21 CFR § 11 Overview for Materials Testing and Electronic Records

What is 21 CFR § 11?

21 CFR § 11 is a set of compliance requirements for electronic records and electronic signature procedures that apply to industries regulated by the U.S. Food and Drug Administration (FDA).

As the world transitions to more electronic-based forms of information storage, sharing and communication, the FDA has developed regulatory guidelines found in 21 CFR § 11 that applies to electronic records created and stored by pharmaceutical, biomaterials and medical device companies. This regulation is intended to ensure that electronic records are trustworthy, reliable and equivalent to paper documentation.

Why is 21 CFR § 11 important?

Test methods and results are the cornerstone of any testing laboratory within a biomaterial, medical device or pharmaceutical company, especially in Quality Control or Production. Historically, these methods and results have been stored in files on paper, signed and submitted accordingly when required, to the FDA. During audits from the FDA, these physical records were pulled from a storage file cabinet for examination.

In recent years, many organizations have been moving toward a more "electronic" approach to recording, sharing, and storing of these important product quality and reliability parameters and results generated by their testing systems. If your organization is using an electronic medium to store and/or submit information, 21 CFR § 11 will apply to you. Although no testing system can be delivered in a 21 CFR § 11 compliant form, the system can be integrated within an organization's internal processes to form a 21 CFR § 11 compliant solution. Remember, if information is not being submitted to the FDA, 21 CFR § 11 does not apply!

What are the relevant details of 21 CFR § 11?

There are several components to the regulation that affect a laboratory's operating processes where resulting test information is being submitted to the FDA. Common elements to consider for testing systems, which fall under the category of "closed systems" within the regulation, are as follows:

- **Data Security**
  Password uniqueness, aging, formatting
- **Data Integrity**
  No unauthorized access & tracking of permitted changes
- **Audit Trials and Reports**
  Secure & separate databases with unchangeable reporting
- **Electronic Records**
  Efficient paperless submissions
- **Electronic Signatures**
  E-signature with unique user ID, date, time, and location stamps

How do you adapt procedures and processes for 21 CFR § 11 compliancy?

One of three approaches can be used by organizations to address the ongoing 21 CFR § 11 compliancy regulations throughout the pharmaceutical and medical devices industries.

- **Paper**
  The regulation still permits the full submission of paper-based documentation. The issues with this approach include high costs, decreased quality, information storage availability, information retrieval ability, and the general portability of information.
- **Partial Electronic**
  The regulation allows for the electronic records to be stored as equivalent to paper records with handwritten signatures executed. This approach still requires a large amount of printed documentation that carries the same risks and challenges as a full-paper approach, mentioned above, regarding compliancy to the regulation.
- **Electronic**
  This is the real intent of the 21 CFR § 11 regulatory requirements. This approach increases product quality, saves money with automation of processes, establishes easy data storage and retrieval, provides ease data analysis and reporting, increases the portability of information, and diminishes or eliminates human error.

Transitioning Your Lab to a 21 CFR § 11 Compliant Laboratory

Key Transition Phases	Common Challenges	Solutions
Determining that your lab needs to be in total compliance	Often organizations jump into tackling the regulation with the most complex and full coverage solution without really understanding the requirements.	Utilizing smaller, stand-alone solutions is often the most cost effective initial approach. Implementing a solution that is scalable can be important as your business grows and regulatory scrutiny increases.
Creating a compliant and secure data and results environment	Often systems rely on Microsoft® XP or Vista to provide security. A common shortcut is to provide only local authentication that violates the integrity of 21 CFR § 11.	Use an internal security system that ensures password uniqueness and aging, proper formatting and more to ensure unauthorized access.
Establishing secure audit trails	A common shortcut is to use simple files to store audit trail information. Unfortunately, these files can be easily edited by external software packages or, even worse, deleted—which is a big issue for FDA auditors.	Capture and store all audit trail information in a secure and separate repository/database. This is the only way to guarantee full compliance to the 21 CFR § 11 regulation.
Establishing a robust audit trail	Audit trails that can be edited, modified, turned off, or reset will not pass the scrutiny of FDA auditors. Additionally, the audit trail report is often sent in formats that can be edited or modified. Be careful!	Utilize systems that provide the ability to retrieve and compare audit trail information throughout the lifecycle of all records. Reporting should be available via a secure web interface that meets the requirements of 21CFR § 11 and has a history of passing several FDA audits.
Creating electronic records and signatures-- the cornerstone of 21 CFR § 11	Many companies simply ignore this requirement, which will prevent compliancy to 21 CFR § 11 as electronic information is submitted to the FDA.	Find systems that have comprehensive e-signature functionality, which captures and displays a user's full name, unique ID with date, time, and location of the e-signature. Options for signature meaning and definition can also be valuable when auditors make their way through your processes.