

IDT Australia

Manufacturing and Development Capability

Melbourne campus, Victoria, Australia

Active pharmaceutical ingredients | Sterile fill-finish | Oral solid dose | Radiopharmaceuticals

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Contents

Thirteen sections in five parts, from the company and its quality systems through to manufacturing, services and the Australian advantage.

THE COMPANY

01 About IDT Australia 3

02 The Melbourne campus 4

03 Investing for growth 5

QUALITY AND SAFETY

04 Quality and regulatory compliance 6
- 4.1 Licences and authorisations 6
- 4.2 Regulatory inspection history 7
- 4.3 Quality management system 7
- 4.4 Batch release and the Authorised Person 7
- 4.5 Suppliers, contractors and contract laboratories 7

05 Containment, potent handling and safety 8

SERVICES AND INFRASTRUCTURE

10 Analytical services, quality control and microbiology 30

11 Utilities and process water 32

12 Warehousing, storage and distribution 33

MANUFACTURING

06 Active pharmaceutical ingredient manufacturing 10
- 6.1 Chemistry expertise 10
- 6.2 Lower containment manufacturing: Facility A 11
- 6.3 High containment manufacturing: Facilities B, R and L 11
- 6.4 Building 51 API plants: 100 L, 400 L and 4,000 L 12
- 6.5 Radiopharmaceuticals: Facility V 15

07 Sterile finished dosage form manufacturing 16
- 7.1 Sterile platform pathway 16
- 7.2 Formulation 17
- 7.3 Component preparation and sterilisation 18
- 7.4 Aseptic filling and capping 18
- 7.5 Isolator-based sterile fill-finish 19
- 7.6 Lyophilisation 20
- 7.7 Sterile inspection, container closure integrity and washing 21
- 7.8 Sterile equipment and qualification criteria 22
- 7.9 Sterile vial presentation and packaging 23
- 7.10 Quality, containment and qualification controls 23

08 Oral solid dosage form manufacturing 25
- 8.1 Specialised capsule manufacturing and primary packaging 26
- 8.2 Tablet compression and film coating 27
- 8.3 Packaging 28

09 Non-sterile liquid filling 29

WHY AUSTRALIA

13 The Australian advantage 34

01 About IDT Australia

An ASX-listed CDMO manufacturing active pharmaceutical ingredients and finished dosage forms from one Melbourne campus.

IDT Australia Limited (IDT) is an Australian contract development and manufacturing organisation listed on the Australian Securities Exchange (ASX: IDT). From a single campus in Boronia, in Melbourne's eastern suburbs, IDT manufactures active pharmaceutical ingredients and finished dosage forms for clients in Australia, the United States, Canada, Europe and Asia. IDT supports programmes from clinical Phase I to III through to commercial supply.

IDT has manufactured pharmaceuticals on the Boronia site for five decades. Over that period the site has built a specialisation that few contract manufacturers hold in one location: the ability to synthesise a potent or cytotoxic active pharmaceutical ingredient, formulate it, fill it into a sterile vial or compress it into a tablet or fill into hard-shell capsules, test it in on-site laboratories, and release it for supply under a single quality management system.

The company is licensed by the Australian Therapeutic Goods Administration, is registered with the United States Food and Drug Administration and holds authorisations from the Australian Pesticides and Veterinary Medicines Authority, the Office of Drug Control and the Victorian radiation safety authority, so its licences span human and veterinary medicines and controlled substances. IDT operates to PIC/S GMP principles, has been inspected by the US FDA, and has regulatory experience with Japan's Ministry of Health, Labour and Welfare and Brazil's ANVISA, with European engagement through mutual recognition arrangements. IDT is inspected regularly by regulators and by client quality organisations.

Pharmaceutical manufacturing activities

The Boronia site is authorised to undertake the following activities:

CORE MANUFACTURING CAPABILITIES

Active pharmaceutical ingredients 6

- Manufacture of active pharmaceutical ingredients
- Development and scale-up of active pharmaceutical ingredients for clinical trials
- Synthetic and natural-product APIs, including cytotoxic and high-potency
- Reactors from 63 L to 4,000 L

Specialty orals 8

- Manufacture of tablets and hard-shell capsules
- Manufacture of powders and granules
- Contained suites from dispensing through coating and bottling

Sterile fill-finish and lyophilisation 7

- Sterile injectables for clinical trials and registration purposes
- Laminar-flow (3,300 vials/hr) and Grade A isolator lines
- Vials 2R–100 mL; 1 mL prefilled syringes

SPECIALISED MANUFACTURING

mRNA vaccines
mRNA-LNP formulation (via technology transfer) and sterile fill-finish.

Radiopharmaceuticals 6.5
Manufacture of radioactive pharmaceuticals: API and hard-shell capsules in dedicated containment Facility V.

Controlled substances 4.1
Manufacture and supply of Schedule 8 and Schedule 9 materials under the relevant permits and licences.

ADC payloads and linkers
Synthesis of cytotoxic payloads and linkers for antibody-drug conjugates.

SUPPORTING SERVICES

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

Analytical and QC 10
Independent quality control, microbiology and ICH stability on site.

GMP release 4.4
Batch release by an Authorised Person under one quality system.

Labelling and packaging 8
Labelling and packaging, including clinical trial packaging, bottling and cartoning.

Storage and distribution 12
Ambient to −60 °C or below, shipped to Australia, Europe, Canada and the US.

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.

02 The Melbourne campus

Separate buildings, each dedicated to a defined set of activities, on one campus in Melbourne's east.



Figure 1: *Entrance to the IDT Australia Melbourne campus.*

IDT operates from a single campus at 39 to 57 and 68 Wadhurst Drive, Boronia, Victoria 3155. The site covers approximately 12,000 square metres in a light industrial area approximately 26 kilometres east of the Melbourne central business district, with direct motorway access to the city and to Melbourne International Airport.

The campus is made up of a series of separate buildings, each dedicated to a defined set of activities. This building-by-building separation is deliberate: it allows IDT to run campaigns for potent, cytotoxic and radioactive materials in facilities that are physically isolated from one another, and to tailor containment to the requirements of an individual project rather than to a site-wide standard.

Table 1: *Melbourne campus locations and their principal use.*

Building	Principal use
1	Offices, inwards goods warehousing and the non-active material sampling dispensary.
2, 3	Dedicated containment facility for the manufacture of radiopharmaceuticals (APIs & Capsules) under GMP conditions.
4	Analytical and microbiological laboratories and small-scale development activities.
5	Head office. A multi-level building constructed in 2000 with a multi-level underground carpark.
6	Interconnected warehouse area providing GMP warehousing and controlled temperature stores.
7	Constructed in 2001. Sterile finished product manufacturing (Facilities P15, P17, P21, P23, P24 and P32) and three API manufacturing plants (Facilities P5, P8 and P38).
8, 9	Separate API manufacturing plants built between 1995 and 1996 (Facilities A, B, C, K, L and R), and site utilities.
10	Contained oral finished dosage form manufacturing suites, dispensary, stores and offices (Facilities S and T).



Figure 2: *Aerial view of the IDT Australia Melbourne campus, with site locations marked.*

03 Investing for growth

New manufacturing and packaging equipment across sterile fill-finish, oral solid dose and commercial packaging.

IDT has a significant programme of new manufacturing and packaging equipment. It supplements the site's existing capability rather than replacing it, and it is directed at three outcomes: a modern isolator-based sterile fill-finish platform, higher-throughput oral solid dose manufacture, and automated commercial packaging.

The table below summarises the programme, which provides additional flexibility for small to medium-scale clinical and commercial manufacturing, complex product formats and higher-throughput finished-dose operations. Sections 7 and 8 describe each element in detail.



Figure 3: *Isolator-based aseptic filling with robotic handling (left), high-speed blister packaging (centre) and tablet compression (right).*

Table 2: *Summary of IDT's investment in new manufacturing and packaging capability.*

Capability	New or expanded capability
SPECIALTY ORALS (NON-STERILE SOLID ORAL AND LIQUIDS)	
Specialised capsule manufacturing line	Larger fluid bed drying (greater than 50 kg), additional encapsulation capacity and high-speed blister packaging.
Modern oral solid dose manufacturing line	New tablet compression platform and substantially larger production-scale coating capability.
Commercial bottle packaging line	Automated counting, desiccant insertion, capping, induction sealing, labelling and cartoning.
Expanded labelling flexibility	Bottle labelling, plus capability being configured for small sterile vial formats including 2R, 6R, 10R, 20R, 50R and 100 mL.
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.

04 Quality and regulatory compliance

An independent Quality function, with licences and inspection histories across Australian, US and Japanese regulators.

