AusBiotech

The Australian Advantage Handbook

SOCIALS:

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WEBSITE:

ausbiotech.org

Welcome

Australia's life sciences sector stands at the forefront of global innovation — a dynamic ecosystem defined by world-class infrastructure, robust clinical expertise, and a steadfast commitment to scientific excellence.

Our world-class clinical research facilities, Contract Manufacturers (CMO/CDMO), Contract Research Organisations (CRO), laboratory and analytical services, along with robust regulatory, legal and financial expertise, and a highly skilled workforce, position the nation as a trusted partner in advancing medical breakthroughs.

The *Australian Advantage Handbook* has been created to highlight and connect the key players who make this ecosystem thrive.

Complementing this, the dedicated conference stream *"The Australian Advantage: Unlocking Clinical Trials and Contract Manufacturing Excellence"* at the AusBiotech International Conference 2025 will celebrate and explore the nation's unique strengths. Together, the stream and handbook offer a complete view of how Australian capability is driving global life sciences success.

Each company featured in this handbook has the opportunity to tell its story. With a dedicated profile, the organisations expertise and value are positioned before an engaged audience of national and international stakeholders. This visibility not only enhances collaboration but also reinforces your place within Australia's vibrant and growing life sciences community.

For nearly 40 years, AusBiotech has been proud to serve as Australia's life sciences peak body, connecting more than 3,000 members across the entire health innovation pipeline.

Welcome to *Australia's Advantage.*

AusBiotech

Where life science leaders thrive

AusBiotech is Australia's life sciences peak body. For almost 40 years, we have worked to support the growth of our more than 3,000 members as they advance breakthroughs in medical science and develop new innovations to help solve some of Australia's and the world's most complex health challenges.

With our unrivalled membership breadth, representing all stages of the health innovation ecosystem, and drawing on our unique national convening power, we advocate for the advancement of Australian life sciences and our members' success as they research, translate, develop and commercialise new health technologies, while supporting knowledge sharing and collaboration to help our life sciences innovators thrive.

National and Global Reach

AusBiotech has membership in each Australian state, providing a national network to support members and promote the commercialisation of Australian life sciences in both national and international marketplaces. Our initiatives are designed to drive sustainability and growth, offering outreach and access to markets, as well as representation and support for members both nationally and globally.

Website:
ausbiotech.org

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Company Directory

Contract Manufacturer (CMO / CDMO)

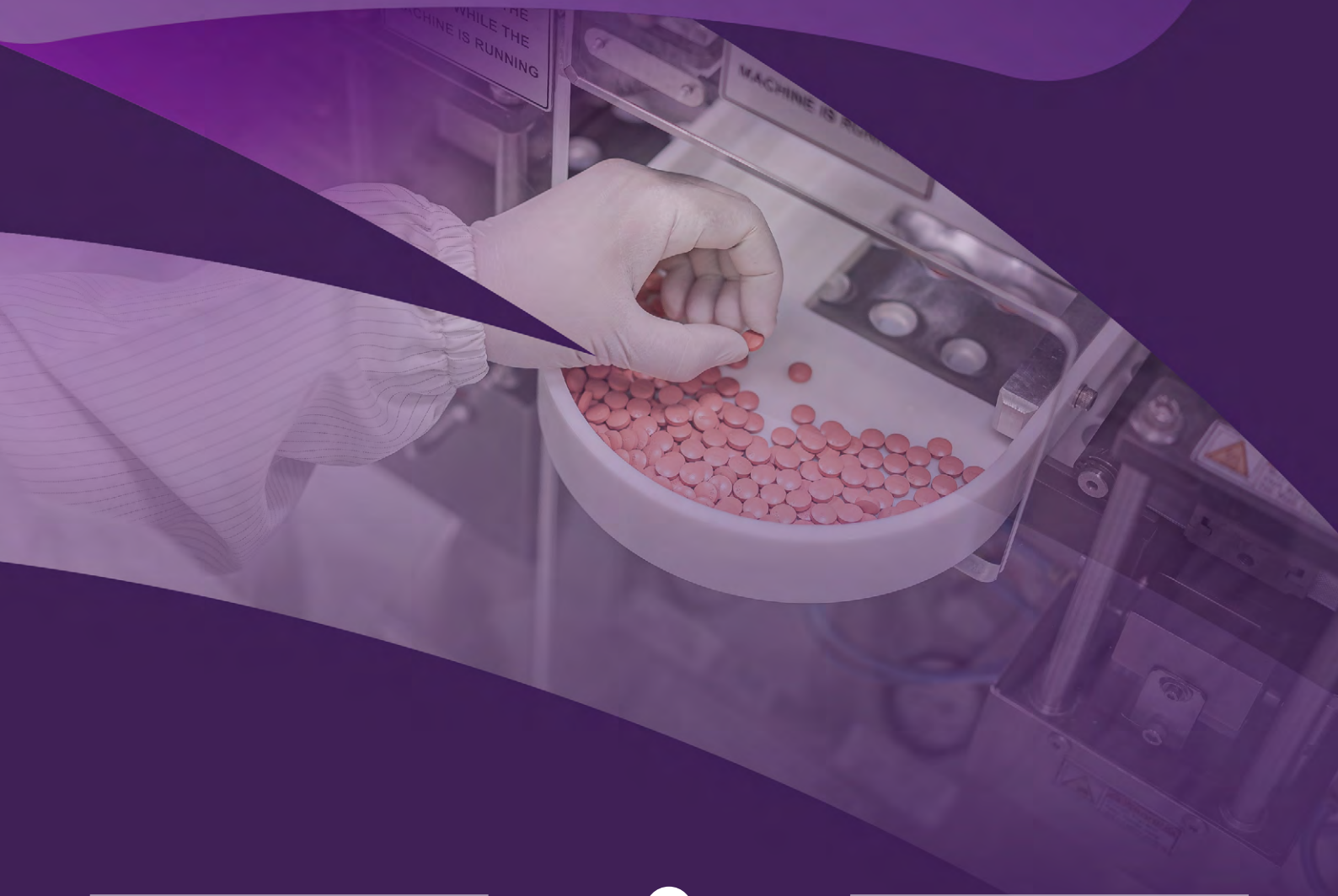
Contract Research Organisation (CRO)

Laboratory & Analytical Services

Regulatory, Legal & Financial Services

AusBiotech

Contract Manufacturers
(CMO / CDMO)



CBE Pure Solutions

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CBE Pure Solutions

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Website:
cbepuresolutions.com

Location:
Melbourne, VIC

Company Overview

CBE Pure Solutions is an Australian-owned GMP contract manufacturing organisation (CMO) specialising in sterile fill-and-finish services, with complementary on-site microbiological testing. Established in 2021, we operate from a state-of-the-art, purpose-built facility in Melbourne designed to meet global GMP compliance standards for patient safety while remaining agile for small-scale clinical trial supply. Our facility is fully licensed by the Therapeutic Goods Administration (TGA) for sterile liquids across all clinical trial phases (I–III). We also hold US FDA establishment registration, APVMA veterinary manufacturing approval, Victoria DHHS poisons licences, OGTR certification for GMO handling, and biosecurity clearances.

