



CASE STUDY ZOSANO PHARMA

IMPEC PROVIDES THE FOLLOWING SPECIALTY SERVICES TO CLIENTS LIKE ZOSANO PHARMA

- cGMP Sanitation and Cleaning
- cGMP Maintenance and Operations
- Glass Wash Operations
- Utility and Environmental Monitoring (viable and non-viable)
- Calibration and Repair
- Lab Equipment Calibration, Repair, and Validation
- Lab Support and Supply Management
- Technical and Operational Procedure Documentation Support
- Lab Cleaning and Wipe Down
- Every Impec employee assigned to a life science/biopharma/biotech customer's site to perform sanitation or facility services work receives in-house training on:
 - cGMP (current Good Manufacturing Practices)
 - GDP (Good Documentation Practices)
 - GLP (Good Laboratory Practices)
 - Contamination and Microorganisms
 - Quality Management Systems

IMPEC GROUP EXPANDED SERVICES TO MEET ZOSANO PHARMA'S NEEDS

Impec Group (formerly Clean Innovation) has gained a reputation among its customers as a company able to provide solutions to any challenges they might pose. This was especially clear to Zosano Pharma, a biopharmaceutical company that needed specialty services for its clean room facilities.

Having worked in demanding environments for high tech companies with exacting standards, the team at Impec knew they could tailor their services to meet even more stringent Good Manufacturing Practices (GMP) regulations. These regulations, which have the force of law, have been enacted by the U.S. FDA to require that drug manufacturers such as Zosano ensure that their products are safe, pure, and effective.

"Impec was initially hired to handle regular cleaning services," said Joe Ventosa, Manufacturing Supervisor at Zosano Pharma. "At the time, Zosano was looking to change the GMP cleaning team. We chose Impec to handle these services as well because they were flexible and easy to work with."

GMP regulations address such issues as recordkeeping, personnel qualifications, sanitation, cleanliness, equipment verification and process validation. Failure to comply with GMP regulations can result in serious consequences including recall, seizure, fines, and jail time.

When Impec was asked to expand its services to meet Zosano's GMP cleaning needs, the company immediately began a rigorous training program, ensuring that every team member from company executives to on-site workers knew what the regulations were and how to follow them to the letter. Continuing on-the-job training was part of the mix as well.

"They progressed really well, said Ventosa. "Impec expanded services for GMP cleaning in the manufacturing facility, having their workers trained for GMP services and increasing knowledge about GMP regulations throughout the company."

The Impec team not only had to follow strict regulations but had to do so in a manner that did not interfere with Zosano's around-the-clock manufacturing process. This meant coordinating a team of up to ten on-site workers conducting facility management activities without disrupting manufacturing.

A commitment to excellent service, working with the customer to make sure regulations were rigorously followed, resulted in a satisfied client.

"Impec has high business standards. The team is very accommodating and they are willing to do anything to satisfy the client and get the job done," said Ventosa. "I won't hesitate to recommend them to any life science firm."

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