replicate designs. In these cases, the ability of the CRO to recruit this large population as a single group should be assessed. When conducting replicate design studies, the dropout rate is often higher than a simple two-period crossover design. As always, the CRO clinic should be capable of recruiting an adequate number of subjects to account for dropouts. Some drug products also require special populations. For example, estrogens are generally dosed to postmenopausal females. Other drugs may be targeted to an elderly population. It is essential that the CRO be assessed for its ability to recruit these special populations.

Bioanalytical Capabilities

Just as the clinical capabilities must be assessed, the bioanalytical capabilities are equally important. Validation lists (lists of analytical methods that are currently available and validated) are available from most CROs. It is critical that the bioanalytical facility be experienced in analyzing the drug (and metabolite, as appropriate) and should be able to provide a written validation report. The validation should be assessed before awarding the study or at least before dosing. In addition to having an appropriately validated method, the facility should follow current GLPs (cGLPs) and have a clean U.S. Food and Drug Administration (FDA) inspection history.

Pharmacokinetic Capabilities

Most companies focus primarily on the clinical and bioanalytical capabilities for CRO selection. However, the pharmacokinetic capabilities should also be critically assessed. The CRO should have validated pharmacokinetic and statistical programs in place and should be compliant with 21 CFR Part 11 (especially in regard to change control).

Timeline Assessment

The list of CROs that meet the company's clinical, bioanalytical, and pharmacokinetic criteria must be assessed for their ability to meet the company's timeline. The CRO must be able to meet the timelines as established by the company management team. In the rare instance that no CRO can meet the timeline, then the company may need to reassess their strategy and internal submission timelines.

Often, the large list of commercial CROs and/or laboratories can be whittled down to between one and three candidates at this point. Once the list has been narrowed, the candidate CRO sites should be evaluated "in person." If, however, too many sites are viable candidates, the sites can be "interviewed" via telephone to evaluate their qualifications. However, the final candidate should be qualified with an on-site inspection.

CRO QUALIFICATION

Due Diligence

If the pharmaceutical firm has used the CRO in the past, they should objectively evaluate their past experience with this CRO. If the experience was good, the firm