

SIEMENS

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COMPLIANCE RESPONSE ERES

SIMATIC

WinCC Unified V20

Electronic Records / Electronic Signatures
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SIEMENS

SIMATIC

SIMATIC WinCC Unified V20 ERES Compliance Response

Product Information

Electronic Records /
Electronic Signatures (ERES)

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Legal information

Warning notice system

This manual contains notices you have to observe in order to ensure your personal safety, as well as to prevent damage to property. The notices referring to your personal safety are highlighted in the manual by a safety alert symbol, notices referring only to property damage have no safety alert symbol. These notices shown below are graded according to the degree of danger.

 DANGER
indicates that death or severe personal injury will result if proper precautions are not taken.

 WARNING
indicates that death or severe personal injury may result if proper precautions are not taken.

 CAUTION
indicates that minor personal injury can result if proper precautions are not taken.

NOTICE
indicates that property damage can result if proper precautions are not taken.

If more than one degree of danger is present, the warning notice representing the highest degree of danger will be used. A notice warning of injury to persons with a safety alert symbol may also include a warning relating to property damage.

Qualified Personnel

The product/system described in this documentation may be operated only by **personnel qualified** for the specific task in accordance with the relevant documentation, in particular its warning notices and safety instructions. Qualified personnel are those who, based on their training and experience, are capable of identifying risks and avoiding potential hazards when working with these products/systems.

Proper use of Siemens products

Note the following:

 WARNING
Siemens products may only be used for the applications described in the catalog and in the relevant technical documentation. If products and components from other manufacturers are used, these must be recommended or approved by Siemens. Proper transport, storage, installation, assembly, commissioning, operation and maintenance are required to ensure that the products operate safely and without any problems. The permissible ambient conditions must be complied with. The information in the relevant documentation must be observed.

Trademarks

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Disclaimer of Liability

We have reviewed the contents of this publication to ensure consistency with the hardware and software described. Since variance cannot be precluded entirely, we cannot guarantee full consistency. However, the information in this publication is reviewed regularly and any necessary corrections are included in subsequent editions.

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Introduction

Life science industry is basing key decisions on regulated records that are increasingly generated, processed and kept electronically. Reviews and approval of such data are also being provided electronically. Thus the appropriate management of electronic records and electronic signatures has become an important topic for the life science industry.

Accordingly, regulatory bodies defined criteria under which electronic records and electronic signatures will be considered as reliable and trustworthy as paper records and handwritten signatures executed on paper. These requirements have been set forth by the US FDA in 21 CFR Part 11 (21 CFR Part 11 Electronic Records; Electronic Signatures, US FDA, 1997; in short: *Part 11*) and by the European Commission in Annex 11 of the EU GMP Guideline (EU Guidelines to Good Manufacturing Practice, Volume 4, Annex 11: Computerised Systems, European Commission, 2011; in short: *Annex 11*).

Since requirements on electronic records and electronic signatures are always tied to a computerized system being in a validated state, both regulations also include stipulations on validation and lifecycle of the computerized system.

Application of *Part 11* and *Annex 11* (or their corresponding implementation in national legislation) is mandatory for the use of electronic records and electronic signatures. However, these regulations are only valid within their defined scope.

The scope of both regulations is defined by the regional market to which the finished pharmaceutical product is distributed and by whether or not the computerized systems and electronic records are used as part of GMP-regulated activities (see Part 11.1 and Annex 11 Principle).

Supplemental to the regulations, a number of guidance documents, good practice guides and interpretations have been published in recent years to support the implementation of the regulations. Some of them are referred to within this document.

To help its clients, Siemens as supplier of SIMATIC WinCC Unified has evaluated the system with regard to these requirements and published its results in this Compliance Response.

SIMATIC WinCC Unified V20 (including the Audit option) fully meets the functional requirements for electronic records and electronic signatures.

Operation in conformity with the regulations is ensured in conjunction with organizational measures and procedural controls to be established by the regulated user. Such measures and controls are mentioned in chapter "Evaluation List for WinCC Unified (Page 17)" of this document.

This document is divided into three parts:

1. The chapter "The Requirements in Short (Page 7)" provides a brief description of the requirement clusters.
2. Chapter "Meeting the Requirements with WinCC Unified (Page 9)" introduces the functionality of the system as means to meet those requirements.
3. Chapter "Evaluation List for WinCC Unified (Page 17)" contains a detailed system assessment on the basis of the individual requirements of the relevant regulations.

The Requirements in Short

The requirements of Annex 11 and Part 11 have the purpose of protecting regulated electronic records and electronic signatures (short: ERES) against manipulation, misinterpretations and incomprehensible changes.

The term "electronic record" means any combination of text, graphics, data, audio, pictorial or other information representation in digital form, that is created, modified, maintained, archived, retrieved or distributed by a computer system for use in a regulated process.

The "electronic signature" is a legally binding equivalent of a handwritten signature. The submission of the signature is a technical process for identifying the signatory, whereas the representation of the signature in connection with the signed action becomes part of the electronic documentation. Since electronic signatures are also considered as being electronic records by themselves, all requirements for electronic records are applied to electronic signatures too.

The following table provides an overview of the requirements from both regulations.