CBE Pure Solutions is the first Australian CMO to introduce qualified isolator technology for both sterile manufacturing and microbiological testing. Our PC2 cleanrooms house advanced Bioquell and SKAN isolators with validated vaporised hydrogen peroxide (VHP) decontamination, providing a uniquely controlled aseptic environment. These capabilities allow us to handle sensitive biological therapies, including vaccines, monoclonal antibodies, bacteriophages, mRNA and gene therapies. In addition to conventional sterility testing, we are pioneering Rapid Microbiological Methods with the ScanRDI® system — the first in Australia — aimed at reducing batch release times from more than 14 days to just 2 days.

Our services include:

- Sterile Liquid Manufacturing for Clinical Trials (Phases I–III): Flexible, small-run sterile fill-and-finish for injectables, infusions and ophthalmic medicines, using cutting edge isolator cabinets.
- Microbiological Testing & Environmental Monitoring: Sterility, endotoxin, microbial limits, preservative efficacy, disinfectant efficacy, validation and development, using traditional and rapid methods.
- Commercial Contract Manufacturing: Specialty medicine and low-bioburden GMP fill-and-finish in vials, using an automated filling.

With an experienced leadership team and a facility incorporating the latest GMP isolator and Rapid Microbiology technologies, Pure Solutions provides high-quality, internationally compliant and agile sterile GMP services to support biotech innovators from early development through late-phase trials.

Cell Therapies Pty Ltd.

Company:
Cell Therapies Pty Ltd.

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celltherapies.com

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enquiries@celltherapies.com

Location:
Melbourne, VIC

Company Overview

For more than two decades, Cell Therapies has delivered GMP contract manufacturing services that turn leading science into approved, lifechanging products. Whether you represent an emerging biotech preparing its first IND or a multinational firm scaling commercial supply, Cell Therapies offers a fee-for-service portfolio to meet your needs and drive program success. As Australia's only biomedical manufacturing facility where CAR T-cells and other cell-based therapies can be produced at commercial volumes, Cell Therapies delivers innovative therapies to Australian patients while also enabling access to the Asia-Pacific markets. The facility supports both autologous and allogeneic products and includes 10 GMP cleanrooms suitable for early to mid-stage clinical trial supply, and 3 large-scale high-throughput GMP manufacturing suites for late-phase and commercial supply with a production capacity of up to 2,000 patient doses per year.

Co-located with the Peter MacCallum Cancer Centre ("Peter Mac") in the Parkville Biomedical Precinct, Melbourne, Australia, Cell Therapies' facility holds current GMP manufacturing licenses and is authorised to supply cell and gene therapies to multiple PIC/S-compliant jurisdictions. Cell Therapies meets many international regulatory agency requirements, including those of the Australian TGA, the US FDA, Japan's PMDA, and Europe's EMA. Cell Therapies is Australia's only TGA-licensed GMP facility for manufacturing of both commercial and clinical trial T-cell products, including CAR T-cell therapies, and has accreditation for supply of regenerative medicine products from Japan's Ministry of Health, Labour and Welfare. Our model combines translational agility, commercial grade quality, and region-specific regulatory know-how, delivering faster starts, predictable cost of goods sold (COGS), and accelerated access for patients.

Cell Therapies' services include:

- Contract manufacturing
- Technology Transfer
- Process Development
- Analytical Testing and Development
- Quality as a Service
- Consulting and advisory

Cell Therapies manufacture a broad range of cell-based therapies:

- CAR-T and TCR-engineered lymphocytes (autologous & allogeneic)
- iPSC-derived therapeutics (immune, neuronal, epithelial)
- Mesenchymal stromal cells & extracellular vesicles
- Tumour-infiltrating lymphocytes (TILs) and NK cell therapies
- Cancer vaccines
- Tissue Engineered Products
- Regenerative Medicine Advanced Therapies and Devices
- Drug Substance to Drug Product
- Cell suspension for injection
- Viral & non-viral gene-modified cell products

Formulytica

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Location: Melbourne, VIC

Company Overview

Formulytica is a leading Australian contract development and manufacturing organisation (CDMO) specialising in advanced formulation and CMC (Chemistry, Manufacturing and Controls) services that enable the successful development of new drugs from early research through to clinical trials and international regulatory submissions. With over a decade of proven expertise and over 200 projects completed, Formulytica partners with biotechnology and pharmaceutical companies worldwide to provide the technical depth and innovative solutions required to transform promising discoveries into effective therapies.

At the core of Formulytica's capabilities is its comprehensive CMC offering, spanning analytical method development and validation to ICH standards, pre-formulation screening, and customised formulation design for a wide range of therapeutic modalities. The company's integrated services extend through stability studies compliant with ICH guidelines, packaging development, troubleshooting of challenging products, technical transfer, and strategic guidance to ensure robust, compliant, and efficient development pathways that meet the stringent expectations of regulators across major global markets.

Formulytica brings particular strength in complex formulation design, with deep expertise across topical, injectable, oral, ophthalmic, and other specialised dosage forms. The team has significant experience with small molecules, biologics, peptides, siRNA, and other advanced modalities, including innovative drug delivery platforms. By integrating pharmaceutical science with a strong problem-solving mindset, Formulytica supports clients in overcoming critical development hurdles such as solubility, stability, bioavailability, and patient acceptability.

A key advantage is Formulytica's access to GMP facilities through established partnerships. The company is co-located with a leading Australian contract manufacturer experienced in commercial-scale manufacture of TGA- and FDA-approved products. Formulytica holds GMP agreements with two TGA-licensed manufacturers covering both sterile and non-sterile dosage forms, providing access to GMP cleanroom facilities for scale-up of developed formulations to clinical trial material. This model enables clients to seamlessly progress from laboratory development to GMP manufacturing within a trusted and compliant framework.

Collaboration lies at the heart of Formulytica's approach. The company works closely with clients to design tailored development programs that not only meet regulatory requirements but also maximise patentability, protect intellectual property, and accelerate timelines to clinical proof-of-concept.

With a commitment to excellence, innovation, and partnership, Formulytica is helping to shape the future of pharmaceutical development in Australia and internationally, supporting the translation of new ideas into impactful therapies that improve patient lives worldwide.

Magellan Stem Cells

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Magellan Stem Cells

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Location:
Braeside, VIC

Company Overview

Magellan Stem Cells is a private Australian biotechnology company with focus and expertise on research, development, manufacturing, and clinical translation of cell therapies.

Magellan is one of Australia's few TGA-licensed, GMP certified facilities for cell therapies and has built a strong reputation in mesenchymal stem cell (MSC) manufacturing, supported by Phase 3–ready facilities and robust GMP infrastructure with a capability of providing outsourced cell therapy and development manufacturing capabilities to external research and biopharmaceutical parties. Our specialist knowledge in MSCs forms the foundation of a broader capability that extends to iPSCs, CAR T-cells. NK cells, exosomes, and other Advanced Therapy Medicinal Products (ATMPs).

Magellan are led by an experienced and diverse executive management team with substantial experience in medical science technology, health systems and business development at a global scale and are supported by internationally regarded Corporate Advisory Board and Medical and Scientific Advisory Board members. Magellan have invested heavily in retaining Australia's skilled scientific workforce in cellular therapeutics and manufacture.

