

CASE STUDY

ANALYTICAL LAB GROUP AND DPS GROUP DEMONSTRATE THE POWER OF PARTNERSHIP



Caroline Carmody

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INTRODUCTION AND INTENDED OUTCOME

When the client is pioneering immunotherapy for people with cancer, work on their behalf takes on new meaning. This magnitude is commonplace for DPS Group (DPS), as their portfolio ranges from life-saving therapeutics to industry-changing biomedicine. The team at DPS understands the significance of successful projects and the hope it brings for patients.

When DPS oversees a project, they are tasked with ensuring every piece of the puzzle works. Sometimes a piece may extend beyond their scope. If so, DPS goes to the client in full transparency and recommends a partner with options of working under DPS's contract or on their own. This case study breaks down the criteria DPS uses to partner and what that means for the client.

The specific example involves a biotechnology company that engaged DPS for its consulting and validation engineering expertise. Known for meeting timelines and ensuring quality control, DPS draws on those abilities to complete the lifecycle facility. However, the scope also called for cleanroom qualifications.

Caroline Carmody, Vice President, Technical Services Operation, DPS Group, offers insights on the need and value of partnerships. In this case, Caroline pulled in Analytical Lab Group (ALG), now part of Element, to ensure the result is an impeccable facility that accelerates the client's mission to eradicate tumors.

THE CHALLENGE

The stakes are high with getting a vaccine or biotechnology to market. Companies in the antimicrobial, pharmaceutical, and medical device space face regulatory and technology-related challenges every day.

Failure to keep up with the latest testing, contamination control, or cleanroom advancement could result in delays and recalls. Companies deal with complex quality standards, and missing a step within those regulations may cost time and money.

Product quality control is job one. Companies cannot achieve that goal without performance indicators, risk analysis, or expertise on the latest solutions or regulations.

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If management contracts any work, they must require rigorous guidelines for their partners, where all parties have confidence in quality protocols and deliverables.

DECISION TO PARTNER

Caroline brings her 20-year career as a commissioning and validation professional to complex biopharmaceutical projects. With this biotechnology client, Caroline provided commissioning, qualification, and validation (CQV) consulting and front-end strategic planning to ensure successful operations.

"We work in a relationship-based industry. I stay in touch with former colleagues and rely on their expertise when necessary," said Caroline. "That is why I partner with ALG – because I've known and trusted them for years."

Caroline is often the client as well, which allows her to see both sides of a project. When Caroline determined that the project needed expertise in environmental monitoring, specifically prevention, sampling, and testing, she called on the ALG team again.

Caroline knew that the client would assess her on this recommendation. She backed her decision on going with ALG on the following three criteria, which has always made for a strong partnership.

SERVICE AND TRANSPARENCY

Based on technical requirements, the client faced a gap that could hinder a fully functioning lab. DPS went to the client to present ALG as the vendor that could hit the ground running, fill the chasm, and maintain timelines.

In the discussion, Caroline explained how the partnership would work and where DPS was the primary contractor; however, DPS would not hinder open communication between the client and ALG. This clarity immediately created a trusting environment that allowed quicker problem solving among all parties. Not adding levels with a growth-stage biotech company maintained nimbleness.

ALG came to the project demonstrating superior service to both clients. Because of their rapid accomplishments, the two ALG principals receive an additional contract. Their success reaffirmed Caroline's decision-making and management style. DPS also gained a happy client because expectations and budget were met, even during a pandemic.

"ALG did everything right the first time. They didn't lose any samples, which is rare and demonstrated their attention to detail," said Caroline. "Pressure was on given time frames and COVID-19; ALG didn't falter."

The secret to success was that quality and caliber reflected in ALG mirrored DPS. The partners complemented each other.

SEAMLESSNESS AND BENCH STRENGTH

DPS wanted one-stop shopping, so the client would not experience any burden with additional administrative work. DPS presented this turn-key approach under the header of commission and qualification statement of work. This unified front ensured white-glove service.

ALG delivered on its environmental monitoring and cleanroom compliance services, which means a future-proof solution.

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"ALG immediately established confidence with the client because of their competence and integrity," Caroline said.

The ALG team at the client site could rely on their colleagues based across the nation. More than 130 scientists and experts with experience in prevention and virology testing; and backgrounds in molecular cell biology, antimicrobial, pharmaceuticals, and biotechnology could offer additional support.

CLEAN AND SAFE

Developing immunotherapies requires clean, controlled rooms that regularly address any possibility of contaminants. DPS needed an experienced partner who shared the goal of contamination prevention. They received that in ALG and their demonstrated leadership in FDA- and EPA-focused laboratories and cleanroom testing.

With more than 25 years of environmental monitoring in pharmaceutical manufacturing, ALG brought solutions to any vexing healthcare cleaning and disinfection challenges that arose. They considered every aspect of a cleanroom that could protect employees, patients, and the environment as a whole.

ALG focuses on infection prevention, with the most comprehensive testing solutions in the pharmaceutical, medical device, biotech, and healthcare spaces. They also provide training in proper aseptic practices to develop the safest possible product.

"I knew ALG could deliver for DPS," said Caroline. "They addressed any variables that hindered the cleanroom. Moreover, they consistently added value with their knowledge of the latest safety measures, testing, and technology."

RESULTS

The partnership is on track to complete commissioning and qualification and meeting all CQV and compliance-related projects. By the end of 2020, the client will house a fully qualified cleanroom and equipment, which can manufacture phase 1 and phase 2 vaccines. The team understood the precision necessary for the cleanrooms to pass USP <797> and <800> guidelines.

Moreover, the result for the client is a project completed as promised and as budgeted. It also means the client now has the tools, testing, and processes to operate successfully and carry out their mission.

For Caroline and the DPS team, success is a strong pipeline of clients based on referrals from successful projects like this one. The partnership with ALG contributes to the growth of new clients.

"Our vision with each client is to up our quality, and we do that with ALG. They share our mentality as super pleasers," Caroline stated. "Because of this mindset, ALG received more work from the client, and that makes me happy and reaffirms my decision to partner with ALG."

CONCLUSION

Caroline's philosophy is that you can never go wrong if your only agenda is to do right by your client. She knew pulling in ALG as a partner was the right thing to do.

"My formula for success isn't unique. It involves being true to our values and finding partners that match those values," Caroline said.



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