Requirement	Description
Lifecycle and Validation of Computerized Systems	<p>Computerized systems used as a part of GMP-related activities must be validated. The validation process should be defined using a risk-based approach. It should cover all relevant steps of the lifecycle and must provide appropriate documented evidence.</p> <p>The system's functionality should be traceable throughout the lifecycle by being documented in specifications or a system description.</p> <p>A formal change control procedure as well as an incident management should be established. Periodic evaluation should confirm that the validated state of the system is being maintained.</p>
Suppliers and Service Providers	<p>Since competency and reliability of suppliers and service providers are considered key factors, the supplier assessment should be decided on a risk-based approach. Formal agreements should exist between the regulated user and these third parties, including clear responsibilities of the third party.</p>
Data Integrity	<p>Under the requirements of both regulations, electronic records and electronic signatures must be as reliable and trustworthy as paper records.</p> <p>The system must provide the ability to discern altered records. Built-in checks for the correct and secure handling of data should be provided for manually entered data as well as for data being electronically exchanged with other systems.</p> <p>The system's ability to generate accurate and complete copies is essential for the use of the electronic records for regulated purposes, as well as the accessibility, readability, and integrity of archived data throughout the retention period.</p>
Audit Trail, Change Control Support	<p>Besides recording changes to the system as defined in the lifecycle, both regulations require that changes on GMP-relevant data are being recorded.</p> <p>Such an audit trail should include information on the change (before / after data), the identity of the operator, a time stamp, as well as the reason for the change.</p>

Requirement	Description
System Access, Identification Codes and Passwords	<p>Access to the system must be limited to authorized individuals. Attention should be paid to password security. Changes on the configuration of user access management should be recorded.</p> <p>Periodic reviews should ensure the validity of identification codes. Procedures should exist for recalling access rights if a person leaves and for loss management.</p> <p>Special consideration should be given to the use of devices that bear or generate identification code or password information.</p>
Electronic Signature	<p>Regulations consider electronic signatures being legally binding and generally equivalent to handwritten signatures executed on paper.</p> <p>Beyond requirements on identification codes and passwords as stated above, electronic signatures must be unique to an individual. They must be linked to their respective electronic record and not be copied or otherwise being altered.</p>
Open Systems	<p>Open systems might require additional controls or measures to ensure data integrity and confidentiality.</p>

Meeting the Requirements with WinCC Unified

The Siemens recommendations for the system architecture, conception, and configuration will assist system users in achieving compliance. More information and help is included in the system manuals for SIMATIC WinCC Unified. Information on the optimal use and performance of WinCC Unified can be found in the application example "Engineering guideline for WinCC Unified".

SiePortal references (online support)

- WinCC Unified - Manuals and Updates, SiePortal under the entry ID 109961592 (<https://support.industry.siemens.com/cs/ww/en/view/109961592>)
- WinCC Unified V20 System Manual, SiePortal under the entry ID 109977308 (<https://support.industry.siemens.com/cs/ww/en/view/109977308>)
- Engineering guideline for WinCC Unified, SiePortal under the entry ID 109827603 (<https://support.industry.siemens.com/cs/ww/en/view/109827603>)
- Central User Management with UMC, SiePortal under the entry ID 109780337 (<https://support.industry.siemens.com/cs/ww/en/view/109780337>)

The requirements explained in chapter "The Requirements in Short (Page 7)" can be supported by the system as follows.

The basic data control policies of a regulated company relate to persons, processes and techniques.

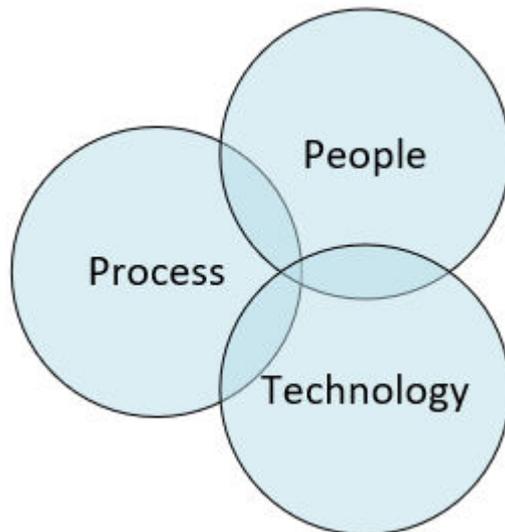


Figure 3-1 Elements of data control

3.3 Data Integrity

Only the sum of all measures can ensure that the system is operated in compliance with the regulatory requirements.

- Process: Procedures, for example, for operation, change management, validation and archiving
- People: Suitable qualification, training of staff and following the established processes
- Technology: Selection and functionality of the basic components as well as specific configuration for the application

3.1 Lifecycle and Validation of Computerized Systems

In Annex 11 from 1992 and in Part 11 from 1997, the law already required that computerized systems need to be validated. Criteria for the validation of the system and its lifecycle were added in the edited revision of Annex 11 from 2011.

Requirements for the validation of computerized systems and for the maintenance of the validated state are also part of other publications, such as the Baseline Guides, the GAMP Guides and the GAMP Good Practice Guides of the ISPE (International Society of Pharmaceutical Engineers (<https://www.ispe.org>)) industry association.

Consequently, the system lifecycle and validation approach should be defined taking into account the recommendations of the GAMP 5 Guide (GAMP 5 - A risk-based approach to compliant GxP computerized systems). Topics such as lifecycle management, system development and operation of computerized systems are also dealt with in detail in the GAMP Guides.

3.2 Suppliers and Service Providers

Suppliers of systems, solutions and services should be evaluated accordingly, see GAMP 5 appendix M2. Siemens as a manufacturer of hardware and software components follows internal procedures of Product Lifecycle Management and works according to a Quality Management System, which is regularly reviewed and certified by an external certification company.

3.3 Data Integrity

Regulated companies should implement integrated data integrity strategies. Of particular interest are the data used to make decisions that have an impact on product quality and patient safety.

