA (activity, HCP, and protein A measurement), ultra-performance liquid chromatography (UPLC) for glycan, protein A, protein L, SEC, PMAP, RP, and CEX, as well as capillary zone electrophoresis (CZE), icIEF, CE-SDS, SDS-PAGE, endotoxin measurements, and more.

Connect with us:
Learn more about our offerings by visiting patheon.com/Brisbane, where you can also request a site tour or watch a video highlighting our core capabilities.

Schedule a site visit

From molecule to medicine

An integrated partner for every step in your drug development journey

Thermo Fisher Scientific provides industry-leading pharma services for drug development, clinical trial logistics, and commercial manufacturing through our Patheon™ brand. We partner with customers in the pharmaceutical, biotech, and life sciences industries as their trusted CDMO to deliver medicine to patients faster. With more than 60 facilities around the world, we provide end-to-end pharma services across all phases of development and commercial manufacturing, including API, oral solid dose, biologics, cell therapy, mRNA, viral vectors, formulation, clinical trial solutions, logistics services, and packaging. We couple our scientific and technical excellence in these areas with a strategic partnership to provide customers of all sizes access to a global network of facilities and dedicated experts across the Americas, Europe, Asia, and Australia. Through our integrated service offerings, we provide tailored solutions to fit your unique drug development journey, accelerating your time to market.

Discover the power of our global network.

For detailed capabilities and capacity information, please contact your Thermo Fisher Scientific representative.

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