

Agilex Biolabs expands GLP Toxicology capacity with new testing facility

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In addition to the new Brisbane facility, Agilex's Adelaide campus houses multiple bioanalytical facilities



Australia's leading provider of toxicology and bioanalytical contract services, Agilex Biolabs has expanded its capacity to better serve the biotech, pharmaceutical and animal health industry with the opening of its new in-vivo testing facility.

After over 25 years of continued support to its industry, the wealth of experience gained by Agilex will now be shared with an even more increased number of sponsors from around the globe as a direct result of a 500% increase in capacity subsequent to the addition of a new purpose built GLP toxicology facility, making Agilex undoubtedly the largest Good Laboratory Practice (GLP) Toxicology service provider in the region.

"We are thrilled to add more talented people to the team, shorten lead times further, be more agile, and enhance our superior level of safety assessment service to the global biotech, pharmaceutical and animal health industries." said Holly Stefl, Agilex's Chief Commercial Officer.

The new custom-built toxicology facility has over 10,000 ft2 of laboratory space and is equipped with state-of-the-art individually ventilated, environmentally monitored, high tech enabled systems scheduled for accreditation by Australia's <u>National Association of Testing Authorities (NATA)</u> as a Biosafety Level (BSL) 2 facility. The already installed modern industry systems and standards ensures that our sponsors will continue to receive the best in the industry with forethought, and results that can be backed by the Agilex brand to the level of accepted regulatory requirements and evaluations of innovative therapeutics and vaccines.

The increased capacity empowers the renowned toxicology team to continue its track record for groundbreaking successes and scientific acumen. As the premier Australian bioanalytical partner for COVID vaccine development, Agilex completed multiple <u>SARS-CoV-2 fast-track programs</u> on behalf of its sponsors in the last two years, including mRNA, adenovirus, and molecular clamp stabilized protein subunit vaccines. In addition, Agilex is the only toxicology study provider in Australia to accommodate CAR-T therapy programs with immunocompromised models.

Services performed at the new testing facility will continue to be compatible with IND-enabling packages for FDA review and/or other international regulatory agencies, per mutual acceptance of data (MAD) agreements. In addition to the new Brisbane facility, Agilex's Adelaide campus houses multiple bioanalytical facilities for new chemical entities (NCEs) small molecules, peptides, biologics, cell and gene therapy, vaccines, and other modalities. The breadth of instrumentation and experienced leadership enables Agilex to deliver robust and reliable data to a wide spectrum of drug developers in nonclinical and clinical phases.