The reliability of the data requires a high degree of data integrity over the entire retention period and also extends to the archiving and retrieval of data.

In addition, the system must have the ability to detect invalid or altered records. On the computer system side, functionalities such as access protection, audit trail, data type checks, checksums, data backup/restore, and data archiving/retrieval help maintain data integrity. These measures and technical characteristics are complemented by system validation, appropriate work procedures and staff training.

IT security

IT security is also essential for achieving and retaining data integrity. For support from Siemens, see Industrial Cybersecurity Services. (<https://new.siemens.com/global/en/products/services/digital-enterprise-services/industrial-security-services.html>)

Continuous recording and archiving

Process data and messages can be recoded and archived by SIMATIC WinCC Unified. This may take place file-based or server-based. A detailed description of the function and the configuration is contained in the document "Configuration of archiving for SIMATIC WinCC Unified systems", see SiePortal entry ID 109782859 (<https://support.industry.siemens.com/cs/ww/en/view/109782859>).

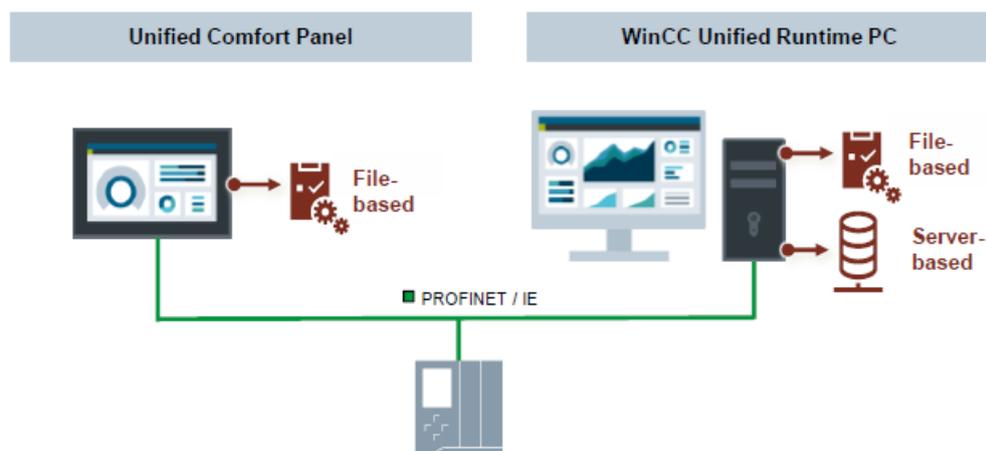


Figure 3-2 Archiving in WinCC Unified

In the case of local HMI panels, the data are buffered on a local storage device (such as an SD card), and then transferred via the network or a USB device.

Chapter 7 of the "WinCC Unified System Manual" contains more information on archiving, see SiePortal references in chapter 3 (Page 9).

Batch-based archiving

The WinCC premium add-on, PM-QUALITY, is used for batch-oriented data archiving. PM-QUALITY automatically manages the local and long-term archives. Data from different sources such as WinCC, PCS 7, WinCC Advanced, WinCC Unified, OPC UA or DA up to the data import can be combined, archived and converted into meaningful reports.

3.4 Audit Trail, Change Control Support

"Audit trails are of particular importance in areas where operator actions generate, modify, or delete data in the course of normal operation." (Guidance for Industry Part 11 – Scope and Application, FDA, 2003)

An audit trail is not required for automatically generated electronic records which can neither be modified nor deleted by the operator. The system provides adequate system security mechanisms for such electronic records.

Changes to the configuration of a validated system are subject to a change procedure and must be controlled accordingly. This can be supported by versioning, system logs and similar means. The following sections therefore distinguish between the requirements for audit trails during operation and the control of configuration changes in engineering.

Operator inputs / recordings during operation

SIMATIC WinCC Unified supports the requirement for an audit trail of GMP-relevant operator actions by recording these actions accordingly (who, what, when, and optionally why). Such electronic recordings are secured through system-side security mechanisms.

The GMP relevant data is defined by the regulated user based on the applicable regulatory requirements.

Recording process data

Process data (e.g. process values, messages and alarms) is stored in the system, without any option for the operator to change this data. No audit trail is required for this data.

Operator input during operation

All changes and inputs of relevant data entered by the operator during operation are recorded in an audit trail by means of the WinCC Unified Audit option package. The relevant data to be tracked in the audit trail can be configured on the engineering system, see Figure 3-3 below. A list of correspondingly configured variables can be extracted from the system.

"None", "Acknowledgment", or "Electronic signature" can be selected as the confirmation type. In addition a comment can be set as optional or as mandatory.

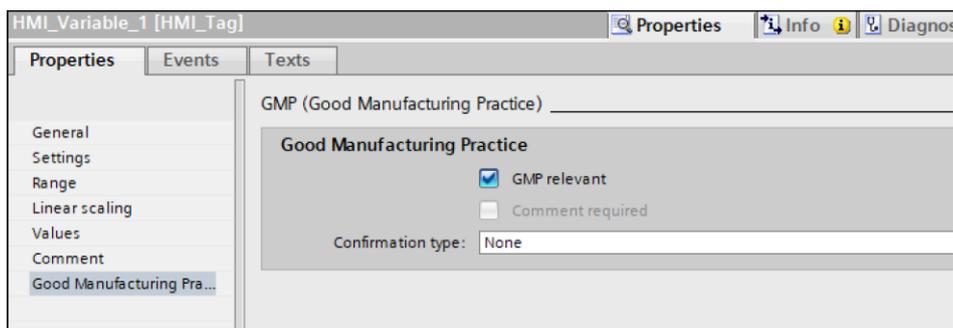


Figure 3-3 Marking a GMP-relevant variable

The audit trail can be saved and archived as a separate file. An integrated algorithm automatically forms a checksum for each data record.

