



learnaboutgmp

MEETING GLOBAL STANDARDS THROUGH A HARMONIZED ONLINE TRAINING APPROACH

MULTI-NATIONAL, MULTI-LINGUAL TRAINING PROGRAM ENSURES FDA WARNING LETTERS ARE ADDRESSED

In 2015, a top-five global pharmaceutical generics manufacturer was slapped hard by the FDA for problems at three plants for ongoing data Integrity Issues.

The resulting corrective and preventive action (CAPA) required retraining of their global workforce to help them address the warning letters that were issued by the FDA.

Not only did the manufacturer have to retrain tens of thousands of employees, but the program entailed multi-lingual content delivered worldwide.

After a thorough evaluation, Learnaboutgmp was the clear choice over twelve other vendors for three main reasons:

- The quality and alignment of their courses with the FDA regulations
- The compelling way the content was delivered, maximizing learning principles
- Unparalleled customer support to ensure the project's success

Now a member of Azzur Group's network of companies and the world's only IACET-certified online life science training platform, Learnaboutgmp harnesses a network of more than 60,000 industry professionals to create courses that are current, aligned with the regulations, and continually updated to help organizations maintain their state of compliance.

Working with the client's SMEs, the Learnaboutgmp team developed and customized seven online courses covering areas such as Data Integrity, GMP, and Contamination Control into 14 languages and seamlessly integrated them into the client's existing learning management system (LMS) for use at 28 manufacturing sites worldwide.

Meeting the Azzur Group promise of **Discover to Delivery™**, the team at Learnaboutgmp delivered the final online courses, including translations, in less than nine months—a true success for both parties.

Today, more than 20,000 staff are fully trained, and the client has successfully addressed the warning letters issued by the FDA.

LEARNABOUTGMP.COM



THE CHALLENGE

Helping a global generics manufacturer address FDA warning letters.



THE SOLUTION

Seven online courses, translated into 14 languages, deployed to 28 global manufacturing facilities - in less than nine months.



THE TEAM

Learnaboutgmp



THE IMPACT

Addressed FDA warning letters successfully and trained more than 20K employees ensuring client compliance and increasing overall quality and safety.