Exosome Diagnostics Achieves ISO 13485 Certification

The company is growing into an IVD manufacturer due to demand for its instrument platform and companion diagnostic tests.

WALTHAM, MA- August 3, 2017 - Exosome Diagnostics, Inc., a leader in the liquid biopsy market, announced that it has received ISO 13485 certification for both its USA and German facilities. This achievement paves the way to be an In Vitro Diagnostic (IVD) medical device design and manufacturing organization. Combined with the company's CLIA certified Waltham laboratory and ISO 15189 accredited Munich laboratory, the IVD certified locations will serve as an integral part of the company's strategy for the instrument platform, companion diagnostics and diagnostics to better the lives of patients worldwide.

The British Standards Institution (BSI) has certified Exosome Diagnostics under ISO 13485:2003 under CMDCAS for the following scope:
"Design, development, manufacture, distribution, installation and service of In Vitro Diagnostic (IVD) medical devices including opto-electromechanical instruments, sample collection kits, reagents and disposables".

As defined by the International Organization for Standardization, ISO 13485 is a standard that specifies requirements for a quality management system (QMS) where an organization needs to demonstrate its ability to provide medical devices (IVDs) and related services that consistently meet customer needs and applicable regulatory requirements.

"This ISO 13485 certification is a testament to the compliance initiatives undertaken by ExosomeDx to design and manufacture IVDs. Working closely with the notified body and appropriate regulatory agencies, Exosome Dx adheres to the strictest standards to provide the highest quality of products to clinicians," stated Raaj Venkatesan, Head of Regulatory Affairs at Exosome Diagnostics. "Exosome Diagnostics has built a team of dedicated quality engineers and managers, regulatory professionals and scientists that has put quality and process as its number one priority," Venkatesan continued.

In February 2017, Exosome Diagnostics launched its Early Access Program for its point of care protein biomarker liquid biopsy instrument. The Shahky™ instrument is the world's first system for exosome specific protein analysis. By targeting disease specific exosomes and removing non-relevant proteins, the signal to noise ratio is significantly superior to that of commercially available technologies.

Exosome Diagnostics also has its proprietary isolation platforms for exosome isolation including ExoLution, ExoLution Plus and ExoLution UPrep to isolate exosomes from various biofluids such as blood, plasma, serum, urine and cerebrospinal fluid.

"Exosome Diagnostics has developed an extremely sensitive liquid biopsy platform including Shahky, ancillary technologies and a proprietary informatics pipeline, that is able to rapidly develop robust companion diagnostic tests for early stage disease detection," stated John

Boyce, President and CEO of Exosome Diagnostics. “The ISO 13485 certification is an essential part of the company’s strategy and reflects the high level of integrity the company upholds in its diagnostic testing process,” Boyce continued.

About Exosome Diagnostics

Exosome Diagnostics is a privately held company focused on developing and commercializing revolutionary biofluid-based diagnostics to deliver personalized precision healthcare that improves lives. The company’s novel exosome-based technology platform, ExoLution™, and point of care instrument for protein capture and analysis, Shahky™, can yield comprehensive and dynamic molecular insights to transform how cancer and other serious diseases are diagnosed, treated and monitored. Visit www.exosomedx.com to learn more.

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