

KREO HMI TUTORIAL FDA – CFR21

Tutorial dedicated to the development of an application FDA cfr21 part 11 compliant

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Introduction

This document provides a brief description of FDA CFR21 part 11 and the procedures in order to develop a KREO HMI application compliant with this regulation.

The purpose is to have the legal equivalence of electronic documents (digital records and electronic signature) compared to traditional paper ones.

In order to be compliant with the CFR21 Part 11 standard, it is necessary to ensure that the recorded data always refer to the operator (Electronic Signature) and, in addition, specific policies are implemented that make it impossible to modify the electronical recorded data.

The regulation

FDA (Food and Drug Administration) is the U.S. agency responsible for controlling and regulating production processes in the food, pharmaceutical, and chemical industries.

It is not only American companies that are subject to its control, but all those that operate in the US and export there.

CFR 21 is a regulation issued by the FDA in 1997 in collaboration with the U.S. government regarding the use of technology in specific manufacturing process procedures.Part 11 is divided into two main sections:

- Electronic Archives
- Electronic Signatures

CFR 21 Part 11 regulates the way in which data stored in electronic support is handled and the related security issues.

The objective of CFR 21 Part 11 is therefore to verify that all procedures adopted in the process comply with the requirements.

CFR 21 Part 11 of the FDA is also a guarantee tool for companies such as ESA SPA, which want to offer their customers high and consistent quality and safety standards in their products.



How to do:

 In order to enable the FDA functionalities it is necessary to open the Configuration – FDA section, select the Enable option and then insert the general settings:

File Ec	dit Action	Tools Help						
TESTMANUALE3	<u> </u>	Info Network FD/	A	Security	Behaviour	Database	SystemFonts	OPC Server
EW107client2	~	🗸 Enable FDA						
Configuration			_					
Pages	(1)	Password length: Min 8 Max 16			Min symbols 0			
Popups	(1)	Min latters 1			Will symbols			
C Sequences	(1)	With rectors 1						
🖉 Tags	(1)	Max number of retries	5					
Alarms	(O)	Signature length Min	4	Max 16				
曼 Datalogs	(O)	Max use of same password in last 10	1					
Recipes	(O)	Max number of days before password expires	365					
O- Scripts	(O)	Days before password expiration warning message	10					
Ö- Javascripts	(O)	Force replace password after the first login						
Ö- Gadgets	(O)							
① Timers	(0)	✓ Auto start □ Can disable						
💮 Tasks	(0)	Max log size (Mb) 20			Max records 100000	0		
Pipelines	(0)	Log path						
	~							



- 2) Create the project pages and enable or not enable FDA functionality on the different project objects. In each configurable function of the objects you will have the below options:
 - enabling FDA tracking
 - additional notes
 - signature/comment required at RUNTIME by interacting with the object itself

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All these options are available on the function settings of each project object and the visualization can be enabled in the dedicated system widget named Events Log. (see the below image)

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Index	Time	Code	Object	User	FDA Note	TagCurrentValue	TagNewValue	ElectronicSign	FDA Comment		•	
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											TrendXY	
										-	Trend	
											ActiveAlarms	
				-						—	AlarmsHistory	
											AlarmsStats	
											RecipeEdit	
			· · · · · · · · · · · · · · · · · · ·								RecipeList	
##	###	Volume (litres	5)								CustomFile	
											EventsLog	
	login	logout	Send Recipe			export FDA						
											FrameHtml	



