



●● innovation containment compliance



IDT is an Australian pharmaceutical manufacturing company with 25 years experience in the development and production of pharmaceutical products for local and international markets.

With an experienced and professional team, operating within world class facilities, IDT is committed to providing a full scale service in the areas of API manufacture, new drug development and scale-up, finish product manufacture, clinical research services and pharmacy services.

Located in Melbourne, Australia, IDT is able to provide a comprehensive range of services, which can be tailored to meet the specific requirements of each customer, whilst receiving regulatory approvals in the shortest time possible due to a rigorous in-house controls process.



Our Services

IDT provides its clients with a full service approach focusing on API manufacture, new drug development and scale-up, clinical research services and pharmacy services.

Our full service approach, highly experienced team and the use of our world class facilities, enables IDT to take a product from development through to final production with ease and expertise.

IDT specialises in the development, scale-up and production of active pharmaceutical ingredients and finished products to international standards of Good Manufacturing Practice (cGMP).

IDT has over 25 years experience in the handling of:

- **Cytotoxic Active Pharmaceutical Ingredients (APIs)**
- **High Potency APIs**
- **Hormones**
- **High potency finished products**

IDT manufactures Active Pharmaceutical Ingredients (APIs) and finished solid dosage forms for world-wide clients in its FDA inspected containment facilities located in Melbourne Australia.

IDT also specialises in the entire post-discovery pharmaceutical life cycle.

Our expertise in the development of new chemical entities from laboratory-scale to full-scale production, combined with our ability to conduct Phase I-II clinical trials, uniquely positions IDT to assist companies at many stages from synthesis to market level production.

Our services to the pharmaceutical industry can be divided into four main segments on the development timeline:

- **API Manufacture**
- **New Drug Development and Scale-up**
- **Clinical Research Services**
- **Pharmacy Services**
- **Finished dosage forms**

IDT provides a powerful integrated package for pharmaceutical product development, from production of APIs through to manufacture and packaging of clinical trial materials and management of clinical trials under international Good Clinical Practice requirements.



API manufacture

IDT specialises in the development, scale up and cGMP manufacture of highly-potent active pharmaceutical ingredients, according to international standards.

IDT has completed many projects with multinational clients, demonstrating our expertise and skill in every stage of the process, including developing active pharmaceuticals for Phase I and Phase II clinical trials, and providing long-term commercial supply.

Our portfolio includes anti-cancer drugs, anti-psychotics, antibiotics, narcotics and anti-inflammatory drugs, and we have built and validated new cGMP manufacturing facilities to accommodate this product range.

Our facilities

IDT has state-of-the-art facilities dedicated to manufacturing high-potency and/or cytotoxic materials using multistep chemical synthesis under cGMP.

The process pipework, filters and pumps are made from inert materials, and intermediates and final products are isolated in either Nutsche-type filters, or centrifuges.

IDT's cGMP manufacturing facilities include:

- **50, 100, 250, and 400 Litre jacketed, stirred, glass lined reaction vessels**
- **750, 2000, and 4000 Litre jacketed, stirred, glass lined reaction vessels**
- **double-cone vacuum dryers, tray dryers**
- **halar-lined 1000mm basket centrifuges, nutsche filters**
- **specialised milling equipment**

A new 800 – 1250 Litre plant is due for completion in 2009. The pipework for each has been made from the most appropriate material: carbon steel, stainless steel, glass, or polypropylene.

We also have facilities dedicated to small-scale development and pilot batches. Typically, these facilities process batches of <2kg for anti-cancer products, and batches of 5-10kg for non-toxic products.

Our standards

Facilities are stand alone suites with respect to air handling, vacuum, steam, nitrogen, low pyrogen water, and heat transfer systems. Only one product is allowed per manufacturing suite.

All activities for the specific product are undertaken in the suite including manufacture, drying, packaging, and labelling.

Each facility has product-handling areas within a controlled environment, designed to achieve US class 100,000 conditions, and we monitor these areas according to a stringent environmental monitoring program.

