



PathoQuest obtains Pharmaceutical Establishment status from French ANSM for its biological drug testing activities

Paris, France - September 29, 2020 – PathoQuest, a leader in quality control solutions based on the company’s expertise and use of cutting-edge genomic sequencing technology, announced that it has obtained the administrative authorization of Pharmaceutical Establishment from the French Agence Nationale de Sécurité du Médicament (ANSM) for its biological drug testing activities.

The Pharmaceutical Establishment status granted by the French ANSM acknowledges PathoQuest's efforts to structure and organize its testing activities to meet the high standards of the pharmaceutical industry for the quality control business: analytical robustness, process standardization and compliance with regulations.

“Today we are moving beyond being a technology company to become a true leader in the quality control testing of biologics with a key focus on viral safety and genetic characterization,” stated Violaine Mélen, PharmD, PathoQuest’s Chief Quality Assurance & Regulatory Affairs Officer, Qualified person. “Having pharmaceutical establishment status is a pledge of quality and a key reassurance factor for the health authorities and the biopharmaceutical companies we partner with. It is also a prerequisite for GMP certification, which we are expecting in the near future.”

“Gaining pharmaceutical establishment status is a major milestone in the implementation of PathoQuest’s growth strategy,” commented Jean-Francois Brepson, PathoQuest’s CEO. “It enables the company to accelerate its capabilities to offer large-scale, high-quality, standardized quality control testing for biological drugs using genomic sequencing. PathoQuest’s objective is to become a leader in this field while also reducing development and biomanufacturing time for biopharmaceutical and biotech companies worldwide.”

More information

Official publication on EudraGMP website:

<http://eudragmdp.ema.europa.eu/inspections/mia/searchMIA.do>

About PathoQuest

PathoQuest offers biopharmaceutical companies a game changing genomic approach to ensuring the biosafety of biologics like cell & gene therapy products, vaccines and recombinant drugs. It also enables a reduction in the time to market for these innovative treatments. PathoQuest’s technology combines an NGS platform with a proprietary sample preparation processes followed by an automated analysis pipeline using the company’s proprietary pathogen genome sequences database.

PathoQuest has signed in 2018 a strategic partnership with Charles River Lab (Boston, USA). Based on its technological platform, PathoQuest has also developed a metagenomic blood-based test (iDTECT®) designed to improve the diagnosis of bloodstream infections and fight against antimicrobial resistance (AMR).

<https://www.pathoquest.com/>

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