idt australia

FASTER PHARMA DEVELOPMENT
GLOBALLY COMPLIANT
& UP TO 45% CASH BACK

“IDT accelerated my product through to the clinic 6 months earlier & I received almost 45% cash rebate!”

FASTER.

IDT helps you reach your development milestones faster. With consistent API scale-up pathways, finished dose manufacture and by using the Australian Clinical Trial Notification (CTN) scheme we can fast-track your product into the clinic without the need to file an IND, saving you 6-9 months of time and money. Clinical studies are initiated typically within just 6 weeks of submission to an independent human research ethics committee (HREC).

GLOBALLY COMPLIANT.

US FDA & TGA audited, all our work is fully ICH cGMP & GCP compliant and meets with the registration requirements of the FDA, EMEA, Japanese PDMA and Health Canada. From initial drug development to clinical trials, we have been the outsourcing partner of choice for 9 of the top 10 pharmaceutical companies worldwide.

& UP TO 45% CASH REBATE.

IDT has helped a number of overseas companies register for the Australian R&D Tax Incentive scheme. This scheme allows eligible companies to claim up to 45% cash rebate on eligible R&D spend*.

IDT AUSTRALIA LIMITED.

IDT is an Australian listed company (IDT.AX). We offer a full range of pharmaceutical product development and manufacturing services from API development through to commercial finished dose manufacture and clinical trials.

IDT PHARMA.

We are FDA certified and specialize in the development, scale-up and GMP manufacture of highly potent, cytotoxic and beta-lactam APIs and finished drug products.

Oral dosage forms such as sprays, powders, gelatin capsules and film coated tablets are manufactured from small R&D to commercial volumes in full containment suites, and our dedicated beta-lactam commercial manufacturing facility can manufacture APIs, tablets, powders and sterile parenterals (lyophilisation) in vials or bulk.

We also offer full GMP analytical testing, method development, validation, ICH stability testing, microbiological and clinical packaging services.

AUSTRALIAN R&D TAX INCENTIVE.

*IDT Australia can assist in accessing up to a 45% cash rebate on preclinical & clinical work performed at IDT via the R&D Tax Incentive scheme.

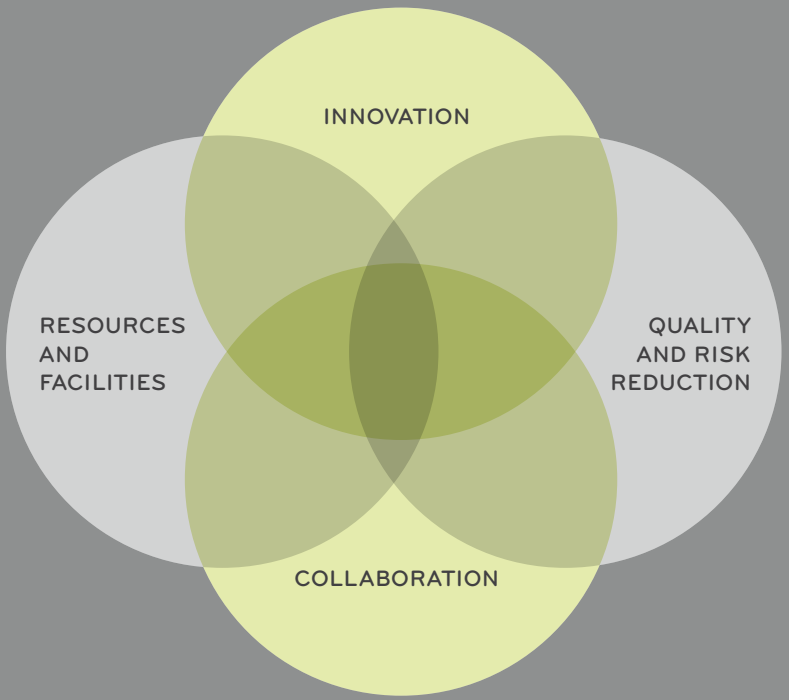
This scheme is the Australian Government's principal measure to encourage industry investment in research and development.

The R&D Tax Incentive is a broad-based, market-driven program that offers a 45% cash rebate for eligible companies with an aggregated turnover of less than $20 million per annum; or a non-refundable 40% tax offset for all other eligible companies. You do not have to be an Australian company to benefit.

WORLD'S BEST PRACTICES FOR SUCCESS.

Successful companies rely on new products to keep them ahead of their competition. But conceiving, then developing drugs, and bringing them to market cost effectively needs knowledge, competence and a proven track record.

For over 30 years, IDT's range of skills, in-house capabilities and broad industry experience combine with proven processes and innovative management tools, to deliver tangible results. From the time we receive your project request we work to better understand your needs and strive to uncover solutions that deliver improved costs, more effective outcomes and faster completion rates.



OUR FACILITIES.

