

Unmatched Results with a Commitment to Accuracy | A Case Study



In late 2016, a major medical device manufacturer was challenged with revamping an existing facility for the assembly of IV bags.

Before commissioning the new space and equipment, the manufacturer required stringent testing on the next product to determine the most difficult-to-sterilize areas of the bags. Azzur's full-scale microbiology lab and expert scientists served as the perfect solution for the client, executing every step of the process from methodology, to procurement, to testing.

Throughout the entire process, the Azzur team worked hand-in-hand with the client. The actual validation of the sterilizer was a multi-step process requiring meticulous coordination.

Testing was executed based on the client's own protocol and began with the inoculation of the product at the Azzur microbiology lab. Once inoculated, the products were transported to a third party where multiple sterilization cycles took place.

Azzur labs was committed to the client at every stage of the game, from inception to execution, providing results unmatched by any other operation during the project, which lasted into 2018.

After undergoing the sterilization process, the products were returned to Azzur in order to complete the testing and analyze the products for growth. This process was repeated for all of the predetermined sites and a cumulative report was developed at the conclusion of testing.

Paramount to the success of this project was Azzur's logistical coordination at every stage of the process. Not only did Azzur's scientists facilitate the transportation of more than 300 samples in a safe and efficient manner, but they also worked hand-in-hand with the client to procure all required materials and protocol-specified equipment.

Because the sterilization protocol and testing were technical and challenging, an Azzur scientist provided hands-on, on-site training for the lab techs to complete the testing method transfer.

THE CHALLENGE

Validation of sterilization process for a new facility

THE SOLUTION

- Validation
- Microbiology Testing
- Training
- Consulting Services

THE TEAM

Azzur Labs

THE IMPACT

- A trusted partnership at every step of the validation process
- Expert consultation & training
- Precise preparation & testing
- Accurate reporting

PUT US TO WORK!

Azzur Labs provides expertise in every stage of the life cycle - from Discover to Delivery™. As a client-centric organization, our success is predicated on our ability to serve our clients. We will work hand-in-hand with you to create efficient, effective testing methods to minimize downtime and deliver the highest quality results.