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automating your world

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21 CFR Part 11 Compliance with Inductive Automation's Ignition Platform

Introduction

Ignition by Inductive Automation is a versatile and powerful platform for SCADA, IIoT, MES, HMI, alarming, reporting, and more. Industry professionals are turning to Ignition for its unlimited licensing model, versatile coding applications, and innovative features but are often curious about compliance with regulatory authorities. Each industry comes with its own set of requirements and regulations, and the pharmaceutical industry is no exception. Automation software must meet a critical set of requirements in order to be considered for inclusion in a manufacturer's ecosystem.

One of the first requirements that must be met is compliance with 21 CFR Part 11, known as Part 11 for short. Part 11 is part of the Code of Federal Regulations that establishes FDA protocols on electronic records and electronic signatures. Part 11 primarily helps define the standards that ensure electronic records and signatures are considered equivalent to paper records. The ability for an automation software to be Part 11-compliant hinges primarily on the audit trail and digital signature capabilities of the software.

Another major concern for automation software platforms is related to data integrity. Data must be Attributable, Legible, Contemporaneous, Original, and Accurate (also known as ALCOA by many of the large pharmaceutical regulatory bodies). ALCOA has since been expanded to ALCOA+ to include Available, Enduring, Consistent, and Complete as a way to fully encompass standards for data security and data integrity.

The Ignition platform is Part 11-compliant and ensures data integrity through implementation of ALCOA+ concepts. This white paper will discuss the various components of Ignition that allow for Part 11 compliance and implementation of data integrity principles. The white paper will discuss what features are enabled by default, as well as expanded capabilities which ensure the platform can adhere to the slight variation in implementation strategies for data integrity, electronic records, and electronic signatures established by different quality groups. The white paper will begin with user access and account security, transition into data integrity, and end with Part 11 compliance to build a holistic view of Ignition's capabilities in the pharmaceutical and biotechnology industries.

User Account Management

Unique user accounts and credentials are a key component for compliance with Part 11 requirements. Ignition features several options for managing users and roles, allowing it to adapt to various use cases and IT environments. These options include internal (contained within Ignition), external (managed by external database or enterprise identity provider), and Active Directory (enterprise-managed). When considering Part 11 compliance, authenticating users through Active Directory or an identity provider is considered a best practice.

Using Active Directory as an Ignition user source, access to Ignition tools and projects is granted to users with their existing username and password from the enterprise Active Directory. This ensures that all users are uniquely identified when accessing Ignition. This also ensures that the credentials of each user are held to the company policies and requirements for complexity, lockout, and forced expiration. When a user is disabled or removed from Active Directory, they will automatically be prevented from accessing Ignition without any additional administrative action.

For more complex IT environments, hybrid user sources in Ignition allow user and role authentication to be split between two types of sources. With Ignition Perspective, identity providers offer an additional option for user authentication. This method offloads the handling of user authentication from Ignition to federated login providers. This has the benefit of allowing Ignition to inherit advanced authentication features provided by the identity provider, such as two-factor or multi-factor authentication.