Audit Viewer displays audit trail data in Runtime; search criteria can be saved.

Time stamp	Audit provider	Type	Object reference	Object name	User	Operator station	Operation	Old Value	New Value	Language	Reason	Integrity	Signature
3/3/2023 3:59:17:571 PM	User Interface	User interface	2.233.1.0.0.0	HMI_RT_Audit_Demo-HMI_Tag_ESIG_FI	Operator	localhost	Updated	0	36	1033		...	<SIGNATURE name=Operator, role=1, status=1 /><SIGNATURES />
3/3/2023 3:59:14:254 PM	User Interface	User interface	2.233.1.0.0.0	HMI_RT_Audit_Demo-HMI_Tag_ESIG_FI	Operator	localhost	Updated	0	36	1033		...	<SIGNATURE name=Operator, role=1, status=1 /><SIGNATURES />
3/3/2023 3:59:02:761 PM	User Interface	User interface	2.233.1.0.0.0	HMI_RT_Audit_Demo-HMI_Tag_ESIG_FI	Operator	localhost	Updated	0	36	1033		...	<SIGNATURE name=Operator, role=1, status=1 /><SIGNATURES />
3/3/2023 3:59:02:586 PM	User Interface	User interface	2.233.1.0.0.0	HMI_RT_Audit_Demo-HMI_Tag_ESIG_FI	Operator	localhost	Updated	0	36	1033		...	<SIGNATURE name=Operator, role=1, status=1 /><SIGNATURES />
3/3/2023 3:59:02:410 PM	User Interface	User interface	2.233.1.0.0.0	HMI_RT_Audit_Demo-HMI_Tag_ESIG_FI	Operator	localhost	Updated	0	36	1033		...	<SIGNATURE name=Operator, role=1, status=1 /><SIGNATURES />
3/3/2023 3:59:01:496 PM	User Interface	User interface	2.233.1.0.0.0	HMI_RT_Audit_Demo-HMI_Tag_ESIG_FI	Operator	localhost	Updated	0	36	1033		...	<SIGNATURE name=Operator, role=1, status=1 /><SIGNATURES />
3/3/2023 3:56:11:747 PM	User Interface	User interface	2.223.1.0.0.0	HMI_RT_Audit_Demo-HMI_Tag_GMPCoInformation	Operator	localhost	Updated	0	39	1033		...	
3/3/2023 3:56:06:658 PM	User Interface	User interface	2.224.1.0.0.0	HMI_RT_Audit_Demo-HMI_Tag_GMP	Operator	localhost	Updated	0	36	1033		...	
3/3/2023 3:56:00:437 PM	User Management	User management			Operator	localhost	Updated		Operator	1033		...	

Figure 3-4 WinCC Unified Audit Viewer

Previously exported audit trail files can be displayed in the Audit Viewer. The integrity of the file is checked and confirmed when it is read in.

Parameter control

Operator actions via the parameter control (also known as PaCo) can also be stored as an audit trail. This must be set accordingly in the configuration. This applies to both downloading parameter sets and changing individual parameters.

Configuration control

In contrast to the audit trail, changes to the system configuration are subject to the procedure of change control. Before they are executed, such changes are planned, their potential impacts evaluated, documented during the execution and finally tested for correct implementation. The documentation of the changes made can be supported by various tools.

Changes to the project configuration

SIMATIC WinCC Unified provides system functions, options, and add-ons to support the control of the system configuration. This includes versioning of software elements and projects as well as backup/restore functions to support the corresponding procedures. The "WinCC Unified System Manual" contains more information, see SiePortal references in chapter 3 (Page 9).

Changes to user management

Different variants must be considered separately here, see also the central and local user management in the following chapter. Changes to the central user management (such as setting up new users, blocking users, etc.) are recorded in the UMC component (User Management Component). There is currently no system log in the local WinCC Unified user management. Therefore, the use of UMC is recommended.

When the UMC component is connected to an Active Directory, the changes are also recorded in the Windows event log. To this purpose the event log of the Active Directory must be configured accordingly, as described in the Microsoft documentation.

3.5 System Access, Identification Codes and Passwords

Users must be assigned the required access rights only, in order to prevent unauthorized access to and unintended manipulation of the file system, directory structures, and system data.

The requirements regarding access security are fully met in combination with procedural controls, such as those for "specifying rights and roles".

Adequate security mechanisms are essential for the secure operation of a system. This applies especially to "open paths" which must be protected by additional measures. Basic principles of the security concept as well as configuration recommendations are contained in the application example "Central user management with the User Management Component" and the UMC basic document included in it, see SiePortal references in chapter 3 (Page 9).

The user management configuration is performed centrally on an engineering system for each application. The "WinCC Unified System Manual" contains detailed information on user management in chapter 13, see SiePortal references in chapter 3 (Page 9).

SIMATIC WinCC Unified supports the protection of electronic records by providing:

- Usage of a unique identification code
- Definition of access authorizations for user groups/roles
- Password settings and password aging
- Blocking a user after a configurable number of failed login attempts

Central user management

When an HMI device is operated in a network, central user management offers significant advantages. It is based on Microsoft Windows technology and the "User Management Component (UMC)", if applicable in a domain structure.

