



## PerkinElmer Introduces NexION® Enhanced Security Software for Streamlined Regulatory Compliance for the Pharmaceutical Industry

*Global leader in analytical solutions releases new software suite for pharma lab instruments to simplify technical compliance with USFDA 21 CFR Part 11 regulations*

WALTHAM, Mass.--(BUSINESS WIRE)-- [PerkinElmer, Inc.](#), a global leader focused on improving the health and safety of people and the environment, today announced the introduction of the new NexION® Enhanced Security™ (ES) Software, to streamline regulatory compliance by pharmaceutical companies. The ES Software platform was developed for users of [PerkinElmer's NexION 300 ICP-MS system](#).

As regulatory compliance is a complex, ongoing and exacting process, the NexION ES Software platform ensures the integrity of electronic data records that are generated under industry-standard protocols within pharma research and QA/QC organizations. It was designed to enable researchers and quality control professionals to meet U.S. Food and Drug Administration (FDA) 21 CFR Part 11 regulations through key compliance-centric features. The software platform enables NexION customers to have confidence that their compliance needs are being met while maintaining high productivity.

The NexION ES Software provides user level management, file protection, and audit trails and is developed and structurally validated following a certified quality system that conforms to Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), and ISO 9001 guidelines. The system provides technical compliance in terms of software development and data integrity, with security features that help create a secure, reliable environment.

The NexION ES Software option is fully compatible with all NexION 300 ICP-MS instruments, allowing both new and existing customers access to the benefits of Enhanced Security. The software platform's development life cycle also conforms to the ISO-9000-3 and IEEE guidelines and combines the power of the Microsoft® Windows® 7 operating system with that of laboratory networks to provide improved performance for all analytical techniques.

As part of the solution, PerkinElmer offers Installation Qualification (IQ) and Operational Qualification (OQ) services and can assist with Performance Qualification (PQ) to support customers' quality management systems.

### **About PerkinElmer, Inc.**

PerkinElmer, Inc. is a global leader focused on improving the health and safety of people and the environment. The Company reported revenue of approximately \$1.7 billion in 2010, has about 6,200 employees serving customers in more than 150 countries, and is a component of the S&P 500 Index. Additional information is available through 1-877-PKI-NYSE, or at [www.perkinelmer.com](http://www.perkinelmer.com).

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Source: PerkinElmer, Inc.

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