

## 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**