Magellan has pursued an internal cellular therapeutic development program with focus on clinical conditions of unmet clinical need which has involved a 15-year structured research approach from pre-clinical proof of concept to late-stage pre-registration pivotal clinical trials with active engagement of national (TGA) and international (EMA, MHRA, FDA) regulatory bodies. This research and development pathway has been supported by an experienced internal clinical development, pharmacovigilance, and regulatory team.

Magellan has a capability to provide collaborative partnership in cell therapy manufacture in addition to providing structured guidance from pre-clinical through to late-stage clinical translation and product registration making Magellan an ideal partner from concept to commercialisation.

'At Magellan Stem cells, we see ourselves as an extension of your team. We offer a collaborative, flexible partnership model that adapts to your program's needs — whether you require donor material, small scale pre-clinical development, process optimisation, full scale tech transfer into GMP, or regulatory support. Our goal is to deliver not just a service, but a seamless pathway to clinical and commercial success.'

PharmSky Research

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PharmSky Research

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Location:
Melbourne, VIC

Company Overview

PharmSky Research is a Melbourne-based Contract Development and Manufacturing Organisation (CDMO) delivering end-to-end drug development and manufacturing solutions. We partner with biotechnology and pharmaceutical companies to transform novel therapies into clinical-ready products safely, efficiently, and in alignment with global regulatory standards.

Our services span the full development lifecycle, from early-stage formulation and analytical testing to GMP-compliant clinical trial material manufacturing and supply. Each stage is designed to ensure products meet rigorous quality, safety, and regulatory benchmarks. Advanced analytical testing, stability studies, process development and optimisation, and regulatory guidance are fully integrated to give partners confidence that their products are developed efficiently and robustly. Expertise covers small molecules, biologics, injectables, oral solids, topicals, and nano liquid emulsions. Each project follows a tailored strategy, helping clients accelerate development timelines, optimise manufacturing processes, and maintain product integrity throughout clinical trials.

PharmSky has experience managing complex biologics, specialised formulations, and novel modalities, supporting seamless transitions from early development to scalable manufacturing. Operating a fully qualified GMP Facility, licensed by the TGA, PharmSky combines advanced development capabilities with robust manufacturing processes, acting as a single, reliable partner. This reduces complexity, ensures consistency, and delivers clinical trial materials on schedule. Our approach allows clients to focus on advancing their therapies, confident that critical manufacturing and regulatory requirements are managed expertly. Working with both domestic and international clients, PharmSky offers practical, flexible solutions to meet diverse project needs. Scientific expertise, operational precision, and regulatory knowledge allow partners to navigate development challenges, accelerate clinical programs, and bring innovative therapies to market effectively.

As one of the leaders in Australia's life sciences ecosystem, PharmSky contributes to advancing healthcare innovation by providing reliable, high-standard development and manufacturing services. Through a commitment to collaboration, continuous improvement, and technical excellence, we enable biopharmaceutical companies to streamline development pathways, navigate complex regulatory environments, and deliver meaningful outcomes for patients worldwide. By integrating scientific expertise, operational excellence, and compliance-driven procedures, PharmSky ensures its partners can confidently progress therapies and achieve strategic goals with efficiency and reliability.

Thermo Fisher Scientific

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Thermo Fisher Scientific

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Company Overview

Patheon Biologics Australia, Thermo Fisher Scientific's biologics drug substance manufacturing facility in Brisbane, is a state-of-the-art site specializing in both clinical and commercial manufacturing. The facility has advanced expertise in single-use biologics technology, offering flexible and scalable solutions to support our partners from early development through commercial supply.

In recognition of its excellence in biologics manufacturing and customer services, the Brisbane facility was awarded the "Best Biologics CMO in Australasia" by IMAPAC in 2023.

It is a key part of Thermo Fisher's global biologics network, which also includes facilities in St. Louis, Missouri, US, Groningen, Netherlands, and Lengnau, Switzerland. Together, these sites provide end-to-end global capabilities, enabling customers to accelerate development and ensure reliable supply across major markets.

The Brisbane site is fully compliant with GMP standards for both clinical and commercial manufacturing. It is approved by the FDA, TGA, EMA, MHRA, Anvisa, Saudi Arabia FDA, and Korean MFDS for both clinical and commercial production. It supports cGMP production for Phase I, II, and III clinical trials, with capabilities that span the full range of upstream and downstream processes, in-house analytical, quality control (QC), and quality assurance (QA) capabilities. With extensive experience across mammalian cell lines, the site delivers high-quality biologics while maintaining the highest standards of safety, efficiency, and regulatory compliance.

Through its world-class expertise and integration into Thermo Fisher's global network, Patheon Biologics Australia plays a critical role in helping biotech and pharmaceutical companies bring life-changing therapies to patients worldwide.

AusBiotech

Contract Research Organisations (CRO)

ACCELAGEN PTY LTD

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ACCELAGEN PTY LTD

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Hawthorn East, VIC

Company Overview

Accelagen is a leading global contract research organisation (CRO). Our mission is to co- create meaningful outcomes that have a tangible impact on the future of human health.

We provide our pharmaceutical and biotech partners with an accelerated, globally-recognised pathway to market. Harnessing our knowledge of local and international regulations, we design the roadmap to maximise success at every stage in the product lifecycle. These plans are brought to life by our expert clinical development and regulatory affairs services teams, who are backed by decades of delivered success and high-quality data.

Accelagen's work is underpinned by our unique reverse journey mapping approach. We build a comprehensive picture of the end goal that aims to define your ambitions and key milestones, with a focus on what the product would look like on the shelf. From there, we work backwards to map the steps to achieve market approval, mitigating against potential delays that may derail your path to approval.

Through expert consultation, close collaboration, and analysis, we develop a clear strategy that holds meaningful outcomes at the fore. We then carefully guide and continuously monitor our strategy to maximise your product's success at every stage of the journey – from product concept and initiation of human studies, through to prototyping and final market authorisation, and beyond.

Adjutor Clinical

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Adjutor Clinical

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Company Overview

With over 250 combined years of experience in Global Healthcare Development, Regulatory and Commercialisation, and a proven track record of registering over 400 medicines & 150 medical devices worldwide, the Adjutor Group brings together Adjutor Clinical and Adjutor Healthcare as your trusted partner in achieving your global business objectives.

Adjutor Clinical is a full service CRO providing end-to-end clinical development support from early development strategy/TPP development, pre-IND and IND services, study design, regulatory submissions, site selection, clinical trial monitoring, data management, biostatistics and clinical study report writing. With deep therapeutic expertise, global partner networks, and a focus on quality and efficiency, we deliver integrated solutions that help sponsors accelerate timelines, control costs, and achieve successful approvals worldwide. Adjutor Healthcare provides comprehensive services in regulatory strategy, product registration and lifecycle management, quality/QMS, market access, and commercialisation, ensuring your innovation reaches the people who need it most.

Our specialists work across prescription and non-prescription medicines, biologicals, cell and gene therapies, medical technologies, and diagnostic tests including IVDs. With one partner managing your program from start to finish, you gain speed, clarity, confidence, and a seamless experience.