IDT is committed to the achievement of corporate quality objectives through compliance with Good Manufacturing Practice and with the requirements of the FDA, the TGA, the APVMA, ICH and EU GMP. The Quality Department is responsible for maintaining the company's objective of manufacturing active pharmaceutical ingredients and finished products to international cGMP standards and is independent of Production.

4.1 Licences and authorisations

IDT holds the following licences and registrations. Copies of current licences can be provided on request, and the current licences are displayed in the foyers at 47 Wadhurst Drive and 68 Wadhurst Drive.

LICENSED, REGISTERED AND ACCREDITED BY

AUSTRALIA

INTERNATIONAL

GMP PRINCIPLES

Australia is a member of the Pharmaceutical Inspection Co-operation Scheme, and IDT's sterile suite complies with PIC/S Annex 1.

Table 3: *Current licences and authorisations.*

Authority	Scope	Reference
Therapeutic Goods Administration (Australia) 39-57 Wadhurst Drive	Manufacture of non-sterile active pharmaceutical ingredients by chemical synthesis, and of non-sterile and sterile finished dosage forms.	Licence MI-28102004-LI-000089-1
Therapeutic Goods Administration (Australia) 68 Wadhurst Drive	Manufacture of finished dosage forms.	Licence MI-2010-LI-05045-3
Food and Drug Administration (United States)	Registered drug establishment, inspected for cGMP compliance.	FEI 3000219354
Australian Pesticides and Veterinary Medicines Authority	Manufacture of veterinary products.	APVMA licence
Office of Drug Control (Australia)	Manufacture and supply of controlled substances, including Schedule 8 (all) and Schedule 9 (limited) drugs by manufacture and by wholesale.	Manufacture permit and associated state licences held for both 39-57 and 68 Wadhurst Drive
Radiation safety authority (Victoria)	Handling and manufacture of radioactive pharmaceuticals.	Radiation licence

Authority	Scope	Reference
Ministry of Health, Labour and Welfare (Japan)	Accreditation of the site as a foreign manufacturer.	Accreditation held

Australia is party to mutual recognition arrangements with the European Union and other jurisdictions covering GMP inspection. On that basis, IDT has not been separately inspected by the European Medicines Agency.

4.2 Regulatory inspection history

IDT is inspected regularly by health authorities and by clients. The table below lists the GMP inspections of the site by competent authorities over the last five years.

Table 4: *GMP inspections of the Boronia site within the last five years.*

Inspection date	Competent authority	Scope
28 April - 2 May 2025	Therapeutic Goods Administration (Australia)	Full GMP
24 - 28 March 2025	Food and Drug Administration (United States)	GMP surveillance inspection
24 and 26 September 2024	Australian Pesticides and Veterinary Medicines Authority	Licence extension
30 November - 5 December 2022	Therapeutic Goods Administration (Australia)	Sterile licence expansion
4 - 6, 18 and 26 August 2021	Therapeutic Goods Administration (Australia)	Sterile licence
1 - 4 March 2021	Therapeutic Goods Administration (Australia)	Full GMP

In addition to regulatory inspection, IDT is audited by its clients and by consultants acting on their behalf, conducts self-inspections to an approved internal schedule, and audits its own contract laboratories, suppliers, contractors and off-site warehouses.

4.3 Quality management system

IDT has defined a quality management system, designed to ensure a phase appropriate risk-based approach is taken to all quality related activities. All quality related activities are documented and carried out in a systematic and approved manner. The Quality department routinely reviews the effectiveness of the QMS through data generated from key attributes. We use this data, along with current industry trends to identify/implement improvements to our system that puts patient safety foremost whilst promoting a Quality Culture across site.

Records relating to the manufacture of active pharmaceutical ingredients and finished dosage forms are held for a minimum of ten years. Records relating to clinical trial materials are held for fifteen years.

4.4 Batch release and the Authorised Person

All active pharmaceutical ingredients and finished products manufactured under GMP conditions are released for supply by an Authorised Person in accordance with the appropriate regulatory standard.

4.5 Suppliers, contractors and contract laboratories

IDT operates a vendor assurance process covering all new and existing qualified vendors, with an established audit programme to monitor vendor performance. Raw material suppliers are approved by the Quality Department, with consideration given to regulatory impact, release testing limits, residual solvent and residual metals requirements, TSE and BSE compliance, genetically modified organism status and latex status. Controls are in place at receipt to guard against counterfeit or falsified materials.

A defined set of specialist analyses is placed with audited contract laboratories. Approval of a contract laboratory follows an audit by IDT, and each laboratory operates under a quality or technical agreement that defines the responsibilities of both parties.

05 Containment, potent handling and safety

Containment specified product by product, through engineering controls, protective equipment and handling procedures.

IDT has a long history of implementing containment methodologies that allow the manufacture of toxic and potent active pharmaceutical ingredients and finished dosage forms. Depending on the level of containment required, a combination of engineering controls, personal protective equipment, and safety and handling procedures is specified in documentation prepared for each individual product.

All manufacturing facilities are made up of segregated processing areas with separate HEPA-filtered supply air. The majority of processing areas are rated as ISO 8 cleanrooms in accordance with ISO 14644. This segregation allows containment to be tailored to individual project requirements rather than applied uniformly across the site. The manufacturing campus is divided into four groups:

LOWER CONTAINMENT → HIGHER CONTAINMENT

Lower containment API	Higher containment API	Finished dosage forms	Sterile finished dosage forms
Lower containment API manufacturing, for example Facility A.	Higher containment API manufacturing, for example Facilities B, P and R.	High and low containment finished dosage form manufacturing, for example Facilities S and T.	Sterile finished dosage form manufacturing, covering liquid and lyophilised vials.

In the containment facilities designed for the manufacture of highly potent or toxic materials, product-handling areas are designed to achieve ISO 8 conditions and are subject to a monitoring programme. Single-pass air is used in process areas, and inlet and outlet air is HEPA filtered. Plant and containment production handling rooms are maintained at negative pressure relative to atmosphere and are surrounded by areas of positive pressure, so that product is contained and personnel are protected. Facilities B, K, L, P, R, V and T can be used to manufacture highly potent or cytotoxic materials.

Air handling is designed to deliver a minimum of twenty air changes per hour, with rooms operated at nominal differential pressures and cleanroom temperatures maintained below 30 degrees Celsius. Pressure differential readings for cleanrooms, airlocks and corridors are recorded daily during production periods. HEPA filter performance is verified by integrity testing against Australian and United States standard specifications, conducted by a NATA-approved contractor.



Figure 4: *Contained product pack-off under high-containment conditions (left) and a cleanroom corridor serving the manufacturing suites (right).*

Personnel who work with cytotoxic or other hazardous materials are subject to a medical monitoring programme. Breathing apparatus, disposable coveralls, double gloves, overshoes and dedicated footwear are worn in containment manufacturing facilities. Facility-specific dress code instructions are displayed at the entrance to each work area.

After manufacture, cleaning procedures are verified by taking rinse and swab samples from plant and equipment to confirm that residual active materials are below acceptance limits. Limits are determined on the basis of health-based exposure limits and the quantity of residue that will not adversely affect the purity of the subsequent product. Cleaning procedures are validated using a risk-based approach involving at least three successful cleaning campaigns, and swab and rinse testing is performed routinely thereafter.

06 Active pharmaceutical ingredient manufacturing

Synthetic and natural-product APIs, including cytotoxic and high-potency compounds, from grams to hundreds of kilograms.

IDT manufactures synthetic and natural product active pharmaceutical ingredients, including cytotoxic and high-potency compounds, on scales from grams to hundreds of kilograms. Manufacturing facilities provide process cooling down to minus 35 degrees Celsius and heating up to 150 degrees Celsius, depending on the plant, with agitation and under inert nitrogen atmosphere or vacuum. Filters, centrifuges and vacuum-assisted solvent evaporation are typically used to isolate product, which is then dried under vacuum in a Nutsche filter, rotary dryer or drying oven, and milled or sieved before packaging as required.

