

BioAgilytix Expands Hamburg Lab to Support Customer Drug Development from Early Phase to Market Authorization

PCR platforms and Good Manufacturing Practices (GMP) certification further enhance European service offerings

HAMBURG, GERMANY, May 8, 2023 /EINPresswire.com/ -- BioAgilytix Labs, LLC ([BioAgilytix](#)), a leading global bioanalytical lab, today announced the expansion and GMP certification of its facility in Hamburg, Germany. The enhanced footprint and addition of world-class resources enable the company to increase the services offered to their clients throughout all phases of their drug development projects.

Also, to further support clients in the European market, BioAgilytix expanded its quantitative PCR (qPCR) assay development, validation, and sample analysis to the Hamburg facility. This initiative continues to support the company's gene and cell therapy programs at any phase of the development process. BioAgilytix's qPCR services include biodistribution, persistence, vector shedding, gene expression, and biomarker support.

BioAgilytix launches the Hamburg lab's new competencies on the heels of another important achievement: certification of Good Manufacturing Practices (GMP) to perform Chemistry and Manufacturing Controls (CMC) testing. Achieving this milestone required the BioAgilytix quality system to undergo extensive evaluations and audits to show standard operating procedures (SOPs), facilities, and operational staff met or exceeded requirements. By expanding its early-stage-to-market-authorization GMP service to Europe, BioAgilytix complements the GMP services available in its Durham, North Carolina facility since 2010.

"With GMP-compliant laboratory locations now in the U.S. and Europe, BioAgilytix is well positioned to partner with clients around the world to offer a full suite of bioanalytical services in support of the global release, production, and manufacture of biologic drugs," said Frank Horling, PhD, Managing Director of BioAgilytix in Hamburg. "In tandem with our recent leadership additions in Europe, these expanded capabilities and strengthened customer relationships will pave the way for further innovation and success in this vibrant market."

On May 4, 2023, the BioAgilytix team and its customers celebrated the unveiling of the Hamburg lab with an official ribbon cutting. The event also included a tour of the facility and presentations on the new full-service offerings.

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About BioAgilytix

As a leading global bioanalytical laboratory, BioAgilytix partners to deliver complex bioanalytical projects to pharmaceutical and biotechnology organizations across all drug development phases. We provide pharmacokinetic (PK), immunogenicity, biomarkers, and cell-based assay services from laboratories in Durham, North Carolina; Cambridge, Massachusetts; San Diego, California; Melbourne and Brisbane, Australia; and Hamburg, Germany.

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