User Access Control

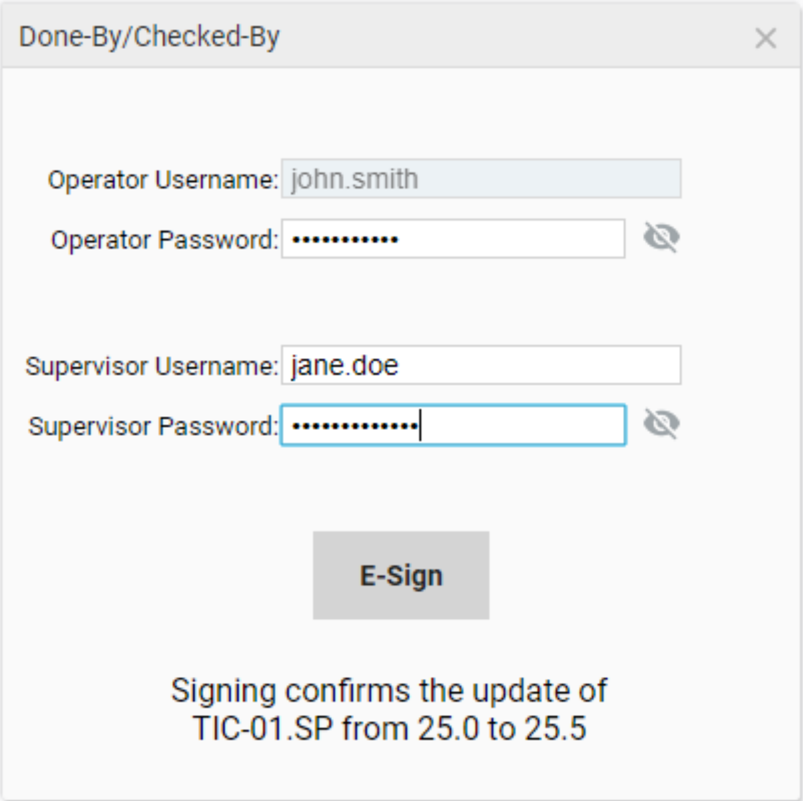
Roles should be configured to ensure users can only access the parts of Ignition for which they are authorized. When configuring a project in Ignition, these roles are referenced by configuring security properties or scripting to enable or disable specific features. Such security can be applied to tags, user interface components, projects, and the Ignition Gateway. These security settings ensure that only authorized users can read or write to tags, interact with user interface components like buttons and text boxes, or modify validated configurations. For example, the ability to acknowledge alarms could be restricted to users with a “Supervisor” role.

Roles can also be stacked together such that an action requires multiple roles. Roles should be assigned with the idea of “least permissions,” where a user has the minimum privileges and access necessary to perform their job, and nothing more. This ensures permission do not “leak” and allow a user to perform actions they are not trained or authorized for.

Additional features are available within Ignition to enhance security beyond basic login and role enforcement. Security permissions can be applied based on locations to require a specific user level and specific operator terminal to be granted access to the system. As an example, this can allow write access to the system only when a user is located locally to a piece of equipment – which is important when considering ALCOA+ principles. To further ensure account access remains unique, Ignition can be configured to automatically logout users after a period of inactivity. This helps ensure that no user intentionally or inadvertently generates records such as audit trail actions under a user account that is not their own.

E-Signatures can be added to Ignition projects that require extra confirmation of user permissions. Utilizing the *system.security.validateUser()* function, users can be forced to provide their credentials before critical actions are performed. Multiple signatures can be required per action without logging off the current user, allowing a supervisor to E-Sign to confirm an operator action. Combining these credential validation methods with Ignition’s audit trail feature ensure that user interactions with Ignition projects are thoroughly controlled, attributable, and accurate. Roles can be utilized to ensure a hierarchal security structure, ensuring that critical audit and data integrity features cannot be altered.