Reactor scale across the API plants

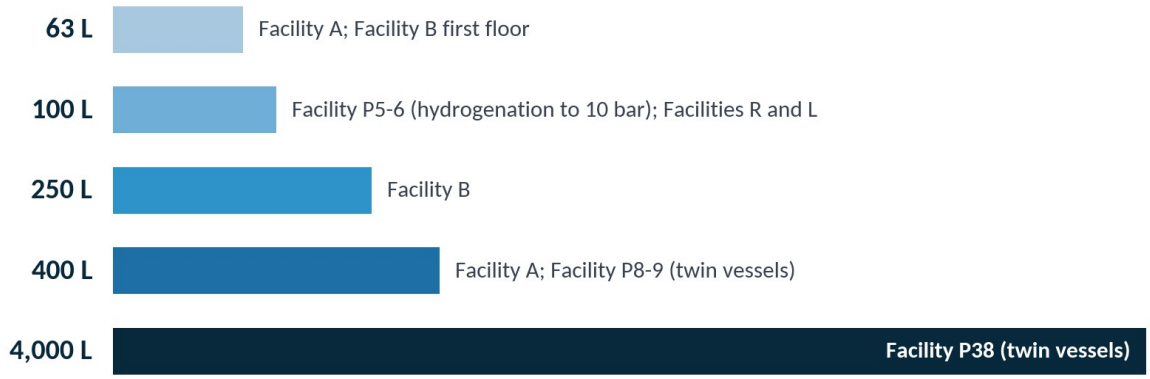


Figure 5: *Reactor scale across the API plants, from 63 L to 4,000 L (bar length on a square-root scale so smaller plants remain visible).*

6.1 Chemistry expertise

IDT's process chemistry group has established expertise in the following areas:

- Natural product isolation.
- Drug delivery systems, including the conjugation of oncology payloads to polymer or peptide moieties.
- Porphyrin chemistry and platinum chemistry.
- Heterocyclic transformations.
- Handling of toxic, moisture-sensitive and oxygen-sensitive compounds and reagents.
- Chromatography, including normal / reverse liquid chromatography, Medium Pressure chromatography and ion exchange.
- Ultrafiltration and reverse osmosis concentration.
- Hydrogenation and cyanation.
- Metal complexation.

6.2 Lower containment manufacturing: Facility A

FACILITY A Lower containment

Multi-purpose glass-lined plant

SCALE	ROOMS	TEMPERATURE	TRACK RECORD
63 L and 400 L glass-lined reactors	8, including 6 ISO 8 cleanrooms	−20 °C to +120 °C	Veterinary and human-use APIs under cGMP

Facility A comprises eight rooms, six of which are rated ISO 8 cleanrooms with HEPA-filtered supply air. The rooms are interconnected so that they may be used as a total system or individually.

The facility contains two major glass-lined reaction vessels of 63 litre and 400 litre capacity, together with a series of interconnected glass reactor vessels that may be independently heated and cooled between minus 20 and plus 120 degrees Celsius. The plant has been designed flexibly to enable multiple products to be manufactured in discrete campaigns, and supports reflux, distillation, vacuum distillation, extraction, separation and crystallisation as routine unit operations. IDT's engineering team can make minor modifications to the plant where a particular chemical process requires it. Product isolation, drying, milling, sieving, blending and packaging are all undertaken under ISO 8 cleanroom conditions.

Services provided include vacuum, compressed air, steam, glycol, nitrogen and Paratherm heat transfer fluid for the 400-litre reactor. Boiler and plant service areas are located outside the plant. The facility has been used to produce both veterinary and human-use active pharmaceutical ingredients under cGMP.

6.3 High containment manufacturing: Facilities B, R and L

Facility B (250 litre)

FACILITY B High containment

250 L multi-purpose plant

SCALE	ROOMS	COOLING	ENTRY
250 L ground floor, 63 L first floor	21, including 8 ISO 8 processing areas	Cold glycol to −20 °C	Triple airlock, showering before exit

Facility B is a 250-litre plant designed for multi-purpose operation with an emphasis on the handling of corrosive and highly potent materials. It comprises 21 rooms, eight of which are processing areas rated as ISO 8 cleanrooms with HEPA-filtered supply air, interconnected so that they may be used as a total system or individually.

The facility contains two plant rooms: one of 250-litre capacity on the ground floor and one of 63 litre capacity on the first floor. A fume hood on the ground floor provides capacity for laboratory-scale glassware and toxic reagent weighing. Entry is via a triple personnel airlock with gowning and showering facilities before exit. Associated equipment includes a Nutsche filter, centrifuge, and bag and cartridge filtration. Product isolation, drying, milling, sieving, blending and packaging are undertaken under ISO 8 cleanroom conditions. Services include vacuum, steam, compressed air, nitrogen, cooling and heating water, and cold glycol to minus 20 degrees Celsius.

What this means for your programme

Potent and corrosive chemistry runs in its own segregated plant, so containment is tailored to your molecule rather than applied as a site-wide standard.

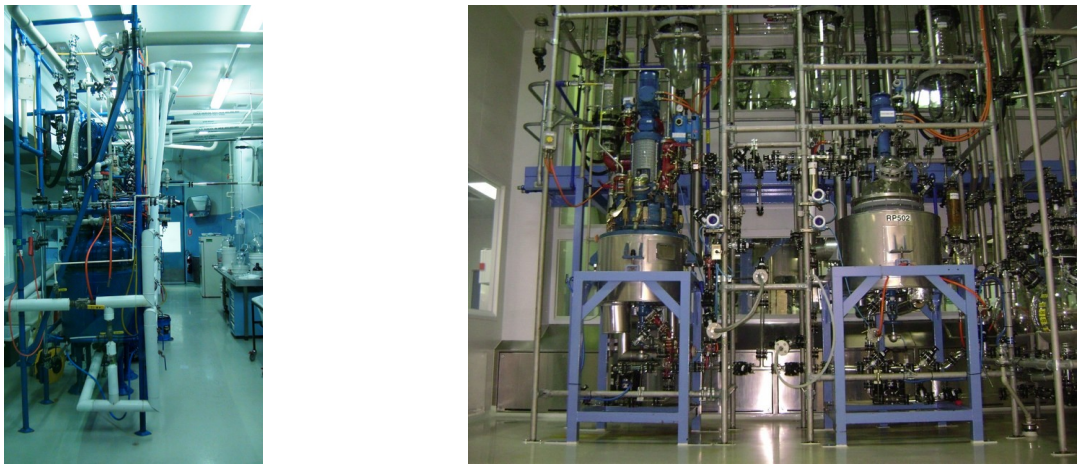


Figure 6: *Multi-level API plant room (left) and glass-lined reactor train with independent heating and cooling (right).*

Facilities R and L (smaller scale)

FACILITIES R AND L **High containment, smaller scale**

30 L to 100 L reactors

PROCESSING AREAS	AIR HANDLING	HEAT TRANSFER	VACUUM
2 per facility, ISO 8, single-pass HEPA	**Dedicated systems per area and airlock**	**−20 °C to 100 °C**	**To 30 millibar**

Facility R comprises five rooms, two of which are processing areas rated as ISO 8 cleanrooms with single-pass HEPA-filtered supply and exhaust air. The two processing areas and their associated airlocks have separate and dedicated air handling systems. Facility L is of similar capacity and layout.

The first processing area contains two bench fume hoods and one full-height walk-in fume cupboard and can accommodate up to two 100 litre glass vessels as required by the project. The second processing area contains two bench fume hoods. The plant is designed for multi-purpose operation with an emphasis on handling corrosive and highly potent materials and can be fitted with reactors from 30 litres to 100 litres. Unit operations include reagent addition, extraction, separation, crystallisation, reflux and vacuum or atmospheric distillation. Product isolation, drying and packaging are undertaken in the main room. A double personnel airlock allows personnel to change into personal protective equipment before entry. Services include compressed air, a heat transfer system operating between minus 20 and 100 degrees Celsius, nitrogen, steam, cooling water and vacuum to 30 millibar.

6.4 Building 51 API plants: 100 L, 400 L and 4,000 L

The building at 51-53 Wadhurst Drive contains both API and finished dosage form facilities, including the sterile plant described in Section 7. All operational areas and their airlocks are qualified to an air quality of at

least ISO 8, with the sterile suites operating in compliance with United States and European requirements for aseptic filling and packaging. Pressure gradients reduce the risk of cross-contamination in all potent handling areas.

Facility P5-6 (100 litre)

FACILITY P5-6 Building 51, potent and corrosive

100 L pilot plant

HYDROGENATION	COOLING	VACUUM	ENTRY
Rated pressure vessel to 10 bar	Cold glycol to −25 °C	To 25 millibar absolute	Triple airlock with showers

The 100-litre plant is designed for multi-purpose operation with an emphasis on corrosive and highly potent materials. There are two jacketed glass-lined vessels suitable for pilot-scale chemical processes. The primary reaction vessel is a rated pressure vessel capable of conducting pressurised hydrogenation reactions to 10 bar with a nominal working capacity of 100litres. The second vessel is glass-lidded with a working capacity of 100 litres. Two 50 litre glass receivers are also available. Associated equipment includes Nutsche filters and bag and cartridge filtration.

Product isolation, drying and packaging are undertaken in a humidity-controlled ISO 8 cleanroom adjacent to the main plant room. The control room is adjacent to the plant room with direct vision of the plant and isolation rooms. A walk-in fume hood supplied with low-pressure steam, vacuum and cooling water is located on the ground floor. Entry is via a triple personnel airlock with showering facilities, and solvent charging is carried out in a dedicated solvent charge room supplied with breathing air. Services include compressed air, cold glycol to minus 25 degrees Celsius, nitrogen, steam, cooling and heating water, and vacuum to 25 millibar absolute.

