

Solution Note

Data Reliability: Capturing the Benefits of Electronic Data Recording



Challenge

For highly regulated businesses, such as those in the food, beverage, biotech and pharmaceutical industries, electronic data recording is invaluable. Maintaining or submitting electronic records brings a range of well-recognized benefits:

- Increased process data accuracy
- More efficient reviews and approvals for regulated products by the Food and Drug Administration (FDA).
- A streamlined manufacturing process
- Enhanced internal evaluation and quality control
- Reduced storage space requirements
- Better sharing and analysis of data.
- Easier, more efficient reporting.

Electronic data also brings a regulatory challenge, however. For example, in the United States, the FDA Title 21 Code of Federal Regulations Part 11 establishes the option for regulated businesses to keep and submit electronic records instead of paper records – but only if certain requirements are met.

These requirements differ according to whether the system is “open” – where access to it is not controlled by those responsible for the content of electronic records – or “closed”, where it is.

In open systems, documents must be encrypted and appropriate digital signature standards used to ensure records’ authenticity, integrity, and confidentiality. Closed systems must also meet a number of specific requirements:

- The system must limit access to authorized individuals
- Authority checks must prevent unauthorized use of the system
- Secure computer generated time-stamped audit trails are required
- It must be possible to retrieve accurate copies of records
- There should be capability to generate complete copies of records in human readable and electronic format for FDA auditing
- Changes must not obscure previously recorded data.

Again, the requirements are designed to ensure records’ authenticity, integrity and confidentiality is safeguarded at all times.

Solution

Honeywell’s eZtrend, Minitrend and Multitrend electronic paperless recorders have all been designed to meet rules for both open and closed systems, and can be validated according to FDA 21 CFR Part 11 rules.

The recorders generate accurate and complete copies of records in both electronic and human readable forms and ensure integrity and security in three ways:

- Providing “data security” for protection of records
- Providing “operational security” that limits access to authorized individuals
- Providing a secure, time-stamped audit trail to independently record the date and time of operator actions.

The result is electronic records that meet or exceed the stringent requirements of the rules.

Data security

All data is time and date stamped and saved in binary encrypted format, and the files cannot be changed without detection. Honeywell’s TrendManager Pro PC-based software, meanwhile, enables users to view the data in a human readable form.

The Trend Manager Pro package of tools is used for graphing continuous and batch data, analyzing and archiving data, configuring the paperless recorder products, setting up scheduled uploads of recorder data or acquiring data in real-time and exporting it to other software packages, such as Excel.

Operation security

The Extended Security System (ESS) firmware option for the eZtrend, Minitrend and Multitrend provides added data security features and traceability to document changes made to the recorder and the user, making them compliant with the FDA rules.

It includes a password system that cannot be disabled for up to fifty user IDs. An administrator can set permissions (individually, by group or by function), set level names, set password character requirements, establish password expiration times, the number of incorrect password entries before users are locked out, and other customizations.

Other features include electronic signatures and messages that can be entered manually (or chosen from a preconfigured list) and placed on the chart display. Messages over the network using Internet Explorer and remote viewing and control can also be added. All are password protected and included as part of the audit trail.

Audit Trails

A message (event) file captures items such as the user logging into the recorder, log-out actions, alarms and process events. It automatically time and date stamps each event to ensure a full audit trail.

Validation

End users are responsible for ensuring they comply with the regulations. To do so requires validation to establish documented evidence showing that the system will consistently operate in accordance with its specification. This includes validating the process to ensure it delivers a safe and effective product to market, and qualifying the equipment to ensure the system is set up and operates correctly in its operating environment.

To ensure proper installation of the paperless recorder components, Honeywell's IQ/OQ Protocol documentation establishes test procedures, specific responsibilities, and acceptance. These provide the evidence that hardware and software have been installed according to the manufacturer specification and configured in accordance with user requirements, and that the recorder operates in accordance with manufacturer and user specifications.

Honeywell can also provide Validation and Conformance Services to help establish evidence that systems perform as expected. This includes gap analysis for validation and 21CFR11 compliance.

The Honeywell Advantage

Built to comply, Honeywell's paperless recorders enable regulated industries to gain the benefits of electronic data collection and reporting while meeting the necessary regulatory requirements. They help measure, display and archive process data flexibly, securely and reliably so users can focus on driving improvements in the operation.



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For More Information

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SO-14-21-ENG
Nov 2015
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