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Achieving 21 CFR Part 11 Compliance with Green Button Go® Scheduler

Digital records are crucial to expediting information flow in the laboratory and are a vital part of an integration strategy. If you work in a regulated lab — good laboratory practice (GLP) or good manufacturing practice (GMP) — traceability, reproducibility, and accuracy of electronic records and electronic signatures are required to comply with the Food and Drug Administration (FDA) 21 CFR Part 11 of the Code of Federal Regulations; Electronic Records; Electronic Signatures (21 CFR Part 11).

Green Button Go® (GBG®) Scheduler provides the validated tools needed for regulated labs to meet these stringent requirements while leveraging integrated laboratory automation systems. This white paper presents a detailed outline of the capabilities of GBG Scheduler and how they can be used to support compliance in automation scenarios.

The Need for Compliance

In the case of 21 CFR Part 11, this regulation requires industries, like those in different subsets of pharmaceutical development and manufacturing, biotech medical device manufacturing, contract labs, and even certain food industries like supplement and additive manufacturing, to operate with quality controls and show proof of compliance.

COMPLIANCE ADDRESSES ALL OF THE FOLLOWING AREAS:

1. **Infrastructure:** Anything and everything that touches data has to be validated to ensure the security, integrity, and retrievability of the data. IT hardware, software, LIMS, databases, and more must all be validated at the system level.
2. **SOPs:** All procedures involving electronic recordkeeping, data integrity, audit trails, modifications, and so forth must be well documented and controlled.
3. **Training:** All personnel working in a regulated lab must be trained in the requirements of 21 CFR Part 11 and all the associated SOPs. Labs must be able to demonstrate that all personnel have been trained.
4. **Audit Trails and Data Integrity:** Labs are required to build and maintain audit trail systems that are unimpeachable. The FDA has to trust that the data they receive came from a system with robust data tampering prevention.

THESE QUALITY CONTROLS ENSURE THAT:

- Software versions are clearly defined
- Security limits unauthorized access
- Data is validated for accuracy, and is properly formatted and protected
- Audit trails record creation and modification of electronic records
- Electronic signatures are captured where needed

This regulation is used to provide guidance and oversight for quality controls and allow labs to leverage new technologies and enable electronic records. This particular regulation stems from the concept that in a regulated environment, electronic records can only be as good as paper records when quality controls are comprehensively defined, and proof of compliance is provided. Compliance with Part 11 also helps companies to improve their competitiveness in the global market.

ELECTRONIC RECORD SYSTEMS HAVE KEY BENEFITS INCLUDING:

1. Reducing the costs of securing and maintaining paper records
2. Solving risks by securing documents, ensuring they are trustworthy and reliable records
3. Ensuring products are consistently manufactured according to quality measurements that meet industry standards

21 CFR Part 11 applies to all FDA-regulated industries and encompasses Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP). This is because these industries produce products that determine the health and wellbeing of millions of consumers.

The Current Landscape of Compliance in the Automated Lab Space

Typically, the burden of maintaining compliance is an arduous and manual process that puts the effort of maintaining requirements on the lab. This may involve labs having to verify that existing software has the required compliance steps baked in and that it fits their own requirements, a long process that can take valuable time and resources.

In this scenario, if the software or digital solution does not fully meet the compliance needs, the data has the potential to be exposed. There may be no good way to identify users, take into account which users are doing which actions, or to protect or encrypt the sensitive documentation. This also means that documentation could be easier to tamper with as a result, so there could be an extra manual effort required to confirm that the data hasn't been tampered with, which takes more manpower and could be impacted by human error.

Along those same lines, when a lab gets audited by the FDA, they must provide reliable evidence that their entire operation is compliant. Because of that, regulated labs prefer to work with vendors that can prove that their products meet the standards and that the processes used in the production of those products are validated and controlled.

Using Green Button Go to Support Compliance

Traditional recordkeeping in lab software often does not fully prioritize the need for compliance with regulations like 21 CFR Part 11. To support compliance, lab software needs to clearly define software versions, limit unauthorized access, validate data for accuracy, record audit trails in the proper format, and capture electronic signatures. Understanding and navigating the complexities of a regulation like 21 CFR Part 11 typically takes time and resources to ensure compliance is achieved. The 21CFR11 Manager extension for GBG Scheduler is a seamless way to integrate tracking and validation with your laboratory automation system. 21CFR11 Manager builds on the flexibility of GBG Scheduler by incorporating authenticity, integrity, and confidentiality of electronic records.

21 CFR Part 11 compliance also encompasses Annex 11 requirements for the EU. This meets GDPR compliance requirements in the EU and provides certain additional measures for maintaining electronic signatures.

GBG Scheduler software is validated to help your lab maintain compliance.

BENEFITS OF 21CFR11 MANAGER EXTENSION WITHIN GBG SCHEDULER:

- Maintain secure user access with customizable password rules and expiration interval
- Lockdown program database, making only locked programs available to end-users
- Assign user roles with defined access and permissions
- Limit system changes to administrators and track changes with user timestamps
- Easily access your audit trail, including event and change logs, security logs, and signature logs

Better Decisions in Less Time, Using More Data

Automation systems can increase efficiency to meet demand and provide consistent, predictable results in your lab. Implementing an automation strategy in your lab could be the differentiating factor in getting to your scientific discoveries faster. Integrated automated systems that leverage the 21CFR11 Manager within GBG Scheduler allow for continual data capture, ensuring that every step of an automated workflow has an audit trail.

Features of GBG Scheduler with the 21CFR11 Manager Extension

The following features are available as part of GBG Scheduler with the 21CFR11 Manager extension. This lab scheduling software offers a fully validated compliance package, giving scientists unique capabilities to adhere to 21 CFR Part 11 quickly and efficiently with built in features, safeguards, and audit trails. Read below to get a summary of what the extension features that collectively allow labs to achieve compliance.

SECURITY

Maintaining a secure database with a clear audit trail is a vital part of 21 CFR Part 11 compliance. GBG offers a secure database to safely store and protect audit log data, user information, and access levels.

CHANGE LOG

Keeping a clean audit trail of change log events is critical to 21 CFR Part 11 compliance. GBG's extension allows for easy tracking of Change Log activities.

USER ACTIVITY LOG

Tracking user activity securely is a key component of compliance. These activities are seamlessly logged for future audits.

SETTINGS LOG

Any changes in the Settings Log are stored securely using GBG's 21CFR11 Manager Extension.

USER MANAGEMENT

GBG's 21CFR11 Manager Extension provides the ability to manage and track users and user activity at different access levels effectively.

WORKFLOWS

Maintaining and managing locked programs, accesses, and audit trails within all workflows is built into GBG's 21CFR11 Manager Extension.

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