TABLE 12.1
Check Sheet Providing Typical Services Outsourced for BA/BE Studies

Service	Sponsor (✓)	CRO (✓)
Bioanalytical Analysis		
Bioanalytical Site Selection and Qualification		
Clinical Study Design		
Clinical Protocol Development		
Clinical Site Selection and Qualification		
Clinical Conduct		
Clinical Monitoring		
Data Management		
Pharmacokinetic Analyses		
Statistical Analyses		
Pharmacokinetic Report Writing		
Integrated ICH Report Writing		
Project Management		
FDA/Regulatory Consultation		

full in-house capabilities and are required to outsource their clinical trials, including bioavailability (BA) and bioequivalence (BE) studies. Although generic companies have internal resources for product development, manufacturing, and release testing, they do not have clinical and bioanalytical capabilities.

It is critical that the CRO and client realize the importance of close collaboration and seamless communication between their organizations. This collaboration is necessary to achieve study success in a timely manner. Key elements necessary for success include the following:

- *Communication* at all levels between the CRO and the Pharmaceutical Company
- *Sensitivity* to both the project specific requirements and timelines
- *Flexibility* to recognize and adjust to unexpected events throughout the project timeline

As the number of outsourced services may vary with each client, it is important that the CRO demonstrate a flexible attitude and responsive approach that will enable a better partnership with the Pharmaceutical Company.

Outsourcing Relationship: Vendor versus Partnership

Before selecting a CRO, a company needs to evaluate their goal for outsourcing and assess the relationship they wish to have with the CRO. The most common relationships include the CRO as a vendor, a preferred provider, or a development partner.