AdeptGroup

ENGINEERING EXCELLENCE

LEAKAGE

Quality Remediation

Client Needs

A pharmaceutical company had repeated leakage from a 1ml ID vial inside a dry ice shipper during drop testing in preparation for Operational Qualification (OQ) as the internal BLA filing deadline approached.

Challenges

The thermal shipper containing the product cannot be used for future shipments until the deviation for this incident is closed and corrective actions are implemented.

Contributing root cause is not identified.

Change of primary packaging (i.e. vial) to resolve the issue would result in lengthy change control process and impact assessment.

Leakage of Category B Dangerous Goods material may subject individuals responsible to criminal and civil penalties.

Results

- Passed Testing to Remain Compliant with CFR Regulations
- Major Root Cause was Identified
- Completed Testing by BLA Filing Deadline

STEPS TAKEN BY ADEPT

- Generated cause-and-effect (Ishikawa) diagram to list all potential root causes of vial leakage.
- Identified relevant stakeholders to assist in pinpointing the contributing root cause.
- Preliminary in-house tests revealed the major root cause to be process related (i.e. vacuum sealing of vial).
- Passed drop testing successfully to remain compliant with relevant CFR regulations.
- Timely qualification (OQ, PQ, HazMat) of the thermal shipper in preparation of BLA.

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