- The UMC allows the set-up of central user management to define and manage users and user groups across software and devices.
- The user groups are created in the UMC and linked in TIA Portal with the corresponding WinCC Unified role.
- The assignment of the WinCC Unified specific function rights for the access to WinCC Unified takes place via the user groups.

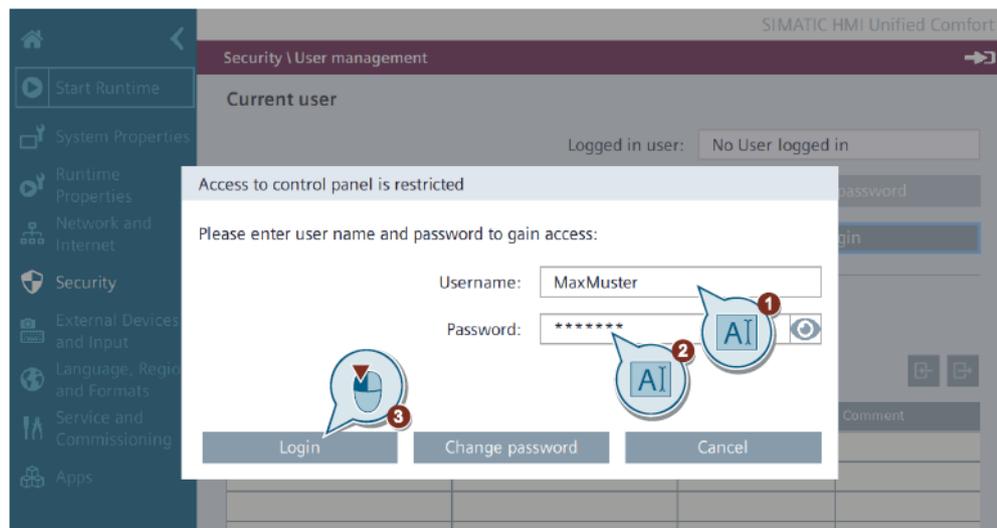


Figure 3-5 Log in of a user at HMI Unified Comfort Panel

Comprehensive instructions on the configuration and functionality of user management with the UMC component are available in the "Connection of WinCC Unified to UMC" manual, see SiePortal references in chapter 3 (Page 9).

User management on local HMI devices

Local HMI panels are quite often installed without any connection to a network. Therefore, the local user management of SIMATIC WinCC Unified can be used on these HMI devices. In this case individual users and their assignment to user groups are only known locally.

- Individual users and their assignment to roles are defined in the WinCC Unified configuration.
- User authorizations are defined for a specific HMI device or WinCC Unified PC.

However, local user management does not have a system log in the current version that would record changes to the user management. This can be defined and documented via the general change control procedure of the regulated user.

3.6 Electronic Signature

Simple electronic signature

The configuration of an electronic signature is available with the WinCC Unified Audit option (Basic or Enhanced).

The electronic signature is executed in a dialog. The variables which may require an electronic signature in the case of changes is specified during the configuration phase. Users can sign electronically by confirming the intended action by entering their password. In this way, the electronic signature is saved in the audit trail along with the user name, time stamp, and the action performed.

The mandatory entry of a comment can be selected.

Multiple electronic signature

With the WinCC Unified Audit Enhanced variant a double electronic signature can also be configured.

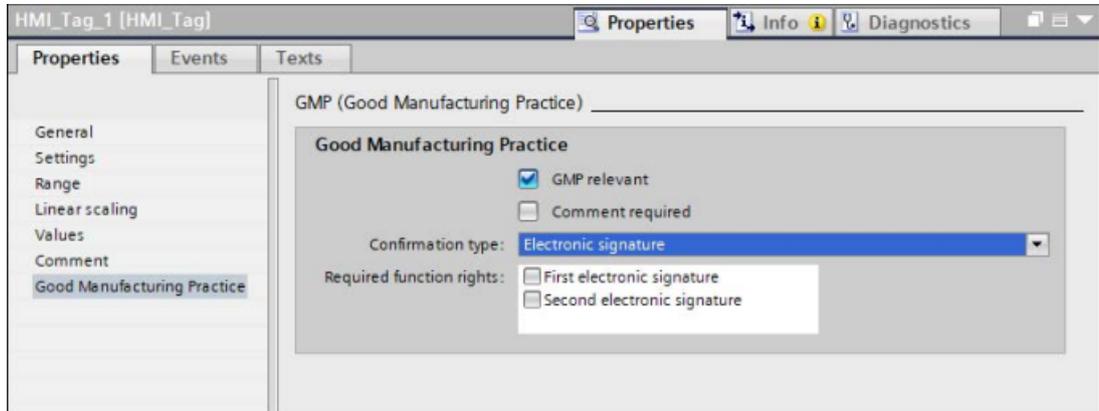


Figure 3-6 Electronic signature - configuration

Evaluation List for WinCC Unified

The following list of requirements includes all regulatory requirements from 21 CFR Part 11 as well as from Annex 11 of the EU-GMP Guidelines. All requirements are structured in the same topics as those introduced in the chapter "The Requirements in Short (Page 7)" of this Compliance Response.

The *requirements* listed fully consider both regulations, regardless of whether technological or procedural controls or a combination of both are needed to fully comply with Part 11 and Annex 11.

The *answers* include, among other things, information about how the requirement is handled during the development of the product and which measures should be implemented during configuration and operation of the system. Furthermore, the answers include references to the product documentation for technical topics and to the GAMP 5 guide for procedural controls that are already considered in the guide.

4.1 Lifecycle and Validation of Computerized Systems

The fundamental requirement that a computerized system, used as a part of GMP related activities, must be validated is extended in the revision of Annex 11 from 2011 by requirements detailing expectations on a system's lifecycle.