3) Now considering a typica RUNTIME page, the interaction with the different objects to be FDA recorded (numeric field, login, logout, recipe download, language change,...) will be displayed the log below:

	lime	Code	Object	User	FDA Note	TagCurrentValue	TagNewValue	ElectronicSign	FDA Comment
	17:24:29 30/6/2021	System / Startup							
1	17:24:34 30/6/2021	Users / Logout		defaultuser					
2	17:24:34 30/6/2021	Users / Login		defaultuser		-			
3	17:25:13 30/6/2021	UI / Input confirmed	w470607	defaultuser	ChangingTag	0	23	Adam Smith	change volume
1	17:25:33 30/6/2021	UI / Button pressed	w5306011	defaultuser	LoginAccess			Admin1	log1
-	1/:25:33 30/6/2021	Users / Login	50004047	Admin					
-	1/:26:35 30/6/2021	UI / Button pressed	w5303401/	Admin	Recipe download			P. Rossi	recl
/	1/:26:59 30/6/2021	UI / Input entered	w53050015	Admin	ChangeLanguag				lang
b	17:27:18 50/6/2021	01 / button pressed	W5207504	Admin				me	expi



4) At each click on the field/key/image object you will get the input request for description and signature (if enabled in the project events):

Index	Time 17:24:29 30/6/2021	Code System / Startup	Object	User	FDA Note	TagCurrentValue	TagNewValue	ElectronicSign	FDA Comment	
1	17:24:34 30/6/2021	Users / Logout		defaultuser						
2	17:24:34 30/6/2021	Users / Login		defaultuser						
3	17:25:13 30/6/2021	UI / Input confirmed	w470607	defaultuser	ChangingTag	0	23	Adam Smith	change volume	
4	17:25:33 30/6/2021	UI / Button pressed	w					Admin1	log1	
5	17:25:33 30/6/2021	Users / Login						D. D. s.si		
7	17:26:35 30/6/2021	UI / Button pressed	W					P. ROSSI	lang	
8	17:27:18 30/6/2021	UL / Button pressed	W	Description				me	evn1	_
	23 Volur	ne (litres)		Cancel		OK				
4				Calicel		UK				
	login log	gout Send	Recipe			export FDA				



5) The same log can be exported in PDF / CSV format through the function: FDATracingExport. Below is an example of the result:

FDA.pdf - A	dobe Acrob	at Reader DC (32-bit)				
File Modifica	Vista F	irma Finestra Aiuto				
Home	Strumen	ti FDA.pdf ×				
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	File T	ype RUNTIME_EVE	NTS_EXPORT			
	Static	on Name EW410N_MAXV	VELL			
	Proje	ct Id testMANUALE				
	FW V	ersion 200				
	Creat	tion Date 30-06-2021				
	Creat	tion Time 17:27:18				
	Id	Time	Module/Action	Object		
		User	Signature	Note	Comment	
			•			
	1	30-06-2021 17:24:29.854	System - Startup			
	2	30-06-2021 17:24:34.921	Users - Logout			
		defaultuser				
•	3	30-06-2021 17:24:34.922	Users - Login			
		defaultuser				
	4	30-06-2021 17:25:13.754	UI - Input confirmed	w470607		
		defaultuser	Adam Smith	ChangingTag	change volume	
	5	30-06-2021 17:25:33.086	UI - Button pressed	w5306011		
		defaultuser	Admin1	LoginAccess	log1	
	6	30-06-2021 17:25:33.159	Users - Login			
		Admin				
	7	30-06-2021 17:26:35.973	UI - Button pressed	w53034017		
		Admin	P. Rossi	Recipe download	rec1	
	8	30-06-2021 17:26:59.260	UI - Input entered	w53050015		
		Admin		ChangeLanguage	lang	
	9	30-06-2021 17:27:18.293	UI - Button pressed	w5207504	·	
		Admin	me	ExportingFDA	exp1	



The FDA events:

Events		>>
OnStart	None	
OnFdaError	None	
OnActivityOn	None	ø
OnActivityOff	None	ø
OnStop	None	ø
OnError	None	ø
OnAnyUserLogin	None	ø
OnAnyUserLogout	None	ø
OnAnyUserLoginError	None	ø
OnAnyUserInfoChanged	None	
OnAnyUserCreated	None	ø
OnAnyUserDeleted	None	ø
OnAnyUserLocked	None	ø
OnAnyUserUnlocked	None	ø
OnUsersReset	None	



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