

## Improving calibration processes

### UCB Pharma uses CompuCal to improve quality and efficiency



UCB manufactures active pharmaceutical ingredients (APIs) for a number of indications including cardiovascular.

#### Benefits at a glance

The key benefits of using CompuCal in the life sciences industry are:

- Regulatory compliance to FDA regulations
- 21 CFR part 11 compliance
- Elimination of costly manual entry errors
- Receive automated failure and out-of-tolerance email notifications
- Reduction in operating costs
- Paperless solution
- Always ready for an audit



**Calibration is an essential element of any instrumentation maintenance program. However, sometimes calibration operations can be time-consuming, paper-based processes that can be prone to transcription errors. With the right tools and planning, efficiency and quality can be improved while lowering costs.**

**Results** UCB has used CompuCal at its Shannon, Ireland facility since 2007. The facility has improved quality and efficiency while lowering its calibration costs. CompuCal helps ensure that UCB is always in compliance with regulations.

**The Challenge** UCB Manufacturing Ireland was using a manual, Excel based system to manage calibrations. There were requirements that the system used be 21 CFR Part 11 compliant and able to use electronic records. A site upgrade in 2006 increased the calibration workload significantly. UCB recognized their need for an electronic calibration management system.

**Our solution** Since 2007, UCB has been using CompuCal to manage its calibration program. Along with the software, UCB was offered resources to provide a turnkey solution with installation, configuration, data migration and full validation.

The CompuCal team was flexible, professional and operated as part of the UCB team, ensuring the project was delivered within time and budget, and was able to adapt to the validation approach at UCB.

**Solution details** CompuCal delivered a fully validated system that was up and running with minimal impact on the site operations. The migration of data was handled very efficiently and validated by CompuCal. Calibrations are now recorded electronically with a paper copy of calibration record also retained.

In the manufacturing environment of API, plant critical instrumentation, pressure, needs to be calibrated on a regular basis. CompuCal manages this schedule and ensures

that UCB calibrates the instruments to the right standards at the right time. CompuCal produces compliant calibration certificates ensuring UCB is compliant with their own standard and those of the US and European agencies. During audits and regulatory inspections, the calibration records are accessed from the electronic record within CompuCal or from the paper copy of the calibration record.

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