Honeywell

Solution Note

Paperless Recording for FDA Regulated Processes with TrendView

Challenge

The benefits of paperless recorders in the process industries are well recognized. Usability, security and networking capabilities help cut workloads and transform data into actionable intelligence.

Features such as real time data acquisition, informational graphics, and the flexibility to store, export and share data improve analysis and make for better decisions. Recorders also significantly cut the burden of compliance, enabling automatic data acquisition and configurable reports.

In FDA regulated industries such as health-care, pharmaceutical, medical-manufacturing, medical-device, biotechnology and life-science, however, electronic records can only be used for compliance in lieu of paper records where strict requirements are met.

The FDA 21 CFR (Code of Federal Regulations) Part 11 code seeks to ensure the authenticity, integrity and confidentiality of paperless records. In "open systems", where access is not controlled, these require documents to be encrypted with appropriate digital signature standards used to ensure records' authenticity, integrity, and confidentiality. For "closed systems" where access is controlled, procedures and controls must ensure the following:

- Limitation of system access to authorized individuals
- Authority checks to prevent unauthorized system use
- Secure computer generated time-stamped audit trails
- Retrievable accurate copies of records
- Complete copies of records able to be generated in readable and electronic format for FDA auditing
- Previously recorded data is not obscured by changes.

Solution

Honeywell's TrendView paperless recorders, the eZtrend, Minitrend and Multitrend, offer easy-to-use, powerful solutions to comply with the requirements of FDA 21 CFR Part 11.

Users can measure, display, and store process and access data securely in accordance with the regulations. The recorders enable users to easily generate accurate and complete copies of records while providing comprehensive security:

- Data archived to an integral database
- Password management ensuring secure user access for up to 50 users
- Encrypted, secure data file protection to protect against data tampering
- A secure, time-stamped audit trail independently records the date and time of operator actions
- A secure download feature protects against unauthorized data access and transfers
- Tamper-proof seals and configuration lock-out protect against unauthorized recorder access

The Honeywell Advantage

Honeywell's Trendview recorders provide fully compliant records for more efficient FDA reviews and approvals of regulated products. Powerful features facilitate an easy set up and effective recording or continuous data or batch data.

An intuitive interface, simple maintenance, flexible networking and connectivity, and secure data ensure the benefits of paperless records in the most stringent regulatory environments.

It Matters. Learn how Honeywell solutions help solve what matters.

For More Information
To learn more about Honeywell's Paperless Recorders, visit our website www.honeywellprocess.com or contact your Honeywell distributor.

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