Facility P8-9 (400 litre)

FACILITY P8-9 Building 51, potent and corrosive

Twin 400 L plant

RECEIVERS	ISOLATION	CHROMATOGRAPHY	COOLING
2 × 200 L per vessel	Two 100 L Nutsche filters; 330 L phase separator	Preparative reverse phase	Cold glycol to −25 °C

The 400-litre plant is designed for multi-purpose operation with an emphasis on corrosive and highly potent materials. The primary and secondary reaction vessels both have working capacities of 400 litres and each is fitted with a high-capacity graphite condenser. Each 400-litre vessel has two associated receivers of 200 litres each. Associated equipment includes a 330 litre glass horizontal phase separator, two 100 litre Nutsche filters with a heat transfer plate and a dedicated 200 litre filtrate receiver, and bag and cartridge filtration. Preparative reverse phase chromatography can also be undertaken.

Product isolation, drying and packaging are undertaken in the adjacent ISO 8 cleanroom. The control room has direct vision of the plant and isolation rooms, and a walk-in fume hood is located on the ground floor. Entry is via a triple personnel airlock with showering facilities, and solvent charging is via a dedicated solvent

charge room supplied with breathing air. Services include compressed air, cold glycol to minus 25 degrees Celsius, nitrogen, steam, cooling and heating water, and vacuum to 25 millibar.

Facility P38 (4,000 litre)

FACILITY P38 **Building 51, potent and corrosive**

Twin 4,000 L plant

THERMAL RANGE	MINIMUM STIRRED VOLUME	FILTER DRYER	PACK-OFF
−35 °C to +150 °C	**226 L**	**2.0 m² Hastelloy Rosenmund**	**Continuous liner, ISPE OEB 4**

The 4,000 litre plant is designed for multi-purpose operation with an emphasis on corrosive and highly potent materials. There are four jacketed glass-lined vessels suitable for large-scale chemical processes. The primary and secondary reaction vessels both have a working capacity of 4,000 litres with two-tiered agitation, and each is fitted with two high-capacity graphite condensers and conductivity indicator transmitters in the base valves. The reactors have a minimum stirred volume of 226 litres and a thermal capability from minus 35 to plus 150 degrees Celsius. Each reactor has a 3,000 litre receiver operating from minus 30 degrees Celsius to ambient. Associated equipment includes a 2.0 square metre Hastelloy Rosenmund filter dryer with temperature control from minus 30 to 120 degrees Celsius, and bag and cartridge filtration.

Product isolation under contained conditions, drying and packaging are undertaken through a continuous liner pack-off system specified to meet ISPE occupational exposure band 4, in the ISO 8 cleanroom on the ground floor of the plant. The control room is adjacent to the plant room with remote video monitoring of the work areas, and a walk-in fume hood is located on the ground floor. Entry is via a triple personnel airlock with showering facilities, and solvent charging is via a dedicated solvent charge room supplied with breathing air. Services include compressed air, cold glycol to minus 30 degrees Celsius, nitrogen, Paratherm heat transfer fluid from minus 35 to 150 degrees Celsius, air cooling and heating, water, and vacuum to 10 millibar.



Figure 7: *Production-scale reaction vessels and associated services in the Building 51 API plants.*

6.5 Radiopharmaceuticals: Facility V

FACILITY V Radiopharmaceuticals

Dedicated containment facility

PRODUCTS	EQUIPMENT	SERVICES	LICENCE
API and hard-shell capsules	Encapsulator, fluid bed dryer, blister packer	Own compressed air and testing laboratory	Site radiation licence

The building at 41 Wadhurst Drive, Facility V, is a dedicated containment facility used to produce radiopharmaceuticals both active pharmaceutical ingredient and finished product (hard-shell capsules) under GMP conditions. The facility contains dedicated equipment including a rotary evaporator, fluid bed dryer, encapsulator, blister packer, flame sealer, liquid scintillation counter, analytical equipment, balances, refrigerators and freezers, together with its own compressed air system and testing laboratory. Radiopharmaceutical manufacture is conducted under the site's radiation licence.

07 Sterile finished dosage form manufacturing

Aseptic filling on laminar-flow and isolator lines, lyophilisation, capping, inspection and integrity testing, compliant with PIC/S Annex 1 and FDA requirements.

IDT's sterile suite and its support areas comply with PIC/S Annex 1 and FDA requirements for the quality of air supplied to the areas and for fill, finish and process flow. IDT holds a TGA manufacturing licence covering sterile finished dosage forms at 39-57 Wadhurst Drive, granted following a TGA sterile licence inspection in 2021 and extended following a sterile licence expansion inspection in December 2022.

IDT's sterile platform runs as one controlled pathway: single-use formulation with temperature control, component preparation and pass-through sterilisation, aseptic filling on both a Groninger laminar-flow line and a Grade A isolator line with robotic handling, lyophilisation on two freeze dryers, capping, external vial washing, visual inspection, container closure integrity testing and labelling. The platform handles six vial formats, from 2R to 50R ready-to-use vials through to 100 mL vials, and 1 mL long prefilled syringes.

Each primary area is served by a dedicated airlock for staff and, for the non-sterile support areas, a materials entry airlock. Pressure regimes between the common corridor, the dedicated airlocks and the sterile and non-sterile manufacturing suites ensure containment and reduce the potential for cross-contamination. Environmental conditions and pressure regimes within each suite are monitored continuously, and total particulates are measured continuously in the sterile suite during manufacturing. Total and viable particulate levels are tested against a schedule in non-sterile operations, and HEPA filter testing is carried out by an approved contractor against a schedule.

The Groninger line and the isolator-based line provide complementary operating options. Programme allocation considers development phase, presentation, batch size, process requirements, containment needs, qualification status and scheduling. The platform is supported by single-use mixing with temperature control, pass-through sterilisation and deactivation, dedicated CIP/SIP support, clean utilities and a qualification master plan pathway, and its modular fit-out meets EU Annex 1 and US CFR requirements for clinical, scale-up and commercial presentations.

7.1 Sterile platform pathway

The sterile platform is modular in design and organised around a sequence of controlled hand-offs. Each stage has a defined equipment owner, a defined quality control objective and a documented qualification point before routine release.

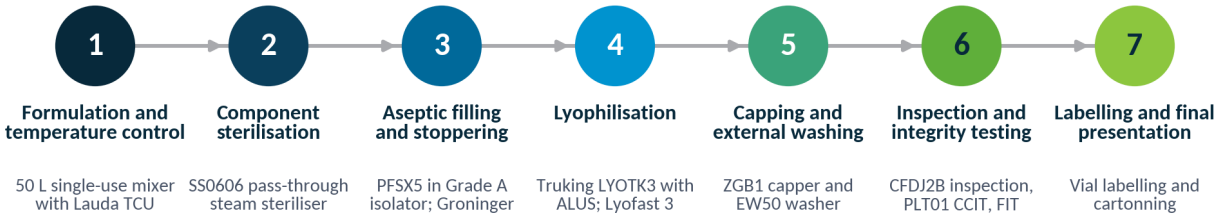


Figure 8: *Seven-stage sterile pathway from formulation to final presentation.*

Table 5: *Sterile platform stages, primary equipment and technical benefits.*

Stage	Primary equipment	Technical benefits
1. Formulation and temperature control	50 L single-use mixer with Lauda VC2000W temperature-control unit	Controlled mixing and temperature profile; product-contact assemblies are single-use.
2. Component sterilisation and transfer	SS0606 pass-through steam steriliser; directional A-to-B and B-to-A workflows	Interlocked transfer, validated cycle and recipe, and controlled release logic.
3. Aseptic filling and stoppering	PFSX5 filling and stoppering module in a Grade A isolator; Groninger laminar-flow line	Ready-to-use vial and 1 mL long prefilled syringe handling, robotic transfer, VHP decontamination and 100% in-process weight checking.
4. Lyophilisation	Truking LYOTK3 with automated loading and unloading system (ALUS); BOC Edwards Lyofast 3	Automated loading and unloading and integrated stoppering for lyophilised presentations.
5. Capping and external washing	ZGB1 vial capper and EW50 external washer; Groninger KVG 211A capper	Controlled closure application and removal of external residue before inspection.
6. Inspection and integrity testing	CFDJ2B visual inspection, PLT01 container closure integrity testing and filter integrity testing	Liquid and lyophilised presentations, subject to format-specific qualification.
7. Labelling and final presentation	Vial labelling and cartoning platforms	Print, inspection, reject and change-part controls for vial and finished-dose formats.