	Requirement	Reference	Answer
4.1.1	Risk management should be applied throughout the lifecycle of the computerized system.	Annex 11, 1	Yes. The PLM (Product Lifecycle Management) process is the development process for Siemens software products. This process includes appropriate risk management. During the validation and operation of a system, risk management must be ensured by the regulated user.
4.1.2	Validation of a system ensures its accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.	21 CFR 11.10 (a)	Yes. The development of the software product (COTS, see Annex 11, glossary) is subject to the Siemens QMS and the PLM process. The regulated user should take appropriate measures to validate the application (see Annex 11, glossary), as well as maintaining its validated state.
4.1.3	Validation documentation covers relevant steps of the lifecycle.	Annex 11, 4.1	Yes. The PLM process contains all relevant documents. The responsibility for the validation of the application (see Annex 11, glossary) is with the regulated user.
4.1.4	A process for the validation of bespoke or customized systems should be in place.	Annex 11, 4.6	Customer-specific applications are verified in the scope of realization according to the responsibilities agreed upon in the project. The validation process is the responsibility of the regulated user.

4.1 Lifecycle and Validation of Computerized Systems

	Requirement	Reference	Answer
4.1.5	Change management and deviation management are applied during the validation process.	Annex 11, 4.2	Yes. The PLM process includes procedures for managing changes and deviations as well as error corrections. The regulated user should ensure appropriate change management and deviation management (see GAMP 5, appendices M8 and D5).
4.1.6	An up-to-date inventory of all relevant systems and their GMP functionality is available. For critical systems an up-to-date system description [...] should be available.	Annex 11, 4.3	The regulated user should establish appropriate reporting, a system inventory as well as system descriptions (see GAMP 5, appendix D6).
4.1.7	User requirements should describe required functions, be risk-based and be traceable throughout the lifecycle.	Annex 11, 4.4	Yes. Specification of requirements is part of the PLM process. For project-specific configuration, the regulated user must describe the user requirements in the lifecycle of the system (see GAMP 5, appendix D1).
4.1.8	Evidence of appropriate test methods and test scenarios should be demonstrated.	Annex 11, 4.7	Ensuring the suitability of test methods and scenarios is an integral part of the PLM process as well as test planning. The regulated user should be involved to agree upon testing practice (see GAMP 5, appendix D5) for the application.
4.1.9	Appropriate controls should be used over system documentation. Such controls include the distribution of, access to, and use of system operation and maintenance documentation.	21 CFR 11.10 (k)	During the development of the product the product's documentation is treated as being part of the product. Thus, the documentation itself is also subject to the requirements of the PLM process. The regulated user should establish appropriate procedural controls during development and operation of the production system (see GAMP 5, appendices M9 and D6).
4.1.10	A formal change control procedure for system documentation maintains a time sequenced record of changes.	21 CFR 11.10 (k) Annex 11, 10	During the development of the product, changes are handled according to the PLM process. The regulated user should establish appropriate procedural controls during development and operation of the system (see GAMP 5, appendices M8 and O6)
4.1.11	Persons who develop, maintain, or use electronic record/electronic signature systems should have the education, training and experience to perform their assigned task.	21 CFR 11.10 (i)	Siemens' processes do ensure that employees have appropriate training for their tasks and that such training is properly documented. Furthermore, Siemens offers a variety of training courses for users, administrators and support staff.
4.1.12	Computerized systems should be periodically evaluated to confirm that they remain in a valid state and are compliant with GMP.	Annex 11, 11	The regulated user should establish appropriate procedural controls (see GAMP 5, appendices O3 and O8).

	Requirement	Reference	Answer
4.1.13	All incidents should be reported and assessed.	Annex 11, 13	The SIMATIC portfolio offers functionalities to support reporting on different system levels. The regulated user should establish appropriate procedural controls (see GAMP 5, appendix O5).
4.1.14	For the availability of computerized systems supporting critical processes, provisions should be made to ensure continuity of support for those processes in the event of a system breakdown.	Annex 11, 16	The regulated user should appropriately consider the system in its business continuity planning (see GAMP 5, appendix O10).

4.2 Suppliers and Service Providers

If the regulated user is partnering with third parties for planning, development, validation, operation and maintenance of a computerized system, then the competence and reliability of this partner should be considered utilizing a risk-based approach.

	Requirement	Reference	Answer
4.2.1	When third parties are used, formal agreements must exist between the manufacturer and any third parties.	Annex 11, 3.1	The regulated user is responsible for establishing formal agreements with suppliers and third parties (see GAMP 5, appendix O2).
4.2.2	The competency and reliability of a supplier are key factors when selecting a product or service provider. The need for an audit should be based on a risk assessment.	Annex 11, 3.2 Annex 11, 4.5	The regulated user should assess its suppliers accordingly (see GAMP 5, appendix M2).
4.2.3	The regulated user should ensure that the system has been developed in accordance with an appropriate Quality Management System.	Annex 11, 4.5	The development of SIMATIC products follows the PLM process stipulated in Siemens' Quality Management System.
4.2.4	Documentation supplied with commercial off-the-shelf products should be reviewed by regulated users to check that user requirements are fulfilled.	Annex 11, 3.3	The regulated user is responsible for the performance of such reviews.
4.2.5	Quality system and audit information relating to suppliers or developers of software and implemented systems should be made available to inspectors on request.	Annex 11, 3.4	The content and extent of the documentation affected by this requirement should be agreed upon by the regulated user and Siemens. A joint non-disclosure agreement should reflect this requirement accordingly.

