Avance Biosciences Completes Successful FDA Inspection

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Avance Biosciences
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HOUSTON, Oct. 30, 2018 /PRNewswire/ -- Avance Biosciences, Inc., a leading biological testing company supporting drug development and manufacturing, announced today that its Houston facility was inspected by the U.S. Food and Drug Administration on October 01 through October 04, 2018. This inspection focused on the firm's quality management system, operation procedures, and data integrity, as well as various analyses performed on a specific drug product from one of its clients. This inspection resulted in no FDA Form 483 (inspectional observation).

As a provider of biological testing services, Avance Biosciences offers a broad range of molecular biology and microbiology assays in compliance with current Good Manufacturing Practices (21 CFR Parts 210 & 211) and Good Laboratory Practices (21 CFR Part 58) to support its clients' regulatory submissions.

Avance's CEO, Dr. Xuening Huang commented, "We are very pleased with the outcome of our FDA inspection and proud of the outstanding quality of the services that our lab provides. Our staff is committed to strict adherence to cGMP and GLP regulations and that was reflected in the outcome of this successful inspection."

Avance's Vice President of Operations, Dr. David Wall commented, "Quality is an integral part of our organization. Our laboratory has successfully passed numerous client audits throughout the past several years, and now our first FDA inspection has been completed successfully. We find that transparency and open communication among all parties are crucial for our success, and have served us well in this case."

This inspection's success is a testament to the strength of Avance's quality management system and its overall commitment to quality. Drug development firms are under the constant scrutiny of the FDA, and must be selective when choosing a testing services provider for their regulatory submissions. The FDA inspection result provides an extra level of assurance to Avance's clients that they have made the right selection.

About Avance Biosciences

Avance offers cGMP/GLP compliant biological testing services in support of drug development and manufacturing. Its leading scientists have designed, validated, and tested thousands of assays under cGMP/GLP regulations for the FDA, EPA, and European and Japanese regulatory agencies. Avance's team has extensive knowledge and experience working with scientists, QA/QC professionals and project managers from over 100 pharmaceutical and biotechnology companies and organizations throughout the world.

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