Serving Customers with Analytical Testing from Assay Design through Product Release

Avance Biosciences uses the most advanced technology to smooth regulatory paths

In Houston, TX, scientists at Avance Biosciences help a wide range of customers take drugs from early testing through manufacturing. This contract research organization (CRO) specializes in biologic assay design, assay validation, and sample testing for Good Laboratory Practice (GLP) and Current Good Manufacturing Practice (cGMP) submissions to regulators, plus testing drugs for release as products. It's a fast-moving business.

"We grew 30% in 2020 and 80% in 2021," says Xuening Huang, PhD, CEO and co-founder of Avance Biosciences. "In the first few months of 2022, we've grown another 54%."

Much of Avance's growth comes from its diverse capabilities. The company's scientists can help with a wide range of projects—from ones involving gene editing, such as CRISPR, to various applications of viral vectors. Plus, Avance works with a range of high-technology platforms, including next-generation sequencing and digital droplet PCR (ddPCR).

Advances in gene editing

Improvements in methods of gene-editing technologies promise more effective treatments for genetic diseases and cancer. "We're working with a lot of pharma industry partners who use gene editing to modify a stem cell or T cells and put those cells back in the patient's body as a treatment," Huang says. "Because you are modifying the human genome, they want to know whether it's safe, and we provide innovative assay solutions to help our clients determine that."

A key concern among regulators about therapies based on gene editing is identifying on- and off-target activity. For off-target events, biopharmaceutical companies need more than computational studies, because testing must also be done to thoroughly analyze and resolve any off-target modifications, such as deletions, insertions, inversions, point-based mutations, and translocations. For CRISPR-based therapies, Avance can analyze off-target effects with various cGMP/GLP processes, including rhAmp sequence panels and next-generation sequencing (NGS) on Illumina platforms. In addition, Avance uses ddPCR technology to analyze gene edits—including homology-directed repair, nonhomologous end joining, and chromosomal translocation—created with CRISPR or other gene editing methods. The ddPCR approach detects gene editing events at frequencies as low as 0.5% or less.

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Avance offers GMP next-generation sequencing services, such as sequencing assays for on/off- target events, that can be applied to manufacturing and drug product release of therapies based on gene editing.

To show the potential efficacy of therapies based on gene editing, drug developers must also confirm that a CRISPR-based or other gene editing therapy performs the intended edits, such as a gene knockout, which Avance can do with NGS technologies.

Beyond the testing required to apply for investigational new drug (IND) approval from regulators, Avance offers services, such as guide RNA sequencing under cGMP, that can be applied to manufacturing and drug product release of therapies based on gene editing.

In all projects at Avance, an in-house quality system ensures accurate results. For instance, the company developed independent cGMP and GLP quality units. Such a system approach guarantees compliance within Avance and the services that it provides.

Improvements through early adoption

Avance adds to its capabilities in analytical technology to stay ahead of the evolution of drug development. In February, for example, Avance announced that it would start using Mission Bio's Tapestri Platform.

This platform provides high-throughput analysis that determines a cell's genotype and phenotype. So, this technology reveals a cell's DNA signatures as well as its protein makeup. Avance will use Tapestri to analyze the transduction efficiency of lentivirus in autologous cell therapies. The platform will also be used to study gene therapies.

"We'll be the first ones to utilize that workflow and that instrument in a cGMP environment," Huang says. "So, that's an example of being an early adopter of a technology and getting it into a regulated environment."

Avance will continue to validate new technologies to expand its analytical portfolio. Only then can biopharma companies push the boundaries of developing tomorrow's therapies in the safest and most effective ways. ■

Contact our technical staff to discuss how we can support your assay testing needs.

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