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GMP-compliant configuration in WinCC Comfort / Advanced (TIA Portal)

Comfort Panels, Mobile Panels, WinCC Runtime Advanced (TIA Portal), SIMATIC Logon, SIMATIC WinCC Audit (TIA Portal)

https://support.industry.siemens.com/cs/ww/DE/view/109744244

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Table of Contents

1 Task

Introduction

In industries, e.g. the pharmaceutical industry, or the food and luxury food industry, there are various regulations regarding the traceability and documentation of production data. These include, among others, the following regulations:

- Complete tracing of operator control actions carried out by operators, using a timestamp (creation of audit-trails)
- Protection of important process steps using an electronic signature
- Archiving of accountable user actions

The option package SIMATIC WinCC Audit (TIA Portal) supports you in implementing a GMP-compliant configuration. Via the option package, you can also automatically create, document and archive the Audit Trails.

Overview of the application example

The application example teaches the following skills:

- Implementing a GMP-compliant configuration via an HMI control panel
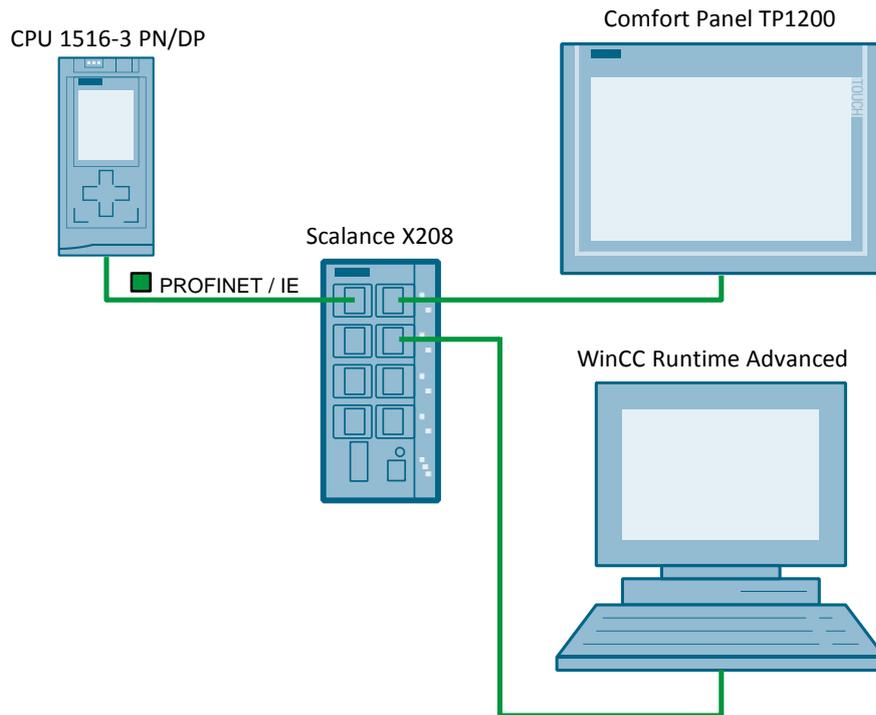- Displaying recorded Audit Trails with WinCC Audit Viewer

Figure 1-2

Audit Trail

Time	Operation	Operator
07:05 am	Recipe "Orange" selected	E. Meier
07:08 am	Start line 1	E. Meier
13:20 pm	Recipe "Water" selected	K. Fuchs
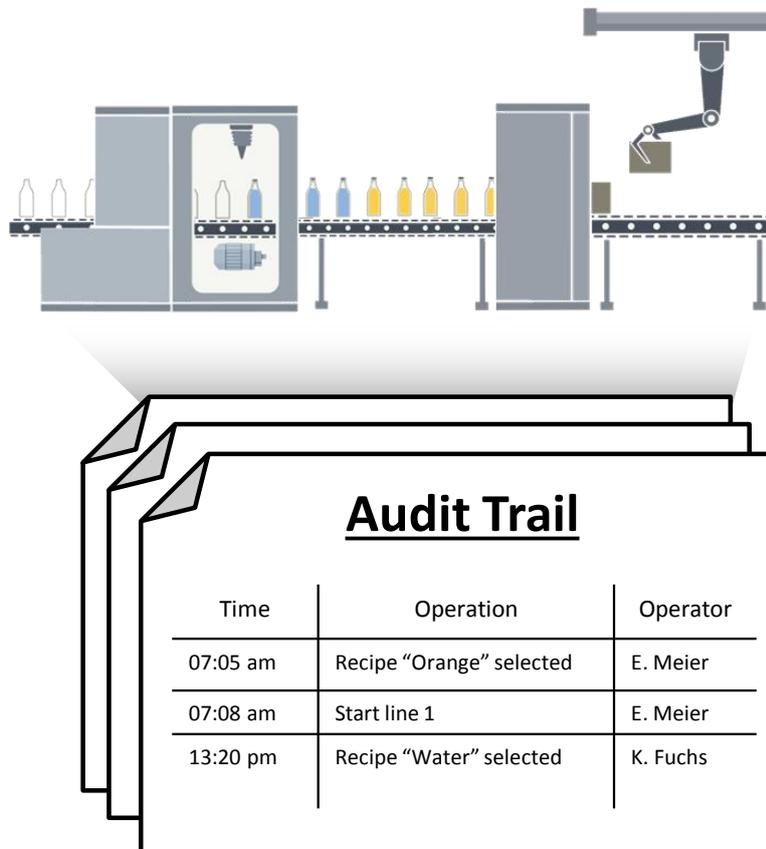
2 Solution

2.1 Overview

Schematic layout

The figure below shows a schematic overview of the most important components of the solution:

Figure 2-1

Advantages

The solution presented here offers the following advantages:

- Time and cost savings
- Reducing the engineering effort
- Electronic recording of Audit Trails as opposed to paper documentation

Topics not covered by this application

This application example does not contain a description of:

- The basics of configuring with TIA Portal
- Basics of HMI configuration
- Comprehensive information on GMP

Basic knowledge of these topics is assumed.

