Questions to ask your Statistician

- **Is your statistician trained in statistics?**

Some in-house "statisticians" are actually individuals trained in another discipline with peripheral exposure to statistics via SAS® programming, short course, or self teachings. BioSTAT statisticians have advanced degrees in statistics and average more than 30 years of industry experience.

- **Is your statistician experienced in nonclinical and animal health studies?**

Statisticians working in other disciplines such as clinical trials, manufacturing, or academia are not familiar with the unique issues associated with nonclinical and animal health studies. Since 1994 BioSTAT has been devoted exclusively to these industries and their distinctive nuances.

- **Is your statistician GLP compliant? Does he/she utilize in-house QA services?**

GLP compliance is of particular importance if statistical services are contracted from an outside source. BioSTAT statisticians are GLP trained and all GLP study activities are conducted with in-house QA oversight and subject to internal SOPs. Our office and procedures have been audited by sponsor laboratories and we welcome such involvement by our clients.

- **What is your statistician's Quality Control process?**

An individual statistician working alone has no checks and balances mechanism. While QA personnel can assure that conformance with regulations is maintained, unless they are formally trained in statistics, it is unlikely they can provide quality control over the intricacies of a complex statistical analysis. If the protocol described a repeated measures analysis of covariance with fixed effect terms for treatment group, time, sex, and interactions, and random effects for litters nested within groups and pups nested within litters*groups, could your statistician's QA personnel assure that the methodology was accurately carried out and reported?

A BioSTAT SOP requires all GLP projects be subject to our quality control process which requires 100% duplication of all results by an independent statistician. The process supplements BioSTAT's QA review and assures the statistical integrity of every BioSTAT project.

- **What software is utilized by your statistician?**

Has your statistician's software been subject to IQ/OQ validation? Does he/she own the software and thus have 100% control over its security? Does he/she use open source code statistical software? Is the software a "black box" package in which limited statistical methods are menu driven by the user? Is the software capable of the most current methodologies? Does it calculate exact p-values or approximations? Are protocol statistical methods dictated by the software's capabilities or are the statistical methods customized to address the specific study design and objective of each protocol?

BioSTAT utilizes single-use SAS® programs customized to each individual project and subject to our QC process. Upon project completion, the programs are archived with the specific project material. This allows us to adopt state of the art methodology and take advantage of the most current statistical and software technologies.