Agilex Biolabs

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Agilex Biolabs

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Location:
Adelaide, SA and Brisbane, QLD

Company Overview

At Agilex Biolabs, precision, speed, and trust drive everything we do. As Australia's leading bioanalytical laboratory, we specialise in clinical trial support — delivering data that moves your program forward.

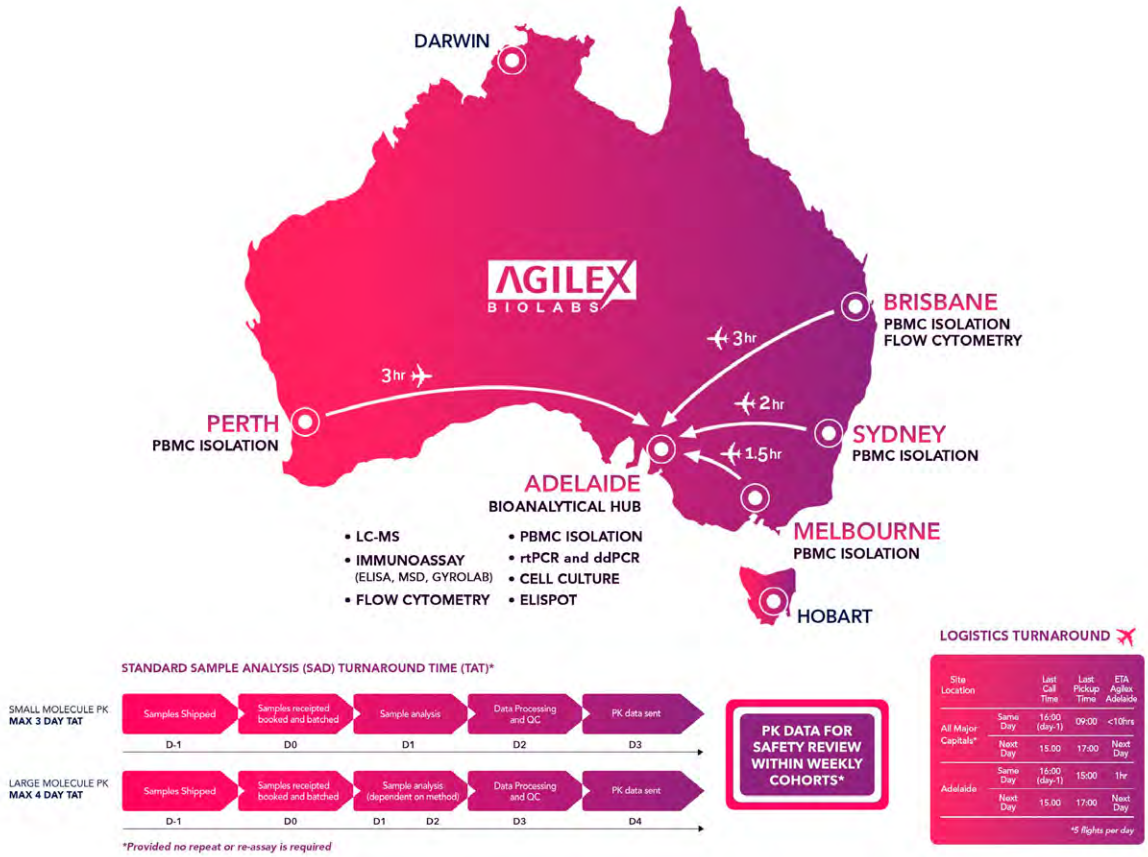
With almost 30 years of experience, our scientists and regulatory experts turn complex studies into clear, reliable results. We provide bioanalysis for small molecules, biologics, and cell and gene therapies, under FDA, EMA, and TGA quality systems.

Our LC-MS/MS and immunoassay platforms power high-quality PK/TK, biomarker, and immunogenicity testing with proven accuracy and efficiency. Every method is validated. Every timeline met. Every result built on purpose.

When you work with Agilex Biolabs, you get more than data — you get a partner committed to turning great science into clinical success.

Key Strengths:

- Highly experienced: PK/PD services across most drug modalities and a diverse range of disease indications.
- Multi-site expansion: Greater reach across Australia and flexibility for sponsors.
- Co-location with Phase I units: Seamless integration with early-phase trials.
- 3 x FDA-audited: Proven regulatory compliance and global credibility.
- Science-first team: Scientists who understand the challenges of translating research into medicine.
- Transparent and realistic: Open and honest about timelines so that trials can be planned appropriately.



Alithia Life Sciences

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Alithia Life Sciences

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Location:
Australia

Company Overview

Alithia Life Sciences is an Australian integrated service provider specialising in clinical operational management including full service CRO capabilities. Our bespoke services cater to Pharmaceutical, Biotechnology, Medical Technology, and research institutions aiming to execute their clinical trials in Australia and New Zealand.

Our mission is to work with our clients to deliver efficient accomplishment of their project, add value to their programs, and to ultimately enable improvement of human health and wellbeing. By leveraging our in-depth local expertise and tailored solutions, we ensure successful and efficient clinical research outcomes.

Services Include:

- Clinical strategy, clinical study design, project feasibility and bespoke project costings.
- Clinical project management and clinical operational support from functional service provision through to full CRO service capability.
- Education, promotion and mentorship of local and international companies.
- Sponsor executive management and business support including local directorship.
- Access to extensive networks of clinical sites, key opinion leaders (KOLs), vendors and other business professionals including R&D tax, financial and legal to support clinical research and development.

We pride ourselves on employing clinical trial experts, with all our clinical project staff having an average of over 15-20+ years of operational expertise and industry experience across various therapeutic areas including early phase studies, neurology, rare and paediatric diseases, medical device, ophthalmology, dermatology, endocrinology, cardiovascular, oncology, cell & gene therapy and vaccines.

Point of Difference:

- Agile, bespoke, transparent services that take a personalised approach to providing exceptional services.
- All work is undertaken in Australia.
- All staff are career experts in their field, are passionate and fully engaged in the project from start to completion and have an average of over 15+ years of industry experience.
- Our breadth of expertise in commercial and biotechnology settings across medicines, biologics and devices can support projects from Phase I through to Phase III. This includes experience in developing products for jurisdictions such as FDA/EMA/KFDA/TGA.

Avance Clinical

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Avance Clinical

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Website:
avancecro.com

Location:
Adelaide, SA

Company Overview

Avance Clinical – Accelerating Biotech Innovation Globally

Avance Clinical is the leading Australian-owned Contract Research Organisation (CRO), trusted by biotechnology companies worldwide to deliver high-quality, efficient, and flexible clinical trial solutions. With more than 30 years of experience, Avance Clinical partners with biotech innovators from first-in-human studies through to pivotal trials, leveraging Australia's globally recognised clinical trial environment to accelerate development and maximise value creation.

The Australian Advantage

Biotechs partnering with Avance Clinical benefit from Australia's streamlined regulatory framework, including no IND requirement and rapid ethics approvals that enable study start-up within 5-6 weeks. In addition, companies can access up to a 43.5% R&D rebate on eligible expenditure, reducing overall costs.

