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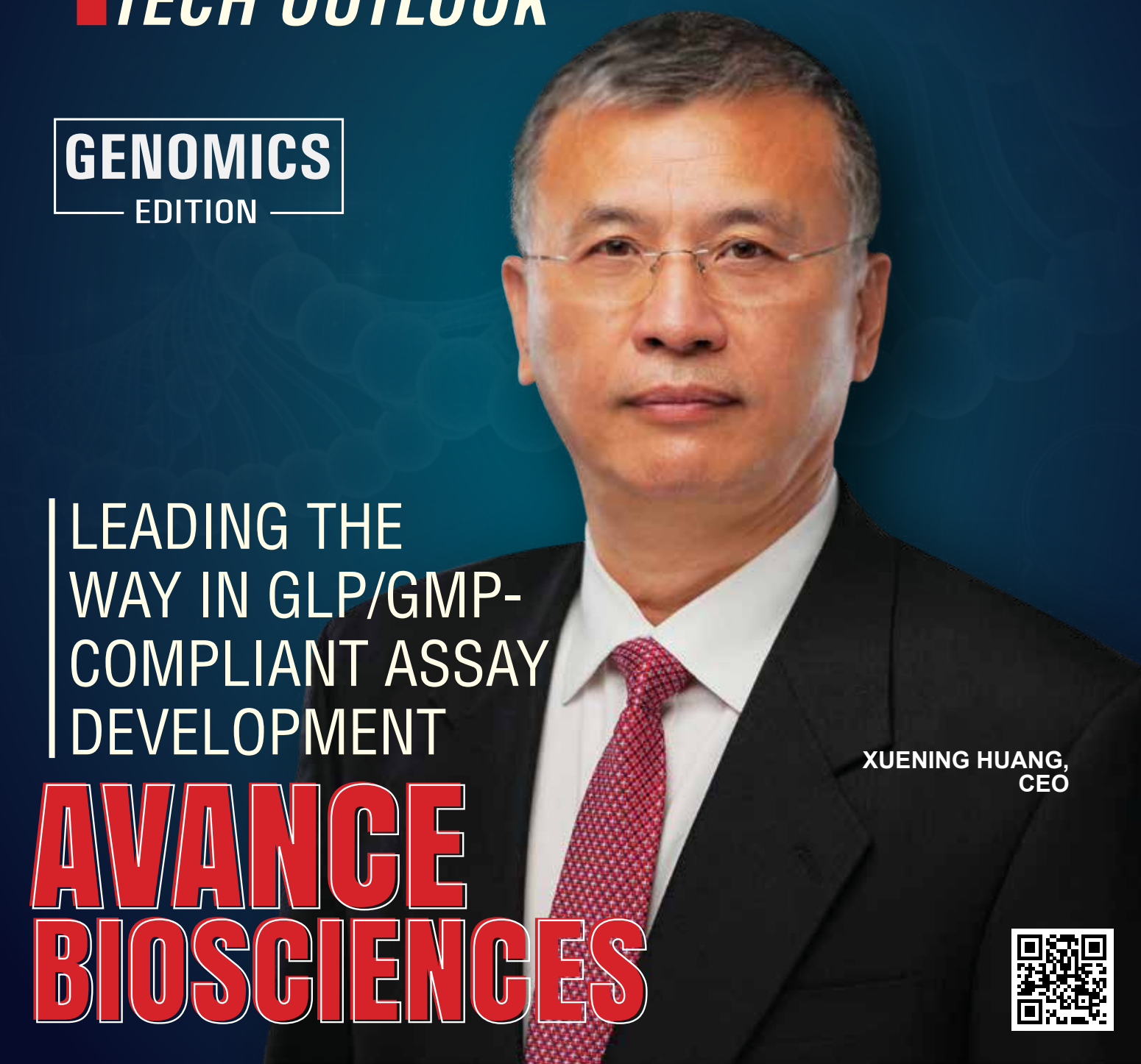
GENOMICS EDITION



LEADING THE WAY IN GLP/GMP-COMPLIANT ASSAY DEVELOPMENT

XUENING HUANG, CEO

AVANCE BIOSCIENCES

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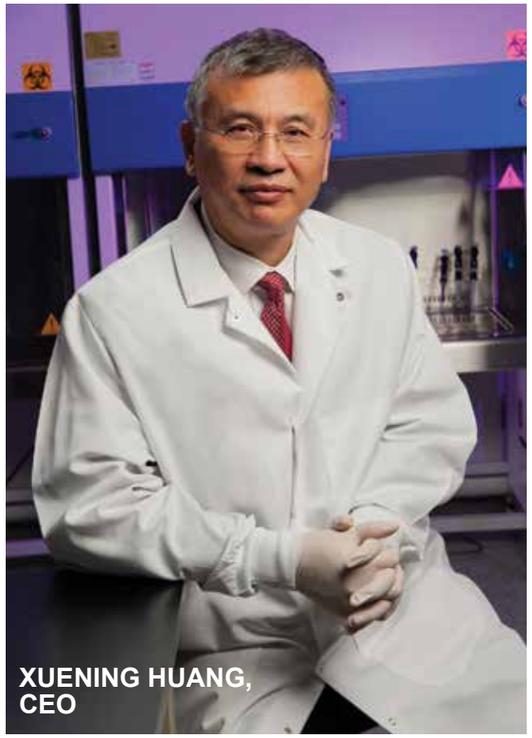
AVANCE BIOSCIENCES

