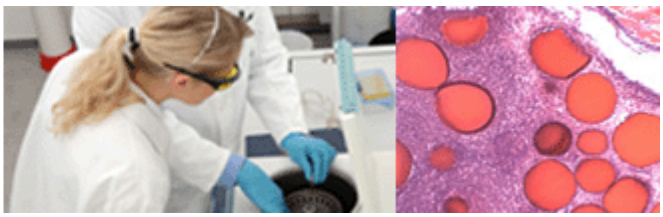
Comparative Biosciences Inc.

CBI News



The Reliable Resource for the Biomedical Community — **January 2011**

Featured Animal Models at CBI

Laser induced Choroidal Neovascularization in Rabbits

Aspergillus-Induced Eosinophilic Esophagitis and Pneumonitis in Mice

Monosodium Urate-Induced Gout in Mice

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Quick Links

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CBI welcomes Mike Zamora, our new Business Development Manager. Contact Mike at **mike_zamora@compbio.com**

What Does It Cost an Organization to Maintain USDA and OLAW Compliance?

Clients universally expect CROs to comply with USDA and OLAW regulations, in addition to GLPs, yet such compliance is a major source of overhead expense. Have you ever wondered how much this compliance costs an organization?

The cost of compliance is formidable. The following are our rough estimates of the cost, including labor and lost opportunity costs for such tasks as IACUC meetings, document preparation and maintenance, consultants, IACUC steering committees, facility inspections, training, risk management and occupational health activities:

- Small company with 50 employees or fewer: $200,000/year
- Medium-sized organization: $200,000 - $1M/year
- Large organizations: >$1M/year

These costs are undoubtedly a contributing factor in the "off-shoring" of preclinical work to Asia, especially China, where labor costs are already substantially less than in the US. We question whether US sponsors are as concerned about the compliance of Asian CROs as of US CROs and whether sponsors are prepared to take on the role of the USDA in ensuring compliance where the USDA lacks jurisdiction.

The CBI Newsletter would welcome input on this from our readers. Do our figures seem about right? Do these overhead costs have a significant effect on drug development?

FDA Takes a Position on Draft Reports and Final Reports

A recent FDA Warning Letter to another CRO includes some findings that are of general interest (see http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm222775.htm). One of the key lessons is that draft reports from contributing scientists (also known as principal investigators) cannot be included in a final study report. Contributing scientist reports are reports such as pathology, bioanalytical, pcr, etc., that support the main study report. The GLPs require that a final report shall include the "signed and dated" reports of contributing scientists (21 CFR 58.185(a)(12). It is sometimes difficult to obtain final signed and dated reports from third-party contributing scientists and a CRO must always make every effort to meet sponsor timelines that may be very aggressive. However, the requirements of the GLPs are clear. If, for some reason, a report absolutely must be finalized without a final signed and dated report from a contributing scientist, CBI will document this as a GLP deviation.

Another item of concern in the same Warning Letter is the following: "Furthermore, given that ... Study Directors invite the study sponsors to comment on and edit both the contributing scientist reports and the final report, bias in data interpretation and reporting cannot be ruled out." We do not believe that FDA meant that sponsors should not be allowed to comment on draft reports (how would they apply this principle to studies conducted in-house by the sponsor?). However, the finding does illustrate that the FDA is concerned about the possible introduction of bias into studies performed at CROs. It is CBI's practice to solicit comments from the sponsor at the draft report stage, but comments are incorporated into the report only after critical review by the study director. We think this simple recognition of the study director's responsibility as the single point of study control (21 CFR 58.33) adequately addresses the FDA's concern.

For information on pre-clinical ophthalmic pharmacokinetics, efficacy modeling and toxicology services offered at CBI, contact Mike Zamora, Business Development Manager

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