

CASE STUDY

SensiNet® Enables FDA-Compliant Temperature Monitoring and Data Collection

Customer

A leading-edge, specialty pharmaceutical company.

Background

The Company deploys best of breed production management systems. The company is required to comply with FDA regulations for monitoring and documenting their production process.

Problem to Solve

The Customer wanted to deploy an FDA-compliant temperature monitoring system on an existing production line that is capable of meeting temperature measurement accuracy requirements as well as data logging reliability requirements.

In addition, the customer already had existing production management software and wanted the new temperature system to integrate directly with what they had in order to avoid the expense of deploying new software.

Because this was an existing facility, the customer also wanted to avoid the expense and downtime of installing a wired network which would entail new data network wiring.



The SensiNet® Solution

The company chose the SensiNet® solution to provide centralized data collection and to integrate with its existing software infrastructure on their production line. 130 SensiNet monitoring points are installed in 3 manufacturing buildings.

Result

SensiNet met all the customer's requirements in terms of cost, reliability, and specific temperature monitoring capabilities, while providing FDA-validated data collection. SensiNet was installed over a period of several days without bringing down the production line. The system was certified for FDA 21 CFR Part 11 monitoring requirements and is in production.