2.2 Hardware and software components

2.2.1 Validity

This application is valid for the following versions:

- STEP 7 Professional V14
- WinCC Advanced V14
- SIMATIC Logon V1.5 SP 3
- SIMATIC WinCC Audit (TIA Portal)

2.2.2 Components used

The application example has been created with the following components:

Hardware components

Table 2-1

Component	Qty.	Article number	Note
CPU 1516-3 PN/DP	1	6ES7516-3AN01-0AB0	-
SIMATIC Memory Card 256 Mbyte	1	6ES7954-8LL02-0AA0	-
SIMATIC Comfort Panel TP1200	1	6AV2124-0MC01-0AX0	Alternatively, other Comfort Panel can also be used (requires device exchange)
Industrial PC SIMATIC IPC 547E	1	6AG4104-3….-….	Alternatively, other IPCs can also be used (requires device exchange)

Software components

Table 2-2

Component	Qty.	Article number	Note
STEP 7 Professional V14 Upd 1	1	6ES7822-1A.04-0YA5	-
WinCC Advanced V14 Upd 1 (Engineering)	1	6AV2102-0AA04-0A.5	-
WinCC Runtime Advanced 128 PowerTags V14 Upd 1	1	6AV2104-0BA04-0A.0	-
SIMATIC Logon V1.5 SP3 Upd 3	1	6ES7658-7B…-….	optional
SIMATIC Logon Remote Access for 3 Clients		6ES7658-7B.00-2YB0	optional
SIMATIC WinCC Audit for SIMATIC Comfort/Mobile Panels	1	6AV2107-0RP00-0B.0	-
SIMATIC WinCC Audit for Runtime Advanced	1	6AV2107-0RA00-0B.0	-
AuditViewer V7.0 SP3	1		-

3 Basics

3.1 Good Manufacturing Practice (GMP)

GMP stands for "Good Manufacturing Practice". The term refers to certain guidelines designed to ensure the quality of production of, e.g. pharmaceuticals, substances, cosmetics and food. Next to production, the GMP guidelines also demand high quality standards on processing, packaging and storage. If the GMP guidelines are not complied with, companies are not allowed to manufacture the respective products.

The most important regulatory basis is the Title 21 CFR Part 11 of the US Food and Drug Administration on electronic data recording and electronic signatures. Further country-specific and industry-specific regulations also apply.

Note	Before implementing a project, observe the respective country- and industry-specific laws and regulations concerning GMP.

3.2 WinCC Audit (TIA Portal)

WinCC Audit (TIA Portal) is an option package of WinCC (TIA Portal). This gives you extended functions of WinCC (TIA Portal) Engineerings, whereby you are able to ensure the GMP compliance of your project.

Note	A detailed description on the WinCC Audit functions can be found on the websites about GMP validation (see link) under the section "GMP Engineering Manuals" Good Manufacturing Practice

3.2.1 Function extension with WinCC Audit

If you activate the WinCC Audit (TIA Portal) option, the following additional functions will be made available:

- Archive Audit Trail
- Audit Trail Protocol for printing archived changes
- System function "Notify User Action"
- "GMP relevant" markings for tags and recipes possible
- Electronic signature
- Archiving tags and messages with checksum

3.2.2 Supported HMI control panels

The WinCC Audit (TIA Portal) option is available for the following control panels:

- TP277
- OP277
- MP277
- MP377
- Comfort Panels
- Mobile Panels 277 and Mobile Panel 2nd Generation
- WinCC Runtime Advanced

3.2.3 Licensing

In order to be able to use the functions of WinCC Audit (TIA Portal) in the Runtime of the operator panel, you need to license each used HMI control panel individually. The following licenses are available for this purpose:

- SIMATIC WinCC Audit for SIMATIC Panels: 6AV2107-0RP00-0B.0
- SIMATIC WinCC Audit for Runtime Advanced: 6AV2107-0RA00-0B.0

How to license the different HMI control panels is described in Chapter 4.2 .

3.2.4 Restrictions

If you use WinCC Audit (TIA Portal), some functions and configurations will be restricted. Further information can be found in the manual "WinCC Advanced V14 – Options" in chapter 1.4.2 "Restrictions (Panels, RT Advanced)".

The manual can be found in the appendix of the entry "SIMATIC WinCC Advanced V14":

https://support.industry.siemens.com/cs/ww/en/view/109742297

3.3 User administration in GMP

The user administration plays a central role for a GMP-compliant manufacturing process. In the pharmaceutical industry, for example, it must be ensured that recipe data can only be changed by authorized personnel.

Depending on the plant concept, you can implement the following two types of user administration:

- Local user administration
- Central user administration (SIMATIC Logon)

A detailed description, as well as the pros and cons of both concepts, are described in the application example "User Administration in WinCC (TIA Portal)":

https://support.industry.siemens.com/cs/ww/en/view/109738532

In this application example, you can furthermore find detailed step-by-step instructions on how to realize a local or central user administration at the plant.

4 Configuration

Prerequisite

In this chapter, you can find all necessary configuration steps on how to implement a GMP-compliant configuration in WinCC. As a prerequisite, you already must have created a project with at least one of the supported HMI control panels (Chapter 3.2.2).

4.1 Activating GMP

To be able to use "Good Manufacturing Practice", you first need to activate it. The following table shows which steps are necessary for this.

Table 1-4

No.	Action
1.	Open the HMI control panel in the project navigation.
2.	• Open the Runtime settings of the HMI control panel (1). • In the context menu, select "GMP" ("Good Manufacturing Practice") (2). • Activate the checkbox "Configuration conforms to GMP") (3).
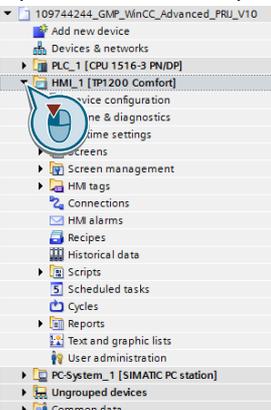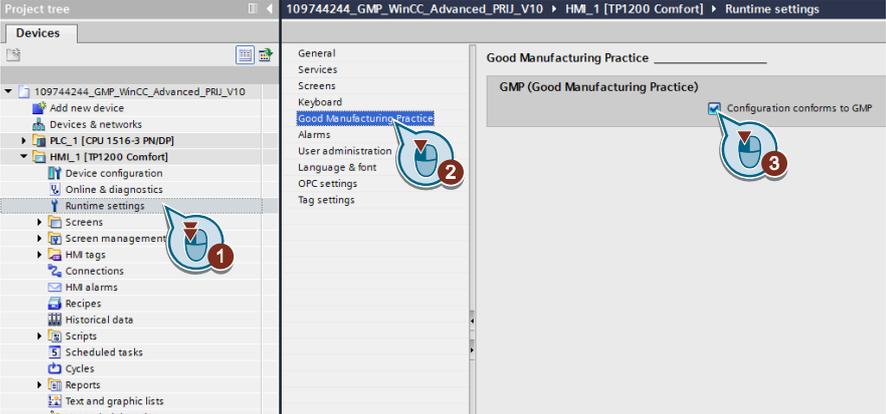
4.2 Licensing HMI control panel

WinCC Audit (TIA Portal) is an option package subject to licensing. This chapter shows you how to license the respective HMI control panels.

