



Specialty Pharmaceutical Company

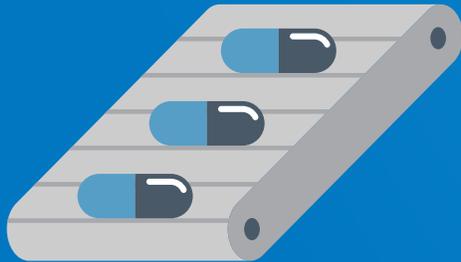
The Client

The client is an innovative pharmaceutical company. Its products include specialty drugs for treating rare genetic disorders. The company produces its medicines in facilities that meet or exceed Current Good Manufacturing Practices (CGMP), regulations enforced by the U.S. Food and Drug Administration (FDA). These specialty drugs help relieve difficult, debilitating conditions in children and older patients worldwide.



Need / Challenge

The client turned to Clarity Consultants to identify and provide an experienced learning and development (L&D) professional who also had pharmaceutical knowledge. The client's target dates for required multiple FDA inspections and the start of operations allowed just eight weeks for the consultant to design, develop, and pilot the training.



The client was in the process of staffing and piloting a new facility to produce a new drug. About half of the 65 new employees were experienced with drug manufacturing, and the others, recent college graduates, had limited experience. To ensure that the drug was manufactured properly, in compliance with CGMP and other FDA standards, the client wanted to train all of the new employees in a certain drug manufacturing technique.



Solution:

What Clarity Did

The Clarity Consultants L&D professional worked in the plant, observing the new employees as they learned the client's manufacturing process and prepared the plant to go on line. To develop the training, she relied primarily on two subject matter experts (SMEs), one who was expert in the manufacturing technique, and the other expert in compliance issues.

Because the SMEs and other employees were focused on readying the plant for manufacturing and learning their specific job tasks, the consultant was attentive to and respectful of their needs when working with them.

The consultant developed a five-hour course, which included three hours of classroom training and two hours of laboratory time for practice and testing. To pass the training, the learners had to successfully perform the technique in the lab. The training material the consultant developed included a PowerPoint deck for the classroom training and also provided to the learners as a handout; several videos; and a job aid. The consultant trained the trainers, observed the pilot class, and provided feedback and coaching to the trainers.

Results: **The Outcomes**

Of the 65 new employees, all but two successfully performed the technique after their first training session. The other two employees passed after taking the class a second time. Moreover, the outside quality inspector gave the new plant a high rating.

The pharmaceutical company considered the training so effective that it rolled it out to its other plants. In addition, the company asked the Clarity L&D consultant to stay on and develop eLearning courses for new manufacturing equipment.

All in all, this client gained several benefits from working with Clarity Consultants:

- The new employees learned manufacturing skills that meet or exceed industry standards.
- The consultant was able to develop the training without interfering with the work of the employees or SMEs.
- The build-out and start-up of the plant were completed on schedule.

Breakouts: **Quotes from Consultant**

“Time and SME availability were major factors. Because of the challenges, it’s important to be attentive to and respectful of the clients’ needs when working with them.” - Clarity consultant



ABOUT



clarity
CONSULTANTS

Clarity has over a quarter century of expertise in placing elite learning and development professionals in high-demand positions in large, global organizations.

There is a reason why over eighty percent of Fortune 500 firms rely on Clarity to staff their projects. Our background, skilled consultants, and broad range of experience across industries and sectors help set us apart from the competition.

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