7.2 Formulation

The formulation suite contains a cabinet for the dispensing and formulation of potent actives, with a range of balances and mixing equipment to support different batch sizes. A pass-through into the non-sterile manufacturing suite allows transfer of the vessel while separating operator movement from product movement. The non-sterile manufacturing suite provides a staging area for the preparation of equipment and materials entering the sterile suite.

The formulation rooms are flexible spaces, with equipment able to be moved in and out as required by the project, and single-use componentry is used to minimise the risk of cross-contamination. This flexibility gives IDT the capability to formulate complex large molecules, including vaccines and biologics, as well as small potent molecules.

Single-use formulation and temperature-controlled processing

Single-use formulation capability supports smaller-volume sterile product preparation and transfer into the filling platform.

- Fifty litre single-use mixer with a Lauda VC2000W temperature-control unit.
- Temperature-controlled mixing through a dedicated temperature-control unit.
- Single-use product-contact assemblies, supporting reduced cleaning burden and flexible product changeover.

7.3 Component preparation and sterilisation

Equipment preparation takes place in a separate suite comprising a wash bay and an equipment preparation room. Pre-fill vial washing is provided by a Groninger ASVG 100 washer capable of cleaning 3,300 vials per hour, supplied with water for injection from the centralised system at greater than 80 degrees Celsius. Vials are trayed off under laminar flow conditions ready for entry into the depyrogenation oven.

Vial depyrogenation is provided by a Fedegari FOD1/1 dry heat oven built as an interface between the non-sterile and sterile suites, with a capacity of 3,000 twenty millilitre vials. The oven is fitted with HEPA-filtered air supply to provide positive pressurisation, and recirculated air is HEPA filtered through a high-temperature filter. Equipment requiring sterilisation for entry to the sterile suite passes through a Fedegari FOF3/9 steam steriliser, supplied by a Stilmas PSG200DTS pure steam generator.

Pass-through sterilisation and deactivation

An SS0606 double-door pass-through steriliser supports controlled material transfer and directional sterilisation and deactivation workflows.

- Forward transfer: load from Side A, complete a validated sterilisation cycle, then release to Side B.
- Reverse transfer: load from Side B, complete a validated deactivation and decontamination cycle, then release to Side A.
- An interlocked double-door philosophy maintains separation between the two sides and prevents simultaneous door opening.
- Cycle direction, recipe and successful completion form part of the controlled release logic for the receiving-side door.
- The arrangement provides a stronger platform for controlled movement of equipment, components and waste associated with potent or aseptic manufacturing.

7.4 Aseptic filling and capping

The sterile suite is accessed via a double airlock system that protects against contaminants entering the sterile zones and against potent errant material exiting them. The suite operates with a PIC/S Grade B background supported by HEPA supply and exhaust filters, and a Grade A unidirectional flow area over all equipment. Unidirectional flow coverage extends to the outfeed from the capping operation.

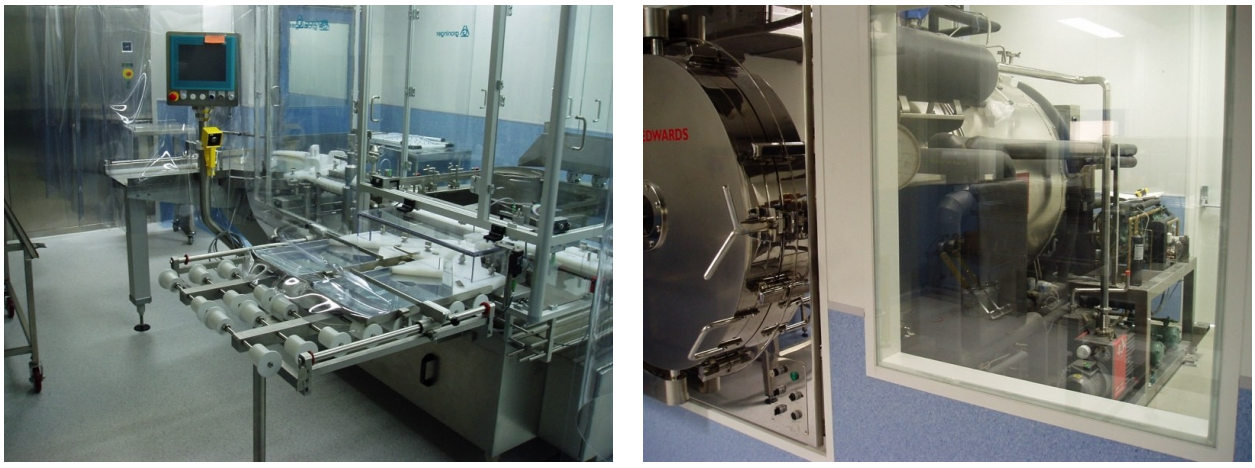


Figure 9: *Aseptic vial filling line (left) and freeze dryer within the sterile suite (right).*

Vial filling is provided by a Groninger vial filling machine capable of filling at a rate of up to 3,300 vials per hour. The line has two filling heads, and product is sterile filtered into the Grade A zone via two peristaltic pumps to the filling needles. The filler is configured to partially insert stoppers suitable for lyophilisation and can fully insert stoppers for terminally sterilised product as required. Filled vials are trayed off automatically for transfer under unidirectional flow to the lyophiliser. The line accepts both ready-to-use vials and bulk vials washed and depyrogenated on site.

Stoppered vials are delivered to a Groninger KVG 211A vial capping machine via the Grade A unidirectional flow area, which encompasses the capper through to the outfeed. The capper has a capacity of applying and crimping 3,300 aluminium caps per hour. Filter integrity testing is performed using a Sartorius Sartocheck 5, and single-use fluid transfer is supported by a Quattroflow four-piston diaphragm pump and Levitronix pump control.

7.5 Isolator-based sterile fill-finish

IDT's sterile fill-finish platform combines ready-to-use container processing, prefilled syringe capability, isolator technology and a highly automated aseptic product pathway.

- Vial processing across 2R, 6R, 10R, 20R and 50R ready-to-use vials and 100 mL vials.
- One millilitre long prefilled syringe filling and stoppering.
- Integrated Grade A isolator-based aseptic processing with vaporised hydrogen peroxide decontamination and reduced operator intervention.
- Robotic de-lidding, de-nesting and re-nesting, and controlled container transfer through the aseptic process.
- One hundred per cent individual container in-process weight checking, with automated feedback to the filling system.
- High-potency sterile product processing supported by barrier isolation and controlled transfer design, subject to containment qualification.
- Closure control, including automated stopper-height verification.
- PFSX5 filling and stoppering module from Truking Technology Limited, housed in the Grade A isolator.

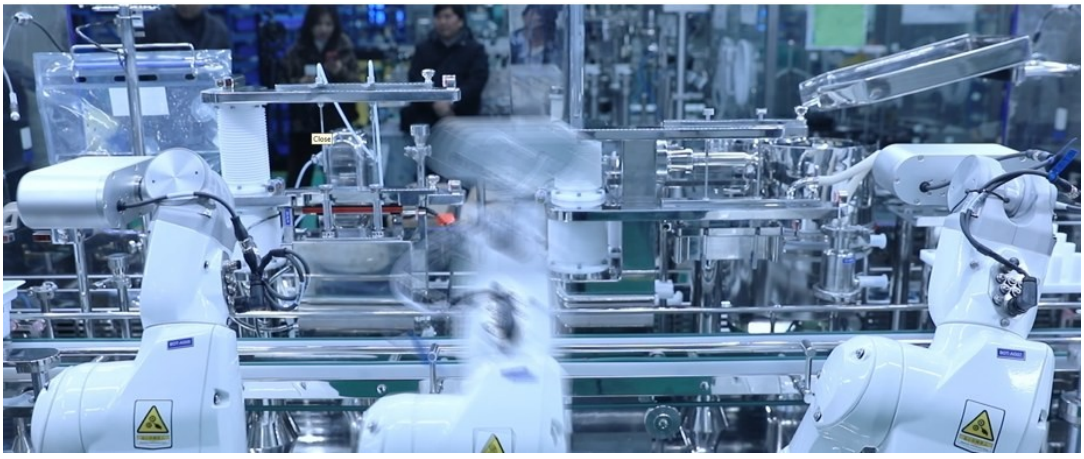


Figure 10: *Isolator-based aseptic filling with robotic container handling.*

Why this matters for clients

The combination of ready-to-use containers, isolator barrier technology, robotic handling and 100 per cent in-process weight checking addresses the two constraints clients most often raise about small-batch sterile supply: container format flexibility, and the level of operator intervention in the aseptic core. Together with the prefilled syringe format, it broadens the range of presentations IDT can offer from clinical supply through to commercial manufacture.

