idt australialimited

ASX: IDT · Melbourne, Australia · October 2026

CAPABILITY STATEMENT · STERILE MANUFACTURE

Sterile Fill-Finish and Lyophilisation

Two decades of aseptic manufacture on a sovereign Australian campus, now expanded by a major investment in sterile capability.

Improving Lives Through Pharmaceutical Innovation



PURPOSE

We make medicines that improve the lives of patients around the world.

Fifty years of cGMP manufacture on one Melbourne campus.

MISSION

To improve and save lives through the reliable manufacture of effective, innovative medicines.

VALUES

Integrity

Quality first, with best-practice governance and global compliance.

Ownership

Every role here helps a safe medicine reach a patient.

Ambition for excellence

Better solutions for clients, delivered with pace.

WHAT WE DO

Everything a Programme Needs, On One Site

Three manufacturing capabilities, and the services that wrap around every one of them, from technical transfer through clinical supply into commercial manufacture.

WHAT WE MAKE

Small molecule API

Drug substance from 1 mg to 1,000 kg, including cytotoxics, on reactor trains from 5 L to 4,000 L.

Solid oral dose

Capsules and tablets at commercial rate in high-containment suites, plus non-sterile liquids.

Sterile fill-finish

Aseptic vial filling and lyophilisation, including mRNA and lipid nanoparticle products.

ACROSS THE LIFECYCLE

Clinical, Phase I to III

Commercial supply

WRAPPED AROUND EVERY PROGRAMME

Technical transfer

Receipt of an incoming process, gap assessment and demonstration batches ahead of GMP.

Labelling and packaging

Primary and secondary packaging, clinical trial material, blinded supply and coding.

Storage and distribution

Controlled storage, cold-chain handling and dispatch to clinical and commercial markets.

Project management

A dedicated project driver and a standing team for the life of the programme.

Regulatory support

CMC documentation, dossier support, Drug Master Files and inspection readiness.

All of it runs under one quality system, on one site.

REGULATORY STANDING

A Globally Accredited cGMP Manufacturer

IDT operates inside a quality system that international regulators already inspect — with licences spanning human and veterinary medicines and controlled substances.

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

GMP licensed operations

FDA

Audited — US experience

EUROPEAN MEDICINES AGENCY

European engagement

PIC/S
Pharmaceutical Inspection Co-operation Scheme

PIC/S GMP principles

厚生労働省
Ministry of Health, Labour and Welfare

Japan experience

ANVISA

Brazil experience

APVMA

Veterinary medicines

Australian Government
Department of Health, Disability and Ageing
Office of Drug Control

Controlled substances

idt australia

THE SITE

A Single Integrated GMP Campus in Melbourne

Every function that a programme touches — manufacture, testing, warehousing, engineering and release — sits inside one 12,000 m² freehold site.



SITE ZONES

01	Inwards goods
02	Warehouse
03	Manufacturing facilities
04	QC / R&D laboratories
05	Administration
06	Controlled store / future manufacturing
07	API and FDF manufacture
08	API manufacture
09	Utilities
10	Solid oral dose form manufacture

THE STERILE PLATFORM

A Major Investment in Sterile Manufacture

Isolator filling, a commercial freeze dryer and automated packaging, added to a proven sterile suite on one site and one quality system.

A$14M+

invested in sterile, digital and facility capability

Filling, automation and utilities are built and governed together, so a transfer does not depend on separate systems being made to agree later.

STERILE FILL-FINISH AND LYOPHILISATION

Advanced sterile fill-finish line

Ready-to-use vials and 1 mL long prefilled syringes, isolator-based aseptic processing, robotic handling and 100 per cent in-process control.

Expanded lyophilisation line

New integrated freeze-drying platform with automated loading and unloading and increased shelf capacity.

Sterile inspection and integrity line

Semi-automatic vial inspection, deterministic vacuum-decay container closure integrity testing and expanded vial washing.

Pass-through sterilisation line

Bidirectional sterilisation and deactivation material transfer through a double-door pass-through steriliser.

The slides that follow describe how the platform is configured, area by area.

Every Step from Bulk to Pack, on One Site

The sterile platform runs as one controlled pathway from bulk compounding through to secondary packaging — supporting multiple product presentations without forcing one fixed configuration.

STAGE 01

Bulk compounding of the formulation

Bulk solution compounded on single-use assemblies, then sterile-filtered.

STAGE 02

Component preparation

Washed and depyrogenated or ready-to-use components, with pass-through sterilisation.

STAGE 03

Fill, stopper and cap

Laminar-flow and isolator lines for RTU vials and 1 mL PFS, with 100% IPC weighing.

