The documentation received will be used to define the qualification and validation strategy to be followed by applying a scientific risked-based approach. As an example of how important it is to receive a complete package, refer to the following example:

Example:
Transfer of Product ñAò, complete packaging line and associated documentation between two sites. The receiving site should have previous experience as a packaging site of a similar process.

1. Documentation Requirements:
   The sending site:
   The sending site will provide the following equipment documentation as available:
   - Å System Level Impact Assessments (SLIA)
   - Å Component Level Impact Assessments (CLIA)
   - Å System Level Commissioning Plan (SLCP)
   - Å Installation Qualification (IQ), Operational Qualification (OQ) & Performance Qualification (PQ)
   - Å Calibration documentation and history
   - Preventative maintenance documentation and history
   - System specific training materials
   - Cleaning procedures and certificates
   - Specifications, equipment manuals and drawings
   - Standard Operating Procedures (SOPs) for operation, cleaning, maintenance, and support.

   The receiving site:
   - Perform a gap and risk assessment of the equipment and process to be transferred using the documentation received from the sending site. The site evaluates the risks involved in the packaging technology transfer and develops a plan to address the gaps.

   - Review the System and Component Level Impact assessments from the sending site and system classification. Determine whether or not new impact assessments should be performed or use the sending site assessments as part of the qualification efforts.

   - If the equipment is re-classified, refer to validation guidance for qualification requirements according to equipment classification.

   - Evaluate if the qualification documentation provided by the sending site will meet site requirements. If not, the receiving site can develop a plan to address the missing information. If documentation is acceptable then evaluate if any additional testing is required from an operation range stand point. If an operational range needs to be extended then OQ testing will be required. If the product and process requirements are satisfied no additional OQ testing is required.

2. Validation Strategy should be as follows:
   Receiving site should define the validation approach to be used in a Validation Project Plan or Project Commissioning and Qualification Plan (PCQP).

