Cambridge Biomedical

Assay Development and Validation Services

Regardless of your size or requirements, outsourcing non-strategic tasks has become a common practice in biotechnology and pharmaceutical development laboratories. Clients use Cambridge Biomedical's development services to meet their assay needs allowing their strategic development resources to focus on new product development. An experienced Cambridge Biomedical team focusing on your project will shorten your timeline to complete a robust assay with validation documentation that can be used to support regulatory submissions.

Cambridge Biomedical is a unique **Contract Laboratory Service Organization** that combines solid science with unparalleled levels of customer service. Our services are built on a wide technology base supporting pre-clinical and clinical efforts in research through GLP level services in a CLIA certified, FDA registered and CAP accredited Laboratory.

Time is always of the essence. In the pharmaceutical industry, each day of delay in drug development results in $1-$1.5 M in lost revenue. In biotechnology and biopharmaceutical companies, outsourcing development has become a standard tool to leverage existing funds by completing projects sooner.

Validation and assay development time can be reduced by working with Cambridge Biomedical's team of scientists.

Efficient assay development combined with Cambridge Biomedical's qualification and validation procedures and services can shortened your timelines.

Cambridge Biomedical's capabilities include a seamless track from the start of validation through technology transfer to laboratories working under CLIA or GLP quality levels or transfer to your laboratory that is measured in weeks not months.

Resources on Demand improve your research efficiency.

Using Cambridge Biomedical reduces your need to staff development and validation groups with varied specialists. Our clients take advantage of scientists when required in any phase of a project.

As a contract laboratory our overhead is dramatically lower. Costs are further reduced by using staff only on an as needed basis resulting in savings of typically 40%.

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Matching your needs to the best technology is essential.
Unlike many laboratories, we do not limit your choice of assays to a selection of available methods or technologies. Cambridge Biomedical's experience is a key element allowing us to choose the right approach to best meet your needs. Our senior staff members are experts in the scientific disciplines of Microbiology, Molecular Biology, Immunoassay development and biomedical and clinical chemistry and are available to share with you their experience in assay development, validation and complex testing at CAP or GLP quality levels. We offer a wide variety of technologies such as ELISA, PCR, particle agglutination, fluorescence polarization immunoassays, antigen capture, HPLC and other chromatography methods as well as automated analyte assays.

Proven Validation processes begin with a thorough evaluation and understanding of the project requirements. Staff is selected to work directly with clients who are familiar with the requirements to provide documented evidence for your submissions package.

Searches are performed to take advantage of any existing technology or kits that are available on the world wide market. Some of the elements included in a validation package include accuracy; inter and intra assay precision; stability; robustness testing; linearity; specificity; sensitivity; interferences; reportable range and if appropriate clinical reference ranges.

Technology Transfer from the development group of a qualified or validated assay can occur either to the client's or Cambridge Biomedical's laboratories where it can be run under CAP or GLP quality levels.

Samples may be aggregated and stored in the conditions required to be run in a batch mode to minimize costs and maximize the precision and quality levels. Cambridge Biomedical has a client tested technology transfer procedure that allow assays developed or optimized at Cambridge Biomedical to be transferred to you. The technology transfer does not stop at sending information. Cambridge Biomedical staff can be involved in every stage beginning with your staff observing the assay at Cambridge Biomedical to our staff running the first batches in the client's own facility. Cambridge Biomedical can also work with the client to provide proficiency and accuracy testing on an ongoing basis.

Our onsite CAP laboratory capable of running under GLP guidelines allows assays to be transferred from the development group and run routinely to support clinical trials. You

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have the choice of initially running your samples at Cambridge Biomedical and then transferring the assays at your convenience. A strong **Quality Unit** works as a partner with the operations and development teams to assure that critical elements are built into all aspects of the planning, implementation, review and documentation processes. Our clients work with the Quality Control and the Quality Assurance groups to assure compliance with the necessary regulatory requirements. We are flexible in developing programs to address additional areas that are requested by our clients.

For **more information** on Cambridge Biomedical or the services we provide, please contact us or visit our website