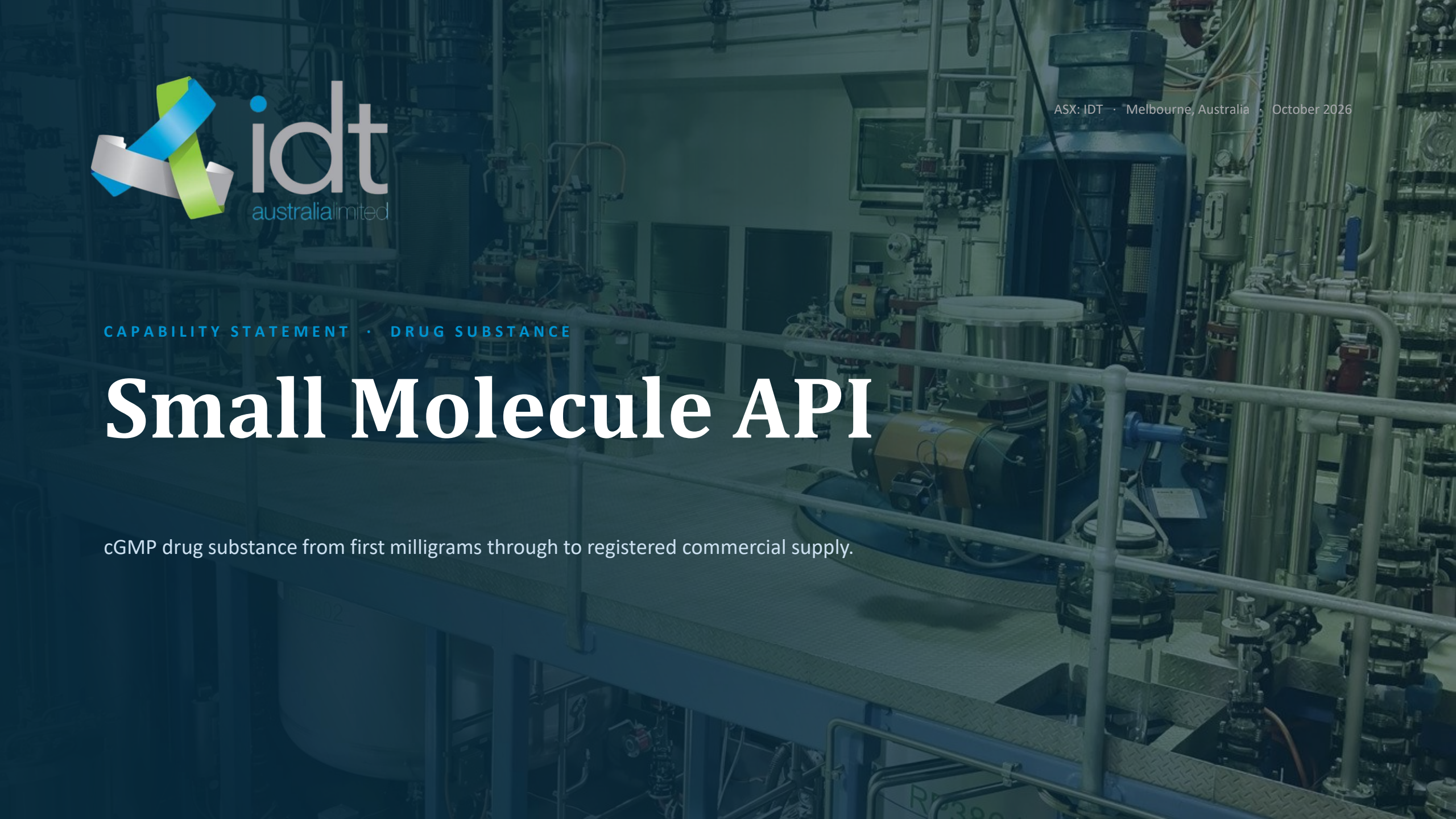


idt australia limited

ASX: IDT · Melbourne, Australia · October 2026

CAPABILITY STATEMENT · DRUG SUBSTANCE

Small Molecule API

cGMP drug substance from first milligrams through to registered commercial supply.

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

From Technical Transfer to Finished Dose

A programme arrives as an existing process, whether from your own laboratory bench or from another CDMO or CMO. It is manufactured as drug substance and leaves as a finished dose form.

