

## CASE STUDY

# Navigating GMP Readiness Under Pressure

How GDI Ainsworth's Life Sciences team accelerated EMPQ readiness, overcome construction setbacks, and stay on schedule



## Project Details

### Location

U.S. - based biotechnology manufacturing facility

### Number of Buildings

1 new manufacturing facility

### System Implemented

GMP cleaning program, SOP development, post-construction cleaning, and emergency response cleaning services

### Project Goal

Prepare GMP cleanrooms for Environmental Monitoring Performance Qualification (EMPQ) while the remainder of the facility was under construction

## Impact at a Glance

- ✓ Achieved EMPQ readiness on time despite construction setbacks, keeping the project on track
- ✓ Delivered **\$120,000 USD** in cost savings by maintaining schedule integrity and avoiding costly delays
- ✓ Ensured readiness for engineering runs **ahead of manufacturing deadlines**
- ✓ Delivered a seamless, highly responsive cleaning program under tight timelines



## Challenge

The client was opening a new manufacturing facility but faced construction delays that jeopardized their ability to start EMPQ for their cleanrooms.

They required immediate, specialized GMP cleaning services—while construction was still underway—to meet aggressive readiness timelines.

The situation demanded rapid mobilization, flexibility, and strict adherence to GMP standards despite evolving site conditions.



## Methodology

Aligned cleaning strategy with EMPQ requirements to support an accelerated qualification timeline

Coordinated closely with client teams to anticipate shifting construction and staffing needs

Developed and refined SOPs to standardize GMP processes and eliminate rework

Implemented proactive inventory and supply readiness to support rapid response needs

Deployed GMP-trained personnel prepared to adapt to evolving site conditions and last-minute requests



## Solution

- ✓ Integrated post-construction and GMP cleaning program tailored to the qualification schedule, covering all daily, periodic, and pre-EMPQ needs for each GMP suite.
- ✓ Emergency cleaning support—including evenings, early mornings, and weekend mobilization—to protect project continuity
- ✓ Flexible on-site response and staffing scalability to address unexpected events, evolving schedules, and urgent cleaning priorities while maintaining project momentum
- ✓ SOP guidance and documentation support to standardize processes across engineering, quality, and cleaning teams
- ✓ High-touch communication with the client to align on progress, clarify evolving expectations, and maintain operational transparency



## The Ripple Effect

- ✓ Created a reliable framework or emergency response and rapid deployment
- ✓ Demonstrated operational excellence that minimized downtime and project risks
- ✓ Set the stage for ongoing efficiencies in future cleaning and qualification cycles