

protEcol™ Services

Process Development & Manufacture of Recombinant Proteins and Peptides

Why partner with protEcol™ Services?

Experience & Expertise

Over 20 years experience in process development and manufacture of therapeutic proteins using *E. coli* expression systems

Local

A global company offering global solutions, operating a purpose-built, world-class facility in Adelaide, South Australia

Complete Manufacturing Solutions

A full range of services provided to take biopharmaceuticals from proof of concept to cGMP manufacture for clinical trials

Quality, Flexibility & Speed

Design of strategic manufacturing solutions to meet budget and commercial objectives, balanced with quality risk management

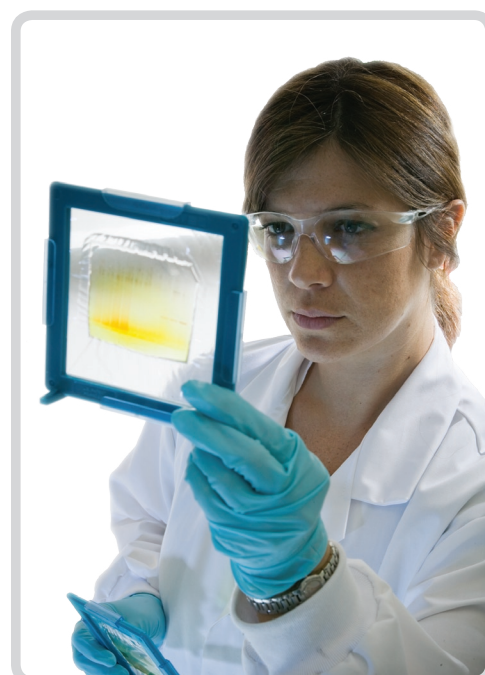
Return on Investment

Access to expertise and technologies for translation of laboratory processes to scalable, commercial production

Partner for Success

Focus is on open, collaborative client partnerships—we are an extension of your team

For more information on protEcol™ Services contact Hospira:
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Thebarton SA 5031, AUSTRALIA



Discount vouchers available to eligible Australian research groups

Hospira is a partner in the National Collaborative Research Infrastructure Strategy (NCRIS), providing process development and manufacture of recombinant proteins in accordance with cGMP, under Capability 5.5 "Biotechnology Products".

NCRIS is a national project supported by the Australian Federal Government and the Government of South Australia.

For more information on NCRIS, visit www.ncrisproteins.org

Put protEcol™ Services on your team and realise the benefits of working with the microbial expression experts

Process Design

a comparatively quick and cost-effective strategy to determine process feasibility

- Cell line development
- Cell banking
- Proprietary expression systems using qualified host strain

Process Development

relevant to stage of development and appropriate quality, quantity and cost

- Fermentation development
- Separation and purification development
- Statistical experimental design—'Quality by Design'
- PEGylation technology
- Formulation development

Analytical Services

assay development for in-process evaluation, release testing and protein characterisation

- Physicochemical analysis of proteins and peptides (e.g. RP-HPLC, FPLC, SEC, MS, ELISA, electrophoresis)
- Impurity and safety testing (e.g. endotoxin, bioburden, host cell protein, host cell DNA)
- Design of accelerated and real-time stability studies

Process Scale-Up & Technology Transfer

scaling of production to meet clinical and commercial milestones

- Scale-up to 100 L or 500 L scale
- Single site location for an accelerated technology transfer to cGMP operations

cGMP Contract Manufacturing

manufacture of therapeutic peptides and proteins in accordance with cGMP

- TGA licensed facility, compliant with ICH Q7: GMP Guide for Active Pharmaceutical Ingredients
- 1,000 m² state of the art production site
- Dedicated teams for Manufacturing / QA / QC / Validation / Regulatory Affairs

Steps in manufacturing development

Process Design

Process Development

Scale-up
Technical transfer

Validation

Commercial Supply

Pre-clinical
Studies

Phase 1

Clinical
Development

Submission

Commercialization

protEcol™ Services integrated expertise solves process challenges at each phase