1. New product transfers during development through manufacturing.
2. Transfers within or between manufacturing and testing sites for marketed products.

Other more descriptive types of TT involve the following types:

1. Intra-site transfer, process scale-up, or transfer with same or larger equipment.
2. Intracompany transfer, from sending (originator) site to receiving site.
3. Outsourcing-CMO transfer, from originator site to contract manufacturing site.
4. Insourcing-CMO transfer, from contract manufacturing to originator site.
5. Inter-CMO transfers, from sending CMO site to other receiving CMO site.
6. Intercompany transfers from innovator company site to licensed partner receiving company site.

Manufacturing of sterile lyophilized product essentially involves two distinct processes. First, manufacture of sterile solution in vials, which involves all the unit processes in the sterile product manufacture for an aseptically produced product, such as compounding, sterile filtration, and filling into sterile containers such as vials. This step is immediately followed by the lyophilization process in which the filled vials are subjected to the lyophilization process inside a freeze dryer to get a final dry product.

Technology Transfer Execution

General Activities

Some of the key general activities involved in the TT process are listed below:

1. Start TT activities at the manufacturing (receiving) site.
2. Establish TT key performance indicators (KPIs).
3. Procure and assemble a complete technical data package from technology originator (or sending) site/R&D/company/CMO and verify completeness of the data.
4. Start site TT activities in preparation for experimental and/or process justification trials.
5. Perform process design for the site based on originator site process information.
6. Initiate and write a technology transfer plan.
7. Initiate and write a validation master plan document.
8. Perform an aseptic processing validation evaluation.
9. Develop the initial manufacturing instructions for experimental, stability, and/or clinical trials.
10. Train operators in the manufacturing process and the master batch records (MBRs).