IDT has developed and implemented a Validation Master Plan that uses development, installation, and operation qualification protocols for validating all development and manufacturing processes.

The plants are designed to manufacture several active pharmaceutical ingredients, we have implemented stringent measures to ensure that cross-contamination is not possible. These measures place emphasis on validated cleaning procedures, including rinse and swabbing techniques and associated analytical verification.



Our staff

Our full service approach, highly experienced team and the use of our world class facilities, enables IDT to take a product from development through to final production with ease and expertise.

All of our staff understand the need to adhere to all relevant standards in drug development and manufacture. With regulations becoming increasingly stringent, their ability to understand and implement regulatory requirements is of considerable importance.

IDT is committed to providing quality services and products. All of our staff are highly qualified in appropriate scientific areas.

At IDT, we have developed and maintained extensive and efficient quality systems to control all aspects of our business, including change control, failure management, classified environment management, batch record management, raw material management, cleaning, analytical validation, training, and DMF adherence. Our quality systems exceed all international regulatory requirements.


As a small, Australian-owned organisation that has a culture built on the importance of quality, we take pride in the fact that we work as a flexible team, meet tight deadlines and budgets, and continually deliver products and services of the highest standard.

IDT is regularly inspected by the US FDA and Australian TGA.

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A close-up photograph of a person wearing blue nitrile gloves holding a small, clear glass vial with a yellow cap. The vial is held in front of a white laboratory instrument, which has a black tray with circular wells. The instrument is labeled "1200 Series" in the upper left corner. The background is slightly blurred, showing more laboratory equipment.

1200 Series

Product Development Services

IDT delivers a powerful, integrated package for pharmaceutical development and offers a range of high quality services to the global pharmaceutical industry.

With our expertise and state of the art manufacturing facilities and equipment, we can help our clients with any manufacturing problem, process scale-up, equipment validation, and the preparation of manufacturing and process control documentation.

At IDT we have the capability and facilities to develop a wide range of dosage forms. We can supply formulated study supplies and services including:

- **Preclinical**
- **Prototype formulation screening**
- **“First in man” studies**
- **Formulation/process optimisation**
- **Scale up/technology transfer**
- **Commercial manufacturing technical support**
- **Development and manufacturing of High potency and cytotoxic solid dosage forms**

Clinical Trial Services

IDT offers a comprehensive range of specialist manufacturing, packaging and dispensing services for clinical trial supplies all of which can be tailored to your requirements. We manufacture, under GMP, active and placebo clinical trial supplies in a variety of dosage forms including tablets, capsules, suspensions, liquids, and ointments.

Oral Dosage Forms

IDT manufactures, under contract, tablets and capsules for many different applications and we are capable of handling a wide range of batch sizes. We have facilities for tablet coating in batches suitable for coating stability trials, clinical trials, and commercial supply.

- **Tablets** - Immediate release, sustained release, delayed release, high potency, cytotoxic, film coated
- **Capsules** - Powder or granule filled, high potency, cytotoxic
- **Powders** - Powder in bottles, high potency, cytotoxic

- **Liquids** - Solutions, suspensions, and emulsions
- **Topical Dosage Forms** - Creams, ointments, gels, and lotions

Clinical Manufacturing

Our clinical manufacturing services include:

- **High potency solid dosage form manufacturing**
- **Active compound and placebo manufacturing**
- **Sourcing of comparator drugs**
- **Over-encapsulation and encapsulation**

Stability Testing


IDT is experienced in managing every key component of stability trials for APIs or finished products. This includes preparing the protocol, storing samples in validated storage facilities, and conducting physical and chemical testing using validated testing procedures.

Pharmacy Services

We provide a comprehensive range of services all of which can be tailored to suit your requirements. Our consultancy services ensure that all aspects of a trial are addressed and completed to the highest standard including blinding, randomisation, code breaks, labelling, packaging, storage and distribution of drugs and retrieval and disposal of supplies.

Our project management and regulatory affairs services include:

- **Regulatory planning and support.**
- **Single point contact project manager assigned to every project**



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