API Manufacturing Facilities

General Containment Facilities
20-50 (x4), 60, 100 (x2), 250 & 400 litre
Dedicated, secure
HEPA filtered air (in and out) ISO8
Closed system for equipment
Protection for operators
Waste Incinerated
Non-containment 400 and 2000 litre

β-lactam API and Finished Product Manufacturing Containment Facilities

22, 4x100, 2x400 and 2x4,000 litre
PIB facility
Sterile lyophilised facility
20-5000 vials
Tablet facility
Roller compaction
Dry blend
Coating
0.5-40kg blend

Drug Product – Oral

Oral Dosage Forms – Capsules and Tablets
Containment environment
Manufacture from small scale to commercial quantities
Up to 50,000 units / hour
API and Finished Dosage Form development
Analytical method development
Dry blending / Wet granulation
Film coating

Drug Product – Injectable

Small run sterile fill-finish and lyophilization
Class A sterile filling room
Vial filling - 4,000 / hr, half or full stoppering
5mL – 100mL vials
Freeze dryer
3,000 20mL vial capacity
-55 to +80°C
Sterile liquid, powder or lyophilized filling

IDT CMAX.

We are Australia's largest and most experienced clinical trials unit, with a 21 year track-record and over 13,000 active volunteers on our database.

Fast study startup times are routine and specific age, gender and ethnicity requirements are readily accommodated in our 50-bed Phase I unit at the Royal Adelaide Hospital.

We take advantage of the Australian CTN scheme to fast-track your product into clinical trials, without the need to file an IND and with a greatly reduced preclinical data package.

Studies are initiated on approval by an independent local human research ethics committee sitting weekly. Our typical study startup time is just 6 weeks.

Our studies are fully ICH GCP compliant and comply with the registration requirements of the US FDA and EMEA.

We have run over 500 Phase I-IV studies to date.

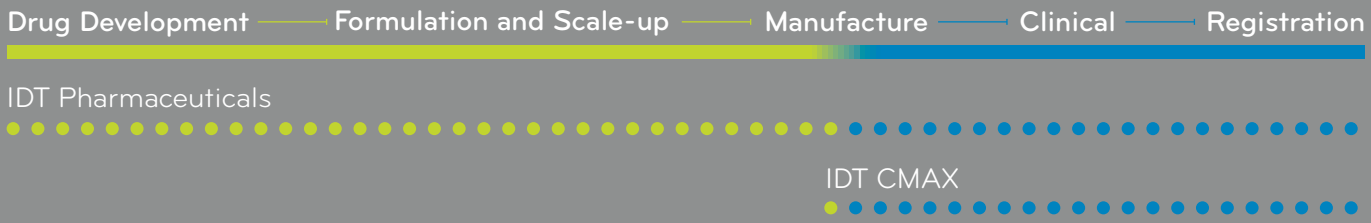
CLINICAL EXPERIENCE.

	# Studies.
Pain / Anaesthesia (inc. S8)	55
Dermatology	38
Metabolism / Endocrinology	36
Infectious Diseases	33
Vaccine	33
Monoclonal Antibody	26
Neurology	21
Oncology	17
Women's Health	15
Allergy / Respiratory	14
Renal	10
Gastrointestinal	9
Cardiovascular	7
Rheumatology	6
Japanese Studies	4
Haematology	4

(data as of Mar 2015)

SOLUTIONS AT EVERY STAGE OF DEVELOPMENT.

From initial drug development to Phase IV clinical trials, IDT has been the outsourcing partner of choice for some of the world's most influential pharmaceutical companies, including 9 of the top 10 pharmaceutical companies worldwide.



IDT PHARMA.

- Pharmaceuticals - Contract Manufacturing FDA certified and TGA licensed for API and Finished Dose Form, High Containment High Potency (including Penem API and FDF). GLP/GMP.
- Drug Development - R&D, Pharmaceutical Testing (analytical and microbiology), scale-up for API and Finished Dose Forms.

IDT CMAX.

Clinical development - FDA inspected, Phase I studies (largest Phase I unit in Australia), first-in-man, ethics, site selection and monitoring for Phase II-III.

IDT AUDIT HISTORY.

USFDA Full GMP (API) on-site inspection	January 2015
TGA Full GMP (Finished Product, API) on-site inspection	September 2013
USFDA Full GMP (Finished Product, API)	February 2013
TGA Full GMP (Finished Product, API) on-site inspection	February 2011
TGA Full GMP (Finished Product, API) on-site inspection	June 2009
USFDA Full GMP (Finished Product, API) on-site inspection	May 2009
Health Labour and Welfare (Japan) (Non-sterile API)	February 2009
TGA (Sterile Product Finished Product) on-site inspection	July 2008
TGA Full GMP (Finished Product, API) on-site inspection	July 2007
TGA Full GMP (Finished Product) on-site inspection	August 2004

IDT Australia can assist in accessing up to a 45% cash rebate on work performed.

Australia's R&D Tax Incentive is the Australian Government's principal measure to encourage industry investment in research and development. The R&D Tax Incentive is a broad-based, market-driven program that offers a 45% cash rebate for eligible companies with an aggregated turnover of less than $20 million per annum; or a non-refundable 40% tax offset for all other eligible companies.

Please contact us for more information or visit www.ausindustry.gov.au.

For more information about how IDT can assist in your drug development contact us:

IDT Australia Limited
45 Wadhurst Drive, Boronia Victoria 3155, Australia

Tel +61 3 9801 8888 **Fax** +61 3 9801 8773
Email webmaster@idtaus.com.au

www.idtaus.com.au