

Case study: Sphere Healthcare

Overview

Sphere Healthcare approached Cleanrooms Australia to build a microbiology lab within their existing Sydney manufacturing facility to enable the in-house testing of the active ingredients used in their pharmaceutical products. Cleanrooms Australia successfully completed work on the ISO-compliant lab with no disruption to other areas in the manufacturing facility.

Background

Sphere Healthcare is a large-scale contract manufacturer for the pharmaceutical industry. Sphere produces 650 million gel capsules per year and is fully licensed by the Therapeutic Goods Administration to manufacture Complementary Healthcare Products.

The company also specialises in delivering the best Australian-made infant formula for both local and Asia/ Pacific markets.

Their 14,650m² headquarters is located in the Sydney suburb of Moorebank and features integrated production, logistics, research and development, laboratories, quality assurance, sales and marketing and customer support functions.

Sphere Healthcare approached Cleanrooms Australia to build a microbiology lab to facilitate on-site testing of samples of the active ingredients used in their products in order to comply with Therapeutic Goods Administration regulations.

The solution

Before approaching Cleanrooms Australia, Sphere Healthcare was sending samples off-site for testing. This was an extremely expensive process and the company determined that bringing the testing in-house represented significant cost savings.

Cleanrooms Australia was commissioned to engineer a solution that utilised their current equipment, and included work on the mechanical services and windows and doors of the facility that consisted of several ISO 7 and 8 mixed-flow cleanrooms.

As such, the design included several windows to ensure Sphere technicians could see from one room to the next, and provision was also made for the inclusion of a wash-down area.

The critical factors

As the microbiology lab was to be located within Sphere's greater manufacturing facility, it was vital that construction works did not disrupt operations in other areas.

This required careful planning that included the sectioning off of other areas to ensure materials could be moved in and out of the microbiology lab during construction without the need for production shutdowns elsewhere in the facility.

The process

After carrying out an assessment of the client's current equipment, we made some necessary modifications and installed an additional unit.

Following that, we worked in conjunction with the client and the tradespeople they already had on site to complete work on the mechanical services and windows and doors of the facility.

We used Gantt charts to ensure all project timelines were successfully met.

The results

We successfully commissioned the microbiology lab and it has been running without issue since.

The client has since decided to employ an external company to carry out testing at their on-site microbiology lab in order to remove potential bias associated with involving company-employed staff in the testing process.

Conclusion

Cleanrooms Australia successfully completed work on an ISO-compliant microbiology lab that enabled Sphere Healthcare to bring their sample testing process in-house. This represented a significant cost saving for the client. The lab remains in successful operation.