Figure 1: Example of Done-By Checked-By Capability



Done-By/Checked-By

Operator Username: john.smith

Operator Password: ••••••••••••

Supervisor Username: jane.doe

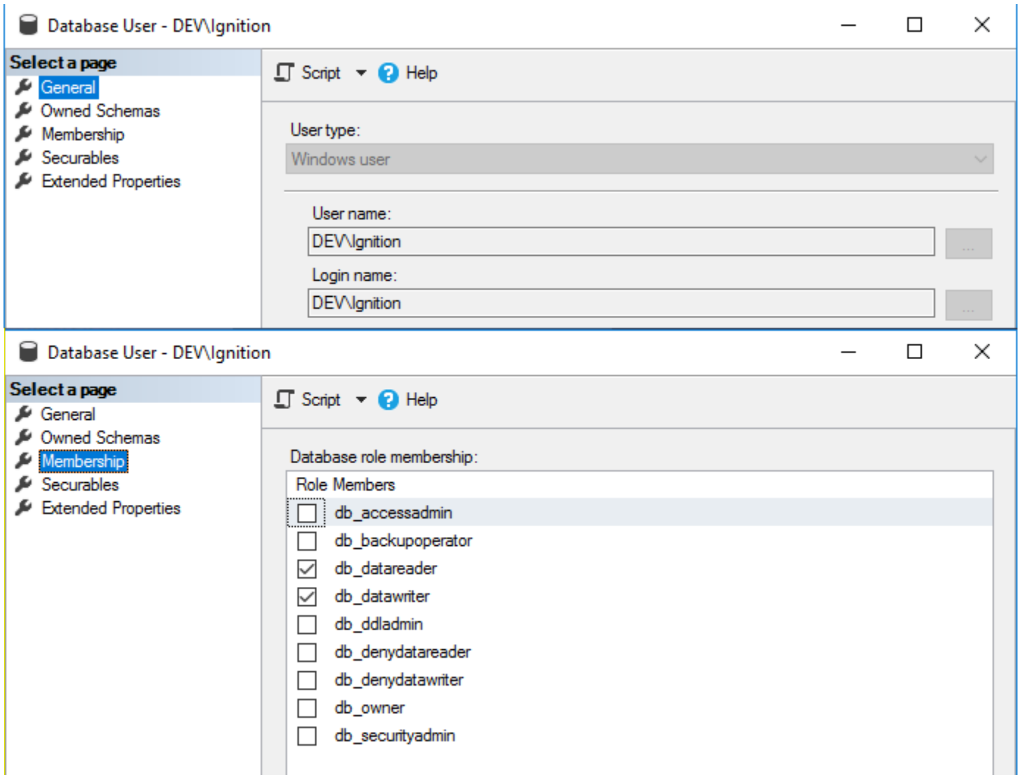
Supervisor Password: •••••••••••••••

Signing confirms the update of
TIC-01.SP from 25.0 to 25.5

Data Integrity
Ignition uses databases for the Tag Historian Module, alarm journal, and audit trail, as well as when utilizing expanded functionality for project-specific purposes. Although Ignition supports connections to multiple database types, the following security considerations generally refer to Microsoft SQL Server. For security-conscious configuration details of other database types, consult with your database administrator (DBA).

To ensure data integrity of SQL databases, logins and permissions must be strictly configured for each database. An exclusive account should be configured for Ignition to connect to SQL with "read/write" access. No other users should have "write" access, as this would allow tampering with historical and audit trail data. This account should be an Active Directory managed account where possible, and the account username and password information should be shared sparingly to avoid non-Ignition use of the account. The account should only be used for this single purpose so that the password can be reset if needed without disrupting other applications or services. The built-in "sa" account should never be used for the database connection.

Figure 2: Configuration of Active Directory account with read/write database permissions. (Alternatively, the user can be set as db_owner.)



User type: Windows user

User name: DEV\Ignition

Login name: DEV\Ignition

Database role membership:

Role Members

- ☐ db_accessadmin
- ☐ db_backupoperator
- ☑ db_datareader
- ☑ db_datawriter
- ☐ db_ddladmin
- ☐ db_denydatareader
- ☐ db_denydatawriter
- ☐ db_owner
- ☐ db_securityadmin