4.2.1 Licensing SIMATIC panels

Table 4-2

No.	Action
1.	• Right-click on the control panel you would like to license (1). • In the context menu, select "HMI Device maintenance" (2). • Then click on "Authorize/License" (3). The "Load licenses" dialog box opens.
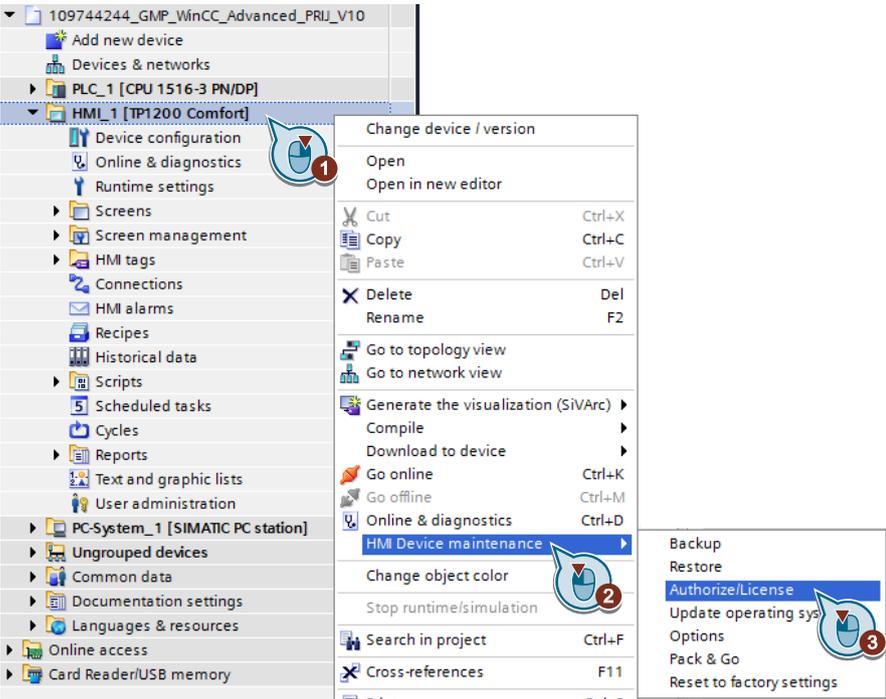
4.2 Licensing HMI control panel

No.	Action
2.	• Set the respective communication parameters (1). • Click on "Start search" (2). • Choose the control panel to be licensed (3). • Click on "Load" (4). The "Automation License Manager" opens.
3.	Under "My Computer" you can now find the HMI control panel to be licensed, together with the corresponding IP address.
4.	Select the license "WinCC Audit for SIMATIC Panel" on your PC and drag it to the "HMI_Panel".
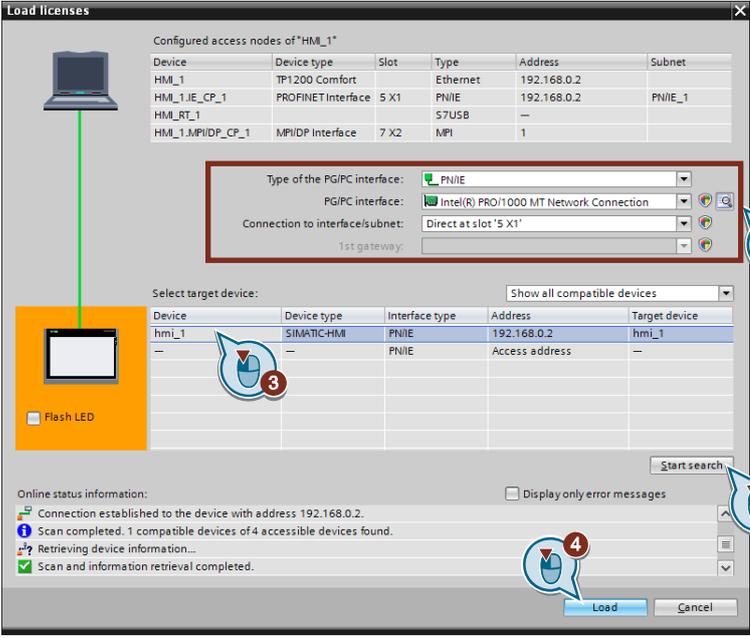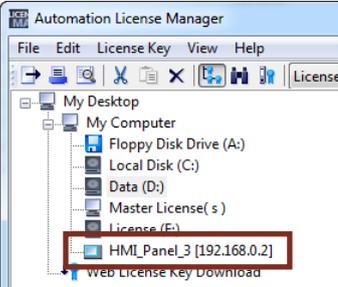
GMP
Entry ID: 109744244,   V1.0,   05/2017

11

No.	Action
5.	If you select the licensed SIMATIC Panel in the "Automation License Manager" now, all licenses that have been loaded to the SIMATIC Panel will be displayed. Licensing is complete and you can close the "Automation License Manager".
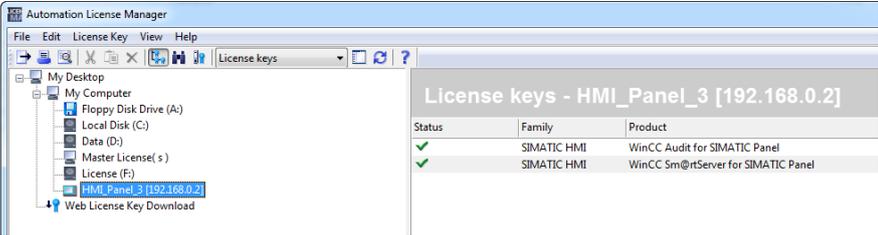
4.2.2 Licensing Runtime Advanced

If you have WinCC Runtime Advanced installed on your PC, the "Automation License Manager" will automatically be installed as well. Therefore, the license transfer works the same way as usual in SIMATIC STEP 7 (TIA Portal) or SIMATIC WinCC (TIA Portal).

Further information on licensing can be found in the manual of the "SIMATIC Automation License Manager":

https://support.industry.siemens.com/cs/ww/en/view/102770153/70701911051

4.3 Configuring function extensions

4.3.1 Creating Archive Audit Trail

Audit Trail as CSV file

As soon as you have checked the "Good Manufacturing Practice" option box, you can find the additional tab "Audit Trail" under "Historical data".

