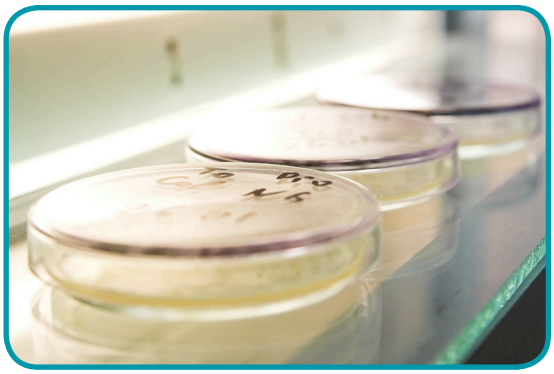
Case Study

Case Study: Intertek

Background

Intertek provides leading Total Quality Assurance services such as auditing, certification, consulting, inspection, sourcing, testing and analysis, and training to their customers across 100 countries.



Earlier this year, Mesa Labs' Compliance and Validation Services were contracted by Intertek to perform temperature mapping qualifications on their stability chambers to ensure Food and Drug Administration (FDA) and International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) compliance.

The Challenge

The FDA's Current Good Manufacturing Practice for Finished Pharmaceuticals Regulation (21 CFR Part 211), and ICH require that products undergoing stability testing must be kept at the specific environmental conditions that were defined in the stability testing protocols. To meet these requirements, temperature mappings of the stability chambers used to store the products must be completed on a defined schedule so that there is documented evidence that the equipment used for the stability testing is able to maintain the required environmental conditions.

The Solutions

Mesa experts performed temperature mappings using both Mesa's DataTrace MPIII and MPRF data loggers to record the temperature and relative humidity data in Intertek's stability chambers. The data loggers were placed throughout the stability chambers in pre-determined patterns, so that temperature and/or relative humidity readings from representative areas of the stability chambers were captured.

The temperature mappings were performed for a minimum of 24 hours in each stability chamber, after which the data was retrieved from the data loggers. Using DTPro Software, the data was analyzed and reviewed to determine that the stability chambers were in fact able to maintain the necessary environmental conditions.

By using Mesa's Compliance and Validation Services, Intertek was able to show that all of their equipment being used for stability testing was able to meet the 21 CFR Part 211, FDA, and ICH requirements.

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