4.3 Data Integrity

The main goal of both regulations is to define criteria under which electronic records and electronic signatures are as reliable and trustworthy as paper records. This requires a high degree of data integrity throughout the whole data retention period, including archiving and retrieval of relevant data.

4.4 Audit Trail, Change Control Support

	Requirement	Reference	Answer
4.3.1	The system should provide the ability to discern invalid or altered records.	21 CFR 11.10 (a)	This is made feasible by means of the following functions: Time stamping, revisions, versioning for configuration and documents, and audit trail for operational entries.
4.3.2	For records supporting batch release, it should be possible to generate printouts indicating whether any of the data has changed since the original entry.	Annex 11, 8.2	Operational modification of data is recorded and can be printed in a report with internal or add-on functions.
4.3.3	The system should provide the ability to generate accurate and complete copies of electronic records in both human readable and electronic form.	21 CFR 11.10 (b) Annex 11, 8.1	Yes. Accurate and complete copies can be generated in electronic format or on paper.
4.3.4	Computerized systems exchanging data electronically with other systems should include appropriate built-in checks for the correct and secure entry and processing of data.	Annex 11, 5	Yes. Depending on the type of data, such built-in checks include value ranges, data type check, access authorizations, checksums, etc. and finally the validation process including interface testing.
4.3.5	For critical data entered manually, there should be an additional check on the accuracy of the data.	Annex 11, 6	The system has integrated plausibility checks for data entry. In addition, an operator dialog can be realized as an additional check mechanism.
4.3.6	Data should be secured by both physical and electronic means against damage.	Annex 11, 7.1	In addition to the system's access security mechanisms, the regulated user should establish appropriate security means like physical access control, backup strategy, limited user access authorizations, regular checks on data readability, etc. Furthermore, the data retention period should be determined by the regulated user and appropriately considered in the user's processes (see GAMP 5, appendices O3, O4, O8, O9, O11 and O13).
4.3.7	Regular backups of all relevant data should be done.	Annex 11, 7.2	The regulated user must establish appropriate processes for data backup and restore (see GAMP 5, appendix O9).
4.3.8	Electronic records must be readily retrievable throughout the records retention period.	21 CFR 11.10 (c) Annex 11, 17	Yes. When exporting archives, the regulated user must establish procedural controls for archiving and retrieval of data (see GAMP 5, appendix O13).
4.3.9	If the sequence of system steps or events is important, then appropriate operational system checks should be enforced.	21 CFR 11.10 (f)	Yes. For example, allowances can be made for a specific sequence of operator actions by configuring the application accordingly.

4.4 Audit Trail, Change Control Support

During operation, regulations require the recording of operator actions that may result in the generation of new relevant records or the alteration or deletion of existing records.

4.5 System Access, Identification Codes and Passwords

	Requirement	Reference	Answer
4.4.1	The system should create a record of all GMP-relevant changes and deletions (a system-generated "audit trail"). For change or deletion of GMP-relevant data, the reason should be documented.	21 CFR 11.10 (e) Annex 11, 9	Yes. Changes during operation can be traced back by the system via an audit trail and contain information with time stamp, user ID, old and new value, as well as an optional comment. The audit trail is secure within the system and cannot be changed by a user.
4.4.2	Management systems for data and documents should be designed to record the identity of operators entering, changing, confirming or deleting data including date and time.	Annex 11, 12.4	Yes. Operator interventions are recorded with identification code and time stamp.
4.4.3	Changes to electronic records shall not obscure previously recorded information.	21 CFR 11.10 (e)	Yes. Recorded information is not overwritten and is always available in the database.
4.4.4	The audit trail shall be retained for a period at least as long as that required for the subject electronic records.	21 CFR 11.10 (e) Annex 11, 9	Yes. This requirement is technically feasible and must be taken into account in the regulated user's procedural controls for data backup and archiving (see GAMP 5, appendices O9 and O13).
4.4.5	The audit trail should be available for review and copying by regulatory agencies.	21 CFR 11.10 (e)	Yes. The audit trail can be made available and also exported in electronic form.

4.5 System Access, Identification Codes and Passwords

Since access to a system must be restricted to authorized individuals and the uniqueness of electronic signatures also depends on the authenticity of user credentials, user access management is a vital set of requirements regarding the acceptance of electronic records and electronic signatures.

	Requirement	Reference	Answer
4.5.1	System access should be limited to authorized individuals.	21 CFR 11.10 (d) 21 CFR 11.10 (g) Annex 11, 12.1	Yes. The system access can be regulated via the user account control. The individual authorizations must be specified by the regulated user. Procedural controls should also be established by the regulated user, as described in GAMP 5, appendix O11.
4.5.2	The extent of security controls depends on the criticality of the computerized system.	Annex 11, 12.2	System security is a key factor during design and development of SIMATIC products. Nonetheless, since system security strongly depends on the operating environment of each IT system, these aspects should be considered in security management (see GAMP 5, appendix O11). Recommendations and support are available from Siemens Industrial Security.

