



Agilent releases new NovoCyte Flow Cytometer system software

10 February 2023 | News

NovoExpress enables regulatory compliance for pharmaceutical and biopharmaceutical manufacturing

Agilent Technologies Inc. has announced the release of new NovoExpress software that introduces integrated compliance tools for NovoCyte flow cytometer systems. The compliance-enabling features enable users to meet regulatory requirements defined in FDA 21 CFR Part 11 and Annex 11.

There is immense pressure on pharmaceutical and biopharmaceutical manufacturers to demonstrate compliance with regulatory requirements such as 21 CFR part 11. NovoExpress software compliance features provide essential tools for ensuring that the data and electronic records generated with NovoCyte flow cytometers are trustworthy, authentic, and reliable, as required by regulatory authorities worldwide, and also meet GxP manufacturing compliance guidelines.

The new NovoExpress software strengthens support for customers conducting flow cytometry as a cellular-analytics tool in therapy development, manufacturing, diagnosis, and prognosis applications. Combining Agilent instrumentation and software, NovoCyte systems deliver a workflow that is automatable and auditable. Enabling data integrity consistent with requirements defined in FDA 21 CFR Part 11 and Annex 11 for electronic records and electronic signatures is an important hurdle to overcome for pharmaceutical and biopharmaceutical manufacturing customers.