7.6 Lyophilisation

A BOC Edwards Lyofast 3 freeze dryer, with five shelves, approximately 50 kg ice capacity and capacity for approximately 3,000 × 20 mL vials per run, is available within the sterile suite for drying moisture-sensitive product. Trays of vials are loaded via the Grade A unidirectional flow. On completion of the drying cycle, vial stoppers are pressed home within the lyophiliser under either air or nitrogen atmosphere. The drying cycle is monitored and controlled from an operator interface outside the sterile area, with all critical parameters logged. The unit has an ice capacity of 50 kilograms and can process approximately 3,000 twenty millilitre vials per run. The dryer has been validated for steam sterilisation using pure steam from the sterile facility's pure steam generator.

A second integrated lyophilisation capability complements IDT's Lyofast freeze-drying capability described above.

- Integrated freeze-drying platform with a six plus one shelf configuration and approximately 3.7 square metres of gross shelf area.
- Automated loading and unloading between the sterile filling isolator and the freeze dryer, reducing manual intervention during critical aseptic transfer steps.
- Compatibility across small and larger vial formats.
- Integrated stoppering within the freeze-drying process and coordinated transfer back into the aseptic line.
- Additional freeze-drying capacity provides flexibility for clinical and commercial lyophilised products alongside the Lyofast platform.
- Truking LYOTK3 freeze dryer with automated loading and unloading system (ALUS).
- Approximately 75 kg ice capacity and approximately 8,000 to 9,000 2R vial positions per run (indicative).



Figure 11: *Freeze dryer with automated loading and unloading system.*

Table 6: *Freeze-drying platforms, available basis and qualification limitations.*

Platform	Available basis	Important qualification limitation
BOC Edwards Lyofast 3	Five shelves; approximately 50 kg ice capacity; approximately 3,000 × 20 mL vials per run.	A tray and chamber drawing and loading study are needed for vial sizes other than 20 mL. The 20 mL reference can be scaled directly to other sizes, however this is an approximation only.
Truking LYOTK3	Six plus one shelf arrangement; approximately 3.7 m² gross shelf area; approximately 75 kg ice capacity; approximately 8,000 to 9,000 2R vial positions per run.	Estimate only. Final shelf dimensions, usable area, tray or nest choice, loading pattern, stopper clearance, heat-transfer constraints and the validated cycle are confirmed on qualification.



Figure 12: *Indicative freeze-drying capacity: ice capacity and 2R vial positions per run.*

How the planning ranges are formed

Using 2R as an example, a 2R vial is approximately 16 mm outside diameter. For the LYOTK3, using a practical 18 to 20 mm handling pitch and approximately 80 to 85 per cent of the gross shelf area as usable loading area gives a geometric planning range in the order of 8,000 to 9,000 vial positions across approximately 3.7 m².

For the Lyofast 3, a separate screening proxy of approximately 6,000 to 7,000 2R positions is formed by normalising the stated 3,000 × 20 mL vial basis against a typical larger-vial-to-2R pitch ratio.

These figures are indicative and support planning estimates; validated batch capacities, cycle times and product loads depend on the product and unit configuration.

7.7 Sterile inspection, container closure integrity and washing

Dedicated downstream inspection and container-integrity technologies support the sterile platform.

- Semi-automatic visual inspection across the 2R, 6R, 10R, 20R and 50R vial range.

- Inspection of both liquid and lyophilised vial presentations, subject to format-specific qualification.
- Deterministic container closure integrity testing using vacuum-decay technology for offline and sample integrity testing.
- Vacuum-decay testing does not require helium or carbon dioxide tracer gas; it detects changes in pressure within an evacuated test cavity around the sealed container.
- Post-fill external vial washing, removing residue from sealed vials across a broad vial size range.
- CFDJ2B semi-automatic visual inspection platform.
- PLT01 vacuum-decay container closure integrity testing with format-specific test tooling, and filter integrity testing qualified by method.
- ZGB1 vial capper for controlled closure application, and EW50 external washer for post-fill cleaning.
- Dedicated CIP/SIP skid (LYO1.5S) providing cleaning and sterilisation support for the associated equipment train.

7.8 Sterile equipment and qualification criteria

The sterile systems were developed in collaboration between IDT and Truking Technology Limited (China). The table below sets out each asset's capability contribution and the design or qualification evidence required before routine use. Capacities and format ranges are governed by approved technical specifications, vendor drawings, FAT and SAT evidence and qualification records.

Table 7: *Sterile equipment, capability contribution and qualification criteria.*

Asset	Capability contribution	Design or qualification criteria
Groninger vial filler and KVG 211A capper	Vial filling and aluminium-cap application at approximately 3,300 vials per hour, accepting ready-to-use vials or bulk vials washed and depyrogenated on site.	Demonstrated format fill rates, fill accuracy, stopper and cap recipes, and line clearance.
BOC Edwards Lyofast 3	Freeze dryer with approximately 50 kg ice capacity and approximately 3,000 × 20 mL vials per run.	Qualified cycles, chamber and tray drawings.
PFSX5 filler/stopper and Grade A isolator	Ready-to-use vial and 1 mL long prefilled syringe processing with VHP decontamination and robotic handling.	Isolator interfaces, utilities, glove and door configuration, alarms and VHP cycle acceptance.
LYOTK3 lyophiliser and ALUS	Integrated freeze-drying with automated loading and unloading.	Shelf dimensions, 2R load plan, stoppering clearance, cycle design and transfer interfaces.
ZGB1 vial capper and EW50 external washer	Downstream closure application and external vial cleaning.	Cap formats, torque and height controls, washer recipe, water quality and drying requirements.
CFDJ2B visual inspection	Semi-automatic inspection for 2R, 6R, 10R, 20R and 50R formats.	Liquid and lyophilised inspection criteria, defect library, lighting, reject logic and qualification samples.
PLT01 CCIT and filter integrity testing	Vacuum-decay CCIT with format-specific test tooling; filter integrity testing qualified by method.	Vial and PFS cavity, reference standard, recipe, acceptance limit, calibration and data-integrity controls.
SS0606 pass-through steriliser	Double-door, directional sterilisation and deactivation or decontamination workflows.	Cycle validation, interlocks, load patterns, door logic and release status.
CIP/SIP skid LYO1.5S	Dedicated cleaning and sterilisation support for the associated equipment train.	WFI and PW, pure steam, air, drain, return and validated cycle requirements.

7.9 Sterile vial presentation and packaging

Sterile vial labelling and packing use Truking's modular integrated packaging line, alongside semi-automatic and manual processes. Each packaging module is SCADA controlled and integrated to ensure a seamless handshake from one module to the next. The line labels vials and syringes and cartons at approximately 50 vials per minute (design limit), and is serialisation-capable.

Naked vials of different sizes are labelled and cartoned according to client requirements. Packaging covers clinical batch sizes of approximately 1,000 units through to commercial batch sizes above 20,000 units, and includes serialisation and kit formation for clinical trials. Labelling and downstream presentation are configured with separate change parts, recipes and inspection criteria where the container geometry or label specification requires it. The line also complements other formats such as bottle packing for solid dose preparations, while a separate high-throughput bottle, vial and cartoning pathway is retained for sterile products.

Table 8: *Sterile presentation areas and control points before release.*

Presentation area	Capability	Control point before release
Sterile vial formats	2R, 6R, 10R, 20R, 50R and 100 mL presentations.	Format-specific parts, recipes, handling studies and qualification samples.
Prefilled syringe pathway	1 mL long PFS filling and stoppering within the sterile platform.	PFS nesting and de-nesting, closure, inspection, CCIT tooling and transport controls.
Vial labelling	Small-container labelling, including 2R vials at approximately 16 mm outside diameter.	Label presence, print and inspection, reject logic, printer technology and label matrix as controlled-specification items.
Cartoning	Automatic cartoning within the finished-dose packaging train.	Carton, leaflet, aggregation and traceability, and format change parts confirmed by product presentation.



Figure 13: *Sterile presentation formats: 2R, 6R, 10R, 20R, 50R and 100 mL vials and 1 mL long prefilled syringes (indicative relative sizes).*

7.10 Quality, containment and qualification controls

Sterile capability is only meaningful when the surrounding controls are designed at the same level as the equipment. IDT's sterile platform therefore links barrier protection, sterilisation, clean utilities, data integrity and qualification evidence to the equipment sequence.

Table 9: *Sterile control areas, platform intent and evidence required for release.*

Control area	Platform intent	Evidence required for release
Barrier and asepsis	Grade A isolator, VHP decontamination, controlled transfer and reduced operator intervention.	Smoke studies, VHP cycle qualification, glove and door integrity, environmental monitoring and aseptic process simulation as applicable.

