PROJECT TITLE **GLX High Barrier Pouch Solution: DOE and Sealing Process OQ/PQ**

COMPANY X Pack LLC

SCOPE

X-Pack LLC is a medical device company in San Diego, CA that provides patient focused innovations for structural heart disease, critical care, and surgical monitoring. Its Advanced Packaging Technology (APT) business unit focuses on the research and development of new devices and technologies, including packaging innovation.

The APT group will evaluate various new high moisture-barrier materials to compare the films' performance to the current foil pouch. The design input of concern for this portion of the process is that the new pouch must have high moisture-barrier properties: moisture must be retained within the pouch to ensure the GLX tissue integrity. Voice of Customer has determined that the new pouches must be transparent. The evaluation of new pouches will include the testing of three different transparent pouch samples, and determine the appropriate sealing parameters.

The first phase of the project will be to create a DOE (Design of Experiment). The objective of the DOE is to define a method by which to determine the appropriate sealing parameters which will produce a pouch meeting the packaging specifications. The packaging protection requirements will be driven by the product specifications provided by the GLX valve team.

The second phase of the project will be to perform an OQ/PQ (operational qualification and performance qualification) for the Sencorp Sealer 24AS/2's use with the new high-barrier transparent material. The objective of the OQ is to document the appropriate equipment parameters that will produce pouches meeting the pre-defined requirements. The PQ will ensure that the sealer's performance is reproducible, within the OQ's specified range.

DELIVERABLES

1) Final Seal Parameters DOE Report
2) Final Sealer OQ/PQ Report
3) Final report summarizing APT's Results