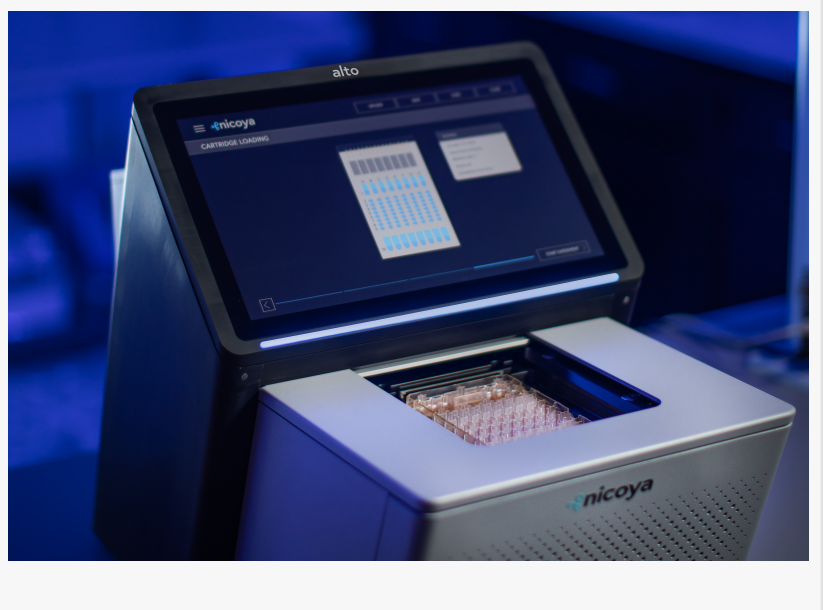


Nicoya Lifesciences introduces the Alto GxP Suite to help enhance regulatory compliance for drug development

KITCHENER, ON, CANADA, November 12, 2024 /EINPresswire.com/ -- Nicoya®, a pioneering life science instrument company specializing in innovative biosensor technology, is pleased to announce the launch of the [Alto GxP Suite™](#). Designed for Nicoya's [Alto™ Digital SPR™ system](#), the Alto GxP Suite provides software features and services to support regulated labs in meeting rigorous compliance requirements, such as the FDA's 21 CFR Part 11 guidelines, during drug development.



Characterizing biomolecular interactions is vital at all stages of pharmaceutical R&D, from discovery to process and analytical development as well as quality control. Nicoya's Alto provides unmatched ease of use and cost savings for measuring binding kinetics, biomolecule quantitation, screening, and epitope characterization. With the new Alto GxP Suite, Alto's capabilities now extend to better support regulated environments.

The Alto GxP Suite includes a software expansion with user access controls, secure raw data storage in an edit-protected format, and electronic signatures with configurable levels to lock and sign key steps. It also provides comprehensive audit trails that record modifications and system events for complete traceability. To further support compliance, the suite also offers qualification services and kits, including installation (IQ) and operational (OQ), and performance qualifications (PQ). Labs can use qualification kits for independent validation or opt for on-site validation by services from Nicoya experts.

"Data integrity and regulatory compliance are essential in drug development," said Ryan Denomme, CEO at Nicoya. "The Alto GxP Suite will assist labs to achieve regulatory compliance for binding assays while delivering the benefits of simplified assays, ease of use, reduced hands-on time, and overall enhanced efficiency in the lab."

The Alto GxP Suite is now part of Nicoya's Digital SPR offerings. For more details on how the suite can support your lab's compliance needs, visit nicoyalife.com/alto-gxp-suite.

About Nicoya

Nicoya is a Canadian life sciences tools company specializing in innovative biosensor technology for the academic and biopharmaceutical sectors. In their mission to improve human life, Nicoya provides scientists with user-friendly and integrated solutions that accelerate label-free biomolecular analysis. Information about Nicoya can be found at nicoyalife.com.

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