Control area	Platform intent	Evidence required for release
Material transfer	Double-door pass-through steriliser with directional A-to-B sterilisation and B-to-A deactivation and decontamination.	Cycle development and validation, interlock challenge, load pattern and receiving-side release logic.
Container closure integrity	Deterministic vacuum-decay CCIT for product- and package-specific testing; no helium or CO2 tracer required.	Validated cavity and tooling, reference standards, acceptance limits, calibration and 21 CFR Part 11 data-integrity controls.
Filter integrity	Filter integrity testing for sterilising-grade filter assemblies and product-specific process needs.	Method, wetting fluid, pressure and flow range, reference filters, acceptance criteria and instrument qualification.
Cleaning and sterilisation	CIP/SIP skid support for equipment cleaning and sterilisation, with WFI, PW, pure steam and clean air interfaces as required.	Validated cycles, flow, temperature and pressure recording, drainability, hold times and cleaning acceptance criteria.
Utilities and environment	Controlled HVAC, EMS and BMS, WFI and PW, pure steam, clean compressed air, nitrogen and electrical services sized by approved equipment data.	Utility load list, peak and normal demand, connection points, alarms, recovery time, classification and commissioning evidence.

Every element of the sterile platform demonstrates a clear trace from user requirement through design qualification, factory acceptance testing, site acceptance, and installation and operational qualification. Product and format availability is subject to the applicable validation and qualification evidence, including aseptic process simulation where required, in compliance with EU Annex 1 and US regulatory requirements.

08 Oral solid dosage form manufacturing

High-containment suites at 68 Wadhurst Drive, from dispensing through compression, coating, encapsulation and blister and bottle packaging.

The building at 68 Wadhurst Drive was designed to provide a generic high-containment set of suites for oral solid dosage form manufacturing. The facility provides dispensing, blending, high-speed granulation and drying, tablet compression and hard capsule filling, and includes small-scale cleanrooms for clinical trial packaging. It is compliant with local and United States regulatory requirements for the manufacture of non-sterile solid dose products.

The suites are complemented by a higher-capacity process and packaging train covering larger-scale fluid bed drying, automatic encapsulation, high-speed blister packaging, production-scale tablet compression and film coating, and automated bottle packaging.

Each dedicated suite is supported by airlocks for materials and personnel. All rooms and airlocks meet at least ISO 8 conditions, and all suites have separate and dedicated air handling systems. All processing rooms have HEPA-filtered supply and exhaust, and where isolators are used the supply and exhaust streams are also HEPA filtered. HEPA filter integrity and total particle counts are on an annual testing regime, and microbiological testing by settle plates and air sampling is on a rotational programme tied to the manufacturing campaigns.

Table 10: *Oral solid dosage form unit operations and capability.*

Unit operation	Capability
Dispensing	Inactive excipient dispensary with capacity to sieve excipients prior to loading into product-specific intermediate bulk containers. A negatively pressured isolator enables highly potent dispensing, sieving, milling and other unit operations, with transfer to intermediate bulk containers via high-containment split butterfly valves.
Blending	Wall-mounted intermediate bulk container blender handling containers up to 280 litres, with smaller sizes available. A V-blender suite handles blends up to 56 litres. A laboratory blender matched to 10, 50 and 100 litre stainless steel intermediate bulk containers supports development-scale work.
Granulation and drying	High-speed granulator-dryer for the combination of liquid binders or actives with powder blends, fitted with a cone mill for sizing granule prior to transfer. All additions to and from the granulator-dryer are made through split butterfly valves. A 300 litre high shear mixer provides formulation mixing of actives with excipients to achieve homogeneous blends.
Dry granulation and milling	Roller compactor for granule formation, with ribbon passed through a variable-speed cone mill for sizing prior to blending. Screen and speed selection allows gentle sifting and de-lumping through to aggressive sizing.
Tablet compression	A 16-station tablet press producing approximately 60,000 tablets per hour, with tablet de-duster and metal detector, housed within a negatively pressured isolator for contained tablet manufacture. Dust extraction is via a high-containment bag-in bag-out filtration system, and the active blend is transferred to the press via intermediate bulk container and split butterfly valves.
Encapsulation	An encapsulation suite comprising a hard-shell capsule filling machine matched to a capsule de-duster and metal detector within a negatively pressured isolator, capable of filling speeds up to 38,000 capsules per hour in capsule sizes 0, 1, 2 and 3. A second small-scale encapsulation suite provides up to 20,000 capsules per hour in capsule sizes 0 and 3.

Unit operation	Capability
Checkweighing	An automated capsule checkweigher with controlled hopper feeding and a rotating sorting drum for 100 per cent weight checking of capsules. Each capsule is weighed using a sensitive load cell and compared against predefined upper and lower recipe limits. Capsules outside the specified limits are automatically diverted to a reject bin, while compliant capsules continue to the accept bin.
Coating	Two coating units allow work across a range of batch sizes: a trial-scale unit for up to 1 kilogram of tablets and a 10 kilogram production-scale fully perforated pan unit with a dedicated HEPA-filtered heating unit and spray gun fed from a peristaltic pump.
Tablet and capsule counting	A counting system that dispenses a pre-defined number of tablets or capsules into each bottle. Adjustable hopper and vibration settings control product feeding, while bottle height and alignment are set for accurate dispensing. Target product and container counts are entered via the operator interface, with filled bottles removed and replaced as required.
Induction sealing	An induction sealing system for sealing filled and capped bottles of tablets and capsules. The system allows adjustment of sealing height and power to suit the bottle and cap configuration, with start-up checks performed to confirm induction seal integrity.
Labelling	A bottle labelling system for applying pre-printed labels to filled bottles, with a printer to add batch-specific information such as batch number and expiry date. The system includes adjustable bottle guides and gating for controlled bottle separation and a vision detection system to verify the printed label.
Controlled drugs	Safes and a vault are available for the storage of controlled drugs, supported by the site security system.

Batches of up to 40 kilograms can be manufactured on the tabletting set-up. All equipment and facilities are qualified prior to use and are on a risk-based requalification plan, with maintenance and calibration scheduled through the site preventative maintenance system.



Figure 14: *Contained granulation and drying (left) and isolator-housed tablet compression (right).*

8.1 Specialised capsule manufacturing and primary packaging

A dedicated higher-capacity process and packaging train supports specialised capsule products and other small to medium-batch finished-dose applications.



Figure 15: *High-speed blister packaging platform for capsule and tablet products.*

- Larger fluid bed drying capability for increased batch capacity.
- Automatic encapsulation capacity providing greater scheduling and product flexibility.
- High-speed blister packaging for capsule and tablet products, including aluminium-PVC and aluminium-aluminium formats.
- Integrated vision inspection, batch and lot coding, and electronic machine controls on the blister platform.
- A dedicated primary and secondary packaging workflow designed to support efficient movement from manufacture through to finished-product packaging.

8.2 Tablet compression and film coating

Higher-capacity compression and coating equipment complements the contained tablet and capsule manufacturing capability described above and supports flexible commercial production.

- Automatic tablet compression platform with interchangeable B and D tooling architecture and modern electronic control, audit and recipe functionality.
- Additional turret and tooling configurations broaden tablet-format capability as required.
- Production-scale film coating platform for larger batches, with approximately 12 to 40 kilogram coating capacity.
- Coating-liquid preparation based on a 30 litre jacketed, temperature-controlled slurry tank with pneumatic agitation.
- Integrated product-transfer, dust-control and cleaning arrangements supporting reliable routine manufacturing.



Figure 16: *Tablet compression platform (left) and production-scale film coating unit (right).*

8.3 Packaging

IDT packages clinical trial supplies on site, including capsules, tablets, dried herbs and liquid dosage forms on a small scale. Clinical trial finished products are quality control tested and released prior to final packaging, with packaging and labelling performed according to master batch records. Commercial packaging capability includes capping, conveying and induction sealing, together with the automated bottle-packaging train described below.

Automated commercial bottle packaging

An automated bottle-packaging train complements IDT's clinical and small-scale packaging capability and supports higher-volume commercial tablet and capsule presentation formats.

- Automatic bottle unscrambling and feeding.
- Desiccant insertion capability for relevant product presentations.
- Electronic tablet and capsule counting and bottle filling.
- Automatic capping and induction sealing.
- Automatic bottle labelling with print and inspection functionality.
- Automatic cartoning within the packaging train.
- A design basis of approximately 50 bottles per minute, subject to product, count and bottle-format qualification.
- Multiple commercial bottle formats supported through dedicated change parts.

Bottle and vial labelling

The labelling platform provides flexibility across both oral solid dose bottle formats and small sterile vial presentations.

- Commercial bottle-labelling capability integrated into the automated bottle-packaging train.
- Small-container labelling, including 2R vials at approximately 16 millimetres outside diameter.
- Label-presence detection, print and inspection, and reject functionality.
- Multiple product formats supported through dedicated change parts and recipe selection.