With one of the largest portfolios of first-in-human and early phase trials in Australia, Avance Clinical helps clients move quickly while generating high-quality data accepted by the FDA, EMA, and other agencies. This proven capability enables confident, timely decisions at critical development milestones

Global Reach, Local Expertise

Avance Clinical's operations extend beyond Australia to North America and Asia, offering biotechs a truly global pathway. Through the **GlobalReady** model, clients transition seamlessly from early-phase trials in Australia to multi-country studies, maintaining speed, consistency, and regulatory alignment. This approach de-risks expansion and ensures continuity across programs.

Comprehensive Services for Biotechs

Avance Clinical delivers an integrated suite of services bridging pre-clinical to clinical development:

- **ClinicReady:** Pre-clinical and translational consulting to guide biotechs confidently from the lab to first-in-human studies.
- **Project Management:** Dedicated leaders embedded with client teams to drive timelines, budgets, and milestones from early phase through Phase II–III.
- **Medical and Scientific Affairs:** Expert support for study design, regulatory pathways, and medical oversight.
- **Biometrics:** In-house data management, biostatistics, and pharmacokinetics ensuring regulatory-ready reporting.
- **Safety and Pharmacovigilance:** Comprehensive safety oversight, medical monitoring, and global reporting.
- **Medical Writing:** Protocols, investigator brochures, and regulatory submissions tailored to international standards and fundraising needs.

Innovation and Collaboration

Avance Clinical's biotech-only model ensures agility and collaboration, combining therapeutic expertise, lean decision-making, and advanced technology. Flexible, customised solutions reduce risk, optimise timelines, and generate the data needed for licensing, partnerships, and investment milestones.

Partnering with Purpose

Avance Clinical's mission is simple: accelerate biotech innovation so life-changing therapies reach patients faster. With hundreds of successful partnerships and one of the largest early-phase portfolios in Australia, Avance Clinical stands as a trusted partner in scientific progress - helping biotechs navigate complexity, secure investor confidence, and deliver breakthroughs to patients worldwide.

Get in contact with our team today

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Biointelect

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Biointelect

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Website:
biointelect.com

Location:
Sydney, NSW

Company Overview

Biointelect: Integrated CRO and Consulting Expertise Driving Life Sciences Innovation

Biointelect is a globally recognised Australian consulting and advisory firm offering a unique blend of full-service Contract Research Organisation (CRO) capabilities and commercialisation consulting. With deep roots in the full health innovation ecosystem, Biointelect provides end-to-end support across the entire development pathway from early-stage research through to market access and health system integration.

CRO services built for velocity and quality. As a boutique CRO, Biointelect delivers a bespoke, science-driven model that adapts to the specific needs of each study. The experienced team's agility and cross-functional collaboration ensure high-quality execution, streamlined communication, and fast, informed decision-making. Clients benefit from a single, dedicated point of contact overseeing all aspects of trial delivery, supported by a highly specialised team with deep early-phase expertise and a proven track record across complex clinical trials.

Networks ensure acceleration and scale. The company maintains strong collaborative relationships with Key Opinion Leaders and research sites across Australia, enabling reliable recruitment and operational excellence. Our capabilities are supported by strategic partnerships with US and EU CROs, allowing seamless progression from early phase trials in Australia to later phase trials that need a global footprint.

Regulatory without roadblocks. From early strategy to dossier build and submissions, Biointelect guides ANZ, APAC and global regulatory pathways, coordinating queries, navigating designations to accelerate decision timelines. Our integrated consulting backbone connects R&D, CMC, market access and policy so your regulatory plan is technically sound and commercially rightsized.

Director Services for effortless Australian entry. Biointelect's Director Services are particularly valuable for international clients establishing Australian subsidiaries ensuring a smooth entry into the Australian research landscape, backed by Biointelect's deep local knowledge and regulatory expertise. These services include governance setup, clinical trial oversight, and support for R&D tax claims, ensuring a smooth entry into the Australian research landscape.

Backbone of commercial expertise. Biointelect's consulting arm provides strategically and technical guidance across R&D planning, market assessment, market access and policy shaping. The company has delivered projects for more than 200 clients globally, including biotech and pharmaceutical companies, universities, research institutes, and government agencies.

Biointelect's team across Australia and formal global partners combine deep expertise to offer tailored solutions that accelerate development, mitigate risk, and enhance the probability of commercial success globally. Whether supporting early-stage innovation or navigating complex regulatory pathways, Biointelect stands as a trusted partner for biotech companies seeking to bring transformative health solutions to patients.

BRINGING INNOVATIONS TO LIFE
STEP BY STEP

CMAX Clinical Research

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Location:
Adelaide, SA

Company Overview

CMAX Clinical Research, Australia's first and leading early-phase trial facility, has been advancing the future of healthcare since 1993. Delivering over 800 studies, including more than 200 first-in-human trials, CMAX continues to be a trusted partner for sponsors worldwide and helps biopharmaceutical companies accelerate their programs with speed, precision and confidence.

The CMAX facility has a purpose-built, 78-bed clinic which operates 24/7 in Adelaide's BioMed City – a $3.6 billion health and medical precinct surrounded by world-class hospitals, universities and research institutes. With on-site laboratories, pharmacy access, a 24-bed ambulatory cardiac telemetry unit, low-acoustic EEG suites, negative air pressure rooms and advanced clinical infrastructure, CMAX offers a fully integrated, state-of-the-art environment to conduct even the most complex studies.

Australia is recognised globally for its clinical trial excellence. Sponsors benefit from streamlined regulatory processes that allow trials to be set up within tight timeframes, remain cost effective and produce data accepted by the FDA, EMA, MHRA and other major regulators. In addition, CMAX services are eligible under the Australian R&D tax incentive, providing sponsors with generous financial advantages.

CMAX brings together a large, highly trained team of clinical research professionals, including experienced Principal Investigators, physicians, nurses and support staff. Together, they deliver excellence in first-in-human, bioavailability, bioequivalence, DDI, vaccine, biosimilar and early-phase patient trials. Quality Management Systems have been refined over decades, with FDA and TGA inspections completed without critical findings.

With a dedicated in-house marketing and participant engagement team, CMAX consistently achieves strong recruitment outcomes. More than 90% of their sponsors are international, spanning the US, Greater China, Europe, Korea and beyond – a testament to their global reputation and reliability.

For over three decades, sponsors have chosen CMAX for their outstanding facilities, operational excellence, innovation and flexibility. This approach enables CMAX to consistently deliver trials efficiently, safely and to the highest scientific standards.

Fusion Clinical Research

FUSION CLINICAL RESEARCH

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Fusion Clinical Research

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Website:
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Location:
Adelaide, SA

Company Overview

Fusion is a Clinical Research company which works in a purpose-designed, modern facility in Adelaide with Sponsors and Contract Research Organisations (CROs). Fusion is supported by a referral network of General Practitioners and Specialists to conduct and manage studies that evaluate the safety, efficacy and quality of medical interventions which can include drugs, biologics, devices and diagnostics.

