- Summary of subject dropout information for each study
- Summary of protocol deviations
- Summary of bioanalytical standard curve and quality-control (QC) data
- Standard operating procedures (SOPs) dealing with bioanalytical repeats of study samples (the FDA also requires copies of each SOP to be included in the ANDA submission)
- Composition of meal used in fed BE studies

Unless a sponsor intends to create each of these tables internally, the CRO needs to be aware that these tables are required. Special considerations should be given to chemistry, manufacturing, and control (CMC)–related tables that contain data that are not normally provided to CROs. The sponsor must decide (early in the process) as to whether the CRO or the sponsor will provide these tables. If the CRO provides this service, then these data must be provided by the sponsor to the CRO in a timely manner. However, many sponsors consider these CMC data to be highly confidential and may insist that their own regulatory affairs department enter these data.

Clinical

Protocol Development

Before 1999, the FDA OGD published a large number of drug-specific guidances that provided the basic information needed to conduct a generic BE trial. With the publication of general BA/BE Guidance, the Agency "withdrew" the drug-specific guidances. However, in the past several years, the FDA has published approximately 900 BE recommendations for specific products [5]. Most of these guidances provide some protocol design considerations, but sponsors generally are left to their own resources to determine specific guidance on numbers of subjects, timing of blood samples, etc. It is important that an RFP specify the expectations for protocol development. Three possible options exist, each with a different cost structure:

- Level 1: Client provides final clinical protocol.
- Level 2: Client provides protocol "outline," including design and all specifications; CRO provides final protocol.
- Level 3: Client provides objective; CRO provides design and protocol.

Unless the sponsor provides the final clinical protocol (as in Level 1), the following items must be addressed in the RFP to obtain an accurately priced study.

Protocol Format

Some pharmaceutical firms are quite strict when it comes to formatting requirements. If the firm requires the CRO to follow a specific format (developed by the company), then this information (and the format) should be provided within the RFP. On the other hand, many companies do not have a preference for protocol format. They are only concerned that all of the relevant parameters are included in the protocol. For these companies, CROs can often provide a standardized (and shorter) format for less money. Another advantage to using this standardized approach is that