

FDA – 21 CFR PART 11 COMPLIANCE GUIDE



Using Honeywell HCiR series to create 21 CFR Part 11 FDA compliant Application: Electronic Records & Signatures

Honeywell Modular system solution “Controller + HMI” are an optimized and outstanding solution for Pharmaceutical and Life Science manufacturers requiring a cost-effective system that is fully compliant with 21 CFR Part 11 FDA.

Honeywell HCiR series can reach to this application programming Environment, HCiR allow the system to be validated to the 21 CFR Part 11 regulations by featuring functions and features that enable.

USER MANAGEMENT FUNCTIONALITIES:

- Password protected individual unique user account.
- Password complexity
- Configure a character count for password with Flexibility
- Configurable trials to modify password for user accounts

- Password validity
- Multiple password level for each User Authority

AUDIT TRAIL (TRACKING):

- Non-editable Audit Trail Data Format
- The time-stamp of the modification of the parameter value and user making the modification
- The Audit Trail records following details:
 - User creation
 - User Login/Logout
 - Configurable block by Administrator
 - Old value and new value of parameter change
 - The time-stamp of each event



SYSTEM DATA AND DATA BACKUP:

HCiR offers the basic connectivity for data exchange with Honeywell solutions, Experion, ControlEdge PLC, RTU, HC900, MasterLogic PLC by followings:

- Communication : Modbus
- Data file Transfer(FTP)
- USB, SD card










ELECTRONIC DATA RECORD AND STORAGE:

Review of the reports on the HMI Screen for Production, Alarms and event(trail). And also these data are available to save into SD card and user can copy/move the data to external memory(USB).

VIEW OF THE ALARM/EVENT DATA :

Detected alarm/event data is stored in internal memory. Capture and Printing: The captured screen is available to print out on-line thru a printer to support PCL format.

PRODUCT LINE

	1024 X 768	800 X 600	640 X 480T	WIDE	800 X 480
15"	 HCiRX15-TE-FD-NC			-	
12.1"	 HCiRX12-AE-FD-NC	 HCiRX12-TE-FD-NC		-	
10.4"		 HCiRX10-TE-FD-NC		10.1"	 HCiRW10-TE-FD-NC
8.4"		 HCiRX08-TE-FD-NC		7"	 HCiRW07-TE-FD-NC
5.6"			 HCiRX05-TE-FD-NC	5"	 HCiRW05-TE-FD-NC





COMPLIANT

Solutions to facilitate validation and reduce compliance costs with system self-documentation, electronic change management of control configuration, 21 CFR part 11 compliance and enforcement and verification of operating instructions.

EXPERIENCED

More than decades working with the world's leading pharma businesses, with specialists who bring a lifetime's experience in pharma.

FAST

A unique approach to project execution with LEAP™ project execution and technologies such as our Universal I/O remove risks and accelerate schedules.

SCALABLE

Delivering the most advanced technologies to the smallest and largest operations, with flexible solutions.

VIRTUAL READY

A Virtual Engineering Platform allows for virtualization and simulation of all DCS components for cost effective change implementation in a validated environment.

SECURE

Industry leading cyber security, access control and protection against message flooding and denial of service to ensure system availability.

For more information

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THE
FUTURE
IS
WHAT
WE
MAKE IT

Honeywell