idt australialimited

ASX: IDT · Melbourne, Australia · October 2026

CAPABILITY STATEMENT · FINISHED DOSE FORMS

Specialty Orals

Solid Orals and Liquid Orals

Capsules, tablets and non-sterile liquids. Formulation, manufacture, packaging and release on one site.

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.

GMP licensed operations

Audited — US experience

European engagement

PIC/S GMP principles

Japan experience

Brazil experience

Veterinary medicines

Controlled substances

We can make it here, today

TGA-licensed commercial manufacture under domestic regulator expectations — an inspection-ready GMP and QC environment already supplying the Australian market.

We meet global expectations

FDA audit experience, PIC/S GMP and Annex 1 principles, plus MHLW and APVMA experience with mutual recognition where applicable.

We handle difficult materials

Schedule 8 and 9 capability including medicinal cannabis, MDMA and psilocybin clinical material, cytotoxics and radioactive licence capability where approved.

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

DOSE FORMS

Three Oral Dose Forms, One Site

IDT manufactures hard-shell capsules, tablets and non-sterile liquids — supporting the same product from prototype batches through clinical supply into registered commercial manufacture.

Hard-shell capsules

Up to ~100,000 capsules per hour

- Various capsule sizes supported
- Blend formulation development support
- Powder and granule fills
- Clinical trial material through to commercial supply

Tablets

Up to ~100,000 tablets per hour

- Supports various tablet formats
- Immediate and modified release
- Coated and uncoated tablets
- Various shapes, colours and sizes

Non-sterile liquids

30 mL to 500 mL bottles

- Up to 3,000 bottles per day at 50 mL
- Solutions and suspensions
- Bottling, capping and labelling
- Controlled and standard formulations

NON-STERILE SOLID ORAL DOSE

Inside the Oral Solid Dose Facility

A building designed as high-containment suites for oral solid dose. Every suite has its own air handling, all rooms and airlocks meet ISO 8, and supply and exhaust are HEPA filtered, including through the isolators.

Dispensing and blending

- Inactive excipient dispensary with sieving into product-specific IBCs
- Negatively pressured isolator for highly potent dispensing, sieving and milling
- High-containment split butterfly valve transfer
- IBC blender to 280 L, V-blender to 56 L, laboratory blender for 10, 50 and 100 L

Granulation and milling

- High-speed granulator-dryer with cone mill for granule sizing
- Fluid bed drying above 50 kg for larger batch capacity
- All additions through split butterfly valves
- 300 L high shear mixer for homogeneous blends
- Roller compactor with variable-speed cone mill for dry granulation

Compression, encapsulation and coating

- 16-station press, isolator-housed, with de-duster and metal check
- Automatic compression platform with interchangeable B and D tooling
- Production-scale film coating at approximately 12 to 40 kg
- Encapsulation in sizes 0 to 3, plus a second small-scale suite
- 100% capsule checkweighing; batches to 40 kg on the current set-up



Manufacturing suite



Contained granulation and drying



Isolator-housed encapsulation

idt australia

Solutions and Suspensions, 30 mL to 500 mL

A dedicated non-sterile liquid line for small to medium scale clinical and commercial supply. Filling runs under laminar-flow filtered air to keep bioburden down during open-product and container handling.

Filling

- Semi-automatic single-head liquid filling machine
- In excess of 1,000 bottles per hour, subject to product, fill volume and container format
- Laminar-flow filtered air over the filling operation
- Flexible fill volumes, subject to product and container qualification

Closure, sealing and labelling

- Automated container counting and handling
- Automatic capping for a controlled, repeatable closure
- Induction foil sealing for tamper evidence and product protection
- Automated bottle labelling, then secondary packing to approved instructions

Control and changeover

- GMP-controlled batch documentation
- Line clearance and reconciliation at every changeover
- Product-specific cleaning and changeover procedures
- Solutions and suspensions, clinical through to commercial supply

1,000+/hr
BOTTLES, SUBJECT TO PRODUCT AND FORMAT

30 – 500 mL
FILL VOLUME RANGE

Laminar flow
FILTERED AIR OVER FILLING

One line
FILL, CAP, SEAL, LABEL AND PACK

DEVELOPMENT

Formulation Development That Survives Scale-Up

IDT develops the formulation with the commercial equipment in mind — so a blend that works at laboratory scale still works on the production line.

STAGE 01

Pre-formulation

API characterisation, excipient compatibility, flow and compressibility assessment.

STAGE 02

Formulation design

Blend design, granulation route selection and prototype manufacture at laboratory scale.

