

**De-coding 21 CFR Part 11:
Introducing Eutech CyberScan 6000 Series
Meters with Software**

Background

21 CFR Part 11 was introduced in 1997 by the FDA to encourage wider use of electronic data technology. With predicate regulations such as GMP, GLP and GCP as its base, 21 CFR Part 11 defined a set of criteria to control, validate and provide an audit trail on electronic data.

In August 2003, the FDA released the "Industry Guide, Part 11, Electronic Records; Electronic Signatures – Scope and Application." The agency narrowed scope of 21 CFR Part 11 on items such as systems validation, time-stamped audit trails, and methods used to reproduce and retain electronic records.

Although all necessary for data integrity, 21 CFR Part 11 remains as one of the most challenging regulations imposed by FDA on the biotechnological and pharmaceutical industries. It affects all systems that generate, store and manipulate electronic data.

Complying with 21 CFR Part 11

So the question is, how much is enough, and how much is too much? Not all systems and data are subjected to the 21 CFR Part 11 regulations. In determining what systems and data to include, a company may start off with asking the following questions:

- Are these records and signatures required by current regulations?
- Are these records and signatures part of an S.O.P that is required by the current regulations?
- Are these records and signatures required for regulated activities?

Once the requirements are defined, the next step is to identify the systems where data is recorded, edited, transmitted and archived. Then ensure full audit trail at these junctions to track any actions performed on these data.

Both a closed system and an open system (see Fig 1 for FDA definition), require full time-stamped, audit trail records documenting any data manipulation. An open system will also require document encryption and use of appropriate digital signature standards. This may seem like a daunting amount of documentation, but a good 21 CFR Part 11 software package will simplify your processes significantly.

Figure 1: Definitions

According to the US Food and Drug Administration

A closed system means as an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.

An open system means an environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.

The Data System

A complete compliance plan starts with the system processing your data. Eutech's CyberScan 6000 series with 21 CFR Part 11 software allow users to manipulate their research data directly from the computer:-



- Expand the memory space of your meter to your personal computer hard-disk
- Manage multiple projects under separate ID logins– password security protects each ID login data from tampering and accidental deletion
- Record every detail of data collection, viewing and manipulation to present a full-audit-trail report
- Generate comprehensive reports for printer or computer output
- Allow real-time data logging and real-time graphing from your computer
- Detect electrode signature and calibration solutions used in projects

Controlling and containing the research data is possible since the software is equipped with analysis functions and the data stored can be protected under individual accounts, thereby limiting access to only the user.

The software comes with an audit trail that automates the process entirely. Each data point generated is stamped with time and date; each time the user accesses, views or edits the data, an entry stamped with time, date, meaning of the action, and the user responsible is created on an activity log.

Choosing the Right Tools

Complying with the 21 CFR Part 11 regulations may seem like an exhaustive task, but it can be simplified if you have the right tools.

The CyberScan 6000 Series meters with 21 CFR Part 11 Software provides a direct link between the research instrument and the storage/analysis system; it provides data security and simplifies the audit trail process by recording all activities. The software manages activities from data generation to data storage.

Yet, even with the most comprehensive software, a compliance plan is still reliant on how the relevant personnel use the system, and is only complete when the right tools are used in tandem with proper training, guidance and a comprehensive S.O.P in place.