AZZUR GROUP

SETTING UP A SYSTEM OF SUCCESS

HOW A TEAM OF ON-SITE VALIDATION EXPERTS OFFSET THE CHALLENGES OF GETTING A NEW BIOPHARMACEUTICAL MANUFACTURING FACILITY UP AND RUNNING

In 2016, a top-20 U.S. biopharmaceuticals manufacturer faced the challenge of building a new active pharmaceutical ingredient (API) manufacturing facility from the ground up. With limited in-house resources to dedicate to the validation of the new facility, the client sought an outside team to lead and execute the qualification—in the middle of a full QMS integration effort. Azzur Group was the solution—proving full-scale GMP-compliant project management and execution with an autonomous team of project managers and engineers who collaborated with the client's validation team at every step of the process.

Working on-site for the entirety of the project, the Azzur team of subject matter experts (SMEs) was charged with supporting acceptance testing and DQ/IQ/OQ/PQ. The Azzur team worked hand-in-hand with the client to develop a customized validation master plan, helped the manufacturing organization drive the schedule and project resources and clarified the qualification execution strategy ensuring the implementation of the validated state.

Once commissioning was complete, the team of Azzur SMEs partnered cross-functionally on system testing and qualification including, but not limited to:

- DQ/IQ/OQ for process equipment
- DQ/PQ for utilities, including purified water, steam in place, clean in place, ammonia, water for injection, compressed air, hydrogen, etc.
- Analytical Laboratory Instrumentation
- Controlled Temperature Units (CTUs)
- HVAC/Cleanroom Certification
- Buffer Generation
- Steam In Place (SIP)

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THE CHALLENGE

Facility start-up for new API manufacturing facility, from the ground up

THE SOLUTION

- Design qualification
- Facility validation master plan
- Verification/Qualification for installation, operation, and performance

THE TEAM

Azzur New England

THE IMPACT

On-site, autonomous engineering consultants who efficiently support validation activities for the new manufacturing facility, ensure the client was set up for success by mitigating impact to client staff and their day to day roles.

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Throughout the two-year project, as many as 20 validation engineers with project managers, were on site to support the client. The Azzur team worked cross-functionally to a guarantee a smooth transition between each stage in the process. These departments included:

AUTOMATION
ENGINEERING
FACILITIES
IT
MANUFACTURING
METROLOGY
QA
QC
VALIDATION

A true illustration of the Azzur Group promise of Discovery to Delivery™, the team led the client from project conception to execution with confidence, complementing their in-house team and providing significant value to the client ensure their deadlines were met.

FACING A COMMISSIONING & QUALIFICATION CHALLENGE? LET AZZUR GROUP BE YOUR GUIDE.

At Azzur, our goal is to understand the unique requirements of your process and product and to build a plan focused on the associated critical aspects while maintaining regulatory compliance. SMEs are backed by real-world experience and the technical skills to help make your project a success.

Our C&Q project experience spans the pharmaceutical, biotechnology and medical device industries and includes products that utilize various platforms and at various phases of their product lifecycle. Azzur's SMEs have C&Q experience with facilities, utility systems, support equipment, process equipment, analytical instrument, cleaning processes, CSV, and sanitization/ sterilization processes.

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