

BUSINESS DESCRIPTION

A-Bio Pharma Pte Ltd is a Singapore-based biologics Contract Manufacturing Organization (CMO) that provides a full range of process development and manufacturing solutions for cell culture systems. cGMP manufacturing of biologics are performed in either a 200L or 500L train.

The production train consists of ISO 5, 7, and 8 cleanroom processing suites that are linked via air-locks to a dual corridor system, which ensures unidirectional flow of personnel, equipment and materials.

Range of services include:

- Process Development
- Analytics Development
- Quality Assurance / Regulatory Services
- GMP Manufacturing
- Quality Control

Total Facility Area	7,100 m ²
GMP Production Area	2,000 m ²
Special Material Handling	GMP bioprocessing in ISO 5, 7, 8 areas, BSL-2LS
Capabilities by Phase	Production for Phase I, II and III clinical trials
Regulatory Status	Facility designed to meet US FDA and EU EMEA GMP requirements
Key Customers Served	GlaxoSmithKline Biologicals, Novo Nordisk, A major US Biopharma Company. Previous projects mainly in process development and cGMP production of recombinant proteins and monoclonal antibodies.

EXPERIENCE OF TECHNICALTEAM

CEO	20+years of bioprocess development and biologics manufacturing experience in US large biopharmaceutical companies including Bristol-Myers Squibb Company, Merck & Co., Inc. and Hoffmann La-Roche, Inc. Has broad range of experience in various vaccines, recombinant proteins and antibody fusion proteins. Most recent post was VP and GM, Process Development and Biologics Manufacturing, BMS. Launched in 2006 the first BMS internally developed biologics for rheumatoid arthritis, Orencia TM .
Biotech Operations	25+years of bioprocess development and biologics manufacturing experience in US large biopharmaceutical companies including Merck & Co., Inc. and Hoffmann La-Roche, Inc. Has hand-on experience in various recombinant proteins and monoclonal antibodies. Most recent post was Sr. Investigator, Cell Culture and Fermentation, Bioprocess Development, Merck & Co., Inc. Launched a monoclonal antibody for Roche in 2005.
Bioprocess Development	25+years of pharmaceutical industry experience with Novartis. Previous position was VP, head of Technology focused on global analytical sciences and technology development for drug development, including protein characterization.
Quality	25+years of experience in quality assurance and control in US biotech industry. Previously was Director, Head of Quality, for Genentech/Tanox. Has direct experience in developing many therapeutic proteins and monoclonal antibodies, including Xolair TM .

SERVICES OFFERED		
Manufacturing Services	Number and Size of Bioreactors, Total Capacity	Types of Products Produced
Cell Culture (mammalian and insect)	8x2L, 6x10L and 1x40L in Process Development labs (total 116L); 1x40L, 1x200L and 1x500L in cGMP clean rooms (total 740L).	Monoclonal antibody, recombinant proteins & other insect and mammalian cell-derived biologics.
Support Services	Description	
Process Development	The Process Development Team identifies and develops optimal, cost effective, and reliable production processes, as well as offering comprehensive support for seamless transitions and scale up from shake flask scale to non-GMP production at 40L scale. The Process Development Team consists of 2 key groups, namely the Upstream and Downstream Development Group.	
Cell Line Development/ Expression Systems	(a) Transfection	(b) Evaluation of candidate cell lines
Cell Banking	(a) Master cell bank	(b) Working cell bank
Incubators	(a) Roller bottle incubator	(b) CO ₂ incubator
Analytical Testing and Biosafety Testing	(a) Appearance (b) Aggregates (c) pH (d) Sterility (e) LAL Endotoxin (f) Protein concentration by A280 (g) Potency, Biological activity (h) Identity & Purity	(i) Protein A contaminant (j) Host cell protein contaminant (k) Residual DNA contaminant (l) Carbohydrate analysis (m) Immunoglobulin class & subclass (n) Mycoplasma by ELISA (o) Microbiological ID (p) Peptide mapping
Stability Testing	(a) Appearance (b) Particulate (c) IEF (d) SDS-PAGE (reduced & non-reduced)	(e) SE-HPLC (f) Binding ELISA assay (g) LAL and sterility (only at Month 12 and 24)
Purification	(a) Harvest and concentration of products using UF/MF systems (b) Purification of proteins and vaccines using robust downstream process steps including various liquid chromatography unit operations with viral inactivation and viral clearance steps	
Nucleic Acid Chemistry	N.A. can be developed to meet customer needs	
Formulation	Basic bulk formulation for drug substance. Product formulation may be outsourced. Company will audit and manage this operation as per customer's preferences.	
Fill and Finish	To be outsourced. Company will manage this operation as per customer's preferences.	
Storage and Distribution	Raw materials, intermediates and products are held in quarantine till released, based on cGMP guidelines for sampling, testing, evaluation and release.	
Regulatory Services	(a) DMF (Type V listed at FDA), EDMF (b) CMC & Quality Data preparation (c) Support for regulatory application - IND & BLA, EUDRA CT & MAA (d) Liaison with regulatory authorities	