Table 4-3

No.	Action
1.	Select the "HMI_1" in the project navigation and double-click on "Historical data". In the work area, the archive editor opens.
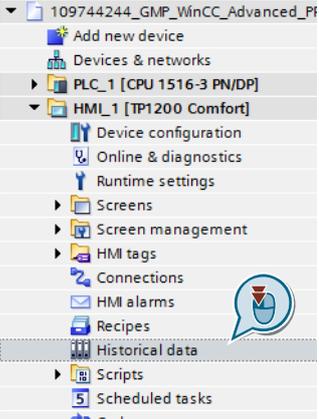
4.3 Configuring function extensions

No.	Action
2.	• Open the "Audit Trail" tab (1). • Mark the automatically created "Audit Trail" in the chart (2). • In the inspector window, adjust the settings of the Audit Trail (3). **Note:** Information on how to store an archive file from a panel onto a network computer can the found in the application example "Integrating HMI Control Panels in TCP/IP Networks and access to a NAS or to a shared Windows folder": https://support.industry.siemens.com/cs/ww/en/view/92346478
3.	In the area navigation under "Settings", you have the option to make further settings.
4.	**Optional** • In the inspector window, open the "Events" tab (1). • In the area navigation, click "Low free Space" (2). • Add the system function "ShowSystemAlarm" (3). • Enter a message text (4). It will be output as soon as the storage space on the medium falls below the configured minimum volume (from step 3).
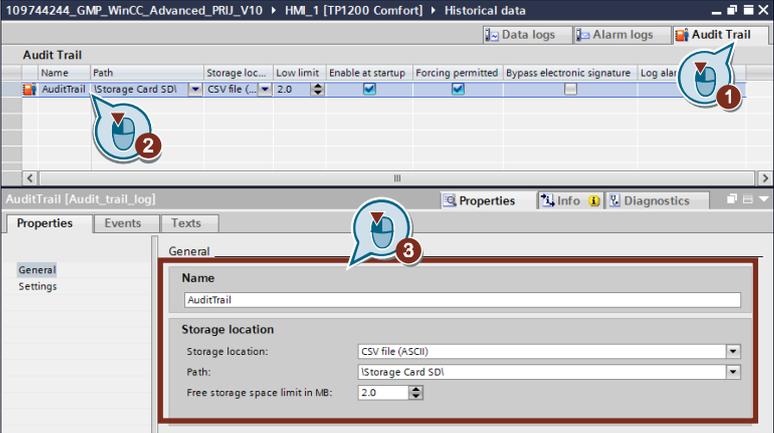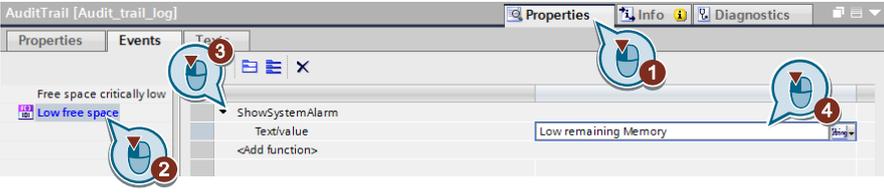
Note	A precise description of the individual parameters can be found in the manual "WinCC Advanced V14 - Options" in chapter 1.2.3 "Parameters for Audit Trail", as well as in chapter 1.2.8 "Archiving concept of Audit Trail".

Audit Trail as RDB file

If you store an Audit Trail as RDB file and want to view it via the WinCC Audit Viewer at a later time, the following settings have to be made.

Table 4-4

No.	Action
1.	**Changing the logging language** • Open the "Runtime settings" of the control panel (1). • Under "Historical data", select "English (United States)" as "Logging language" (2).
2.	Open the Control Panel in Windows.
3.	**Changing the Windows format** • Open the "Clock, Language and Region" category in the control panel (1). • Click on "Region and Language" (2). • Select "English (USA)" as format (3). • Confirm your selection with "OK" (4).
4.	Now, create the Audit Trail as described in Table 4-3.
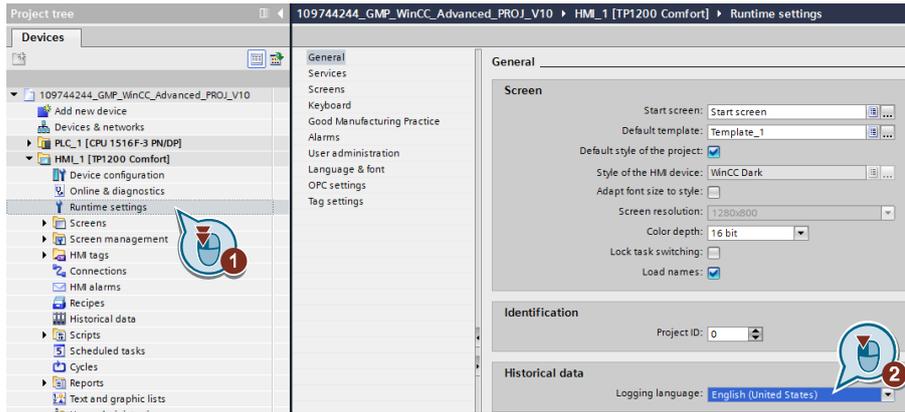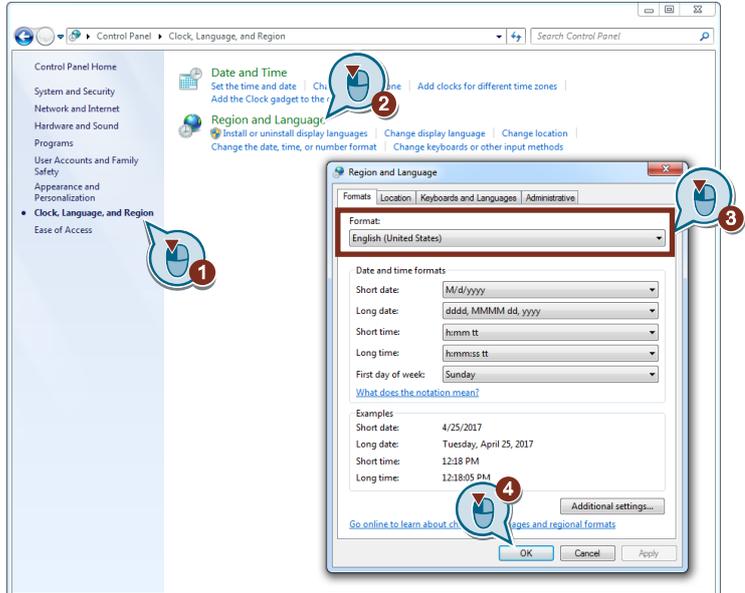
4.3.2 Recording tags

This chapter describes how to capture and record a manual change of the tag value in Audit Trail. This assumes, that GMP relevant tags have already been created.