LEADING THE WAY IN GLP/GMP-COMPLIANT ASSAY DEVELOPMENT

By Stacey Smith

XUENING HUANG, CEO

Genomic technologies and their usage have seen extensive growth in the past decade. Over the years, these technologies have evolved significantly and can now be used to develop new classes of therapeutics such as gene therapies and viral based vaccines. However, scientists and pharma companies have been continuously analyzing how to confirm that these genomic based therapies are not only effective but as equally important safe. And next-generation sequencing seems to be one of the solutions to their needs. In the complex genomic research landscape, which calls for access to in-depth information, next-generation sequencing has become the go-to solution widely used by research organizations. A company that has made a mark in this context is Avance Biosciences. Based in Houston, Avance is a contract research organization that has come a long way in the drug discovery and development landscape with specialization in genomic assay development, validation, and sample testing in compliance with Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) regulations. In a market with many research firms carrying out genomic based testing services, Avance stands out with its DNA/RNA sequencing



and real-time and digital PCR services due to its ability to conform to these regulations. “We have established a very good reputation, having managed so many assay development, validation and sample testing projects for clients in the past 10 years. We can offer creative testing solutions to our clients worldwide to address their assay development challenges,” explains Xuening Huang, CEO at Avance Biosciences.

Next-Generation Sequencing and Testing Services

Avance’s expertise facilitates a multitude of assay testing needs that further support drug development and biologic product manufacturing. In the present scenario, where the market is witnessing new kinds of biologics, businesses need sophisticated genomic assays to help them find answers to what type of drugs they have, whether they are safe, and what kind of patients can use the treatment. This is where regulatory compliance comes into the picture. To comply with the set guidelines, drug development companies need to submit data to regulatory agencies such as the FDA and similar regulatory agencies in Europe, Canada and Asia. “Clients prefer to come to us because we not only have the experience but also understand what the regulatory requirements are in terms of genomic testing. Our clients want those assays done with good regulatory compliance,” adds Huang.

Apart from maintaining regulatory compliance, the process of genomic assay development and validation needs to be completed quickly, considering several organizations are competing in the same therapuetic area. Each of them wants to be the first one in the market to do so. Avance helps clients with the same, ensuring that the genomic assay development, validation, and testing is completed in a short span. The company also extends support to its customers when they have an internal assay developed that they need to transfer or require design support, whether it’s a next-generation sequencing assay or a safety assesment of a biovaccine. Often, clients seek Avance’s expertise in designing a robust assay to support an animal study/ pre-clinical study; the same assay can then be validated to support a clinical trial. As part of the assay development process, it is critical to develop a robust DNA/RNA extraction method for biological samples. “Our clients understand that a good assay starts with nucleic acid extraction, with good quality and high recovery. Each year Avance team extracts DNA/RNA from hundreds of thousands of samples. We can provide the expertise to our clients to ensure that their samples are tested in compliance with FDA regulations,” says Cal Froberg, vice president - sales marketing at Avance Biosciences.

> **We have established an excellent reputation, having managed so many assay development, validation, and sample testing projects for clients in the past ten years**

A Consultative Approach

Since its inception, Avance has garnered a vast client base, not just because of its trusted genomic testing and validation services but also because of its consultative approach to assist the clients. “We try to understand what questions we are trying to answer and what problems we are trying to solve along with the outcomes they are looking for. Based on our years of experience, we advise them based on what they are looking to achieve,” adds Froberg. Avance operates as its customers’ trusted partner and an extension of their team with expertise in genomic assay development, whether

DNA or RNA. “They are coming to us looking for that expertise to address their issues,” he adds. Avance’s clients also come to us with specific requests. For instance, they inquire about needing an assay to identify potential off target events for a gene editing drug product. In such cases, it is crucial to understand what data the FDA may want to prove the drug’s safety. Hence, customers seek Avance’s specialized support to find a solution. “In these cases, they are going to come to us and inform us that the FDA wants us to provide with certain information to support our drug implication. We then work closely with their technical team and understand their needs, work internally with our scientific team, and come up with a complete, sophisticated proposal,” adds Huang.

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This is how the Avance team approaches assay development that is transferred from the scientist to do a pilot study to prove the concept. When the concept is proved, the team talks to the customer and more people on their side and looks at it from the quality perspective. This enables them to understand how to validate this kind of genomic path and get it approved by the FDA. This is followed by another round of sophisticated and robust scientific design. “We started offering this kind of validation at our place to get the assay validated. If it is NGS sequencing, then we will get a sample from the client who started testing those samples using this validated assay. In this case, compared to our competitors, we are the first one using NGS sequencing under our GLP/ GMP system,” adds Huang.

Further, in the times of COVID-19, Avance is providing qPCR, ddPCR, NGS, and other molecular testing methods to facilitate COVID-19 diagnostic assay validation, vaccine development, and clinical trial testing. “Initially when the pandemic happened, there was certainly a lag in business. As the new reality set in upon everybody, we realized that we still need to do what needs to be done, and we saw an increase in conversations with clients and programs specifically targeting Covid-19,” adds Froberg. Due to the pandemic, there has been an evident rise in the need for outsourcing testing and validation, and with its recently opened additional facility in Texas, Avance is well-equipped to fulfill that need. With some robust guidelines and organizational structure in place, the company could continue operations without any interruption as the pandemic hit.

With such a proactive and consultative approach, Avance’s future looks promising, especially as it plans to enter other international markets such as China, where it’s establishing a testing facility. At present, there are many exciting biological discoveries, and the Avance team holds an in-depth understanding of how the biologic system works. This makes them capable enough to explore the opportunities to design new assays to support new kinds of genomic therapeutics.

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The annual listing of 10 companies that are at the forefront of providing Genomics solutions and transforming businesses