

## **METHOD TRANSFER**

After ANDA approval, the test methods will be applied to the validation batches and routine product testing conducted by quality-control laboratories. Hence, the test methods must be transferred to the quality-control laboratories. There could potentially be a difference in the geographic location of the research and development laboratory and the quality-control laboratory. The experience of the instrument operator and experience with the application of the test methods could vary from laboratory to laboratory. Therefore, the knowledge and experience must be passed to the new laboratories. The receiving laboratory must demonstrate its ability to perform the test method. A method transfer SOP or protocol must establish the requirements for satisfactory method transfer.

### **OBJECTIVE OF THE METHOD TRANSFER**

The method transfer is part of the technology transfer process. The method transfer can improve the understanding of the analytical methodology for both the originating and the receiving laboratories. The receiving laboratory personnel performing the test method should be trained on the test method. The receiving laboratories must be cGMP compliant. When the receiving laboratory is a contract laboratory, appropriate auditing of the laboratory by quality assurance personnel is necessary. When a method transfer (crossover) study is performed, the results from both laboratories can serve as “intermediate precision” data.

### **DOCUMENTATION OF METHOD TRANSFER**

#### **Method Transfer Protocol**

To confirm that the receiving laboratory has the full grasp of the test methods, the transfer process must be documented. If the transfer process is driven by a method transfer protocol, this protocol should define the manner of method transfer, the role and responsibility of the laboratories involved, and the acceptance criteria for a successful transfer and reporting items.

One way of method transfer is by a crossover study involving both the originating laboratory and the receiving laboratories. In executing the method transfer protocol, both laboratories can test the same lot of product and the results are compared for closeness. The second way of method transfer is for the receiving laboratory to perform a mini-method validation (e.g., to reproduce the method accuracy, precision, and linearity), which demonstrates that the laboratory can fully reproduce the performance characteristics of the test method.

#### **Method Transfer Report**

Upon the completion of the method transfer protocol, the test results are summarized and compared with the preapproved acceptance criteria to determine whether the receiving laboratory is qualified to perform the test method. The transfer report should indicate whether the transfer is successful. All transfer data must be recorded and reviewed. Any deviation from the protocol must be documented and discussed. The report must include the justification for the deviation to the protocol and impact on the test method.