Table 4-5

No.	Action

1.	In the project navigation, open the standard tag table of the HMI control panel.
	
	▼ ☐ 109744244_GMP_WinCC_Advanced_PROJ_....
	 🔹 Add new device
	 🔹 Devices & networks
	 ▶ 🔲 PLC_1 [CPU 1516F-3 PN/DP]
	 ▼ 🔲 HMI_1 [TP1200 Comfort]
	  📐 Device configuration
	  🔹 Online & diagnostics
	  🔹 Runtime settings
	  ▶ 📁 Screens
	  ▶ 🔲 Screen management
	  ▼ 📁 HMI tags
	   🔹 Show all tags
	   🔹 Add new tag table
	   🔹 Default tag table [44]
	  🔹 Connections
	  ✉ HMI alarms
	  🔹 Recipes
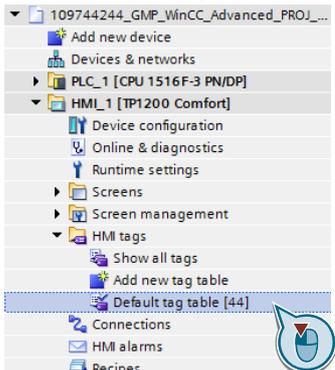
2.	• In the tag table, mark the tag relevant for GMP (1). • In the "Inspector window" open "properties" (2). • In the area navigation, click on "Good Manufacturing Practice" (3).

4.3 Configuring function extensions

No.	Action
3.	• Activate the "GMP relevant" checkbox (1). • Open the drop-down list to select the confirmation type (2). • Select the confirmation type "Acknowledgment" (3). **Optional** Activate the checkbox "Comment required", in case you want to capture an additional comment during the change of the tag value in the Audit Trail.
4.	Save your project and load it to your control panel.
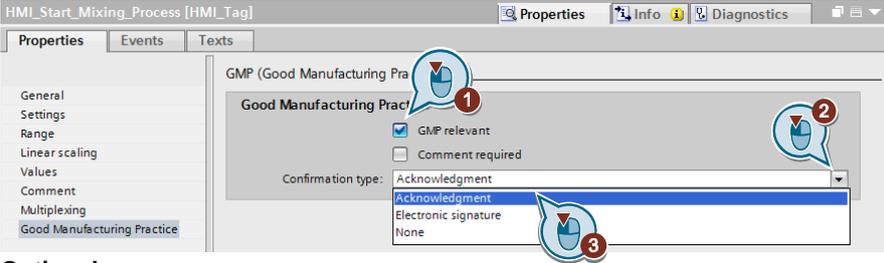
Confirmation type "Electronic signature"

Depending on the confirmation type, a dialog in Runtime for entering the configured information is displayed. The following figure exemplifies the confirmation dialog, if you select "Electronic signature" and "Commentary required".

Figure 4-1
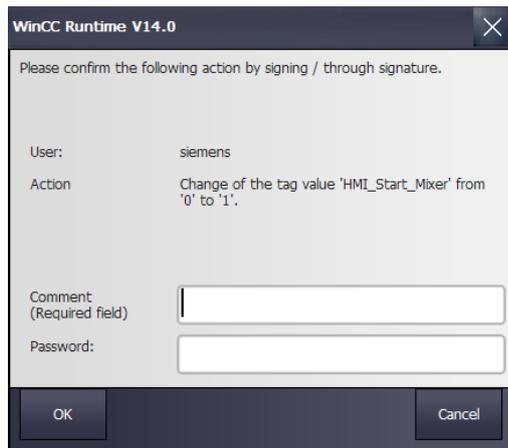
Upon selecting "Electronic signature", a logged on user needs to confirm the operator control action with his password. The operator control action and the authorized user are both captured in the Audit Trail.

If the user enters the wrong password, the operator control action will not be executed.

| Note | Electronic signatures can also be realized centrally with SIMATIC Logon and its included software component, SIMATIC Electronic Signature.

Further information is available in the manual of von "SIMATIC Logon V1.5.3" in the chapter "What is SIMATIC Electronic Signature".

https://support.industry.siemens.com/cs/ww/en/view/109738714/3870564107 |

4.3 Configuring function extensions

4.3.3 Recording recipes

This chapter describes how to capture and record a change of the recipe data in Audit Trail. This assumes, that recipes complying with requirements of a GMP-compliant configuration, have already been created.

General information on the recipes can the found in the manual of "WinCC Advanced V14" in the chapter "Working with recipes (Basic Panels, Panels, RT Advanced)":

https://support.industry.siemens.com/cs/ww/en/view/109742297/91389190283

Table 4-6

No.	Action
1.	In the project navigation, open the "Recipes" of the HMI control panel.
2.	• Select the "ColorSelection" recipe (1). • In the "Inspector window" open "properties" (2). • In the area navigation, click on "Good Manufacturing Practice" (3).
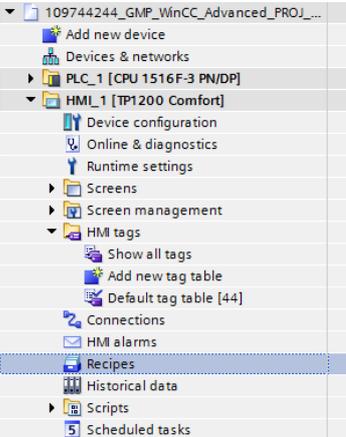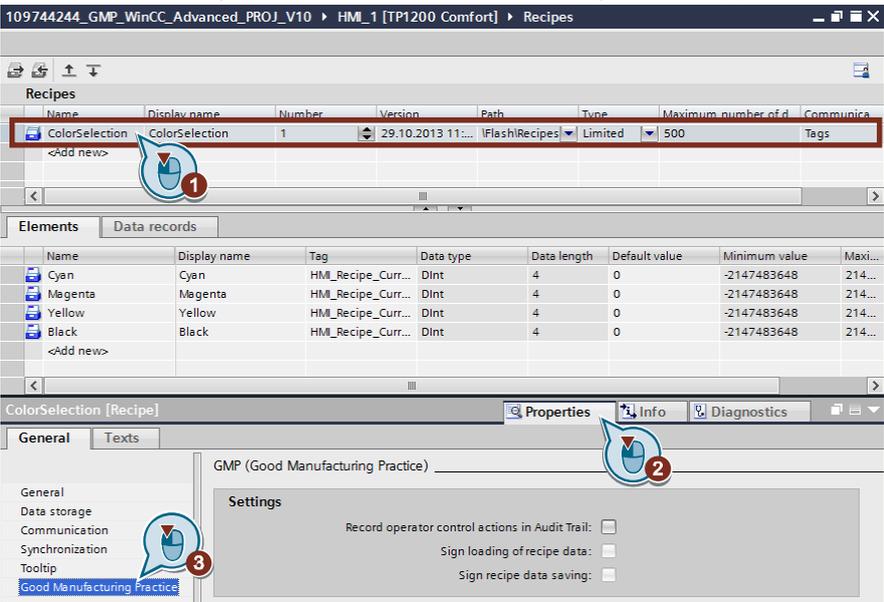
4.3 Configuring function extensions