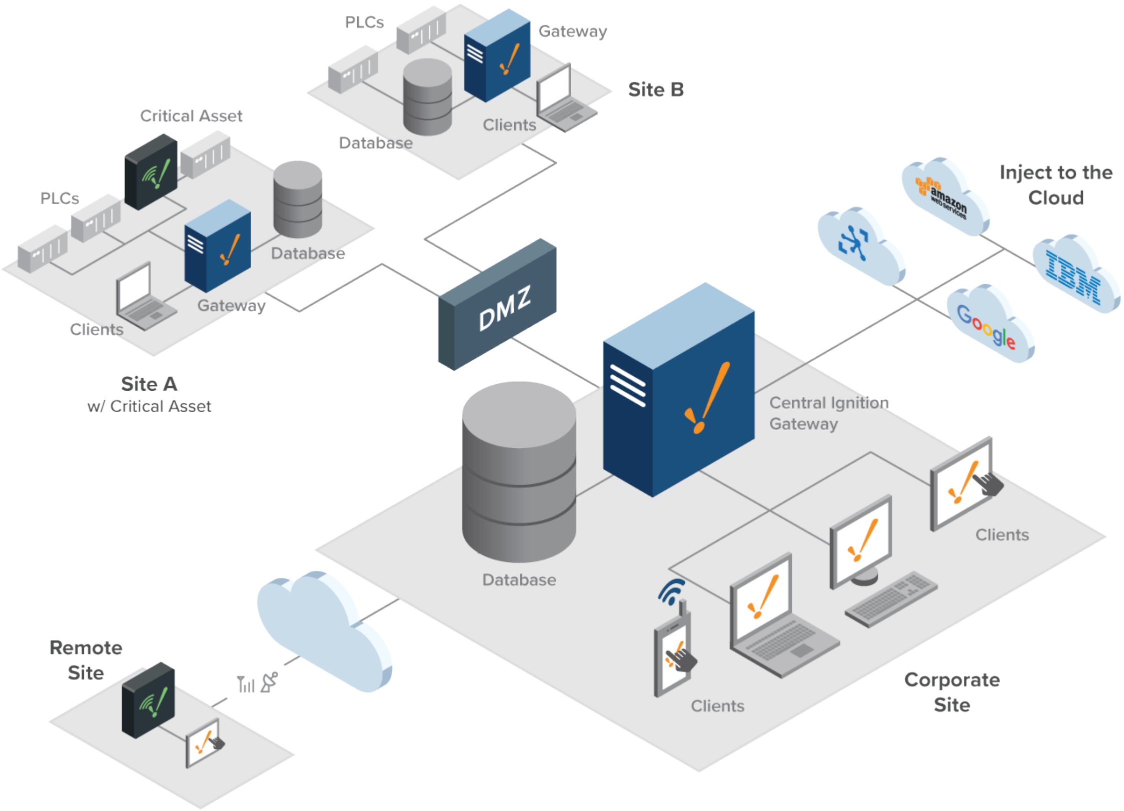
Other users can be configured with read-only access to databases for querying data; however, any validated data provided by the system should be presented as read-only reports. Tools and controls are available within Ignition for creating displays to review data, such as trend charts and customizable tables. Tools are also available to generate reports to be printed or exported in read-only formats like PDFs. This allows standard validated report templates to be reused with minimal testing required. Since the report data is read-only from the data source and read-only in file type (pdf), data cannot be tampered with, contrary to processes that utilize spreadsheet-based data exports that do allow potential data tampering.

Regular scheduled full and incremental backups should be configured for long-term storage of data. The backups should be kept on a separate disk or offline media. The backups should be tested annually for corruption and restorability. Ignition provides features to schedule automatic gateway backups. Database backups can also be automated with scheduled tasks or advanced methods such as server clustering.

To further enhance data integrity within Ignition, the design of the network and related components should be considered. In an ideal setup, process equipment should be located on a network that is separate from office systems such as end-user computers. This segregation ensures that validated systems and their data cannot be tampered with intentionally or inadvertently by users who should not have access to them. In such a setup, firewall rules can be applied to allow only specific required access to Ignition between the two networks. For example, specific network ports can be opened so that users on the office network can access an Ignition client to view report data, but not access the equipment the data originated from.

When configuring connections to data sources in Ignition, unique non-expiring system accounts and passwords should be used where possible; use of anonymous connections should be avoided to ensure traceability of audit trail and log information. Secure encrypted protocols such as OPC UA are preferred to ensure data integrity across the network. Direct connections are preferable to indirect connections (such as passing data across multiple OPC servers). By keeping architectures simple, configuration and communication issues can be avoided that could otherwise impact the integrity of end data.

