LEANBIOLOGIX

OPERATIONAL EXCELLENCE
FOR SCIENCE MANUFACTURERS

EVALUATION

of Shipping System Qualification Data

THE LEAN PROCESS

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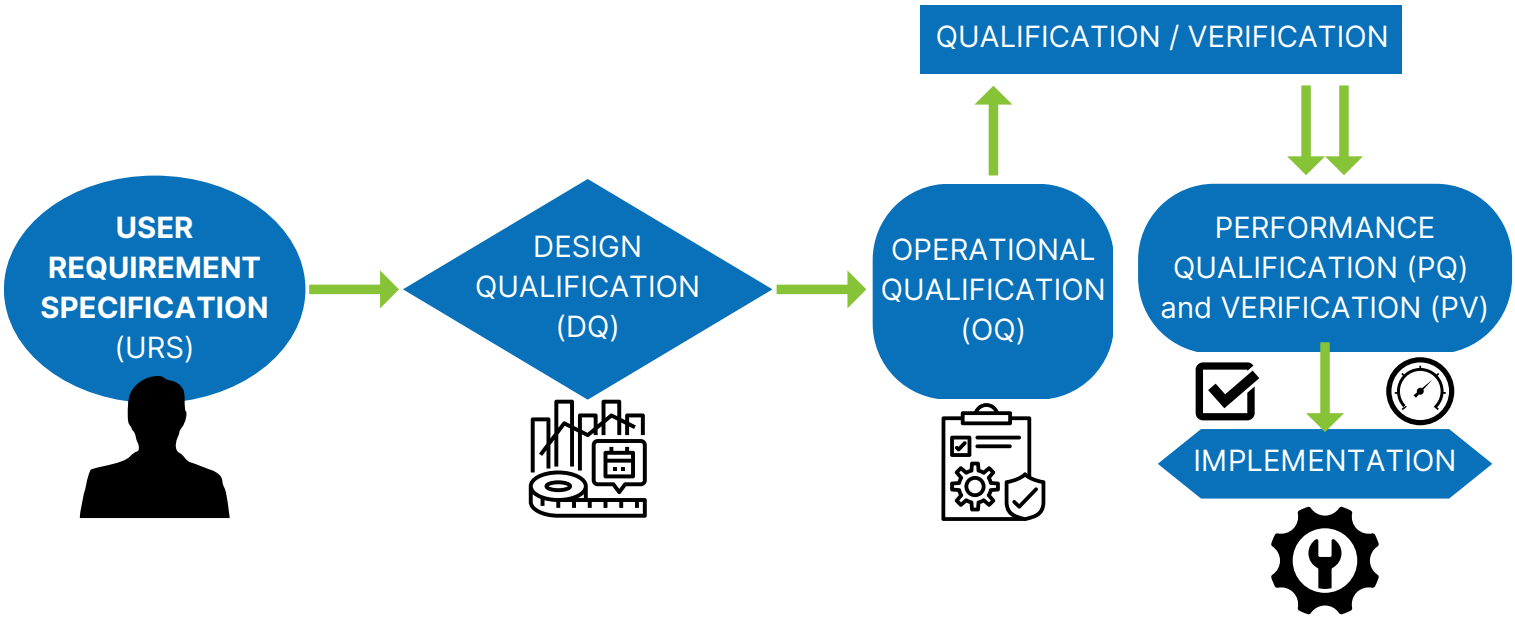
Purpose and Introduction

The intent of this strategic document is to outline the recommendations by *Lean Biologix* on how to evaluate qualification data provided by thermal shipping system manufacturers and vendors. Leveraging a pre-existing qualification package can be a tremendous time and money saver, but it needs to be done correctly.

The *Lean Biologix* approach is risk-based, technically sound, and compliant with regulatory guidelines. The process will ensure successful implementation of the thermal shipping system in your supply chain.
This document covers evaluation of the following qualification data from shipping system manufacturers and logistics providers:

- Thermal Operational Qualification (OQ) [pg.3]
- Distribution Operational Qualification [pg.5]
- Performance Qualification (PQ) [pg.6]



Qualification Data Evaluation

Not all qualification packages are created equal. When Company A and B both present a qualification package indicating their shipping system is qualified for 96 hours of duration, the performance of the two systems can vary drastically in the field. By following the strategy developed by Lean Biologix on how to evaluate qualification data a company can be confident that they are making the right decision on which shipping system to use in their supply chain.

