

Drug Discovery

Research

Clinical Screening

HTS Instrument Services

# Need A Hand with FDA's 21 CFR Part 11?

## PerkinElmer Can Help!

**Now Available!!!**



### 21 CFR Part 11 Compatible Software Now Available for TopCount®!

PerkinElmer Life Sciences is firmly committed to meeting your needs in the demanding, ever-changing pharmaceutical and biotechnology industries. To assist in your compliance planning, we would like to announce 21 CFR Part 11 Compatible Software for **TopCount** which includes instrument access security, electronic record (data) security and audit logs functionality.

#### ► Instrument Access Security:

Supports User ID and password authentication. User manager allows set up of user groups with varying rights for individual users.

#### ► Electronic Record (Data) Security:

All data are automatically stored in a secured directory until archived from the system.

#### ► Audit Logs:

Creates a separate protected file that records user log-in, changes in assay parameters as well as creation, modification or deletion of data.

For more information on 21CFR Part 11 software compatibility, please contact your local PerkinElmer sales representative



[www.perkinelmer.com/lifesciences](http://www.perkinelmer.com/lifesciences)

As the trusted partner of researchers worldwide, PerkinElmer understands you require faster and easier solutions to meet the FDA's regulations. Not only does TopCount now have compatible software for the 21 CFR Part 11 regulation, you can have your existing instrument upgraded *in your laboratory*, or order a new instrument with this option. Now that's faster! The software has recognizable Windows® features, making it easy to use, too. Read on for all the new features and how they meet the 21 CFR Part 11 regulation.

## TopCount 21 CFR Part 11 Compatibility Software- Key Features

### Instrument Access Security

#### > Windows operating system features used

- Directory permission to provide secured subdirectories for acquired data, metadata, etc.
- Creation and management of users and groups
- Authentication of User IDs and passwords
- Single ID and password access for user control for both desktop and instrument via the operating system

#### > Securing the instrument access after timeout

### Electronic Record (Data) Security

#### > Secured local subdirectory

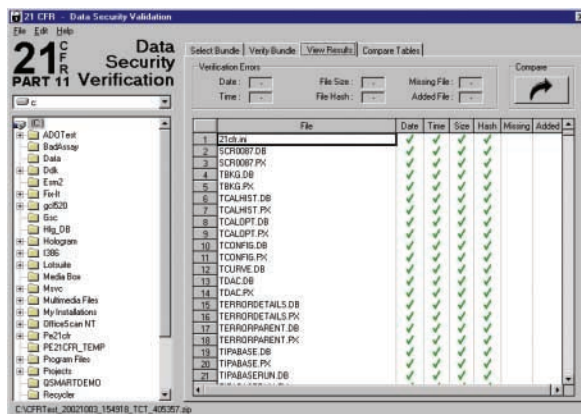
- Accessible only to system administrator
- Contains metadata, instrument support files, raw data, result data and calibration information

#### > Additional data security

- Create hash value (fingerprint) for each file that contains or affects acquired data
- All hash values are stored in a table and encrypted (128-bit encryption scheme)
- All files and encrypted hash table in secured subdirectory can be "zipped" into a file bundle
- File bundle can be moved off the local drive for archiving
- Data verification program to ensure data bundles cannot be tampered with (even outside of secured environment)

### Audit Log

- > Assay run log
- > Assay definition revision log
- > System log
- > Service log
- > ASCII format



### Ordering Information:

Part No.	Description
7001988	<b>21 CFR Part 11 security option for TopCount NXT systems (installed with new instrument orders only)</b> <i>Contains 21 CFR Part 11 security option program and distributable data verification program installed and on CD, manual, license ID key for 21 CFR Part 11 security, license to use the program on one TopCount.</i>
7001989	<b>21 CFR Part 11 security option field upgrade for TopCount NXT systems (software only)</b> <i>This upgrade requires the computer to meet (or exceed) the minimum specifications. Contains 21 CFR Part 11 security option program and distributable data verification program on CD, manual, license ID key for 21 CFR Part 11 security, license to use the program on one TopCount, system inspection, field upgrade installation and training.</i>
7001990	<b>21 CFR Part 11 security option field upgrade for TopCount NXT systems (software and computer upgrade)</b> <i>This includes a new computer system that meets (or exceeds) the minimum specifications. Contains 21 CFR Part 11 security option program and distributable data verification program on CD, manual, license ID key for 21 CFR Part 11 security, license to use the program on one TopCount, a new computer system that meets or exceeds the minimum specification, system inspection, field upgrade installation and training.</i>



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