Fusion Clinical Research was launched in 2020 as the Phase II-IV Division of CMAX Clinical Research, expanding the service to later phase trials. Fusion Clinical Research undertakes clinical trials in 2 core areas Vaccination Clinical Trials and Patient Treatment Clinical Trials Importantly our network provides a rich database of patients through community and specialist practices ranging across a breadth of medical issues from obesity, mental health, to diabetes and dermatology.

Our experienced team consists of doctors, nurses, scientists and technicians with a focus on patient care and client service. Adelaide is recognised as home to some of Australia's leading medical research facilities.

The City's North Terrace boasts one of the largest health and life sciences clusters in the Southern Hemisphere. Fusion has links to these facilities to underpin the clinical research work at its Norwood clinic. Ultimately, clinical research companies such as Fusion bridge scientific discovery and clinical practice. Through rigorous and meticulous execution, and regulatory expertise, we generate credible evidence needed to bring safe and effective therapies to patients, advance medical knowledge, and support healthcare decision-making. Fusion collaborates with groups worldwide to accelerate timelines, control costs, and ensure patient-centred outcomes and equitable access internationally.

In summary, clinical research is the foundation of medical innovation, improving patient care, and ensuring the safety and efficacy of treatments. Fusion's clinical trials are essential for testing the efficacy and safety of new medications, therapies, and medical devices. Without clinical research, new treatments cannot be validated leading to better healthcare practices and guidelines, improving patient outcomes and quality of life. It also provides healthcare professionals with evidence-based information that aids in making informed decisions about patient care. Trusted research. Proven results. Fusion.

IQVIA Biotech

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Location:
Sydney, NSW

Company Overview

IQVIA Biotech is a biotech-specialized CRO delivering flexible clinical development solutions for biotech and emerging biopharma companies. Our clinical solutions are built on 25 years of unmatched experience with therapeutically aligned expertise, uniquely designed to deliver full-service solutions on a global scale. Learn more at iqviabiotech.com.

Partner with us today to accelerate clinical development through tailored solutions, advanced analytics, and a global network. With expertise spanning oncology, rare diseases, and emerging therapies, our team delivers results that matter — from first-in-human studies to regulatory approvals. Discover how IQVIA Biotech can help bring your breakthrough to patients faster.

Molecule2Market Pty Ltd

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Molecule2Market Pty Ltd

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Location:
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Company Overview

Molecule2Market (M2M) is a highly experienced Australian based Contract Research Organisation (CRO) supporting pharmaceutical, biotechnology, medical device and academic clients globally.

We specialise in the delivery of high-quality clinical trial services across all phases, with particular expertise in early phase and complex studies. Our team has worked across a broad range of therapeutic areas including oncology, neuroscience, infectious diseases, immunology, paediatrics, allergy, ophthalmology, cardiovascular, osteoarthritis and dermatology. This diversity of experience allows us to anticipate challenges, adapt quickly and ensure every project receives the specialised attention it deserves.

M2M offers a full suite of services including study design, ethics and governance support, project management, monitoring, data management and medical writing. We take pride in providing flexible and tailored solutions that meet the unique needs of each client while upholding the highest standards of scientific and operational excellence.

As a member of the global AICROS network, M2M connects clients to experienced, independent CRO partners across Europe, Africa, Asia and the USA. This collaboration enables the seamless conduct of multi country studies while maintaining consistent oversight, a strong commitment to quality and local expertise. Clients benefit from global reach combined with the personalised service of a highly experienced local partner.

Our success is built on people. The M2M team is professional, approachable and deeply committed to the success of every project. We are known for our responsiveness, our ability to navigate complex regulatory environments and our dedication to building long term partnerships. With a proven track record of delivering both regional and international studies, we help bring innovative therapies from concept to patients reliably and efficiently.

At Molecule2Market, our mission is clear: to provide clients with trusted expertise, global collaboration and uncompromising quality, ensuring every study is conducted with integrity and purpose. By operating in Australia, our international clients also benefit from access to competitive R&D tax incentives and a favourable early phase clinical trial environment that can accelerate development timelines.

Novotech

NOVOTECH™
Biotech's Partner at Every Phase

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Novotech

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Company Overview

Novotech is a globally recognised full-service clinical research organisation (CRO) and scientific advisory company trusted by biotech and small- to mid-sized pharmaceutical companies to guide drug development at every phase. With a global footprint that includes 30+ offices across the Asia-Pacific region, North America, and Europe and partnerships with 5,000+ trial sites, Novotech provides clients an accelerated path to bring life-changing therapies to market by providing access to key clinical trial destinations and diverse patient populations. Through its client-centric service model, Novotech seamlessly integrates people, processes, and technologies to deliver customised solutions that accelerate the path to market for life-changing therapies. By adopting a true partnership approach, Novotech shares a steadfast commitment to client success, empowering innovation, and advancing healthcare worldwide.

Recipient of numerous industry accolades, including the Frost & Sullivan CRO Company of the Year award for 19 consecutive years, Novotech is recognised for its excellence in clinical trial execution and innovation. Its deep therapeutic and regulatory expertise, combined with local market insights, ensures streamlined clinical trials, optimised data analytics, and accelerated patient recruitment strategies. Together with clients, Novotech transforms scientific advancements into therapies that improve global health outcomes, embodying a mission of driving innovation and delivering impactful results.

Pharmaceutical Innovation and Development Group (PIDG)-Adelaide University

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Company Overview

TThe Pharmaceutical Innovation and Development Group (PIDG) — a core pillar of the Centre for Pharmaceutical Innovation (CPI) at Adelaide University — is your strategic partner in tailored drug delivery innovation, empowering you to de-risk development and maximise ROI through optimised safety, efficacy, and IP protection.

With over 180 years of academic excellence and deep integration within the Adelaide Biomedical Ecosystem, PIDG bridges the gap between discovery and delivery. Surrounded by world-class hospitals, clinical trial units, and CROs, we provide end-to-end support across the entire drug development cycle — including preclinical development, clinical trials, and regulatory registration — ensuring every program is scientifically optimised, commercially viable, and protected by a strong IP framework.

Pathways for Partnerships

1. Tailored Drug Delivery Development & IP Protection

Drug development is inherently risky — with over 90% of candidates failing before reaching patients. PIDG's integrated service model is designed to de-risk innovation, accelerate timelines, and transform potential into market-ready products through:

- Expert Formulation Development – Small and large molecules, proteins, and gene-based therapeutics, with expertise in solubility, stability, taste masking, bioavailability optimisation, and targeted PK design.
- Quality Analysis & Bioanalysis – Method development, validation, PK assessment, and QC testing supporting global regulatory submissions.
- Preclinical & Clinical Trial Supply – GMP-like material for first-in-human and Phase I studies, ensuring quality, data integrity, and accelerated progression.

Each program is supported by a strategic IP framework to protect innovation, strengthen patent portfolios, and extend product exclusivity — securing sustained ROI.