Thermal OQ

When evaluating thermal OQ data, *Lean Biologix* recommends focusing on the following aspects of the data package:

Payloads

- ☐ *Are maximum and minimum loads included?*
- ☐ *Can payload bracketing sufficiently represent the payload configurations being used to ship?*

Thermal mass

- ☐ *Is the thermal mass of the payload representative of the products being shipped? i.e. Is the qualification performed with bottles of water when you are planning to ship pre-filled syringes?*

Ambient Profiles

- ☐ *Is the qualification performed against industry standard such as ISTA 7D or 7E? If not, can justification be provided to ensure the profiles are worst-case or representative of the supply chain?*

Repeatability

- ☐ *Is triplicate (N=3) testing performed for each payload configuration, to make sure the results are consistent and repeatable.*

Qualification Data Evaluation

Thermal OQ (continued)

Thermal Mapping

- ☐ *Are there enough thermocouples to assess the entire payload space?*
- ☐ *Is the worst-case temperature location identified for temperature monitoring of actual shipments?*

Equipment Calibration

- ☐ *Is all the equipment calibrated?*

Post-Verification

- ☐ *Can data accuracy be confirmed via post-verification of thermocouples and other equipment?*

Refrigerant Preconditioning

- ☐ *Does preconditioning require special refrigeration / freezer units?*
- ☐ *Can the process be supported in the supply chain?*

Equilibration

- ☐ *Does qualification data include equilibration time after pack-out?*
- ☐ *Does it work for the product's time out of refrigeration allowance?*

Data Rounding

- ☐ *Is the data rounded and does the rounding rule make sense?*

Duration

- ☐ *Does the tested payload stay within qualification parameters and does this meet the supply chain requirements?*

Qualification Data Evaluation

Distribution OQ

Vendors rarely test more than one container closure. There is a high likely hood that the payload tested is not representative of the container closure of the specific product.

Payloads / Product Presentation

- ☐ *Are maximum and minimum loads included?*
- ☐ *Can the payload bracketing sufficiently represent the payload configurations / product presentation that is planned for shipment?*

Test Sequences

- ☐ *Is the qualification performed against industry standards such as ASTM D4169 or ISTA Series 3? If not, can justification be provided to ensure the test sequences are worst-case or representative of the supply chain?*

Repeatability

- ☐ *Is triplicate (N=3) testing being performed for each payload configuration?*

Temperature Control

- ☐ *Is the qualification performed at the intended product temperature or product state (i.e. liquid vs. solid)?*

Equipment Calibration

- ☐ *Is all of the equipment calibrated?*

Temperature Monitoring

- ☐ *Are temperature loggers used and are they placed in the worst-case temperature location as defined in the thermal OQ?*

Package Integrity Inspection Criteria

- ☐ *Is acceptance criteria for post-inspection stringent enough for the product being tested?*

Qualification Data Evaluation

Performance Qualification (PQ)

More often than not vendors will not have the ability to perform a PQ as it is specific to the pharmaceutical product. Regulatory bodies are paying more attention to product lane specific PQ. It is critical if there is a gap in PQ data that it is closed to maintain compliance.

Payloads / Product Presentation

- ☐ *Are maximum and minimum loads included?*
- ☐ *Can the payload bracketing sufficiently represent the payload configurations / product presentation that is planned for shipment?*

Lane Selection

- ☐ *Are the lanes tested in PQ representative or worst-case supply chain lanes in terms of distance, duration, and mode of transportation?*

Duration Calculation

- ☐ *Is start and end time of PQ shipment clearly defined?*

Temperature Monitoring

- ☐ *Are temperature loggers used?*
- ☐ *Are they placed in the worst-case temperature location as defined in the thermal OQ?*

Package Integrity Inspection Criteria

- ☐ *Is acceptance criteria for post-inspection stringent enough for the product being tested?*

Technical Assessment

The result of the qualification data evaluation should be summarized in a technical assessment document. Based on the assessment, a determination should be made on if the pre-existing qualification data can be leveraged, or if further qualification activities are required before the shipping system can be implemented. Any identified risk should be listed, with risk-mitigation measures proposed to address those gaps.

	Gap	Risk	Risk Mitigation Action
Thermal OQ	Thermal OQ only completed on empty payload.	No data on max load could lead to temperature excursions in winter months.	Run Thermal OQ MAX Load Only.
Distibution OQ	Distribution OQ completed on IV Bags instead of product container closure.	Chance of damage in commercial supply chain.	Complete full distribution OQ on MIN/MAX in the product container closure.
PQ	PQs run not at all on commercial supply chain.	Possible excursions in commercial supply or additional regulatory body scrutiny.	Run the PQ seasonally (winter/summer).

Conclusion

This document outlines the strategy recommended by *Lean Biologix* on how to evaluate qualification data provided by shipping system manufacturers and logistics providers. The leveraging strategy proposed by LBX ultimately will need the cooperation of a customer's stakeholders and QA based on the risk tolerance levels of the customer company. By following this industry-proven strategy, you can be confident that you are making the right decision on your shipping system selection.

References

- ASTM D4169, Standard Practice for Performance Testing of Shipping Containers and Systems
- ISTA Series 3, General Simulation Tests