


Introduction

The Biologics Unit was established with project grants from the Innovation & Technology Commission (known as "Industry Department" in the past) of the Hong Kong SAR Government with the purpose of building a state-of-the-art facility and operation expertise unique in Hong Kong for use by the biotechnology industry from Hong Kong and other Asian region. Biotech start-up companies will find this arrangement beneficial because they do not need to invest heavily on capital equipment, manpower on one hand and at the same time cut down costs like depreciation, instrument maintenance to the minimum.

Being a unit of a non-profit making organization, we provide our service on a cost-recovery and pay-per-use basis.

Our unit has three major service areas: (1) process development from laboratory to pilot scale, (2) production of commercially unavailable biomass and biomolecules at a pilot scale as tools for biomedical research and as active pharmaceutical ingredients for clinical studies, and (3) production of generic biopharmaceuticals (biogenerics) for supply to the less developed market including China. We also act as a technology platform for developing prospective products resulting from pure research to bring them into the clinical research arena.

Process Development

The goal is to devise a process suitable for cGMP manufacturing that establishes procedures to minimize manufacturing downtime, streamline scale-up and maximize product yield and product purity. Process development services include molecular biology, media optimization, scale-up of fermentation and bioreactor runs, product recovery and purification design and product assay. Through collaboration with our strategic partners we can provide help in selection of an appropriate production system (bacteria, yeast, insect cells, mammalian cells) and cell line development (from cloning to GMP cell banking).

Molecular Biology	Upstream Process Development	Downstream Process Development
• Plasmid modifications • New construct development • Strain / Plasmid characterization • Screening of production strains • Comparability studies (Strain and product)	• Microbial expression systems and mammalian expression systems • *Pichia pastoris, Escherichia coli,* insect cell, Chinese Hamster Ovary (CHO) cell • Microbial fermentation • Cell culture bioreactors • Monoclonal antibodies • Media optimization / development • Product recovery • Concentration • Protein refolding (inclusion body systems)	• Chromatographic purification • Tangential flow filtration • Assay qualification • Protein characterization

Table 1: service scope of process development

Contract Manufacturing

We offer the service for manufacturing of therapeutics, vaccines, plasmid DNA and diagnostics up to demonstration batch. Our unique expertise allows us to focus primarily on protein-based target that can mostly be produced by bioreactors and large-scale fermenters. Table 2 summarizes our current service areas.

Class of Biologics	Sub-class	Culture		Product Development	Process Development	GMP Cell Banking	Analytical Development	Non-GMP Fermentation	GMP Fermentation	Non-GMP Down Stream	GMP Down Stream Processing	GMP Final Bulk	GMP Formulation	GMP Filling	Animal Test Facilities
		Fermentation	Cell												
For Evaluation / Research	Recombinant DNA-based Drug Substance	X	X		X		X	X		X					
	Monoclonal Antibodies		X	X	X		X	X		X					
	Nucleic Acid, Fungus	X	X		X		X	X		X					
Vaccine For Prophylaxis	Attenuated Microbial Cell	X	X	X	X		X	X		X					
	Live Microbial Vector	X	X		X		X	X		X					
	DNA Vaccine														
	Purified Protein	X	X	X	X		X	X		X					
	Conjugated Polysaccharides														
	Live Attenuated Viruses														
	Multiple Antigen Peptide Vaccines														
	Virus-like Particles														
	Live Viral Vectors														
For Therapeutic Use	Bacterial Preparation														
	Antitoxins / Antisera														
	Blood Products														
	Cytokines	X	X		X			X		X					
	Probiotics														
	Hormones	X	X	X	X			X		X					
Diagnostic Reagents for *in vivo* Test	Components of Protein in Nature	X	X	X	X			X		X					
Diagnostic Reagents for *in vitro* Test	Components of Protein in Nature	X	X	X	X			X		X					

Table 2: summary of our service along the production chain

Bio-analytical Laboratory Service

We offer a wide range of laboratory testing service with our in-house array of state-of-the-art analytical instruments. These tests are available to ensure the quality of your vector / host system before protein expression and your end-product after purification.

Tests Before Process Development / Production*	Tests after Process Development / Production*
• Characterization of prokaryotic cell • Characterization of eukaryotic cell lines • PCR-based bio-safety test • Phage testing • Copy number testing • Bacterial endotoxin • Mycoplasmas • Sterility test	• SDS-PAGE • Determination of isoelectric point • N-terminal protein sequencing • Amino acid analysis • Ultra-violet spectrum determination • Total organic carbon • Residual DNA impurities • Residual host cell protein • Viral clearance • Bacterial endotoxin • Mycoplasmas • Pyrogen

** Customized tests are available with advanced instrumentation (e.g. MALDI-TOF/TOF, X-ray analysis) that are available at Department of Biochemistry, CUHK.*

Profile of Target Collaboration

Our manufacturing facility was GMP-certified by the Therapeutic Goods Administration (TGA) in Australia in 1998. Currently we focus our effort on non-GMP process development and non-GMP production. We will proceed to attain GMP qualification from the SFDA (State Food & Drug Administration, Peoples' Republic of China) and TGA in the coming few years.

	Process / Purification Development	Non-GMP pilot-scale production	GMP Pre-clinical production	GMP clinical trial production	GMP commercial batch production
University Research	✔	✔	TBA	TBA	No
Entrepreneur Projects	✔	✔	TBA	TBA	TBA
Biotech Start-up Companies	✔	✔	TBA	TBA	TBA
Biopharmaceutical Companies	✔	✔	TBA	TBA	TBA

TBA = to be available

Successful Stories

We successfully completed a number of research and production projects like

- GMP production of anti-malaria vaccine candidate TBV25H for Phase I & II clinical trial for the World Health Organization (WHO) and the National Institutes of Health, USA;
- Production of veterinary vaccine recombinant paramyocin against *Schistosomiasis* for the Queensland Institute of Medical Research, Australia;
- GMP production of malaria blood-stage vaccine P30P2-MSP1 for the National Institutes of Health, USA;
- Production of a drug-screening enzyme for F. Hoffman-La Roche, Switzerland.

Intellectual Property Policy

Your intellectual properties will be strictly protected by a mechanism that is completely separate from those of the Chinese University of Hong Kong. A non-disclosure agreement between the related parties will be signed before any transfer of material and technical know-how. Being a subsidiary of a university, we will firmly uphold the standard and policy without any compromise.

Talk to us and explore this opportunity to make better use of your money for your R&D projects.

Biologics Unit

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