Figure 3: Example Network Diagram



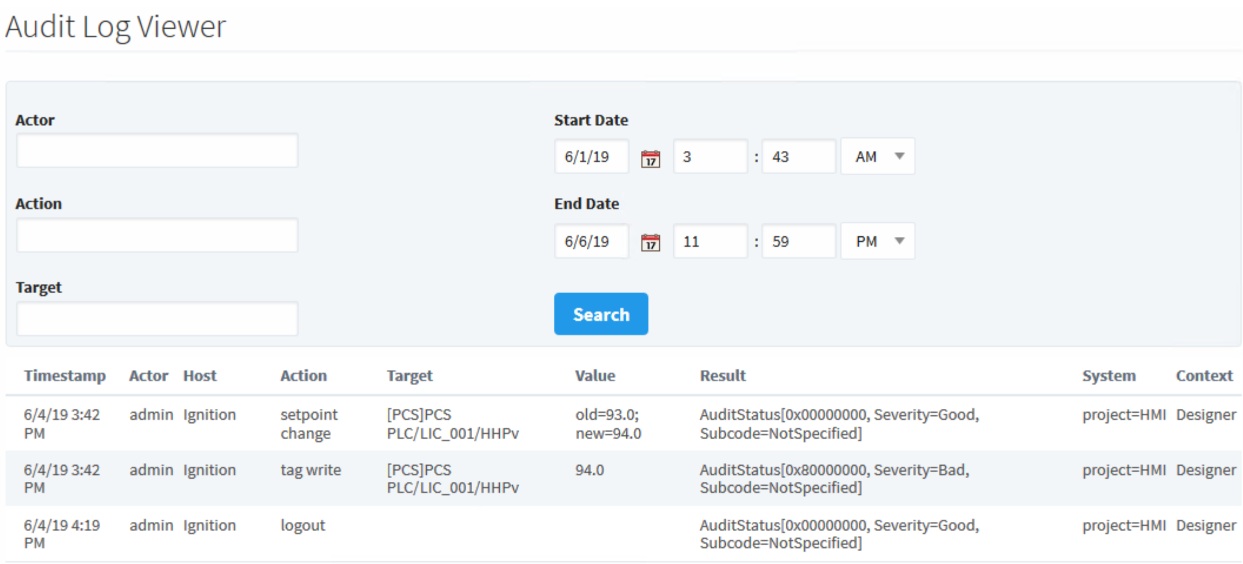
Audit Trail

Ignition provides an audit trail to record contemporaneous logs of user actions within the system. Multiple audit profiles can be created and applied to projects based on specific user requirements and retention periods. By default, Ignition will record a timestamp, username, computer name, and details about each audited action. Default audited actions include tag writes, SQL commands (UPDATE, INSERT, DELETE), project changes from the Ignition Designer, and user login/logout events.

Because the audit trail information is stored in a SQL database, the default audited actions can be extended. During any scriptable event or binding (for example, clicking a button to switch a system from Auto to Manual mode), a SQL INSERT query can be configured to add an event to the audit trail. Security challenges or E-signature events such as “Done By” and “Checked By” information can be added to every scriptable event within the audit trail. By configuring these actions in a template object, audited actions can be simply applied throughout the project without redundant configuration or validation testing. Audit trail data can be reviewed from the Ignition Gateway or queried and presented in tables or reports.

A common example of extending the Ignition audit trail is recording when a user has changed the value of a setpoint from an HMI. For this action, a text input component would be configured within a template. Using event handlers on this component, a script is utilized to detect when the value of the text field is changed. When the value is changed, a query is executed to insert an entry into the audit database table. All fields can be filled in to match built-in audit events, including the current user, current host name, and timestamp. In this example, the “action” field can be populated as “setpoint change”, and the “value” field can be populated with the old and new values for the setpoint. With this configuration completed inside a template, it can be reused throughout the project without extra configuration or testing.

Figure 4: An example audit trail log with an expanded “setpoint change” action.



Audit Log Viewer

Actor

Action

Target

Start Date 6/1/19 3 : 43 AM

End Date 6/6/19 11 : 59 PM

Timestamp	Actor	Host	Action	Target	Value	Result	System	Context
6/4/19 3:42 PM	admin	Ignition	setpoint change	[PCS]PCS PLC/LIC_001/HHPv	old=93.0; new=94.0	AuditStatus[0x00000000, Severity=Good, Subcode=NotSpecified]	project=HMI	Designer
6/4/19 3:42 PM	admin	Ignition	tag write	[PCS]PCS PLC/LIC_001/HHPv	94.0	AuditStatus[0x80000000, Severity=Bad, Subcode=NotSpecified]	project=HMI	Designer
6/4/19 4:19 PM	admin	Ignition	logout			AuditStatus[0x00000000, Severity=Good, Subcode=NotSpecified]	project=HMI	Designer

Summary

Data integrity principles and Part 11 compliance are part of the framework that ensures humans receive quality medicines and treatments free of potentially harmful defects. Compliance helps provide a means to collect critical data that can be displayed without alteration as well as a system to track operator actions and events. The Ignition platform complies with Part 11 and adheres to data integrity principles.

Ignition includes a comprehensive set of user access controls and a robust audit trail. These features are designed to offer powerful default functionality while also providing users the ability to expand the default functionality. This allows the audit trail to capture any information deemed critical by an organization or individual quality group without compromising on data security and integrity. For more information, please contact Inductive Automation at info@inductiveautomation.com.