

Case Study: Confidential Client

Background

A cGMP contract development and manufacturing organization, based in Irvine, California, supports the pharmaceutical, biopharmaceutical and medical device industries.

The customer's GMP services includes parenteral manufacturing (liquid/lyo), formulation development, analytical chemistry, analytical development, biopharmaceutical development, stability storage, structural chemistry, microbiology, and drug delivery device testing.



The Challenge

The customer has 66 chambers (refrigerators, freezers, incubators and ovens), which require semi-annual validation and qualification of the temperature. Using a competitive logger, they had to wait 24-48 hours to determine if the temperature had been out of specification. The process involved a pre-test of 4 hours, the 24-48 hour IOQ cycle, and then another 4 hour post-test with a competitive data logger. During this cycle, they were unable to tell if the loggers failed or remained within specifications until the full process had been cycled through.

The Solutions

The Mesa Labs' MPRF data loggers provided the customer with the flexibility to restart the validation if they see the real-time temperature go out of the specified range. Prior to using the Mesa Labs MPRF data logger, they were using a competitive product without real-time data capability. By using Mesa's MPRF logger, they were able to decrease the cycle time by 12 hours on every chamber! Since 3 chambers are qualified each month, this saves the customer 432 hours of cycle time each year, estimating \$8,600 in labor savings alone per year.

Testimonial

"The Mesa Labs MPRF data loggers have allow us to view real-time temperature data and stop and restart the qualification of the cycle if required. This has allowed us to become more efficient and reduce labor cost."

- Installation, Calibration & Validation Services