No.	Action
3.	Activate the checkbox "Record operator control actions in Audit Trail".
4.	The checkboxes for sign loading and saving of recipe data are unlocked.
5.	**Optional** Activate the checkboxes "Sign loading of recipe data" and "Sign recipe data saving".
6.	Save your project and load the configuration to the HMI control panel.
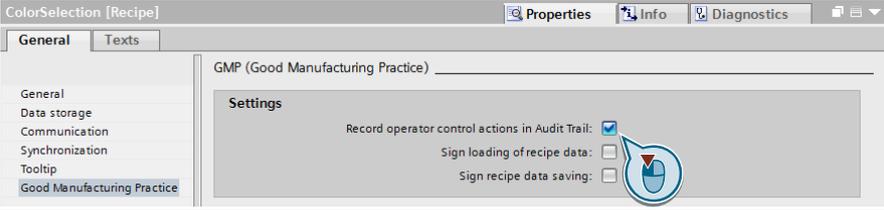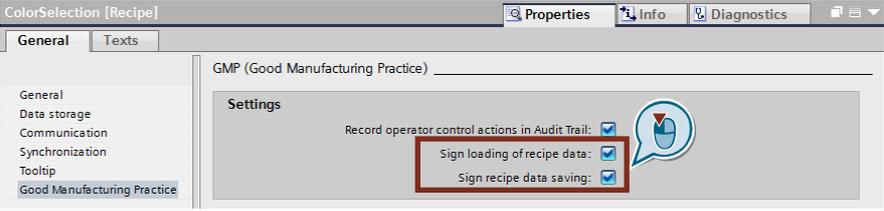
Behavior in the Runtime

If you change or load a recipe in Runtime, a message (depending on the selection) will be displayed to confirm the user action.

Figure 2-3
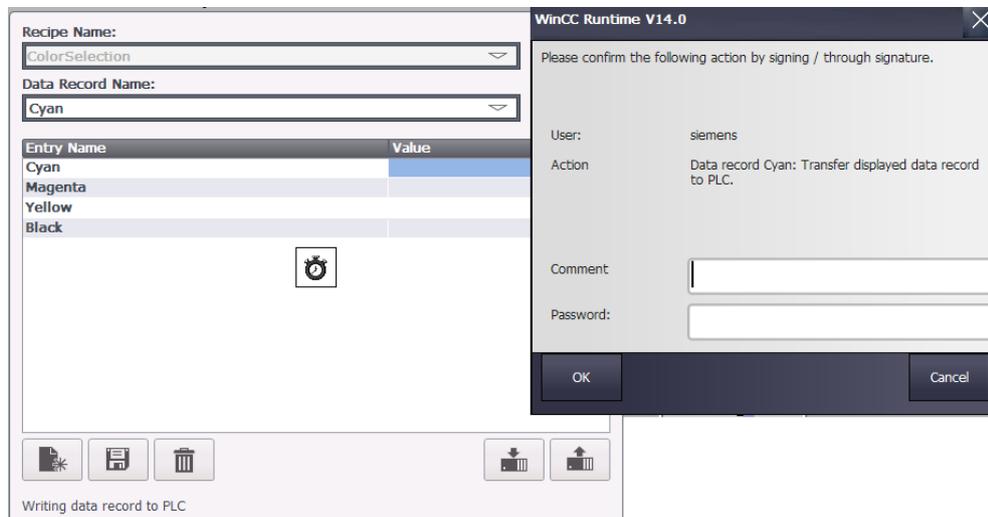
4.3.4 Recording user actions

Automatic recording

The following functions are automatically captured in Audit Trail in Runtime and recorded:

- user administration
  - User logon and logoff
  - Import user administration
- Message system
  - Messages acknowledged by the user
  - Incorrect acknowledgment attempts
- Archive
  - Start and stop archive
  - Open and close archive
  - Delete and copy archive
  - Start sequence archive
  - Long-time archive

Manual recording

Next to automatic recording, you can record user actions manually. For this purpose, the system function "NotifyUserAction" is available to you.

The following table shows how to configure a manual recording, using the example of a button. This assumes that there are already configured screens and buttons.

Table 4-7

No.	Action
1.	Open the directory "Screens" in the project navigation and open the screen with the button, to which you would like to add a manual recording. In this application example "Start screen".

No.	Action
2.	• Select the "Button" (1). • In the Inspector window, click "Properties > Events" (2). • In the area navigation, click "Release" (3).
3.	• Add the "NotifyUserAction" system function to the button (1). • For the parameters "Confirmation type" and "Mandatory commenting", select the corresponding settings from the drop-down list. (2)
4.	Fill in the category, the object name and the description that are to be entered in the Audit Trail. A precise description of the individual parameters can be found in the manual "WinCC Advanced V14" in chapter "NotifyUserAction (Panels, RT Advanced)": https://support.industry.siemens.com/cs/ww/en/view/109742297/69070035211
5.	Save your project and load the configuration to the HMI control panel.
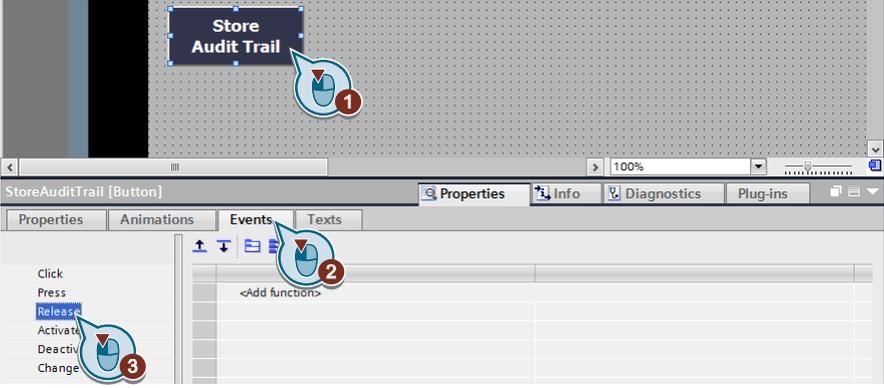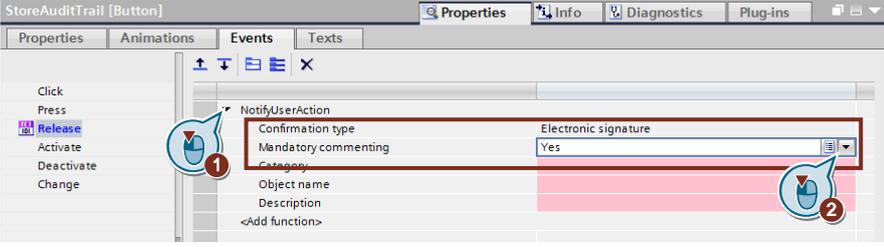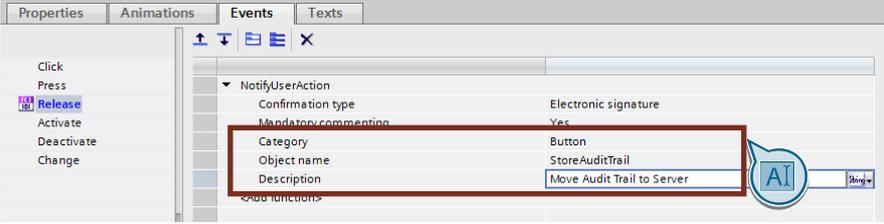
4.3.5 Recording system functions

Depending on the control panel and options used, the use of system functions is restricted.

