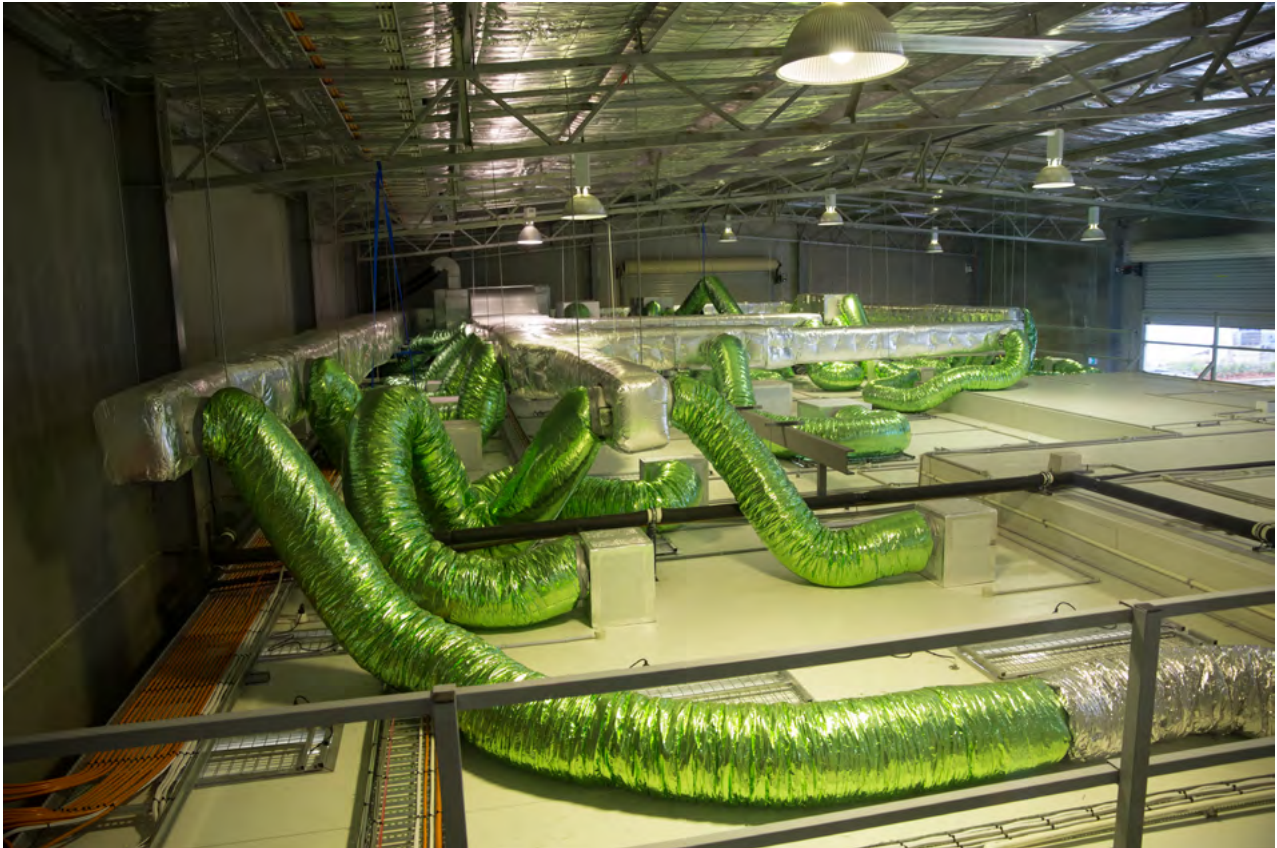


Case study: Cell Sera

Overview

CellSera commissioned Cleanrooms Australia to design and construct an ISO 14644 Class 7 and class 8 mixed flow cleanroom facility for the production of foetal bovine serum for international export. Cleanrooms Australia overcame several challenges, including insufficient power to the building, to deliver a state-of-the-art staged cleanroom facility for one third of the cost of a comparative facility.



Background

CellSera is a 100 per cent privately owned Australian company that produces sterile filtered foetal bovine serum from its state-of-the-art Rutherford labs in New South Wales' Hunter Valley.

The company was founded in 2004, and has grown into one of Australia's largest producers of high quality foetal bovine serum. Foetal bovine serum contains a high content of embryonic growth promoting factors and is most commonly used as a growth supplement for cell culture media.

CellSera commissioned Cleanrooms Australia to design and construct a brand new laboratory that would allow the company to produce foetal bovine serum in an ISO Class 7-compliant facility for overseas export.

The solution

Cleanrooms Australia designed and constructed a 10-room facility containing three separate EU GMP-class cleanrooms and one class-A laminar flow cabinet.

A class-D cleanroom was constructed for the production of CellSera raw foetal bovine serum; a class-C cleanroom is used to prevent cross-contamination during the filtration process; and a class-B cleanroom with a class-A laminar flow cabinet houses the bottling process.

The design includes multiple cleanroom classified production, personnel airlocks, materials airlocks, washdown and support areas surrounding the critical areas. This design also supports the product and personnel flow of the facility and facilitates high production yields with minimised input.

All the cleanrooms are monitored in real-time, and the cleanroom temperatures can be monitored and controlled remotely.

The critical factors

We faced several challenges throughout the project. Despite initial assurances from the Electricity Commission that there was sufficient power to the building to run the cleanrooms, an actual power shortfall was identified, which meant there was not sufficient power to run the required quantity of proposed centrifuges.

To rectify the problem, CellSera would need to pay for the installation of a new transformer, which represented a three to six month project delay. As such, Cleanrooms Australia saw the opportunity to keep the project on track by preparing a staged facility for pre-centrifuge operation that would allow continuous operation utilising their current facility in conjunction with the new facility that was under half power supply. The cleanroom also needed to be prepared to accommodate the use of all the centrifuges when the transformer installation was finally completed.

Additionally, CellSera required the cleanrooms to provide open working space, the existing structure would require reinforcement to accommodate an open design. Rather than modify the existing building the option was taken to engineer structures contained within the cleanroom walls to support the span CellSera required. Part of the cleanroom ceiling was also reinforced to support the remainder of the facility services including the duct and pipe work.

The process

CellSera originally approached Cleanrooms Australia seeking a cleanroom contained inside a shipping container that would roll bottles of serum out from a hatch in the side of the container.

However, the project changed significantly from that point. After considering constructing a new purpose-built facility opposite their current premises, CellSera eventually opted to move their operations into a new building in order to expedite the process.

CellSera provided a mud map of the cleanroom facilities they were planning for their new premises, and following a site inspection, Cleanrooms Australia began investigations as to whether there was enough power to the building and that the facility would be capable of sustaining the cleanrooms.

This was when a power shortfall was identified, and Cleanrooms Australia provided a plan for a staged facility that could continuously operate at half power and then expand as power to the site was increased.

The results

Cleanrooms Australia successfully designed and constructed state-of-the-art cleanroom facilities that met all required specifications. The client knew of a similar cleanroom built in other area of Australia for around three times the price of what was achieved for Cellsera.

The client was very happy with this result and is now a multi-national supplier of bovine serums with a market-leading facility that's among the best of its kind in the southern hemisphere.

Conclusion

Cleanrooms Australia was able to overcome several challenges including insufficient power supply in order to design and construct world-class ISO class-7 laboratory facilities that enabled CellSera to grow into a market leading multi-national supplier of bovine serums.