Technical transfer

TRANSFERRED IN FROM

- Your laboratory bench
- Another CDMO or CMO

- Transferability and feasibility assessment
- Gap assessment against our systems
- Demonstration batches ahead of GMP

API manufacture

- Cytotoxic
- Non-cytotoxic
- Schedule 8 and 9

- Eleven reactor scales, 5 L to 4,000 L
- Batch scale from 1 mg to 1,000 kg
- Five US Drug Master Files on file

Finished dose form

Non-sterile solid oral
Capsules and tablets, including Schedule 8 and 9

Liquid oral
Solutions and suspensions, 30 mL to 500 mL

Sterile fill-finish injectable
Vials, syringes and cartridges

WRAPPED AROUND EVERY STAGE

- Analytical and micro
- Project management
- Packaging and labelling
- Clinical trial labelling
- Storage and distribution

SCALE

Eleven Reactor Scales, 5 L to 4,000 L

A continuous ladder of vessel sizes means scale-up is a series of controlled, evidenced steps — and a campaign can be sized to the batch you actually need.

Feasibility and early clinical

5 L · 10 L · 20 L · 30 L · 50 L · 60 L

Gram to low-kilogram quantities for feasibility work, demonstration batches and first GMP clinical material.

Pilot and scale-up

100 L · 250 L · 400 L

The intermediate steps that prove mixing, heat transfer and impurity profile before commercial volumes are committed.

Commercial

2,000 L · 4,000 L

Full-scale registered campaign manufacture, including the largest pharmaceutical reactor in the Southern Hemisphere.

WHAT THIS ENABLES

Feasibility quantities
Gram to kilogram material on the small vessels, without tying up commercial plant.

Stepwise scale-up
Each step is a modest volume increase, so mixing, heat transfer and impurity profile stay predictable.

Commercial campaigns
The 2,000 L and 4,000 L trains carry registered commercial products at full scale.

Right-sized batches
Small commercial volumes stay economic instead of competing for slots on oversized plant.

Chemistry the Group Has Already Run

IDT's process chemistry group holds established expertise across synthesis, specialist handling and purification. These are the capabilities that decide whether a route transfers cleanly at scale.

MATERIALS HANDLED

- Cytotoxics
- High-potency APIs
- ADC payloads and linkers
- Schedule 8 and 9
- Medicinal cannabis
- Standard molecules

Synthetic transformations

- Heterocyclic transformations
- Hydrogenation and cyanation
- Metal complexation
- Porphyrin chemistry and platinum chemistry

Specialist handling

- Toxic, moisture-sensitive and oxygen-sensitive compounds and reagents
- Natural product isolation
- Drug delivery systems, including conjugation of oncology payloads to polymer or peptide moieties

Purification and isolation

- Normal and reverse phase liquid chromatography
- Medium pressure chromatography and ion exchange
- Ultrafiltration and reverse osmosis concentration

Containment Built for Hazardous Chemistry

IDT has extensive experience handling both hazardous (cytotoxic) and standard (non-cytotoxic) compounds, in facilities designed around the material rather than adapted to it.

Containment and access

- Extensive experience with hazardous (cytotoxic) and standard compounds
- All facilities under dedicated secure swipe-card access
- Segregated suites for high-potency campaigns
- Dedicated change and gowning regimes per suite

Air, utilities and waste

- GMP suites with HEPA-filtered air, better than ISO 8
- In-house expertise in waste treatment and air treatment
- Solvent handling, recovery and controlled disposal routes
- Purified water and monitored process utilities



ADC CHEMISTRY

ADC Payloads and Linkers

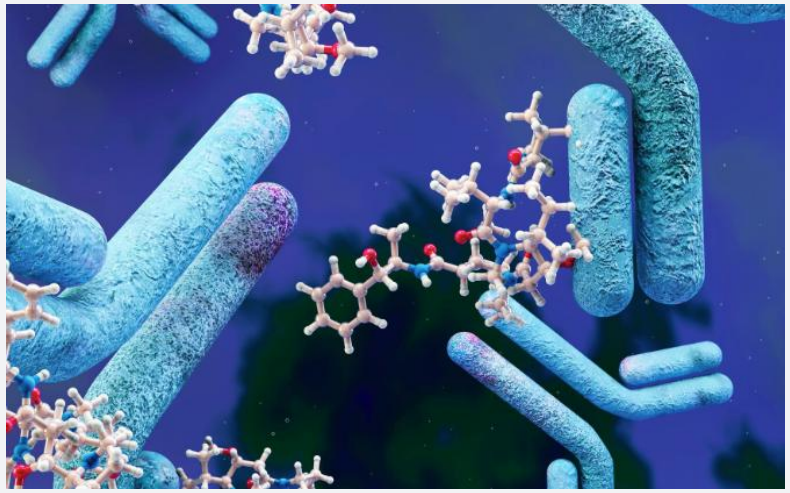
IDT's cytotoxic synthesis heritage extends into the payload and linker chemistry that antibody-drug conjugate programmes depend on — manufactured under GMP on the same licensed site.