In connection with WinCC Audit (TIA Portal), some system functions are recorded in Audit Trail. For further system functions, an electronic signature may be required.

Further information on system functions that are GMP-relevant can be found in the manual "WinCC Advanced V14 – Options" in chapter 1.3.4 "Recording system functions (Panels, RT Advanced)".

4.4 Evaluating Audit Trail

4.4.1 Transferring Audit Trail (Panels)

If you have selected the SD card of the panel as storage location for Audit Trail, you first need to transfer the Audit Trail to a PC in order to be able to view it afterwards.

In this regard, by using the system function "ArchiveProtocolData", you can move the Audit Trail to a connected network computer. During this, you need to observe the following steps:

1. Close all archives (System function "CloseAllLogs")
2. Then move the archive (System function "ArchiveLogFile")
3. Open all archives again (System function "OpenAllLogs").

Note   With the system function "CloseAllLogs", archiving is continued in the background and the data are buffered. As soon as the system function "OpenAllLogs" is executed, the buffered process data are entered into the corresponding archive.

Figure 4-4
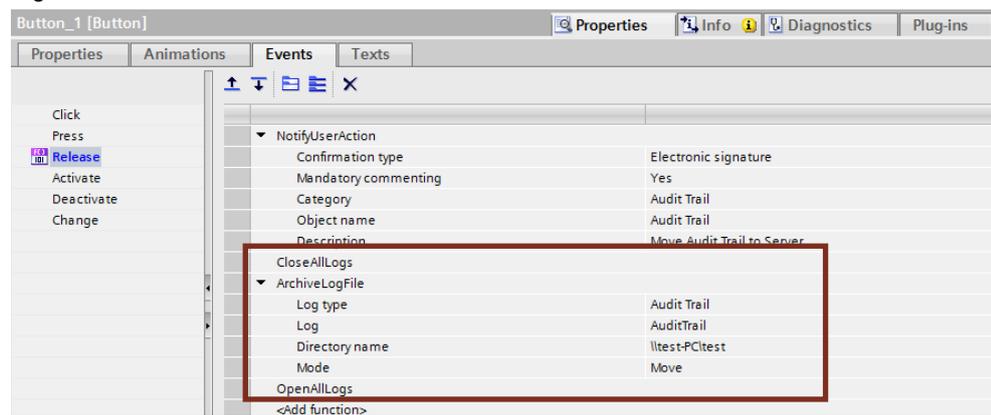
Further information on the system function can the found in the manual of "WinCC Advanced V14" in the chapter "ArchiveLogFile (Panels, RT Advanced)":

https://support.industry.siemens.com/cs/ww/en/view/109742297/76202771339

4.4.2 Viewing Audit Trail

The following table shows you how to evaluate Audit Trail via "SIMATIC Audit Viewer".

Note	The "SIMATIC Audit Viewer" can be found on the installation CD of WinCC Advanced V14 in the "Support" folder.

Prerequisite

To view the Audit Trail, you need to tranfer it from the control panel to a PC.

Note	To be able to open an RBD file with WinCC Audit Viewer, you need to switch the Windows format to "English (USA)" in the Windows Control Panel, see Table 4-4 Step 3.

Table 4-8

No.	Action
5.	Open "All Programs > Siemens Automation > Options and Tools > HMI Tools" and click on "WinCC Audit Viewer".
6.	In "SIMATIC Audit Viewer", click on "Select Database". The "SQL Server / Audit Trail Browser" opens.
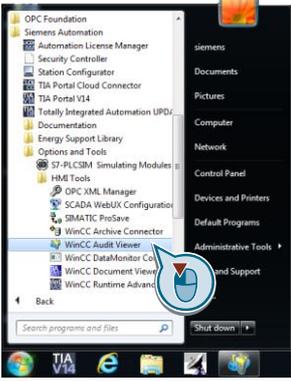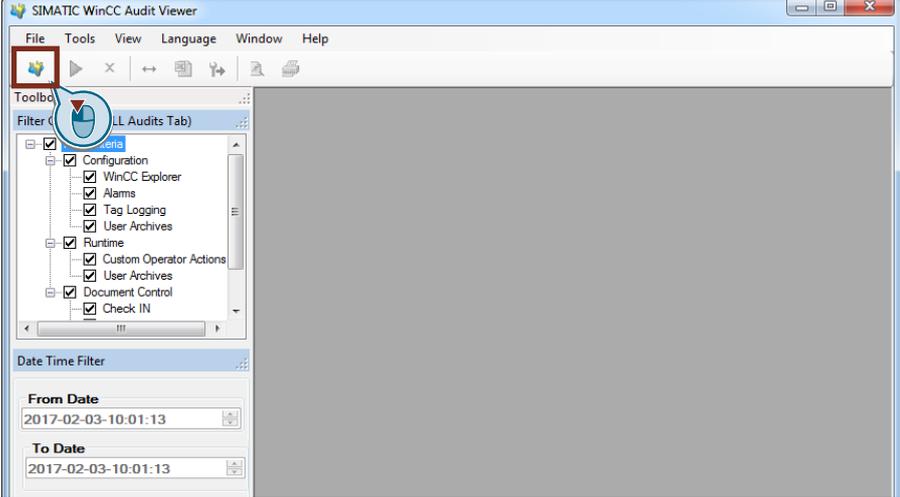
4.4 Evaluating Audit Trail

