Regulatory Reference: FDA CFR - Code of Federal Regulations Title 21

General Discussion
This document provides guidance for establishing a documented process for the transfer of analytical methods, microbiological, and/or bioanalytical methods.

1. Responsibilities of the Transferring Laboratory Qualified Personnel include:

- Identify the qualified personnel to lead, execute, and complete the transfer activities. If a facilitator or 3rd laboratory is used, then their responsibilities should also be identified;
- Provide method specific information to the Receiving Laboratory qualified personnel;
- Provide method specific training and support to Receiving Laboratory qualified personnel, as applicable;
- Generate, review, and approve transfer documents;
- Provide data that have been reviewed and approved, if required;
- Initiate and support investigations as required; and
- Ensure that the Laboratory Qualification Memo is reviewed and approved by the Site Quality Team.

2. Responsibilities of the Receiving Laboratory Qualified Personnel include:

- Identify qualified personnel to lead, execute, and complete the transfer activities;
- Review the method specific information provided by the Transferring Laboratory qualified personnel;
- Ensure the instruments and equipment are available and suitable for use;
- Review and approve transfer documents;
- Ensure data have been reviewed and approved;
- Support investigations, when required;
- Ensure that the Transferring and Receiving Laboratories have approved the Laboratory Qualification Memo prior to using the methods for routine sample analysis.

3. Acceptable Modes of Transfer include, but are not limited to:

- No transfer activity (e.g., compendial methods for excipient appearance testing);
- Method Overview; and
- Comparative Testing.

  For Comparative Testing, results generated by the Receiving Laboratory may be compared with historical data, or to data that have been generated in parallel by the Transferring Laboratory.

  Validation of methods does not require any additional transfer documentation.

4. The Transfer Plan Document(s) should detail the following:

- The test(s) to be transferred,
- The modes of transfer,