4.5 System Access, Identification Codes and Passwords

	Requirement	Reference	Answer
4.5.3	Creation, change, and cancellation of access authorizations should be recorded.	Annex 11, 12.3	Changes within the user administration are recorded in the UMC component. The planning and documentation of the changes are subject to the change control procedure of the regulated user.
4.5.4	If it is a requirement of the system that input data or instructions can only come from certain input devices (e.g. terminals), does the system check the validity of the source of any data or instructions received? (Note: This applies where data or instructions can come from more than one device, and therefore the system must verify the integrity of its source, such as a network of weigh scales, or remote, radio controlled terminals).	21 CFR 11.10 (h)	Yes. The WinCC HMI devices can be configured so that special input data/commands can only be performed from a dedicated device, or from a group of dedicated devices. All other devices then have read-only access rights at the most.
4.5.5	Controls should be in place to maintain the uniqueness of each combined identification code and password, so that no individual can have the same combination of identification code and password as any other.	21 CFR 11.300 (a)	Yes. It is ensured that every identification code is unique within the system. Every combination of identification code and password is therefore also unique.
4.5.6	Procedures are in place to ensure that the validity of identification codes is checked periodically.	21 CFR 11.300 (b) Annex 11, 11	The regulated user should establish appropriate procedural controls.
4.5.7	Passwords should periodically expire and have to be revised.	21 CFR 11.300 (b)	Yes. Password aging can be configured in the user management.
4.5.8	A procedure should be established for recalling identification codes and passwords if a person leaves or is transferred.	21 CFR 11.300 (b) Annex 11, 12.1	Yes. A user account can be disabled or the assigned access rights can be withdrawn for that user. The regulated user should establish appropriate procedural controls.
4.5.9	Following loss management procedures to electronically deauthorize lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable, rigorous controls.	21 CFR 11.300 (c)	The regulated user should establish appropriate procedural controls.

	Requirement	Reference	Answer
4.5.10	Measures for detecting attempts of unauthorized use and for informing security and management should be in place.	21 CFR 11.300 (d) Annex 11, 12.1	Yes. Failed attempts to use the system or to perform electronic signatures are recognized and can be logged. The regulated user must establish appropriate procedural controls to ensure a periodic review of security and access control information logs (see GAMP 5, appendix O8).
4.5.11	Initial and periodic testing of devices, such as tokens and cards, that bear or generate identification code or password information to ensure that they function properly and have not been altered in an unauthorized manner.	21 CFR 11.300 (e)	Such devices are not part of the Siemens portfolio. The regulated user should establish appropriate procedural controls.

4.6 Electronic Signature

To ensure that electronic signatures are generally accepted as equivalent to handwritten signatures executed on paper, requirements are not only limited to the act of electronically signing records. They also include requirements on record keeping as well as on the manifestation of the electronic signature.

	Requirement	Reference	Answer
4.6.1	Written policies should be established that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.	21 CFR 11.10 (j) Annex 11, 14.a	The regulated user should establish appropriate procedural controls.
4.6.2	Signed electronic records should contain the following related Information: <ul style="list-style-type: none"> The printed name of the signer The date and time of signing The meaning of the signing (such as approval, review, responsibility) 	21 CFR 11.50 (a) Annex 11, 14.c	Yes. The listed information is available.
4.6.3	The above-listed information is shown on displayed and printed copies of the electronic record.	21 CFR 11.50 (b)	Yes. The listed information is available.
4.6.4	Electronic signatures shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.	21 CFR 11.70 Annex 11, 14.b	Yes. The electronic signatures cannot be removed or used in any other way.

4.7 Open Systems

	Requirement	Reference	Answer
4.6.5	Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.	21 CFR 11.100 (a) 21 CFR 11.200 (a) (2)	Yes. The electronic signature uses the unique identifiers for user accounts. The re-use or re-assignment of electronic signatures is effectively prevented.
4.6.6	When a system is used for recording certification and batch release, the system should allow only Qualified Persons to certify the release of the batches and it should clearly identify and record the person releasing or certifying the batch.	Annex 11, 15	Electronic signatures are linked to an individual. The system allows strict determinations of which role and/or individual is allowed to perform a signature.
4.6.7	The identity of an individual should be verified before electronic signature components are allocated.	21 CFR 11.100 (b)	The regulated user should establish appropriate procedural controls for the verification of an individual's identity before allocating a user account and/or electronic signatures.
4.6.8	When an individual executes one or more signings not performed during a single session, each signing shall be executed using all of the electronic signature components.	21 CFR 11.200 (a) (1) (ii)	Yes. Performing an electronic signature requires the user ID as well as the user's password.
4.6.9	When an individual executes a series of signings during a single session, the first signing shall be executed using all electronic signature components; subsequent signings shall be executed using at least one private electronic signature component.	21 CFR 11.200 (a) (1) (i)	Yes. Each signature consists of two components (user ID and password).
4.6.10	The use of an individual's electronic signature by anyone other than the genuine owner would require the collaboration of two or more individuals.	21 CFR 11.200 (a) (3)	Yes. It is not possible to falsify an electronic signature during signing or after recording of the signature. In addition, the regulated user needs procedures that prevent the disclosure of passwords.
4.6.11	Electronic signatures based upon biometrics shall be designed to ensure that they cannot be used by anyone other than their genuine owner.	21 CFR 11.200 (b)	Standard tools of third-party manufacturers can be used to create biometric electronic signatures. The integrity of such solutions should be assessed separately.

4.7 Open Systems

The operation of an open system may require additional controls to ensure data integrity as well as the possible confidentiality of electronic records.

	Requirement	Reference	Answer
4.7.1	To ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records additional measures such as data encryption are used.	21 CFR 11.30	Additional security measures should be taken for open systems. For example, support is provided with configuration information in the "Security Concept PCS 7 and WinCC" manual, or by commonly available standard tools for encryption.
4.7.2	To ensure the authenticity and integrity of electronic signatures, additional measures such as the use of digital signature standards are used.	21 CFR 11.30	The system does not provide functionality for digital (encrypted) signatures.

4.7 Open Systems

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