2. Commercialisation of PIDG's Patented Platform Technologies

PIDG offers proprietary, patent-protected drug delivery platforms available for collaboration or licensing, enabling partners to fast-track development, enhance differentiation, and achieve commercial advantage with proven, scalable delivery solutions

Proven Global Collaborations

PIDG has partnered with 50+ international and Australian companies, including Evofem Biosciences, Yaso Therapeutics, Noxopharm, GD Pharma, AFT Pharmaceutical, Semetis, Sirtex, Mayne Pharma, and Hospira. These collaborations span oncology, infectious diseases, neurology, mental health, endocrinology, pain, and cardiovascular therapies, demonstrating our ability to translate breakthrough science into market-ready therapeutics.

Key success stories

- Phexxi®: World's first FDA-approved non-hormonal contraceptive.
- AUKONTALS: First oral Edaravone for neurodegenerative disease; USD $179M upfront plus royalties (China rights).
- Omeprazole Long-Act™ Injection: Weekly long-acting injection, improving adherence and extending IP protection.
- Long-Act™ Platform: Sustained-release system with customisable release from days to weeks, enabling potential once-weekly Levodopa/Carbidopa for Parkinson's therapy.

Benefits of Partnering

Leverage Australia's trusted clinical ecosystem, fast-track regulatory pathways, and up to 43.5% R&D tax incentives — delivering scientific confidence and financial efficiency.

ProPharma

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ProPharma

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Company Overview

For the last 25 years, ProPharma has improved the health and wellness of patients by providing advice and expertise that empowers biotech, med device, and pharmaceutical organisations of all sizes to confidently advance scientific breakthroughs and introduce new therapies.

With deep domain expertise in regulatory sciences, clinical research solutions, quality and compliance, pharmacovigilance, medical information, FSP solutions, and digital transformation, ProPharma offers an end-to-end suite of fully customisable consulting solutions that de-risk and accelerate our partners' most high-profile drug and device programs.

As a full-service Clinical Research Organization (CRO), ProPharma offers comprehensive support across the entire development lifecycle. From early-phase clinical trials through to post-marketing surveillance, we provide expertise in Phase I–IV clinical research, regulatory sciences, pharmacovigilance, and quality assurance, ensuring every project meets the highest scientific and regulatory standards.

Our clinical trials and research solutions are built around patient focus, global reach, and therapeutic diversity. We have extensive experience executing studies across multiple phases and therapeutic areas, tailoring each program to meet the unique needs of our partners. With a client-centric approach, ProPharma delivers scalable and customisable solutions that empower both emerging biotechs and large pharmaceutical companies to navigate complexity, manage risk, and bring innovative therapies to market with speed and confidence.

By combining vast scientific knowledge with regulatory insight, ProPharma ensures that clinical development is not only efficient but also compliant and strategically aligned to achieve approvals and market success. This integration of services allows our clients to benefit from a streamlined approach that reduces cost, shortens timelines, and strengthens the likelihood of achieving program milestones.

Innovation, expertise, and passion are at the heart of everything we do. Whether supporting a first-in-human trial or managing global post-approval studies, ProPharma is committed to improving patient health and safety while delivering the next generation of medicines, technologies, and therapies.

PureCDM

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Location: Melbourne, VIC

Company Overview

PureCDM is an Australian-based, globally connected specialist biometrics solutions provider, bridging the gap between invention, technology, and commercialisation. Our mission is to serve the needs of biotech and medtech companies by providing the highest quality data and analyses, optimising the potential for commercialisation and getting key assets to patients faster. PureCDM's management team brings over 25 years of cross-functional expertise in clinical data management, biostatistics, and regulatory-compliant database design.

Tailored Solutions

PureCDM's biostatistical consulting and delivery teams form the backbone of trial and program-level design, guiding critical decisions from early study development through to regulatory submission. Our data management solutions are built by experts who anticipate and address pressure points in data collection, proactively identifying and resolving issues before they impact timelines. We tailor solutions to the needs of the protocol and deliver transparency through real-time reporting, increasing efficiency and confidence at every stage.

Precision, Discipline and Expertise

In clinical research, data quality is fundamental. PureCDM ensures the right people are in the right roles, applying structured processes and disciplined execution at every step. Our operational strength is matched by deep therapeutic expertise, with our team bringing foresight and insight across complex studies including early phase I/II dose escalation, immuno-oncology, vaccines, paediatrics, rare diseases, regenerative therapies, and medical devices. While our therapeutic breadth is wide, our specialties include oncology and neurology, where data complexity and regulatory expectations demand the highest level of biometrics capability.

Australian Advantage, Global Reach

Australia provides a uniquely favourable environment for clinical development, with streamlined regulatory pathways, attractive R&D incentives, and rapid patient recruitment. PureCDM helps clients take full advantage of these benefits in their early-phase studies. From there, we seamlessly continue as a biometrics partner for phase II and beyond, ensuring consistency and continuity as trials expand globally. This integrated approach preserves data quality, accelerates timelines, and clears regulatory pathways across international markets.

Partnering for Advantage

While many companies rely on full-service CROs, working with a dedicated biometrics specialist offers distinct benefits. PureCDM provides independent, focused biometrics expertise, free from the competing priorities of larger providers. This independence ensures objective analyses, earlier identification of risks, and greater flexibility. Combined with our flexible pricing model which allows clients to scale services according to budgets and milestone achievements, we invest in long-term relationships, delivering de-risked study designs and future-proofed database solutions that meet the highest scientific and regulatory standards for our clients. The result is reduced risk, stronger science, accelerated commercialisation, and faster patient access to life-changing therapies.

Southern Star Research

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Southern Star Research

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Sydney, NSW

Company Overview

At Southern Star Research, we empower small and mid-sized biotech, pharmaceutical, and medical device companies to confidently navigate complex early-phase clinical development across APAC. As Australia's trusted, independent mid-sized CRO, we offer the "sweet spot" advantage: substantial enough to provide comprehensive, globally recognized services, yet agile and client-focused for truly personalized engagement. While our core strength lies in Phase I and II trials, our proven experience and robust infrastructure ensure seamless progression into Phase III when your program demands it.

Founded by industry pioneers, Southern Star Research is built on intellectually engaged partnership, embedded quality, and principled action. This foundational philosophy continues to shape our culture today, guiding how we work, grow, and deliver exceptional outcomes for our clients, patients, and global health.

Our team's depth of experience and scientific understanding means we anticipate challenges early, adapt quickly, and generate data that stands up to global scrutiny – a critical factor for successful regulatory submissions and investor confidence.

For over 15 years, our highly qualified clinical team has successfully supported trials across a wide range of therapeutic areas, spanning both common and complex indications. This extensive experience ensures your program will benefit from insights built across diverse patient populations and clinical challenges.

Our dedication to quality and successful outcomes has earned us significant industry recognition including **Great Place to Work Australia (2024 & 2025), APAC CRO of the Year 2025, and the Frost & Sullivan 2024 Asia-Pacific Competitive Strategy Leadership Award.**

We view our role as more than service providers; we are your trusted advisors, sharing knowledge, offering guidance, and engaging in collaborative decision-making to strengthen your strategies and accelerate your outcomes.

AusBiotech

Laboratory & Analytical Services

ProCan Technologies

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ProCan Technologies

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Company Overview

With origins from a world-leading research institute renowned for its oncology research expertise, ProCan Technologies helps biotech innovators complete targeted, de-risked and accelerated oncology clinical trials.

