integrated report. The group should have all programs fully validated according to the FDA programming guidelines. During the pharmacokinetic site audit, the following areas should be carefully assessed:

- Qualifications of pharmacokinetic and statistical personnel.
- Validation of pharmacokinetic and statistical programs (usually SAS).
- Compliance with 21 CFR Part 11. At the time of this publication, full and complete compliance with Part 11 was not being enforced. However, the CRO should have a written plan and timeline for bringing all postlaboratory functions into compliance.
- Evaluation of format and completeness of pharmacokinetic tables and graphs, statistical output (listings), and a mock final report.

Culture

Although culture cannot be quantitatively assessed, it is important to consider the following key areas.

- Is the culture of the CRO compatible with that of the pharmaceutical company?
- Does the firm expect the CRO to make all decisions with regard to minor protocol deviations?
- Does the firm wish to manage all communications and decisions?

COMPETITIVE BIDS/DEFINING THE DELIVERABLES

In an effort to quickly place a clinical study, the development of the RFP may be rushed and result in a document that is subject to various degrees of interpretation. In light of this, it is important for companies to carefully evaluate competitive bids to assure that each CRO has made the same set of assumptions.

Final Report Content and Format

Ideally, the development of an effective RFP and proposal should begin with the outcomes in mind. That is, the focus on the proposal should begin with the objective of a final deliverable (the report) and should include a description of the content and format of the final report.

Final Written Report

CROs work with a large number of different clients; each client often has their own report format preferences. Therefore, if the RFP does not specifically address the report format, the CRO often will make an assumption regarding the report format. This assumption may or may not be explicitly stated in the resulting proposal. This assumption can make or break a proposal because the report format assumes a number of other important deliverables.

A full International Conference on Harmonization (ICH)–formatted report requires a substantial amount of data analysis of all data in the Case Report Forms