NEW cGMP NMR Services for Pharmaceutical Development and Release Testing

Due to overwhelming requests for cGMP NMR services, we invested heavily in upgrades, instrument compliance for FDA regulations, and validating the software.

LAFAYETTE, IN, UNITED STATES, June 6, 2023 /EINPresswire.com/ -- Triclinic Labs, Inc. is pleased to announce it has completed cGMP Qualification of its 400MHz Bruker NEO Nuclear Magnetic Resonance (NMR) spectrometer. Due to overwhelming client requests for cGMP NMR services, Triclinic invested heavily in upgrades and in making the instrument compliant with Food and Drug Administration regulations for the pharmaceutical industry, including validating the instrument software.

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>
> *Byungsu Kwon, Ph.D.*

Dr. Byungsu Kwon who leads Triclinic Labs' solids and liquids NMR Analysis group announced the new capabilities: "NMR has become a vital technique for chemical development companies not only for structure elucidation but also for use in Chemistry Manufacturing and Control (CMC) requirements. In support of The United States Pharmacopoeia (USP) General Chapter <761> Nuclear Magnetic Resonance Spectroscopy and other Compendial chapters (e.g., <1761>), Triclinic Labs offers multi-dimensional cGMP liquids analysis with a broadband probe allowing for a myriad of experiments (1H, 13C, 15N, 19F, 31P, etc.) at variable temperatures (280K (7C) – 323K (50C)). Our solid-state services, although currently non-GMP, are provided via a 4 mm Cross-Polarization Magic Angle Spinning (CPMAS) probe and associated high-power amplifiers for broadband solid-state NMR analysis.

In addition to the requirements described in the USP documents, any analytical system used for the creation of analysis data for pharmaceuticals must also comply with the US Food and Drug Administration’s (FDA) 21 CFR Part 11 regulations regarding electronic records and validation of electronic signatures. Triclinic Labs has qualified the instrument for cGMP use and has validated the software for compliance. Dr. Kwon stated "Our cGMP NMR analysis capabilities also include method development, validation, and release testing."

For more information on how Triclinic Labs can assist with cGMP NMR sample analysis needs,

please request a free consultation by clicking here. (https://tricliniclabs.com/page-directory/materials-analysis-services/nuclear-magnetic-resonnance-NMR-spectroscopy-services-from-triclinic-labs.html) To contact Byungsu Kwon, you may email him at rfi@tricliniclabs.com.

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cGMP 400MHz NMR System at Triclinic Labs, Inc.