



Compliance Assured With a Rugged and Flexible Solution

The Challenge of Robust Compliance

Working under phase I laboratory regulations, ensuring compliance for the QC team at UCB is a top priority. With regular audits from external bodies such as the MHRA, in addition to internal global compliance audits, having readily accessible and traceable documentation facilitates the audit process.

The calibration and traceability of probes used for mapping at a range of temperatures and conditions is important to ensure reliable and consistent results are generated.

UCB's Flexible Qualification Solution

UCB selected the LabMetrix temperature mapping qualification solution for their mission-critical sample storage equipment. The LabMetrix solution was selected because of its capability to deliver a bespoke solution to qualify the range of conditions required to satisfy UCB's quality standards and ensure regulatory compliance is maintained.

The customisable solution offered by LabMetrix gave UCB the flexibility to tailor individual tests to meet their specific laboratory requirements, whilst minimising system downtime.

“I like the GLP technology, which provides full traceability. The software simplifies the process, removing the possibility of human error.”

Mr James Clipstone, Development Scientist and GMP coordinator, UCB, UK.

Customisable

Working with UCB, custom open door tests were developed and additional alarm and system verification checks performed, all of which were managed through the Validation Master Plan (VMP). Mr. Clipstone, GMP coordinator for the QC stability laboratory, acknowledged that other validation approaches were not sufficiently robust to satisfy Phase I/II laboratory sample storage requirements. In contrast to alternatives, the LabMetrix qualification solution includes those rigorous supplementary tests, giving the department the capability to conduct and control in-house stability storage.

Harmonised Documentation

Mr Clipstone commented
“The document layout is progressive. The single VMP covers all technologies and is indexed and categorised well. With all documentation in one place, it is easy to review and prepare for an audit and demonstrate control of the local storage facility.” Bringing technology to qualification, the LabMetrix solution provides a comprehensive and rugged compliance solution. Streamlining the qualification process, the single set of documents produced, harmonised across technologies and vendors, facilitates the audit process.

Expanding OneSource's Capability

LabMetrix is now part of PerkinElmer's OneSource Compliance Services which offers industry leading compliance solutions for your entire laboratory, helping to streamline laboratory compliance.

Company: UCB

Size: Over 10,000 employees in more than 40 countries.

Business: UCB is a global leader in the biopharmaceutical industry dedicated to the research, development and commercialization of innovative pharmaceutical and biotechnology products in the fields of central nervous system disorders, allergy/respiratory diseases, immune and inflammatory disorders and oncology. UCB has a strong pipeline of molecules in development, both antibody based and chemically derived entities.

Programme details: QC & Stability Group, Analytical Research & Development, UCB Slough, UK.

The QC & Stability laboratory is a licensed GMP facility working on early phase biopharmaceuticals, in particular batch release of drug product and stability testing of drug substance and drug product.

2007: Fridges, freezers, stability cabinets qualified.

2008: Qualification repeated and extended to include additional units and customised door open testing to monitor sample temperatures.