



Medical Device Manufacturer Case Study

Background

A medical device manufacturing facility in Carlsbad, CA has two ISO Class 8 cleanrooms, an ultra low temperature freezer with apoxies, and a home style fridge. One cleanroom is temperature only, and the other is temperature, humidity and differential pressure. For Quality Control, the cleanrooms and the areas outside of them are required to be monitored. To meet requirements, employees were going through the monitoring process using paper data forms for each of their manual sensors. They would record the temperature, humidity and differential pressure data to release the cleanrooms, and then record the data again in the afternoon.

The Challenge

Manually recording the data points resulted in them not being recorded frequently enough to prevent issues. In 2010, the Carlsbad facility hired a Director of Quality that insisted they buy monitoring equipment for their parameters as the chart records were not adequate. On two different occasions during manual data logging, the facility almost lost their cleanroom changing filters. Changing filters need to be monitored for differential pressure in order to prevent ash build up, which impacts the air re-circulation within the cleanroom. Their air handling systems had loaded up with too much ash for the system to handle, and without a monitoring system watching the differential pressure of the changing filters and cleanroom, they barely caught it in time. They needed to monitor these areas at all times during business hours and production to maintain Quality Control and prevent further risk.

The Solution

In October 2010, the facility installed a Mesa CheckPoint G3 system. The monitoring system is ideal for alerting, with alert limits set much lower than their action limits, which gives the facility time to prevent issues from occurring. The system monitors their areas 24/7, including Saturday and Sunday, and sends e-mail alerts to employees on the notification channel. Their director has a company phone and receives immediate notifications from the system to be able to take immediate action, even on weekends.

The Mesa sensors and capabilities allow for immediate alerting for high and low limits, which send e-mail notifications with system information. Upon implementation of the monitoring system, the facility was involved with the Mesa team on performing the qualification and tailoring the written protocol to their specific needs. Now, when the system goes into alert, they are able to take screen captures for documentation in the event of a facility audit.