



RenalytixAI Utah Commercial Laboratory Facility Achieves ISO 13485 Certification

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NEW YORK, April 27, 2020 /PRNewswire/ -- [Renalytix AI plc](#) (LSE: RENX), the AIM-traded developer of clinical grade artificial intelligence *in vitro* diagnostics for kidney disease, announced *today* that it has received ISO 13485:2016 certification for its development and commercial laboratory operations facility in Salt Lake City, Utah. The Company's rigorous development, validation and laboratory testing processes have been independently assessed as being carried out in accordance with ISO 13485, representing a 'high water' benchmark of excellence for its lead product *KidneyIntelX*™ as well as future products.

The *KidneyIntelX* platform incorporates proprietary biomarker measurements, personal health data integration, machine learning algorithms and a comprehensive software solution and therefore requires robust processes and quality control to ensure the highest level of product quality, data integrity and information security. The adoption of this globally recognized international standard for quality management systems provides a best practice and regulatory compliant framework to achieve these objectives.

ISO 13485:2016 is an internationally agreed upon standard that sets out the requirements for a quality management system specific to the medical device industry. RenalytixAI has developed a multi-faceted quality system incorporating not only the requirements of this standard but all other applicable quality standards and regulations. As a legal manufacturer of *in vitro* diagnostics products and laboratory services provider for *KidneyIntelX* and future products, RenalytixAI currently must comply with the Clinical Laboratory Improvement Amendments (CLIA), US 21CFR820 of the FDA (cGMP) and New York State Department of Health (NYS-DOH). It is for this reason that the implementation of a robust and adaptable Quality Management framework that meets or exceeds all regulatory requirements was a strategic decision of the Board made from pre-inception business planning.

"The investment we have made in a comprehensive quality management system not only puts us in a favorable position with regulatory agencies and payors, it provides us a competitive advantage to collaborate with pharmaceutical partners and large health systems," said Sally Bowden, Chief Business Officer/Head of Quality and Regulatory Affairs at RenalytixAI. "This certification also positions us for accelerated international market access for *KidneyIntelX*. More importantly, it provides ordering physicians and patients confidence in the results they are receiving."

As part of ongoing commercialization activities, RenalytixAI is implementing processes and controls to comply with the voluntary ISO/IEC 27001:2013 which specifies the requirements for establishing, implementing, maintaining and continually improving an information security management system. This includes requirements for the assessment and treatment of information security risks tailored to the needs of the organization and, importantly, the needs of the Group's customers and patients.

About Kidney Disease

Kidney disease is now recognized as a public health epidemic affecting over 850 million people globally. The Centers for Disease Control and Prevention (CDC) estimates that 15% of US adults, or 37 million people, currently have chronic kidney disease (CKD). Further, the CDC reports that 9 out of 10 adults with CKD do not know they have it and 1 out of 2 people with very low kidney function who are not on dialysis do not know they have CKD*. Kidney disease is referred to as a "silent killer" because it often has no symptoms and can go undetected until a very advanced stage. Each year kidney disease kills more people than breast and prostate cancer. Every day, 13 patients in the United States die while waiting for a kidney transplant.

* <https://www.cdc.gov/kidneydisease/publications-resources/2019-national-facts.html>

About RenalytixAI

RenalytixAI is a developer of clinical grade, artificial intelligence-enabled *in vitro* diagnostic solutions for kidney disease, one of the most common and costly chronic medical conditions globally. The Company's products are being designed to make significant improvements in kidney disease diagnosis, transplant management, clinical care, and patient stratification for drug clinical trials. For more information, visit renalytixai.com

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