Individual Design class II Safety Cabinets

CASE STUDY - PHARMA INDUSTRY

Customer and Project Profile

Enduser: Pharmaceutical Company in the South East England
Customer industry: Pharma
Project subject: 18 x safety cabinet in painted stainless steel 316 built into the cleanrooms from customer

Project Background

The end-user, a Pharma company located in the North of London, has issued in 2019 a URS (unique requirement specification) to AAF with the question, “can something like this be designed and installed” for the design and supply of new Class II Safety Cabinets to be installed in ‘Upper Floor’ Cleanroom Suite.

As part of the refurbishment of the upper floor cleanroom suite, AAF designed a to be “built in” Class II safety cabinet for the manufacture of cytotoxic, monoclonal antibody and CIVAS product. During the design in close cooperation with customer, a safety cabinet has been designed and established that complies with the requirements of current Good Manufacturing Practice (cGMP), documented in the “Rules and Guidance for Pharmaceutical Manufacturers and Distributors”, 2017 Edition, issued by the MHRA. During the design, it has been taken into account that the cabinet will be used to aseptically manipulate potentially hazardous materials and therefore fully complies with the requirement laid out in BS EN: 12469:2000 for a Class II microbiological safety cabinet.

Design

On the market are many pre-designed “plug and play” safety cabinets available that can be purchased and supplied. None of these safety cabinets however comply to the full satisfaction and requirements of Pharma Company.
The new design would need to be robust, safe, integrated in the suits, modular and at the same time the design needs to be as such that operators can sit with their legs underneath the safety cabinet which means a complete different design for the exhaust - and return filters. The flow balance requires precise tuning between in- and out flow and must be displayed at all times on the outside of the unit for safety. Especially the inflow throughout the opening is important to protect the operator from the vaccines he or she is working on. Next to this high challenging demand, the air in the cabinet itself must be a fully laminar downflow with small accepted deviations which is a unique challenge in reference to the inflow of the cabinet. Supply air HEPA filters, Inflow 0.4 m/s, exhaust flow with double HEPA filters. Housing and materials of coated stainless steel 316. To create low pressure drops (= low sound level) eFRM filters have been installed in the downflow HEPA filtration.

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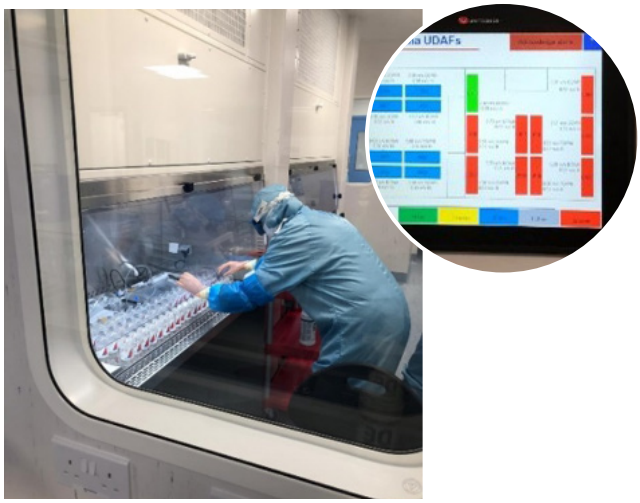
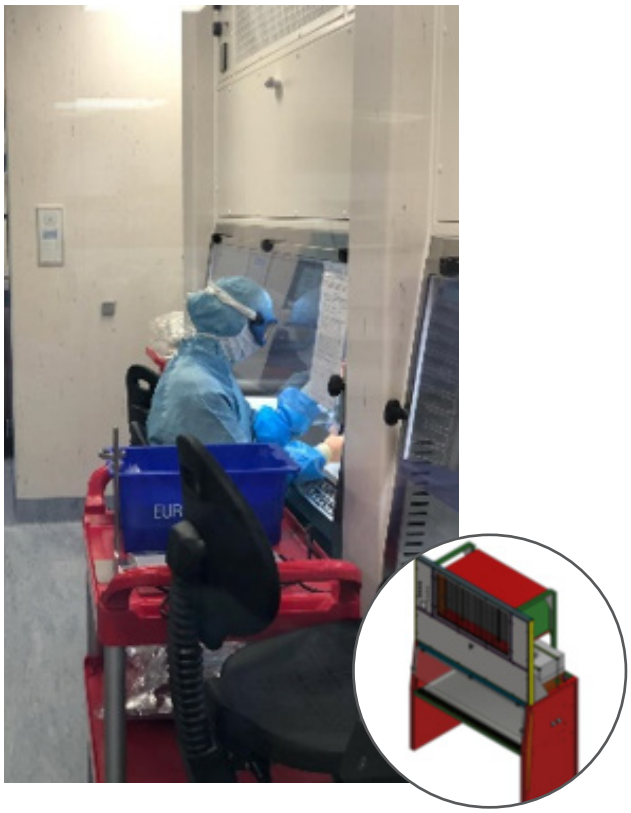
All cabinets and LED lights, inflow and down flow are controlled by 1 AstroDrive SCS 12” screen. The AstroDrive continuous monitors the performance of all 18 cabinets and logs all events in the AstroDrive.



Design execution, sample

To reduce the risk and to establish more insight in the design while taking into account safety, compliance to regulation and ergonomics for the user AAF and Pharma company need to validate the design. To accomplish this, customer issued an order to AAF to manufacture a prototype. The prototype has been built and we learned with continuous insight the many aspects how we could improve the design. We changed the window, installed a larger return fan, created better downflow, moved from pre filter panels to pads, installed a camera between the LED light and installed a dimmer on the controller as the LED lights were to bright and needed milky diffuser to avoid that the light mirrors into the eyes of the user. Small findings that needed adaptation in the design.



Project Execution

After validation of the prototype, **18** cabinets have been built and installed and operation as visualized on the photos included in this document. Although the prototype meant design freeze, we still were able to improve on the cabinet in cooperation with our customer. The final result is something to be proud off for both AAF and Pharma company, a state of the art safety cabinet in compliance to today’s standards to full satisfaction of the customer and users.

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