09 Non-sterile liquid filling

Semi-automatic liquid filling under laminar-flow filtered air, with automated closure, sealing and labelling.

IDT operates a dedicated non-sterile liquid filling capability suitable for small- to medium-scale clinical and commercial manufacture. The filling operation is performed under laminar-flow filtered air to provide enhanced environmental control and minimise bioburden during open-product and container handling operations.

The line is based around a single-head semi-automatic liquid filling machine and is capable of processing in excess of 1,000 bottles per hour, subject to product characteristics, fill volume and container format.

The filling process is supported by automated container counting and handling, followed by automatic capping to provide a controlled and repeatable closure process.

Following filling and capping, containers pass through an induction sealing system to provide an additional tamper-evident and product-protection barrier. Finished containers are then transferred through an automated labelling system, with final products subsequently packed in accordance with approved packaging instructions and product-specific batch documentation.

The capability includes:

- Semi-automatic single-head liquid filling.
- Throughput of more than 1,000 bottles per hour, subject to product and format.
- Laminar-flow filtered air over the filling operation to support reduced-bioburden processing.
- Flexible filling volumes subject to product and container qualification.
- Automated container counting and handling.
- Automatic capping.
- Induction foil sealing.
- Automated bottle labelling.
- Final secondary packaging.
- GMP-controlled batch documentation, line clearance and reconciliation.
- Product-specific cleaning and changeover procedures.

The combination of controlled filling under filtered airflow, flexible semi-automatic filling and automated downstream closure, sealing and labelling provides a practical platform for non-sterile liquid products while reducing manual handling and supporting efficient clinical and commercial supply.

10 Analytical services, quality control and microbiology

Physical, chemical and microbiological testing by a Quality Control department independent of Production.

The Quality Control department is independent of Production and performs physical, chemical and microbiological testing in laboratories at 45 Wadhurst Drive, with radiopharmaceutical and intermediate testing performed in Facility V. The department tests and releases raw materials and critical packaging items, performs in-process testing not performed by the production chemists, and tests finished active pharmaceutical ingredients and finished products for both commercial and non-commercial programmes.

Testing is performed to approved test methods and specifications, with general methodology and equipment use described in standard operating procedures and operator instructions. All analytical data is checked by a second analyst or supervisor. Results are reported on proformas, electronically within Waters Empower, and in analytical, method validation and development reports, with certificates of analysis issued for APIs and finished products.

Table 11: *Analytical and quality control capability.*

Capability	Instrumentation and methods
Chromatography	Multiple Waters Alliance HPLC systems with ultraviolet and photodiode array detection, Waters Acquity Arc with photodiode array, Agilent 1200 with multi-wavelength detection, and Agilent gas chromatographs with autosampler and headspace. Evaporative light scattering, photodiode array and ultraviolet detection are available. Data is acquired and processed in Waters Empower. A single quadrupole liquid chromatography-mass spectrometry (LC-MS) system, operated on independent software, is available for non-GMP work.
Spectroscopy	Perkin Elmer FTIR Spectrum 2 infrared spectroscopy with attenuated total reflectance (ATR) sampling, and Agilent Cary 3000 ultraviolet-visible spectroscopy.
Physical and wet chemistry	Karl Fischer titration (volumetric and coulometric), melting point apparatus, moisture analyser, polarimeter, refractometer, turbidimeter, osmometer, pH meters, conductivity meters, total organic carbon analysis, loss on drying, residue on ignition and general bench analytics, including titrations and compendial wet chemistry identification tests.
Solid dose in-process testing	Hardness, disintegration and dissolution apparatus, and particle size analysis.
Biophysical and molecular	IDT has expertise in the characterisation of complex and nucleic acid-based formulations, including particle size and zeta potential measurement (Zetasizer), plate-reader assays (SpectraMax i3x) and droplet digital PCR. The associated instrumentation is currently dedicated to specific client programmes, and its availability for new programmes is by arrangement.
Microbiology	Total yeast and mould, total aerobic microbial count, specified micro-organisms and bacterial endotoxin testing of incoming materials, raw materials, active pharmaceutical ingredients, intermediates and finished dosage forms, together with environmental monitoring and water testing on controlled worksheets.
Contract laboratories	Full physicochemical characterisation including salt and polymorph screening, characterisation of inorganics and heavy metals, ion chromatography, nuclear magnetic resonance, sterility testing, genotoxicity testing and bioanalytics are placed with audited contract laboratories.



Figure 17: *Chromatography laboratory at 45 Wadhurst Drive.*

IDT conducts ICH stability studies in qualified stability chambers with continuous temperature and humidity monitoring. Stability data is used to support retest periods, expiry dates and storage conditions, and is reviewed as part of the product quality review process.

11 Utilities and process water

Water treated as a raw material, with Water for Injection and Purified Water manufactured on site.

Water is designated as a raw material at IDT and is controlled by the quality assurance function, with sampling and monitoring managed directly by the microbiology and quality control departments. IDT has Water for Injection and Purified Water manufactured in-house.

Utilities include pure steam, hot water, filtered compressed air and gases from approved suppliers.

Critical systems have audit trails and are verified against a common time server.

12 Warehousing, storage and distribution

Secured, temperature-monitored storage and controlled shipment to client locations and clinical sites.

Storage warehouses are secured through a combination of security card entry and locks. Products are stored in temperature-controlled storage areas, with temperature-sensitive products held in cold rooms, refrigerators or freezers under continuous temperature monitoring and recording.

IDT provides ambient, 2 to 8 degrees Celsius, minus 20 degrees Celsius and minus 60 degrees Celsius or below storage, each with dedicated quarantined, released, work-in-progress, research and development and consumables areas. Material status is controlled by the inventory management system and maintained by both segregation and labelling, with orange quarantine, green released and red reject labels applied and the corresponding materials stored in individual warehouse locations.

Products are shipped to clients' nominated locations in Australia, Europe, Canada and the United States in accordance with master packaging instructions. Temperature-controlled products are packed with data loggers to monitor temperature during transit, and tamper-evident containers are used for controlled drug materials. For investigational medicinal products, IDT can ship directly to clinical trial sites at the client's request.

Batch traceability is maintained through invoicing and the computerised inventory management system. Complaints are logged in the electronic quality management system, investigated, and reported to the client, with all records retained so that trends, product-related frequencies and severity can be evaluated. Recall procedures are maintained in accordance with regulatory agency requirements.

13 The Australian advantage

A stringent regulatory jurisdiction, a competitive cost base and a faster route into the clinic.

Clients developing products in Australia can access the Commonwealth research and development tax incentive on eligible expenditure, together with a clinical trial notification pathway that allows trials to commence without a separate regulatory approval step in most cases.

Quality

Recognised for stringent regulatory standards, a mature clinical trials ecosystem and a highly skilled technical workforce. Australia is a member of the Pharmaceutical Inspection Co-operation Scheme, and Australian GMP certification is recognised under mutual recognition arrangements with the European Union and other jurisdictions.

Reduced cost

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

Speed

Two clinical trial pathways. Under the CTN scheme, trials start on Human Research Ethics Committee (HREC) approval, typically within 4 to 6 weeks, with notification to the TGA. The CTA scheme 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%

Refundable tax offset for eligible companies on qualifying R&D spend in Australia

Claimed against the sponsor's own eligible spend, not IDT's cost. The refundable offset applies to companies with aggregated turnover below A$20 million; larger companies may claim a non-refundable offset.

How the R&D tax incentive works

Table 12: *Key features of the Australian R&D Tax Incentive.*

Feature	Detail
Who can claim	Open to all industry sectors and company sizes. Any company that qualifies as an R&D entity and conducts eligible R&D activities can apply.
Refundable offset	Companies with aggregated turnover below A$20 million: the corporate tax rate plus an 18.5% premium, which is 43.5% for companies on a 25% tax rate.
Non-refundable offset	Companies with aggregated turnover of A$20 million or more: the corporate tax rate plus 8.5% where R&D is up to 2% of total expenditure, or plus 16.5% above 2%.
Expenditure cap	The offset applies to eligible R&D expenditure of up to A$150 million.
When to apply	Within 10 months of the end of the income year in which the R&D activities took place.
Administration	Jointly administered by the Department of Industry, Science and Resources, which registers R&D activities, and the Australian Taxation Office, which processes expenditure claims.
Certainty and overseas work	An advance finding can confirm activities are eligible before applying. Expenditure on R&D conducted outside Australia requires an overseas finding.
Upcoming changes	Changes announced in the 2026–27 Federal Budget take effect from 1 July 2028. Until then, the program continues under the current rules.

R&D TAX INCENTIVE Official program information: business.gov.au. Sponsors should confirm eligibility with their own tax adviser.

IDT welcomes enquiries about any of the capabilities described in this document and can arrange a site visit or a technical discussion.

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