

CASE STUDY

Global Biotechnology and Device Testing Organization

Background

A global contract research organization, known for providing unparalleled biotechnology and medical device testing capabilities, strategic guidance, and tactical support to introduce innovative new products to market, sought a comprehensive calibration management solution.

Objectives

The company needed a software solution to ensure regulatory compliance while eliminating its dependence on paper and guaranteeing that the entire team followed the same validation workflows. Technicians tended to take liberties and shortcuts with their documentation, so consistent compliance software was necessary.

In addition, the client looked to expand its sites globally and required a multi-language system.

Solution

Choosing the ProCal software system helped ensure regulatory compliance and validated workflows, provided a paperless system, and resulted in the team following correct practices and standards.

More recently, as the company expanded ProCal overseas, Prime Technologies helped the client add multi-language functionality to their system while the client performed the software validation completely internally. Prime Technologies worked closely with the team, documenting requirements in a URS (User Requirements Specification) and provided support while the client implemented the software solution. In order to streamline the installation and deployment of ProCal, the client hosted the software on their own internal virtual server with Prime Technologies' support setting it up.

The Prime Technologies team has supported the client extensively when initially validating the system, all while meeting aggressive deadlines. Prime Technologies continues to engage with the client via tech support often and provides a timely solution every time.

RESULT

As a result of using ProCal, the company is more efficient and saves time entering results, reporting, and managing data.

Most importantly though, the client has a much better audit experience now that the solution immediately recalls needed data from the click of a button.

As a result of successful implementation and use of ProCal over 13 years:

- the client company has grown from a single site to international deployment
- time to complete an audit has dropped by 50%
- calibrations take 30% less time to complete due to the easy-to-understand user interface, SOP accessibility, calibration specification recalculation, and other base software features

As an added benefit, the client found great value in the additional reporting and metric analysis capabilities (which they initially did not plan to utilize), and they have expanded upon this value with custom reporting that was built specifically for their needs.