Column dimensions

1. Length: ±70%
2. Inner diameter: ±25%, provided a constant linear flow velocity is maintained.

In addition, flow rate changes up to ±50% have been proposed. Work on limits for changes for mobile phase solvent ratios is underway. It is proposed that any method adjustment within these limits will not require additional validation. Proactive revalidation takes into consideration the availability of new technology or perhaps the automation of previously complex or time-consuming manual procedures. In such cases, revalidation may be more comprehensive, depending on the scope of the project.

18.3. Method Transfer

Method transfer is dependent on the intended use of a validated method. If other laboratories such as quality control or stability group are going to use this validated method, then a proper method transfer will be required. Under ideal conditions all laboratories involved should use an interactive approach to achieve method development, optimization, and validation goals in an efficient manner. If the end user has been involved in the development and validation process from the onset of this process as a participant or an observer, then it is convenient to place this method on line in a timely manner. Otherwise, reasonable time and effort will be required for the transfer process to be completed in a timely manner. Validation of a method demonstrates suitability of the method, whereas the method's evaluation and validity is approved by the end user.

The first step in a method transfer is to design a protocol, which is a document consisting of elements as outlined in the validation protocol, and other additional elements such as acceptance criteria, report format, and approval signatures of both the originating and the receiving laboratories. In addition, a detailed test procedure, design of experiments, sampling plan, analyst and equipment, interday and intraday ruggedness, and method transfer report form should also be included for method transfer studies.

Studies required for method transfer include system suitability, linearity, precision (day-to-day, within-day, analyst-to-analyst, analysis of multiple lots), collaboration of laboratories, developer user agreement on split sample results, and use of appropriate statistical standards, e.g., F-Test and t-Test, for evaluation of the method transfer process. The receiving laboratory should allocate enough time for the transfer, participate in interlaboratory studies, anticipate problems, and have a checklist ready of questions for the originating laboratory. For a successful method transfer, it is important to compare equipment or instrumentation in both laboratories. For example, for a chromatographic method, the age of the detector, the column, and the internal diameter of connecting tubing will play significant roles in the generation of comparable chromatograms.

Finally, where is method transfer required? In general, method transfer will be required for a new laboratory, a new method, new personnel, significant changes in a method, from company to a contract laboratory and from research and development group to quality control laboratory and stability group.