Stable Monitoring for Stable Measurements

Q1 Scientific provide world class stability storage facilities for the pharmaceutical, medical device and life sciences industries. As a dedicated provider of stability storage Q1 Scientific understand the needs and requirements of their clients. Their purpose built facility houses over 60 modern stability rooms operating at a wide range of conditions all operating within strict pharmaceutical regulations. Operating since 2012 Q1 Scientific have won multiple awards and proven themselves as a pioneer within the Irish industry.

Q1 Scientific provide world class stability storage to a range of clients. Monitoring and mapping of stability areas with quality instrumentation is critical.

The Application

Continuous monitoring is a critical requirement for stability storage. Clear evidence must be available demonstrating conditions 24/7/365 in addition chambers must be regularly mapped to ensure stability and gradients are within requirements.

Should conditions being to fall out of tolerance notifications must be made immediately so action can be taken to ensure products are not affected.

This results in a large number of measurement devices which all require routine calibration for temperature and humidity.

The Challenge

Q1 Scientific have utilised continuous monitoring systems from several large global suppliers over the past 8 years. Systems included wired and wireless platforms.

As such when seeking a replacement platform Q1 Scienfic's quality and management personnel were able to draw on a wealth of experience to ensure they sourced the very best system for their requirements.

A holistic risk based approach was taken, incorporating a review of each systems technology, hardware, software, support, calibration and validation.

Clear data, simple interpretations

Several months after the initial installation and validation of the system a routine support call was made to site. Marie Morrissey (Stability Lead) explained that the clear four hour summary charts used on their displays had proven to be more beneficial than they ever could have expected. Upon glancing at the data on one day she was able to identify that a particular chamber was showing increased signs of instability albeit well within tolerance.

Stability storage includes refrigerators & freezers at several temperatures.

Further investigation identified that a water pump began to fail. A quick fix that without being identified so early could easily have resulted in an out of tolerance event.

Ease of access and trust in the system has ensured that when events occur personal are able to act quickly. Reports, alarm summaries and full audit trail showing all actions and acknowledgements mean that senior managers review the facility as a whole easily and present data to customers and auditors in moments.

Compliance in the Cloud

One of the growing trends in the Pharmaceutical industry is increasing support for cloud based software solutions. In line with GAMP5 guidelines, projects should always take a risk based approach. It should be noted that any solution (cloud based or on premises) has its own risks. Decisions should be made by performing a thorough analysis as part of a quality risk management process.

The Rotronic Monitoring System cloud service is operated to some of the highest standards available. The software is hosted on a Tier 4 data center with ISO 27001 certification. Our SaaS IT compliance document makes it clear the level to which we continually invest to ensure security, data integrity and continuous operation. These standards are often far higher than those available to end users on premise.

In the event of a site wide lost of internet connectivity, all data is securely logged and optionally displayed locally by the instruments themselves. Upon reconnection RMS automatically backfills and analyses the data for any deviations. Detailed validation documents and built in validation functions ensure that initial and ongoing validation and use for the RMS platform is simple, robust and compliant.

Product Focus

Validated Cloud Rotronic Monitoring System (RMS)

- Full FDA 21 CFR Part 11 and EU Annex 11 compliance
- Designed ground up to comply with and be used within validated GxP applications
- Simple tools for data analysis designed around audits and assessments
- Configurable scripts to test core functions with clear reports
- On going software development following GAMP5 process

Validation Support

- Clear validation documentation including detailed system risk assessment
- Comprehensive eCompliance White Paper detailing how RMS meets regulatory requirements
- Access to a network of validation engineers specialising in system validation

Partnership between Rotronic and local distributor Hanley Controls was a key success factor for this project.

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