Innowera and Compliance with CFR Title 21 – Part 11 - ID 2588

Revised: 2/13/2015
Applies to

- Process Runner
- Process Runner Excel Add-In

DESCRIPTION
Compliance with the FDA regulation on electronic records and electronic signatures (21 CFR Part 11).

SOLUTION

Innowera customers from industries regulated by the Food and Drug Administration (FDA) have asked about the compliance of Innowera software products with the FDA regulation on electronic records and electronic signatures (21 CFR Part 11). We want to help our customers use our products in accordance with the guidelines of all regulatory agencies, including the FDA.

Innowera data management software, Process Runner, when using with SAP, will ask you to login to SAP. You will have to enter User ID and password (if you are using SNC or SSO, it will automatically log you in the same way SAP GUI does). Process Runner uses that information with SAP to first authenticate the user. All subsequent communication with SAP is based on that User ID's authorization as set in that SAP system. There is NO backdoor or exception to this method as that is the only way SAP allows any other remote application to communicate and is the only way Process Runner communicates with SAP. This allows Process Runner full compliance of SAP security and authorization objects implemented for that specific user. If a user wants to further restrict and/or enhance SAP security centrally for all Process Runner users, the software can be used in conjunction with Innowera's Control Panel.

The extent to which a regulated company satisfies the FDA requirements does not depend exclusively on whether the Innowera software is compliant, but on how the regulated company uses Innowera as a tool in their research and their data management. Just as our customers are responsible for validating their processes and systems that use Process Runner, they are also ultimately responsible for adhering to the guidelines for electronic record keeping and electronic signatures. In other words, the use of Process Runner by itself does not make users compliant with this regulation. Providing audit trails and secure record keeping requires a system that satisfies all the components described by the Title 21 regulations, and specifically the Part 11 guideline.

Innowera recommends that our customers contact the FDA for the most up-to-date information on the Part 11 regulations. Both the current 21 CFR Part 11 document (the complete Code of Federal Regulations is revised annually) and the Guidance for Industry Part 11 document are available on the www.fda.gov website. Innowera also welcomes feedback from customers that may help to direct future software development of our products.

Web: www.innowera.com
E-mail: info@innowera.com

Note: Software validation may also be of interest to users in regulated industries. To learn more about the Innowera software validation process, software development life cycle, and other relevant information, clicks the link, Innowera Software Validation Kit, below.

RELATED DOCUMENTS

- CFR Title 21 Part 11
- Innowera Software Validation Kit

Web: www.innowera.com
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