



Improving human health and protecting the environment through scientific research services

WIL Talk

Excerpt from Spring 2007

A newsletter dedicated to keeping our colleagues informed of progress and changes at WIL Research, as well as scientific and regulatory matters of interest.

Rigorous Validation Process, Facility Design and Expertise Defines New Bioanalytical Laboratory

WIL Research Laboratories is pleased to announce the opening of our new 28,000-square foot laboratory complex addition. The focal point of this complex is a state-of-the-art GLP Bioanalytical Laboratory designed to answer the growing demand of our sponsors to further utilize our expertise in bioanalysis.

GLP bioanalysis is receiving ever increasing scrutiny. Recent major initiatives by federal agencies have focused on bioanalytical issues, such as contamination and reanalysis. With industry-wide sensitivity and scrutiny by the agencies in mind, WIL Research developed facility plans and rigorous validation processes to ensure continuation of its reputation for the highest quality, regulatory submission data.

Validation is at the core for a GLP facility. Extensive validation plans were prepared and executed for each part of the new laboratory and all laboratory equipment. Each piece of equipment was installed or re-installed under defined installation qualification parameters. The validation plans included all necessary testing to demonstrate acceptable operational and performance standards and conformance with 21 CFR Part 11. All laboratory areas and equipment are released for use on regulated projects.

Unmatched facility design, plus expandability. At the center of our new laboratory complex is the Chromatography and Mass Spectrometry Laboratory, a custom-designed, 3,700-square foot laboratory that houses the majority of the analytical instruments. The laboratory was designed with all utilities supplied through four octagonal "hubs," with custom-designed instrument benches radiating from seven of the facets. Currently, eight LC-MS/MS instruments are operational, including an API 5000 coupled with a Symbiosis Pharma system for on-line solid phase extraction. Both Sciex and Micromass instruments are used in order to ensure the best available methodology for a particular application. This new facility allows for instrument capacity capable of analyzing in excess of 250,000 samples a year.

The most important aspect of bioanalytical services is experience. WIL has assembled one of the most highly experienced groups of bioanalytical chemists in a contract research organization (CRO). All projects are managed by scientists with extensive bioanalytical research and contracting experience. WIL's scientists have developed and validated methods not only with plasma, but with whole blood, excreta and tissues. Our project managers are directly involved from method development and validation through sample analysis, providing a degree of integration not found at many other CROs.

Whether your needs are the development and validation of a bioanalytical method for a novel compound or sample analysis for a clinical trial, WIL's Bioanalytical Services can provide you with the highest quality results for regulatory submission.