GMP synthesis

- Synthesis of cytotoxic payloads under GMP
- Synthesis of linkers under GMP conditions
- Conjugation of payload to linker under GMP conditions
- Backed by decades of high-potency handling experience

Linker catalogue

- A linker catalogue is available on request
- Established routes, with custom linkers on request
- Payload and linker-payload supply for ADC programmes
- Characterisation by UV, SEC and mass spectrometry



WHAT IDT SUPPLIES TO AN ADC PROGRAMME

- ✓ Cytotoxic payloads, synthesised under GMP
- ✓ Linkers — catalogue routes or custom synthesis
- ✓ Linker-payloads, conjugated and ready for antibody conjugation

HOW A PROGRAMME RUNS

From Technical Transfer to Registered Supply

A drug substance programme at IDT follows a defined sequence, with an agreed deliverable closing each stage before the next begins.

STAGE 01

Technical transfer

Receipt of the incoming route, process gap assessment, hazard and containment review, and reactor fit confirmation.

STAGE 02

Non-GMP demonstration

Engineering and demonstration batches to confirm the process behaves as designed before GMP material is committed.

STAGE 03

GMP clinical supply

Scale-up onto the appropriate reactor train, GMP manufacture of clinical trial material and analytical method transfer.

STAGE 04

Process validation

Control-strategy definition, CPP and CQA mapping, validation protocol execution and process performance qualification.

STAGE 05

Commercial manufacture

Registered campaign manufacture, ongoing stability, release testing, change control and lifecycle support.

TRACK RECORD

Registered Products and US Drug Master Files

IDT holds multiple commercial dossiers and maintains US Drug Master Files supporting marketed products — evidence that the site sustains registered manufacture, not just development campaigns.

US DRUG MASTER FILES ON FILE

Hematoporphyrin Diacetate	**DMF 14839**
Mitoxantrone Hydrochloride	**DMF 12328**
Thiotepa	**DMF 14170**
Acetazolamide	**DMF 12997**
Minocycline Hydrochloride	**DMF 15014**

WHAT A DMF SIGNALS

A sustained regulatory position
Files are maintained and updated, not filed once and abandoned.

Documentation discipline
The CMC package a US filing requires already exists and is kept current.

Openness to inspection
The site is prepared for agency review of the manufacturing record.

Cytotoxic credibility
Several files cover high-potency oncology substances.

IDT also holds multiple registered commercial dossiers in Australia and supports customer filings in Europe, Canada and Japan.

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

Solid state and impurities

- Particle size analysis on site
- Salt and polymorph screening through audited partners*
- Characterisation of inorganics and heavy metals*
- Residual solvents by GC headspace
- Residual metals controlled at raw material approval
- Genotoxicity testing through audited 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.

* 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 Drug Substance Programme to IDT

Six reasons, each verifiable before a batch is committed.

01 Fifty years of cGMP manufacture

Continuous cGMP manufacturing in Australia since 1975, on a site purpose-built for pharmaceutical production.

02 The last small molecule API CDMO in Australia

Sovereign drug substance capability, including the largest pharmaceutical reactor in the Southern Hemisphere.

03 Eleven reactor scales on one site

Scale-up moves in controlled, evidenced steps from 5 L through to 4,000 L, without changing site or manufacturer.

04 High-potency and controlled substances

Cytotoxics, ADC payloads and linkers, and Schedule 8 and 9 material handled in purpose-designed containment.

05 A registered commercial track record

Multiple commercial dossiers and five US Drug Master Files supporting marketed products.

06 One site, one dedicated project driver

Technical transfer, manufacture, testing and release in one place, with a standing team for the life of the programme.

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

How a Drug Substance Enquiry Becomes a Campaign

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

02

Initial conversation

A call to understand molecule class, stage, quantity and timing.

03

Request for proposal

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

04

Technical review

Route, hazard profile, containment and reactor fit assessed.

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

- Structure or compound class
- Stage and intended use
- Target quantity and timing
- Known hazard or potency data
- Existing route, if any

BEGIN YOUR DRUG DEVELOPMENT JOURNEY WITH IDT

Let's Talk About Your Drug Substance

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

Two more capability decks complete the picture

This deck covers drug substance. If you do not have these, ask us for them.



CAPABILITY DECK

Specialty Orals

Solid orals and liquid orals



CAPABILITY DECK

Sterile Fill-Finish

Vials and lyophilisation



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