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Thermo Fisher extends NanoDrop to FDA regulated companies

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New software can be used by pharma, biotech labs to comply with Title 21 CFR Part 11 data integrity regulations

Thermo Fisher Scientific has announced its Thermo Scientific NanoDrop PC Control software + Security Suite for NanoDrop One/One^{C} can be used in compliance with U.S. Food and Drug Administration (FDA) Title 21 CFR Part 11, which governs the security of electronic records and signatures to ensure they are trustworthy substitutes for paper records and handwritten signatures.

The NanoDrop One PC Control + Security Suite Software meets these data integrity standards by providing administrative control over user accounts, an audit trail for user integrity, and the compliant use of electronic signatures. With this release, the Thermo Scientific NanoDrop One/One^{C} Microvolume UV-Vis spectrophotometers can be used in a lab that complies with Title 21 CFR Part 11.

"Regulated pharma and biotech labs can now take full advantage of our powerful NanoDrop One/ One^{C} instruments," said Jim Metzger, general manager, UV/Vis spectroscopy at Thermo Fisher Scientific. "NanoDrop One/One^{C} is the market-leading microvolume spectrophotometer for DNA, RNA, and protein quantification, and we're pleased to extend these critical instruments to labs where compliance is a requirement."

Built with the novel Thermo Scientific Acclaro Sample Intelligence technology, NanoDrop One/One^{C} instruments help researchers identify contaminants in nucleic acid and protein samples and obtain corrected concentration results so they can make educated decisions about sample quality. A simple, automated workflow yields measurements in just eight seconds,

sending users alerts when a contaminant is present.

With the addition of software that includes Title 21 CFR Part 11 compliant features, regulated labs can now meet FDA regulations while obtaining the accurate quantification and purity information they need to ensure downstream application success.