

Case Study: West Pharmaceutical Services, Inc.

Onsite Training Classes

West Pharmaceutical Services, Inc. (West Pharma) (<https://westpharma.com>) designs and manufactures pharmaceutical packaging and delivery systems. Working by the side of its customers from concept to patient, West Pharma creates products that promote the efficiency, reliability and safety of the world's pharmaceutical drug supply. Their site in Tempe, Arizona is a dedicated medical device and contract manufacturing facility.

West Pharma approached Modality Solutions for assistance in Good Documented Practices (GDPs) Training of Cold Chain Operations and Cold Chain/Thermal Packaging Qualification Training Best Practices. The GDP training focused on sustaining the quality and identity of pharmaceutical products throughout the entire distribution process.

The objective of the Shipping Qualification Training Program was to scientifically demonstrate and verify through qualification testing that the product can be transported throughout the cold chain within required temperature ranges and without damage.

Objectives

The focus of our engagement was to:

- Understand the basics of Good Distribution Practices (GDPs) for medicinal products for human use.
- Summarize the main GDP requirements as they relate to premises, equipment, and personnel.
- Outline the principles of the GDP quality systems and quality management.
- Explore risk reduction program development to scale up regulatory compliance and approval.
- Review the importance of packaging qualification in order to provide documented evidence that labeling and packaging processes operate and perform as specified and meet cGMP requirements.
- Develop and execute Validation Master Plans that detail protocol requirements, address equipment installation/qualification, and explain drug product operation qualification and performance qualification for biopharmaceutical shipping lanes.

Approach

In December 2018, Modality Solutions sent two engineers onsite at West Pharma in Tempe, Arizona to conduct in-person training, featuring hands-on exercises. Step by step, participants were brought up to date on thermal packaging qualification and various aspects of warehouse and distribution practices. Hypothetical warehouse and other assessment scenarios were presented to familiarize staff with potential actions to take in the warehouse should they arise in real world situations.

Value to West Pharma

"The training was simple, straightforward and easy to comprehend. I enjoyed the step-by-step approach along with the built-in alerts for common pitfalls and issues.

While it took a few rounds for me to become familiar with cold chain and packaging validation, this training provided a basis of where to start and how to get to the end goal. It will take many trips on the journey to become an expert but this training has given me the confidence to start the journey on my own."

- Julian Gladysiewski

Program Manager, West Pharmaceutical Services, Inc.



Results

Day 1: GDP Training, Review, and Discussion of Thermal Packaging Qualification

- As the group felt confident in their knowledge of Good Distribution Practices, the first part of the day was spent primarily in review with the discussion moving at a quick pace.
- We spent the remainder of the day discussing the topic of Thermal Packaging Qualification where there were many more insights from the group and areas for discussion. We rounded out day one with a request to cover real life scenarios and a detailed walk through of the qualification process for day two.

Day 2: Thermal Packaging Qualification Training and Discussion

- Day two kicked off with a detailed explanation of the thermal packaging qualification process, beginning with the importance of obtaining detailed user requirements, thorough thermal and physical testing, and accurate Validation Master Plans. We used real world examples to help clarify situations and answered questions from the group.