

A Reflection on 25 Years Well Spent: Building Our Reputation as Australia's Premier Bioanalytical and Toxicology Provider

This year, we at Agilix Biolabs celebrate our 25th year supporting Biotechs' drug development programs as they champion safe and effective therapeutics through preclinical and clinical testing to bring relief to patient populations around the globe. This rewarding journey has allowed us to refine our expertise and establish a deep and rich well of experience to draw from as we provide our clients with critical regulated bioanalytical methods and toxicology studies for even the trickiest of novel drug candidates and biomarkers. Together we appreciate and reflect on our first quarter century as we set our sights on what lies ahead.



"If you would have told me back in 1996 this group of driven academics at University of South Australia would become the 150-person regulated bioanalytical powerhouse Agilix Biolabs has become..., I dare say I would have believed you. We are so fortunate to have such talented scientists dedicated to scientific excellence and the spirit of relentless problem-solving— success follows passion. Having been with this incredible team every step of the way, I am proud to celebrate our 25th anniversary and reflect on everything we have achieved. I look forward to a bright future; our mission is to deliver bioanalytical excellence and defendable toxicology data you can rely on, over the next 25 years and beyond. "

- Jason Valentine, CEO



Jason Valentine in the lab with the Premier of South Australia, Steven Marshall

A winding journey from academia to industry partner

In 1996, at the [University of South Australia](#) there was a research lab, and in that lab were some of the brightest bioanalytical chemists in Australia. In addition to academic pursuits, their expertise was sought after by pharmaceutical companies hoping to understand the pharmacokinetic (PK) and pharmacodynamic (PD) properties of their products and meet ever-tightening safety criteria established by the [Food and Drug Administration](#) (FDA) in the United States, and other regulatory bodies around the world. Out of this symbiotic relationship between the University academics and industry, the Center for Pharmaceutical Research (CPR) was born. CPR was a first-in-class clinical trial contract research organization (CRO) and bioanalytical laboratory. Drug developers around the globe could depend on CPR to conduct their early phase clinical trials, develop regulated methods for bioanalysis, and process the samples in house.

Soon our status rose to the attention of the world's leading regulatory agencies. In 2011, we welcomed the FDA for an on-site audit, and steadily built support relationships not only with drug developers in Australia but all over the world, including United States, Asia-Pacific, and European regions.

After two decades of operating together, the regulated bioanalytical division of the business separated so clients conducting nonclinical studies and clinical trials outside of CPR could work with the bioanalytical experts. We decided to establish a fully independent bioanalytical laboratory with room to grow and establish direct relationships with the clients along with global and local clinical CROs.

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Agilex Biolabs Expansive growth

Thus, 2019 marked the genesis of a new identity—[Agilex Biolabs](#), the first laboratory in South Australia focused on providing quality bioanalytical support for drug sponsors aimed at market approval. With a new, independent status and a focused mission, Agilex Biolabs blossomed. Equipped with the full complement of top-of-the-line bioanalytical

tools and a fast-growing team of experienced scientists, we set out on our path to become Australia's number one partner for trusted bioanalytical excellence.

In 2019, when the global COVID-19 pandemic struck, we doubled down on our commitment to the pharmaceutical companies who held so much of the world's hope for a cure. We invested over \$3.5 million in a 30% capacity increase to bolster our support: more instruments, new technology, increased headcount, and additional laboratory space. We were able to add top talent from all over the world and establish a full suite of services for regulated bioanalysis. To our fleet of Sciex API 4000 LC-MS/MS systems we added: Sciex API 6500+™ LC-MS/MS technology; Gyrolab™ Xplore; Luminex MAGPIX xPONENT™; MSD Quickplex 120; and BD FACSymphony™ A3 20 colour flow cytometry analysers.

The pandemic introduced new challenges and highlighted inefficiencies in international relationships and communication. In response, the Agilex Biolabs team launched the world's first bioanalytics client portal. GALEXI™ enables secure and enhanced communications, allowing real-time study management and transparency across time zones so international clients can access information exactly when they need it and avoid delays that tend to accumulate with traditional means of collaboration.

In 2020, toxicology studies were added to our arsenal with the acquisition of [TetraQ's NATA-accredited, GLP-compliant toxicology facility from the University of Queensland](#). Nonclinical studies are critical in evaluating a drug candidate's safety profile and suitability for FIH studies, and now our clients can avoid the time and administrative investment of coordinating tox work and bioanalytical support between separate providers along with taking advantage of the Australian 43.5% R&D tax incentive.

We are committed to evolving our support to address growing areas of therapeutic research and accommodate up-and-coming modalities so that our clients can continue to rely on us for different types of novel therapeutics and biomarkers, from small molecule to large. Last year, [The Premier of South Australia launched our \\$1.5m Vaccine and Immunobiology state-of-the-art laboratory](#). This new laboratory focuses on new and emerging areas of biotherapeutic modalities, including RNA vaccines, siRNA/miRNA clinical targets, and gene therapy.



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The powerhouse lab we have become

Agilex Biolabs now stands tall as Australia's largest and most technologically advanced regulated bioanalytical laboratory for clinical trials.

Our recent additions of toxicology study capabilities and cell and gene therapy analytical techniques have us poised to accelerate our growth as a trusted partner to drug developers worldwide as more and more sponsors turn to Australia as their First-in-Human clinical trial destination for new molecular entities (NMEs) and novel vaccines. Unique to Australia is a remarkably efficient regulatory pathway to FIH studies and the Research and Development (R&D) Tax Scheme, which encourages international biotechnology companies to conduct their studies in [Australia by offering a 43.5% cash rebate](#).

The Agilex Biolabs team is primarily comprised of scientists (85% of our headcount!), and alongside our dedicated management and support staff, we are proud to carry the reputation we've earned as Australia's premier partner for biopharma. Our growing experience spans nearly a thousand studies so far: nonclinical and clinical, proprietary compounds and biomarkers, GLP and non-GLP, large and small molecules, with top biopharma clients in the USA, APAC, and EU.

What's next for the team at Agilex Biolabs

As we enter into 2022, we are excited to move forward in lockstep with our new parent company. In late 2021 [Healius entered into an agreement to acquire Agilex Biolabs](#). With [Healius](#) by our side, we will set our sights and align our resources to provide reliable, high-quality support to the biopharma industry as they broach new frontiers with safe and effective therapeutics. Healius' network of pathology, diagnostic imaging, and other healthcare entities are aligned in our mission to improve health outcomes with quality support services.

With all the additions to our team and service offerings, we've outgrown the current digs. Our Adelaide headquarters will soon be doubling in size with the addition of a second building. This campus is set to become the bioanalytical crown jewel of Australia, with dedicated buildings and teams for large and small molecule projects.

We anticipate that this is the first of many additions for our Adelaide facility as we continue to expand and add capabilities to best serve Australia's growing life sciences sector and our international biopharma clientele. Our Brisbane campus is set to expand also, increasing our animal study capacity 500% by the end of 2022.

"When I think about Agilex Biolabs' 25 years as a company, this team—the people I work with every day—have laid down a legacy," says Holly Stefl, Vice President at Agilex Biolabs. "There is so much value in the collective experience of our scientists. They have worked on therapies that have gone on to change patients' and their families' lives. Agilex Biolabs scientists don't balk at the challenge of new modalities and difficult matrices, adaptation and growth are really where they thrive. I am so proud to be a part of this incredible group and I can't wait to see what our future holds."

Holly Stefl – Vice President of Business Development at Agilex Biolabs
