

Akoya Biosciences Receives ISO 13485:2016 Quality Certification

October 13, 2020

Akoya demonstrates ability to meet regulatory requirements for the development and production of medical-grade devices and related products

MARLBOROUGH, Mass. — October 13, 2020—Akoya Biosciences, Inc., The Spatial Biology Company®, today announced that the company received ISO 13485:2016 certification for the design, development, production, distribution and installation of medical devices and related services. Achieving this ISO certification signifies that Akoya Biosciences meets the strict regulations and demanding requirements of the medical device industry.

"Achieving ISO 13485:2016 certification demonstrates Akoya has successfully implemented a quality management system that conforms to the worldwide standard for medical device and in vitro diagnostic (IVD) manufacturing," said Navin Parwani, Senior Director, Quality Research and Development, Akoya Biosciences. "This certification represents an important milestone for our company and reflects our commitment to safety and quality."

The International Organization for Standardization (ISO) is the world's largest developer and publisher of international standards for the implementation of quality management systems. The ISO 13485:2016 Quality Management Standard for Medical Devices is an international standard that represents the requirements for a comprehensive management system for the design and manufacturing of medical devices. To be certified, organizations must demonstrate an ability to provide medical-grade devices and related services that consistently meet customer and regulatory requirements.

"This ISO certification is testament to the high level of performance and quality assurance we expect with Akoya's products and services. It is further evidence of our unwavering commitment to quality with our expanding global customer base," said Brian McKelligon, CEO of Akoya. "Establishing this level of rigor is an important milestone on our path to develop the Phenoptics™ platform as a clinically robust solution that can deliver reliable and reproducible results."

About Akoya Biosciences

Akoya Biosciences, The Spatial Biology Company®, offers the most comprehensive, end-to-end solutions for high-parameter tissue analysis from discovery through clinical and translational research, enabling the development of more precise therapies for immuno-oncology and other drug development applications. The company has two industry-leading platforms that empower investigators and researchers to gain a deeper understanding of complex diseases such as cancer, and other immune system or neurological disorders. The CODEX® system is the only benchtop platform that can efficiently quantify more than 40 biomarkers and is ideally suited for biomarker discovery. The Phenoptics™ platform is the only end-to-end multiplexed immunofluorescence solution with the robustness and high throughput necessary for translational research and clinical trials. For more information, please visit <https://www.akoyabio.com/>.

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