# Preventing a Product Shortage with Validation and Qualification of an Existing Facility

## THE CHALLENGE

In 2017, a top 20 global biopharmaceutical company faced the challenge of modifying and validating an existing facility to house the production of an injectable prescription medication. The company initially contracted Azzur Group to assist with a long-term technology transfer project.

By 2018, Azzur became a full partner in assisting with the validation activities for their new facility. To avoid a product shortage, the client needed to have the facility ready for operation by the year 2023. Azzur's team of consultants actively partnered with them to determine and drive a strategy that would have the facility fully validated and running by the deadline. Some of the critical areas the Azzur team supported included:

- Analytical, QC Chemistry Equipment Qualification & Method Validation
- Process engineering supporting User Requirements Specifications (URS) / Functional and Design Specifications (FSDS) development for complex systems
- Validation of process hold studies & expedient hold studies
- MS Small Scale Studies
- Manufacturing Batch Record Development
- Validation of mixing & formulation studies
- Support in execution of Process Performance Qualification (PPQ)
- Material Qualification Support
- Cleaning Validation Development
- CMC Submission Support

## THE TEAM

A rotating team of up to 12 Azzurians assisted the client with the cleaning validation, process validation, and lifecycle studies of the facility. The team owned the process and deliverables, becoming active drivers for the project. These deliverables included:

- CMC European Submissions
- Operational Readiness and support of SOPs
- Cleaning Validation
- Process Validation

## THE SOLUTION

Through their active partnership with Azzur, all expedited critical timelines to qualify processes were met, and the client received full FDA approval in February 2023, and drug shortages were avoided.