Offerings:

- TargetQuant™ ADC Panel – see details below.
- Diagnostics Development – discover and develop unique biomarkers that determine a patient's likelihood of response to treatment; this can be incorporated into early-phase clinical trials.
- Prognostic Biomarker Development – develop powerful protein signatures for many cancer types that predict likely cancer outcomes and inform treatment options.

TargetQuant™ ADC Panel – Unlock the Power of Proteomics

The global Antibody-Drug Conjugate (ADC) market is experiencing unprecedented growth, projected to reach A$34.7 billion by 2030. With the advent of successful ADCs like Enhertu (trastuzumab deruxtecan) and Padcev (Enfortumab vedotin), research into identifying and validating novel ADC targets is intensifying significantly.

Most ADCs rely on binding of their antibody component to a protein target on the surface of tumour cells. The success of treatment with an ADC drug interaction depends on one critically important question: Is the target present in the patient's tumour? For most ADCs, the quantity of target protein expressed by the tumour is also important.

ProCan's TargetQuant™ ADC Panel

Using mass spectrometry-based proteomics, ProCan Technologies quantitatively profiles protein abundance, across thousands of real-world, clinically annotated tumour samples representing both treatment-naïve and relapsed disease. Building on these data and knowledge, ProCan Technologies has now developed a targeted panel to directly quantify ADC target expression, the TargetQuant™ ADC Panel.

Our ADC Panel empowers you to:

- Validate Targets
- Identify Off-target interactions – quantify ADC target abundance in matched patient normal tissue samples to provide indications of potential off-target effects.
- Expand Indications – identify additional tumour types
- Prioritise Targets – by comparing candidate targets based on real-world protein abundance
- Develop Biomarkers – correlate protein abundance with histology, clinical outcomes, and co-expression patterns.

AusBiotech

Regulatory, Legal & Financial Services

Piper Alderman

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Piper Alderman

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Melbourne | Perth | Sydney

Company Overview

Piper Alderman: Leading legal expertise in Life Sciences

Piper Alderman is a premier commercial law firm with a proud history spanning over 175 years, serving clients across Australia and internationally. With offices in Adelaide, Brisbane, Darwin, Melbourne, Perth, and Sydney, the firm is renowned for its collaborative, client-focused approach, and commitment to excellence in legal practice.

In the dynamic and rapidly evolving life sciences sector, Piper Alderman stands out for its deep industry knowledge and practical legal solutions. The firm's dedicated Life Sciences & Healthcare Group advises public and private sector organisations, helping them navigate complex regulatory environments, technological advances, funding constraints and competitive pressures.

Piper Alderman's clients include biotechnology, pharmaceutical, medical device, and digital health companies, as well as contract manufacturing organisations, medical research institutes, and universities. Piper Alderman also works with investors and specialist service providers, covering the entire life sciences ecosystem. The firm provides comprehensive legal services, including capital raising, IPOs, takeovers, ASX Listing Rules, operational and strategic contracts, mergers and acquisitions, intellectual property protection and commercialisation, employee relations, information technology, privacy, regulatory compliance, and corporate governance.

The team's broad and deep expertise ensures that clients are supported from early-stage development through to IPO and beyond. For established global operations doing business in Australia, Piper Alderman's local knowledge enables companies to quickly adapt their contracts and governance to local requirements.

The firm's sustained engagement with leading sector organisations such as AusBiotech demonstrates its long-standing commitment to the life sciences industry. Piper Alderman's sector knowledge enables it to offer not only legal advice but also facilitate valuable introductions to experienced board members, executives, collaboration partners, and investors.

Recent highlights for the firm include advising ASX-listed biotech and immunotherapy companies on licensing and collaboration agreements; preparing inter-company agreements between offshore parent companies and Australian subsidiaries; supporting specialty pharma companies in complex manufacturing and distribution negotiations; advising public and private companies on capital raising rounds and assisting start-ups with the key agreements needed for commercialisation of early-stage therapeutic products. The firm has also acted in high-profile regulatory compliance matters, defended major class actions, and provided ongoing employment and corporate governance advice to leading organisations.

Piper Alderman is recognised by industry authorities such as The Best Lawyers® in Australia and Chambers and Partners, reflecting the firm's reputation for service excellence, sector expertise, and client satisfaction.

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RSM Australia

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Company Overview

Our team of advisors helps start-ups and multinational companies navigate their business growth journey. Australia is a premier destination for life sciences innovation, with a robust commitment from the government and substantial investment in the sector.

This has paved the way for biotechnology (biotech), medical device (medtech), and pharmaceutical companies to develop ground-breaking preventive, therapeutic, and diagnostic medicines and devices for human and animal medical conditions in Australia.

Australia boasts world-class researchers, clinicians, facilities, and knowledge, making it an attractive hub for life science businesses. Our team of life science advisors helps start-ups and established multinational companies navigate the entire business growth journey, from preclinical to commercialisation.

We assist clients in staying focused on their scientific innovations and clinical research while also driving meaningful business growth. Our expertise spans across all segments of the life science industry, including biotech, pharmaceuticals, medtech, contract manufacturing organisations (CMOs), clinical research organisations (CROs), and others that support the sector.

We bring in-depth experience and technical capabilities across our service lines to help life science businesses maximise their potential for success, address key challenges, create efficiencies, elevate opportunities and manage risks.

Smartways Logistics

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Australia

Company Overview

Established in 2004, Smartways is proud to celebrate over 20 years of dedicated service to the Australasian healthcare community. We specialise in time-critical, complex healthcare logistics, from patient-on-table emergency deliveries to global, preplanned and temperature-controlled movements.

Our capabilities span every aspect of the healthcare sector, including life science, biotechnology, medical devices, radio-nuclear, pharmaceuticals, and clinical trials. As the industry leader in clinical logistics, we provide tailored services reducing set up times, improving data integrity and providing real time tracking.

Today, Smartways stands as the largest and fastest-growing dedicated medical logistics organisation across Australia and New Zealand, with more than 40 strategically located hubs and a fleet of over 350 highly trained drivers. Our network ensures unmatched coverage, providing daily access to capital cities, regional centres, and country locations.

Operating 24/7, 365 days a year, we deliver reliability when urgency is non-negotiable. At the forefront of cold-chain logistics, Smartways offers Smart-Temp controlled packaging solutions supported by high-tech temperature logging and tracking. These capabilities ensure product integrity throughout the supply chain, meeting the most demanding requirements of healthcare delivery.

Technology and innovation drive every aspect of our operations. With 95% of orders processed online or via seamless system integrations, our automation and AI-powered routing deliver unmatched speed, accuracy, and visibility. These tools equip our allocators to make instant, data-driven decisions while providing customers with live tracking and complete transparency, ensuring every delivery arrives exactly where it's needed, when it's needed.

Beyond logistics, Smartways is committed to creating positive environmental impact. We are the first healthcare logistics company in Australasia to operate as 100% carbon neutral, bearing the full costs of our sustainability program. Our initiatives reduce and mitigate greenhouse gas emissions, underscoring our commitment to both community and planet. Driven by excellence, innovation, and responsibility, Smartways is redefining medical logistics one shipment at a time.

AusBiotech

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