

Solution Note

Compliance with Honeywell's Trendview Recorders



Challenge

Compliance means different things in different industries. Aerospace engineering, defense and related industries face stringent regulatory standards, among them accreditation through Nadcap (National Aerospace and Defense Contractors Accreditation Program). Companies involved in pharmaceutical and medical products manufacturing, meanwhile, must comply with a different set of regulations. What is common to both is the need to ensure process compliance.

Nadcap and AMS2750E

Nadcap audits provide independent certification of manufacturing processes and products to ensure suppliers meet industry-agreed standards that help drive continual improvement in special processes and products.

Aerospace Material Specification AMS2750E defines the pyrometric requirements for thermal processing equipment used for heat treatment. Covering temperature sensors, instrumentation, thermal processing equipment, system accuracy tests and temperature uniformity surveys, it ensures parts or raw materials are heat treated in accordance with the Nadcap standards.

Pharmaceuticals and GAMP

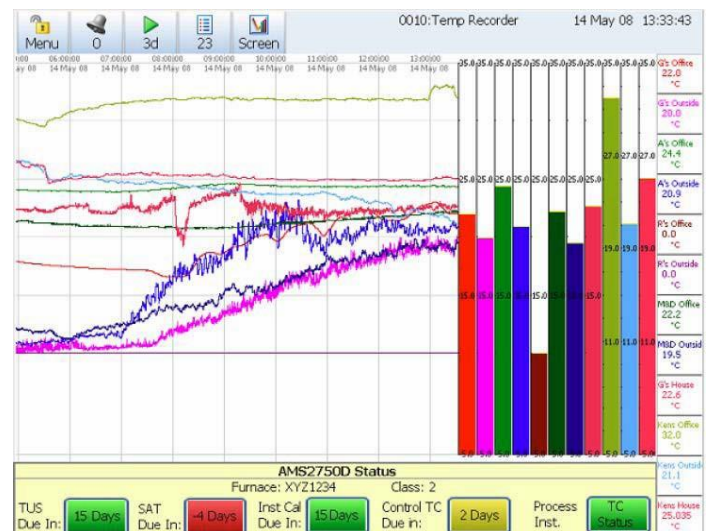
In the pharmaceutical industry, meanwhile, the Good Automated Manufacturing Practice (GAMP) guidelines and procedures help ensure that products meet the required quality standards. A key principal of GAMP is that quality must be built into each stage of the manufacturing process rather than achieved just through testing the final product. GAMP focuses on all aspects of production and standard operating procedures (SOPs) essential to processes that can affect the quality of the finished product.

Solution

In both these cases, recorders are an important part of the qualification of processes to achieve compliance with the required standards.

First, Honeywell's Trendview family of recorders offers two modes to help comply with AMS2750: Process mode to monitor calibration due dates and thermocouple usage conditions for process equipment; and, on the Multitrend recorder, Temperature Uniformity Mode, to use the recorder as a field test instrument for uniformity surveys, capturing data for the required reports. A range of features ease the burden of AMS2750E compliance:

- A Temperature Uniformity Summary screen for easy monitoring of each set point of the survey
- Monitoring and recording for overshoot, min-max, temperature differences and time duration for up to six survey set points
- Thermocouple usage monitoring
- Color coding for due date reporting of Temperature Uniformity Surveys (TUS), System Accuracy Tests (SAT) and instrument calibrations
- Automatic zoom when temperatures enter the uniformity range based on the defined furnace class
- Correction factor entry for each T/C along with T/C calibration and traceability information
- Secure report generation for documenting the TUS, including furnace diagram, equipment identification, and identification of survey personnel and process data.



Process Compliance and Validation

Honeywell's recorders also provide "thorough" IQ/OQ product qualification testing review. This follows the GAMP Supplier Guide used by suppliers of automated systems for the pharmaceutical industry

Honeywell's documentation IQ/OQ package provides verification that all aspects of the recorder installation adhere to Honeywell's recommendations, appropriate safety codes, and approved company specifications and design intentions.

This documentation enables the user to demonstrate standard operating procedures for operator training, written methods for verification of the system elements' calibration and upkeep of the system.

Furthermore, the recorders ensure the security of data – another important aspect of process compliance.

Honeywell's electronic paperless recorders all comply with the FDA 21 CFR Part 11 rule:

- Generating accurate and complete copies of records in both electronic and human readable form
- 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.

For More Information

To learn more about Honeywell's Trendview Recorders visit our website www.honeywellprocess.com or contact your Honeywell distributor.

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The Honeywell Advantage

Honeywell's Trendview recorders provide flexibility, security, accuracy and networking capability to ensure process compliance.

Meeting the highest standards for process monitoring and recording, Honeywell's solutions allow manufacturers to reduce the burden of compliance, so they can focus on their business – whatever the industry.