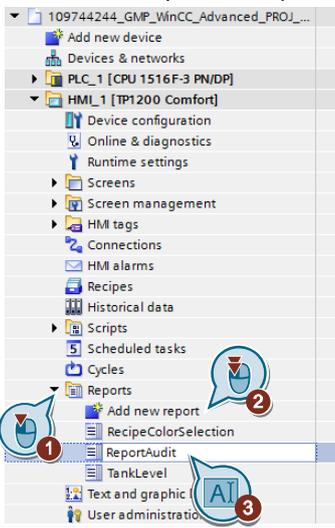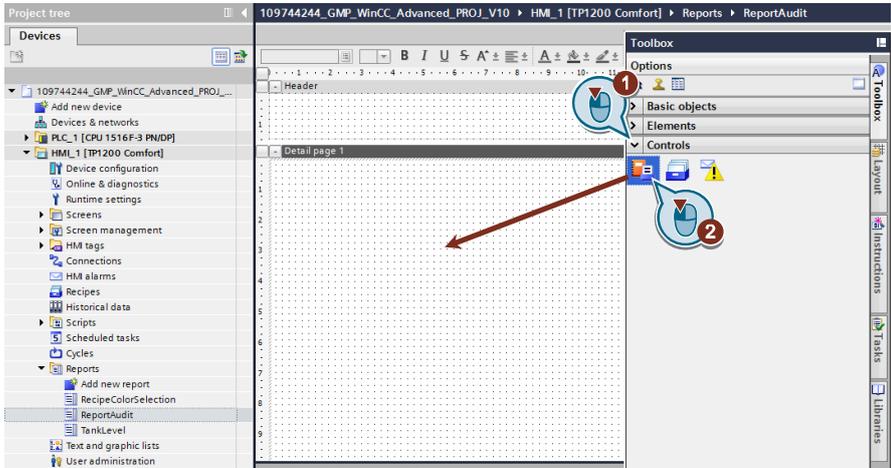| No.	Action
7.	• Click on "Audit Trail / Backups /Archives / Data records" to select an Audit Trail (1). • Navigate to the storage location of the Audit Trail and select it (2). • Click on "Open" (3). In "SQL Server / Audit Trail Browser", the selected Audit Trail appears.
8.	Then click on "OK" in "SQL Server / Audit Trail Browser" to acknowledge the selection.
9.	In "SIMATIC Audit Viewer", all recorded user actions of the Audit Trail are displayed. The "Data Validity Indicator" shows you, whether the Audit Trail file has been modified after the creation.
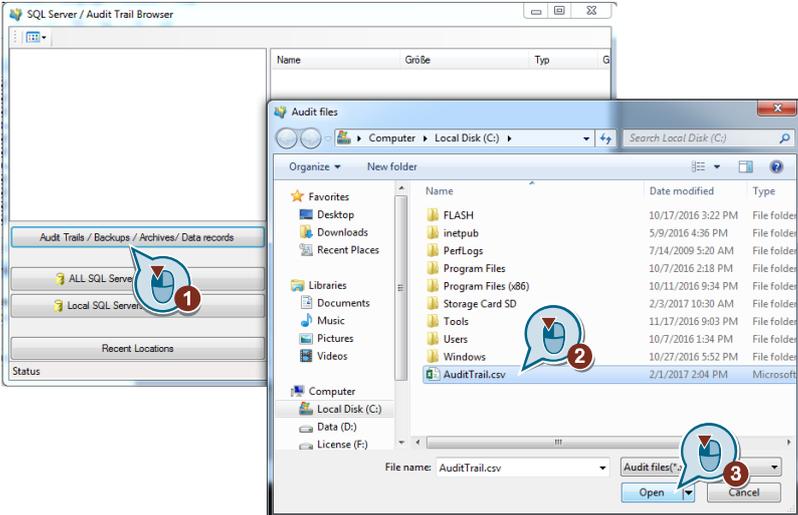
4.4.3 Recording Audit Trail

In WinCC (TIA Portal), reports can be generated automatically. Therefore, you can also document and archive the Audit Trail. This chapter shows you how to record the Audit Trail in WinCC Advanced.

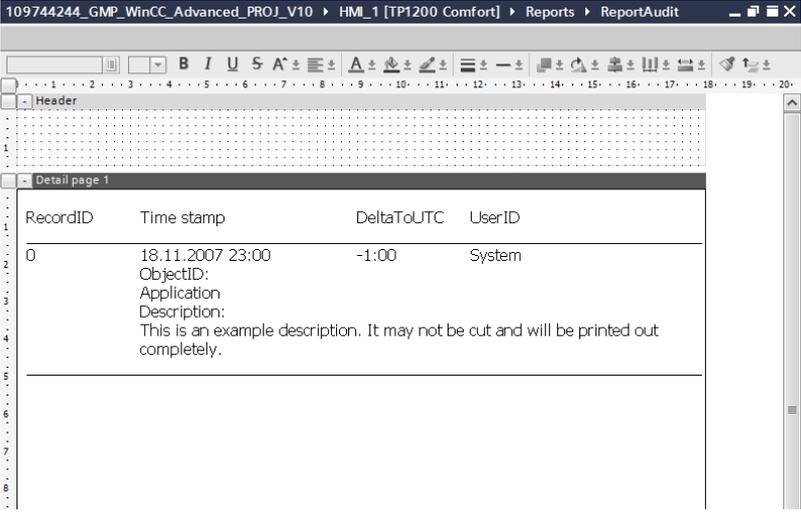| Note	General information on reports in WinCC (TIA Portal) can the found in the manual of "WinCC Advanced V14" in the chapter "Working with reports (Panels, RT Advanced)": https://support.industry.siemens.com/cs/ww/en/view/109742297/91449612811

Table 4-9

No.	Action
1.	• Open the "Reports" folder in the HMI control panel project navigation (1). • Add a new report (2). • Rename the report to "ReportAudit" (3).
2.	• In the work area, open the "Controls" task card and open the "Controls" tab (1). • Select the "Print audit trail" control and drag it into the "Detail page" area via Drag & Drop (2).

4.4 Evaluating Audit Trail

No.	Action
3.	**Optional** Adjust the header and footer line according to your specifications. Further information can be found in the manual "WinCC Advanced V14" in the chapter "Objects and reports (Panels, RT Advanced)": https://support.industry.siemens.com/cs/ww/en/view/109742297/74775254539
4.	The Archive Trail Protocol has now been configured.
5.	Save your project.

5 Links & Literature

Table 5-1

	Topic
\1\	Siemens Industry Online Support https://support.industry.siemens.com
\2\	Download page of the entry https://support.industry.siemens.com/cs/ww/en/view/109744244
\3\	Manual - SIMATIC WinCC Advanced V14 https://support.industry.siemens.com/cs/ww/en/view/109742297
\4\	Manual - SIMATIC Automation License Manager https://support.industry.siemens.com/cs/ww/en/view/102770153
\5\	Manual – SIMATIC Logon V1.5.3 https://support.industry.siemens.com/cs/ww/en/view/109738714
\6\	Application example - User Administration in WinCC (TIA Portal) https://support.industry.siemens.com/cs/ww/en/view/109738532
\7\	Application example - Integrating HMI Control Panels in TCP/IP Networks and access to a NAS or to a shared Windows folder https://support.industry.siemens.com/cs/ww/en/view/92346478

6 History

Table 1-2

Version	Date	Modifications
V1.0	05/2017	First version