STAGE 03

Process fit

Trial runs on production-representative equipment to confirm the process behaves at rate.

STAGE 04

Analytical support

Method development, dissolution profiling, stability-indicating methods and release testing.

STAGE 05

Scale-up and validation

Commercial-scale batches, control-strategy definition and process validation.

Immediate and modified release

Release-profile design supported by in-house dissolution capability.

Blend and granulation development

Selection between direct compression, dry and wet granulation routes.

Stability by design

ICH stability storage and testing on site, with phase-appropriate protocols.

DOWNSTREAM

Labelling, Packaging and Clinical Trial Supply

Finished dose does not end at the press. IDT packages, labels, stores and dispatches — including blinded and comparator supply for clinical trials.

Packaging and labelling

- Primary and secondary packaging
- Automated bottle train: counting, desiccant insertion, capping and induction sealing
- High-speed blister packaging for capsules and tablets
- Label application and variable-data coding
- Cartoning, leaflet insertion and shipper packing

Clinical trial material

- Blinded and comparator supply
- Placebo manufacture matched to the active presentation
- Randomisation-ready labelling and kit assembly
- Controlled storage and dispatch to clinical sites

END TO END

From Clinical Supply to Registered Manufacture

A specialty orals programme stays with the same team across its lifecycle. The people who formulate the clinical presentation are the people who manufacture it commercially.

01 Clinical

PHASE I – III

- Capsule and tablet formulation for clinical supply
- GMP clinical trial material
- Scale-up and process optimisation
- Method transfer and validation
- Labelling, packaging and CTM supply

02 Commercial

ROUTINE SUPPLY

- Process validation and PPQ
- Registered commercial manufacture
- Stability and ongoing release testing
- Supply-continuity and lifecycle support

WRAPPED BY INTEGRATED SERVICES AT EVERY STAGE

- **Analytical & microbiology**
- **Quality & regulatory support**
- **Dedicated project management**
- **Packaging & distribution logistics**

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 by HPLC
- Related compounds: HPLC, LCMS, GCMS*, NMR*
- Residual solvents by GC
- Stability-indicating method development
- pH, Karl Fischer, clarity and particulates
- IR and UV spectroscopy, wet chemistry
- PCR

Microbiology

- Bacterial endotoxin testing (LAL gel clot)
- Microbial enumeration
- Testing for specified organisms
- Sterility testing*
- Container closure integrity testing*
- Environmental monitoring programme

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.

* Available through approved third-party agreements. Additional sophisticated analytical services 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 Specialty Oral to IDT

Six reasons, each verifiable before a batch is committed.

01 All three oral dose forms

Capsules, tablets and non-sterile liquids on one site — a product family does not need three suppliers, and the compression, coating and packaging platform is funded and installed.

02 Commercial throughput

Approximately 100,000 capsules or tablets per hour, so clinical success does not require finding a new manufacturer.

03 Formulation on the same site

Development chemists work alongside the production line, so process fit is designed in rather than discovered later.

04 Clinical trial supply built in

Blinded, comparator and placebo supply, labelling, kitting and dispatch handled in-house.

05 Testing and release in-house

Analytical, microbiology, dissolution and ICH stability on site — no shipping samples between organisations.

06 A globally accredited site

TGA-licensed and FDA-audited, applying PIC/S GMP, with a fifty-year manufacturing record behind it.

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

How a Specialty Orals Enquiry Becomes a Programme

A defined path from first contact to a contracted programme. Confidentiality is in place before any formulation 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 formulation can be discussed openly.

02

Initial conversation

A call to understand dose form, batch size and presentation.

03

Request for proposal

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

04

Technical review

Formulation, release profile and equipment fit assessed against the suites.

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

Programme start

A dedicated project driver and a standing technical team.

USEFUL TO HAVE TO HAND

- Dose form and strength
- Batch size and annual volume
- Formulation status
- Release profile, IR or MR
- Packaging and market

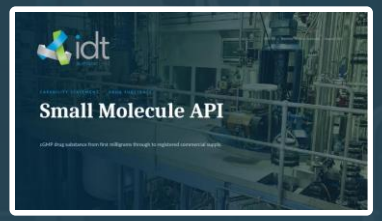
BEGIN YOUR DRUG DEVELOPMENT JOURNEY WITH IDT

Let's Talk About Your Oral Dose Form

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

Also need the drug substance made, or have a sterile programme 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

Sterile Fill-Finish

Vials and lyophilisation



CAPABILITY DOCUMENT

Manufacturing and Development Capability

Facilities, equipment and accreditation in detail

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