



ARE YOU READY?

CONFIDENTIAL CLIENT, *FARGO, NORTH DAKOTA*

ENVIRONMENTAL MONITORING PERFORMANCE QUALIFICATION (EMPQ) AND VALIDATION SUPPORT SERVICES

CASE STUDY: COMPLIANCE &
REGULATORY ISSUES



Environmental Monitoring Performance Qualification (EMPQ) and Validation Support Services

PROJECT OVERVIEW

In early 2022, CAI was approached by a rapidly growing pharmaceutical/biotech company to qualify a new series of aseptic processing rooms.

The project entailed multiple room qualifications, various sampling methods and numerous air handling unit qualifications. CAI provided direct support to the client by generating protocols, project execution and closeout support for the room qualifications. The project also included defining the static and dynamic sampling locations, executing the sampling, and documenting the results in the final summary report for the large number of air handlers that were being qualified.

CLIENT CHALLENGES

At the outset the client needed EMPQ services for qualification activities on a newly completed aseptic processing suite. The client site was growing exponentially to the point where they could not hire and train new employees to handle the rapidly increasing workload. Additional staff support was needed to complete protocol final reports, trend reporting, validation, qualification actions, as well as support for Quality Control activities. CAI agents were on site, and due to the excellent rapport they had with the Client, CAI agents were asked to support the ever-climbing service demand and challenges.

CAI SOLUTIONS

CAI outlined a project plan with the client to ensure all milestones were reached in providing aseptic manufacturing cleanroom qualification, protocol generation and execution, and closeout services to support EMPQ activities. Additional quality control laboratory support staff were requested of CAI i.e. trained laboratory technicians to provide immediate support while the client's new hires were being trained.

CLIENT:
Confidential

LOCATION:
 Fargo, ND, US

TIME FRAME:
2 years

CONTRACT SIZE:
\$3.3M USD



The on-site team reacted to the client's needs throughout the life of the project, providing additional staff support upon request. Below are examples of the many services provided by CAI:

- Testing for particulates during initial room classification.
- Sampling locations, volumes, and acceptance criteria were established per ISO 14644-1:2015,
- Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration.
- Determination of sampling locations for air and surface samples for EMPQ and routine monitoring via risk assessment in accordance with USP <1116> Microbiological Evaluation of Clean Rooms and Other Controlled Environments, PDA Technical Report #13 Fundamentals of an Environmental Monitoring Program, and per local policies and procedures as recorded in the client's document management system.

PROJECT SUCCESS

The initial efforts were a success, and CAI maintained a presence on-site to provide ongoing routine sampling support. This became a long-term initiative as the client continued to grow and their sampling workload increased. CAI provided support from early 2022 through 2023, when an additional phase of room qualifications was initiated and EMPQ activities were once again required. Qualification activities were executed successfully and efficiently with CAI's expertise. To date, CAI has been on-site with the client for over two years and has provided expanded services. As the client has grown their full-time Quality Control team, CAI has also stepped into a training and mentorship role for several of the client's new-to-industry direct hires.

As a result of efforts on-site, the client has increased its available aseptic manufacturing space by nearly 50%. Business continuity was supported through CAI agents to include flexible shift coverage, analytical lab support, validation projects, periodic regulatory reporting, and professional development of supported teams.

This project has shown that continued high standards and quality support can lead to service expansion. CAI has expanded its scope of services for this client from supporting the Quality Control teams with sampling and testing needs, to also providing support for the Validation teams. CAI agents have provided organizational and document support for container closure integrity testing validations, as well as supporting stability study work. In addition, CAI has been asked to support several computer system validation and equipment qualification projects throughout the past two years, to ensure areas were operational ready and completed on time and within budget. CAI has also added value from an operational excellence perspective, advising the client on information gathering for quarterly WFI trending reports. As the client's needs have grown, CAI's agents have continued to step into a variety of roles to support the client's operational efforts, while meeting all the quality standards.





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