STAGE 04

Lyophilisation

Two freeze dryers, one with automated loading and unloading.

STAGE 05

Inspection and CCIT

Visual inspection plus deterministic vacuum decay testing.

STAGE 06

Secondary packaging

Labelling, coding, cartoning, shipper packing and manual pack flexibility.

WHY THIS MATTERS

- Supports multiple product presentations without forcing one fixed line configuration
- Makes technical transfer easier to explain to Quality, MS&T, Engineering and Regulatory
- Converts equipment selection into a defendable control-strategy argument

Preparing the Product and Components

The sponsor’s bulk solution is compounded and sterile-filtered, while components are prepared for either filling line.

Bulk compounding of the formulation

- Sponsor’s bulk solution compounded on single-use assemblies
- Temperature-controlled mixing, recorded batch by batch
- Sterile filtration with filter integrity testing
- Vaccines, biologics, mRNA-LNP and potent small molecules

Component preparation

- Ready-to-use vials and syringes, transferred in through a pass-through steriliser
- Bulk vials washed and depyrogenated on site
- Component route chosen per product and filling line
- Single-use componentry limits cross-contamination

Two Filling Lines, Matched to the Programme

A proven laminar-flow line and a Grade A isolator line side by side, with programmes allocated by phase, presentation and batch size.

Laminar-flow filling line

- Proven Grade A line within a Grade B background
- Ready-to-use or washed and depyrogenated vials
- Liquid fill, or partial stoppering for lyophilisation
- Integrated capping

Isolator filling line

- Grade A isolator with VHP decontamination
- Robotic handling for minimal operator intervention
- Ready-to-use vials and 1 mL long prefilled syringes
- 100% in-process weight control on every unit

CONTAINER FORMATS

Indicative relative sizes



Lyophilisation — Two Freeze Dryers

A proven conventional freeze dryer and a commercial integrated unit, so batch size and stage decide the unit.

Conventional freeze dryer

2.5 m² shelf area and about 3,000 × 20 mL vials per run, steam-sterilised, with stoppering under air or nitrogen.

Commercial integrated freeze dryer

About 3.7 m² shelf area, loaded automatically from the isolator line, with integrated stoppering, for clinical and commercial supply.

Cycles are controlled from outside the sterile area with all critical parameters logged, and transfer as a recipe.

Inspected, Integrity-Tested and Packed

Every unit leaves inspected, integrity-tested, labelled and traceable — on the same site as the fill.

Visual inspection

- Semi-automatic inspection of liquid and lyophilised product
- Particles, cosmetic defects, fill level and cap condition
- Format-specific defect libraries

Container closure integrity

- Deterministic vacuum-decay testing
- Qualified per product with IDT's own reference standards
- Applied across the full format range

Labelling and packaging

- Automated vial labelling and cartoning
- Serialisation-ready batch and expiry coding
- Manual pack flexibility for specialist products

From clinical batches of around 1,000 units to commercial runs above 20,000, including kit formation for clinical trials.

COMPLEX FORMULATIONS

Biologics, mRNA and Lipid Nanoparticles

IDT manufactured the first GMP mRNA vaccine in the Southern Hemisphere, and fills complex biological formulations at clinical scale on the same site that formulates them.

mRNA and LNP capability

- Lipid nanoparticle (LNP) formulation (via tech transfer)
- LNP purification and buffer exchange
- Sterile fill and finish into vials
- Design of experiments on LNP formulation (via tech transfer) ahead of GMP manufacture

Demonstrated track record

- First GMP mRNA vaccine manufactured in the Southern Hemisphere
- 25+ mRNA vaccine candidates manufactured and released for human clinical trials

DELIVERED WITH

sanofi · Doherty Institute · MONASH University

WHY THIS MATTERS FOR STERILE

Sensitive product handling
Controlled temperature and handling regimes proven on live programmes.

Closed flow-path experience
Single-use assemblies and buffer exchange already in routine use.

Formulation on the same site
The formulators and the fill line share one quality system.

25+
mRNA vaccine candidates manufactured and released for human clinical trials

First
GMP mRNA vaccine manufactured in the Southern Hemisphere

20+ yrs
Of aseptic fill-finish and lyophilisation experience

idt australia

INTEGRATED TESTING

Analytical, Microbiology and Stability Capability

Phase-appropriate method development, transfer, verification and validation performed on site — with approved outsource partners for specialised techniques.

