NEXA | EAM Case Study (USA)

Refrigerated Transportation Company

Validation Services:
Refrigerated Trailer Qualifications

About Client

Our client is a leading nationwide asset-based temperature-controlled LTL ("less-than-truck load") transportation provider, offering express delivery and specialized equipment for uncompromised product delivery.

Business Challenge

The Validation team was contracted to design and execute IOPQ qualification studies for 75, 53-foot temperature-controlled freezer trailers. The study results are key to confirming adequate HVAC control for the proper transportation of temperature sensitive products and materials.

Project Challenges

The client was new to the life sciences industry as they previously transported frozen foods. The challenge for the Validation team was to qualify the client's 75 refrigerated trailers to ensure all met the quality standards and protocols required to transport biological products regulated by the FDA.

NEXA was awarded the project as the leading supplier capable of addressing the following project challenges:

- **Qualification Method:** Development of robust testing procedures to ensure compliance with the client's specifications and industry regulations.
- **Project Management:** Coordination with the client to schedule testing of (6) trailers concurrently, with no down time in between testing phases.
- **Schedule:** Completion of all studies in 16 weeks.
- **Equipment:** Utilization of wired temperature sensors to ensure data reliability. The previous vendor encountered data loss and project delays by deploying wireless sensors. Services were completed outdoors with exposure to the elements so additional measures were necessary to protect the testing equipment from damage by changing weather conditions over the 4-month period.

Key Project Details

Project Type
Refrigerated Trailer IOPQs

Location
Texas, US

Project Costs
Confidential

Project Duration
16 weeks

Staff Assigned
Validation Engineers
Validation Manager
Validation Director

- **Staff:** A rotation of (5) Validation Engineers were assigned that specialize in temperature mapping studies to execute the refrigerated trailer qualifications. Additional support staff were assigned to ensure timely delivery of the qualification documents.

Scope of Work

The NEXA validation team partnered with the client on the development of the validation method and protocols to meet the client's risk assessment and budget allocation.

Key deliverables include:

- **Master protocol template development** – which standardized the test methods and simplified the approval process.
- **Installation Qualification** – ensured the diesel-powered refrigerated trailers were installed to the manufacturer's specifications.
- **Operation Qualification** – testing ensured the control and monitoring equipment was properly configured and functioning.
- **Performance Qualification** – Temperature mapping studies that included 12-hour EMPTY, 24-hour MIN load, and 24-hour MAX load to ensure the refrigeration system performed to meet the client's product storage requirements. Open door recovery and power failure recovery studies were also conducted to document recovery times from planned deviations.
- **Certificates of validation** were generated for each trailer summarizing the results of the qualification.
- **Qualification Packages** were provided that included all objective evidence of the qualifications.

As a result of executing a successful project, the client was able to become a qualified vendor to transport blood plasma. The qualifications assured global quality compliance for the safe transportation of all products and materials that require storage at the qualified temperature range. This opened new market opportunities for our client as the trailers are now qualified for GMP use.

Results

Quality Improvements

- Standardized validation methods across the entire fleet of refrigerated trailers
- Single provider enabled consistent deviation management
- Trailers qualified for GMP use

Project Management

- Project oversight by Validation Director.
- Single provider enabled simplified and consistent communication plan.

Schedule

- Completion of all studies in the allocated timeline of 16 weeks.