Endress+Hauser

People for Process Automation

Supplier Declaration

Product: RunTime

Manufacturer: Endress+Hauser Optical Analysis, Inc.
371 Parkland Plaza
Ann Arbor MI 48103, USA

21 CFR Part 11/EU-Good Manufacturing Practices Annex 11
Electronic Record Electronic Signature (ERES)

Endress+Hauser Optical Analysis, Inc. (E+H OA) RunTime was developed according to Good Automated Manufacturing Practices (GAMP) and supports users with account and password protected actions. However, the standalone RunTime does not meet all the requirements of 21 CFR Part 11 and EU-Good Manufacturing Practices Annex 11. For full GMP qualification, RunTime must be executed in combination with integrated cGMP ready platforms such as process analytical technology (PAT) management software (Optimal's synTQ, Siemens's SIPAT) or direct DCS and data historian integrations. For example, current cGMP users of RunTime trigger all analyzer/probe calibrations and data collection from PAT software that has full audit trail and data archival capabilities. Thus, all user actions and resulting data are fully traceable and unmodifiable per compliance requirements.

Please note that the PAT platforms mentioned above are the only offerings preconfigured for implementing RunTime in cGMP. E+H OA has found that alternative solutions would require heavy use of SOPs to meet all the requirements of 21 CFR Part 11 and EU-Good Manufacturing Practices Annex 11.

USA, 08.08 2022
Endress+Hauser Optical
Analysis, Inc.

David Schiller
Head of Quality