Analytical chemistry

- Assay, impurities and residual solvents
- Residual moisture for lyophilised product
- pH, clarity and particulates
- Stability-indicating methods
- PCR

Microbiology

- Bacterial endotoxin
- Bioburden (microbial enumeration)
- Container closure integrity testing
- Environmental monitoring programme
- Sterility testing through approved partners

METHOD LIFECYCLE

- ✓ Method development
- ✓ Method transfer
- ✓ Verification and validation
- ✓ Release testing
- ✓ ICH stability storage and testing
- ✓ Reference standard management

Applied phase-appropriately — the depth of the package scales with your programme.

Specialised analytical techniques are available through qualified outsource partners.

The Australian Advantage

Manufacturing here gives sponsors a stringent regulatory jurisdiction, a competitive cost base and a faster route into the clinic.

Quality

Recognised for stringent regulatory standards, a mature clinical trials ecosystem and a highly skilled technical workforce.

Reduced cost

A competitive cost base, and the R&D tax incentive on qualifying development spend.

Speed

Two trial pathways. CTN starts on HREC approval, typically 4 to 6 weeks. CTA adds TGA review for higher-risk products.

Security

Robust intellectual property law aligned to international standards, in a stable political and economic environment.

R&D TAX INCENTIVE

43.5%

Rebate for eligible companies on qualifying development spend in Australia

Claimed against the sponsor's own spend, not IDT's cost. It lands on the programme, not on us.



ARTICLE Unlocking Australia's R&D Tax Incentive, published by RDI Partners: rdipartners.com.au

IN SUMMARY

Why Bring a Sterile Programme to IDT

Six reasons, backed by the in-house disciplines a sterile transfer depends on.

01 Twenty years of aseptic experience

Sterile fill-finish and lyophilisation delivered on live programmes, not a capability being learned on your product.

02 A$14M+ of sterile capability

Two filling lines and two freeze dryers, adding barrier isolation, robotic handling and 100% in-process weighing to a proven sterile suite.

03 Complex formulations proven

25+ mRNA vaccine candidates released for human clinical trials, including the first GMP mRNA vaccine in the Southern Hemisphere.

04 One sovereign GMP campus

Filling, lyophilisation, inspection, packaging, QC and validation on a single TGA-licensed Australian site.

05 Transfer discipline

A defined transfer plan with agreed deliverables, and a standing transfer team rather than borrowed staff.

06 Evidence, not assertion

100% in-process weighing, product-specific CCIT qualification and Annex 1 thinking — open to sponsor review before transfer.

IN-HOUSE DISCIPLINES

- Quality and regulatory
- Engineering and CQV
- CSV and digital
- QC and analytical
- Aseptic assurance
- Dedicated transfer team

How a Sterile Enquiry Becomes a Transfer

A defined path from first contact to a contracted transfer. Confidentiality is in place before any process detail is exchanged, and no commercial commitment is sought until scope and cost are agreed.

01

Confidentiality agreement

A mutual CDA up front, so the process and control strategy can be discussed openly.

02

Initial conversation

A call to understand fill volume, container, stage and annual volumes.

03

Request for proposal

Your RFP, or our questionnaire if a structured start is easier.

04

Technical review

Container fit, lyophilisation cycle, formulation sensitivity and CCIT route.

05

Proposal and plan

Costed scope, deliverables, timeline and the assumptions behind them.

06

Master Services Agreement

Quality agreement, IP ownership, liability, pricing, change control.

07

Transfer start

A dedicated project driver and a standing transfer team from the first day.

USEFUL TO HAVE TO HAND

- Container format and fill volume
- Liquid fill or lyophilised
- Formulation and stability data
- Batch size and annual volume
- Cold chain and markets

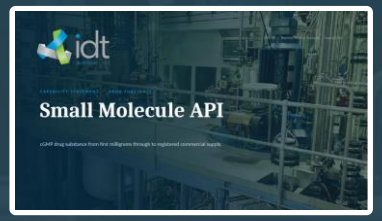
BEGIN YOUR DRUG DEVELOPMENT JOURNEY WITH IDT

Let's Talk About Your Sterile Programme

"Your agile end-to-end partner: from drug substance to finished dose."

Also need your small molecule API made, or have an oral dose form in the pipeline?

Same site, same quality system, same project team. If you do not have these, ask us for them.



CAPABILITY DECK

Small Molecule API

Drug substance, including cytotoxics



CAPABILITY DECK

Specialty Orals

Capsules, tablets and liquids



CAPABILITY DOCUMENT

Manufacturing and Development Capability

Facilities, equipment and accreditation in detail

Head office

45 Wadhurst Drive
Boronia, Victoria 3155
Australia

General enquiries

Telephone: +61 3 9801 8888
Facsimile: +61 3 9801 8773
Website: en.idtaus.com.au

Business development

bd@idtaus.com.au
Request a quote, schedule a meeting or visit our facility