

FDA Allows the First Use of Tracer-QC at Massachusetts General Hospital



LOS ANGELES - Trace-Ability, Inc. announced today that the U.S. Food and Drug Administration (FDA) has allowed the first use of its product, Tracer-QC, for release testing of an imaging agent used in Positron Emission Tomography (PET) – [N-13]Ammonia for injection.

Tracer-QC is an innovative solution that completely automates the traditional PET tracer release testing process, which is known for its complexity, subjectivity and high-skill requirements. The transition to Tracer-QC enables dramatic improvements in process efficiency, ease of compliance, and radiation safety.

Massachusetts General Hospital (MGH), a leader in adopting innovative approaches in the production of radio-pharmaceuticals, has embraced the opportunity to be the proving ground for Tracer-QC. The instrument installed at MGH was validated for performance of two (2) of the release tests for [N-13]Ammonia, a well-known FDA-approved PET tracer used in cardiac imaging. Validation data was submitted to the FDA, leading to the agency's decision to allow MGH to use Tracer-QC in release testing of [N-13]Ammonia.

“Our goal is to help the industry transition to a more streamlined PET drug production and quality control workflow,” says Daniel Yokell, Associate Director for Radiopharmacy and Regulatory Affairs at the Gordon Center for Medical Imaging, Massachusetts General Hospital. “In turn we can hopefully expand patient access to these critical diagnostic procedures outside of large academic medical centers.”

Arkadij Elizarov, CEO of Trace-Ability, lauded the news while also discussing the future of the adoption of Tracer-QC: “Despite the clear value of Tracer-QC confirmed by PET drug manufacturers, there has been some reluctance to adopt the technology due to its fundamental novelty and lack of precedent with the FDA. We appreciate the eagerness with which the MGH team participated in this project, which led to the first FDA approval of Tracer-QC use today. By addressing the major concern about Tracer-QC, this approval by the FDA paves the way for its adoption by the PET industry.”



Tracer-QC

About Trace-Ability, Inc.

Trace-Ability, Inc. is a rapidly growing Los Angeles-based company focused on the development and commercialization of innovative technologies for radio-pharmaceutical production. Led by a team of industry experts and innovative scientists, it launched Tracer-QC as its first product in 2017.

To learn more about the Tracer-QC system, download a product brochure, or watch product videos please visit the official Tracer-QC product site by [clicking here](#). For more information, please either e-mail info@traceabilityinc.com, or call 310-988-0463. Tracer-QC product is available through [LabLogic](#), Trace-Ability's commercial partner.