



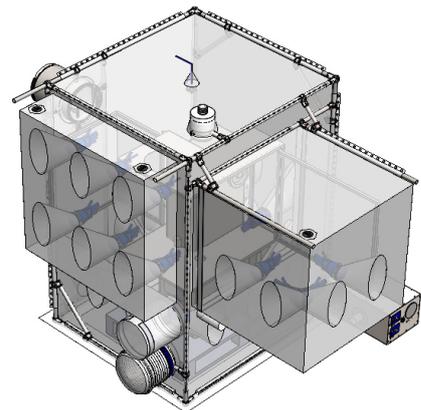
# Containing a Manesty F3 Tablet Press to OEB4 Level

## Challenge

Our client is a prestigious Contract Development Manufacturing Organisation (CDMO) based in the UK and specialising in new formulations.

They were working with a new novel highly potent compound, which they were aiming to compress into tablet form. They approached ONFAB with a request to contain their existing Manesty F3 tablet press to OEB4 level so that the work could be conducted safely.

In order to maintain product consistency and a valid batch profile, it was important to the client to keep their existing SOP and ergonomics where possible; the operator needed to retain their ability to control and adjust the press power and tablet dies.

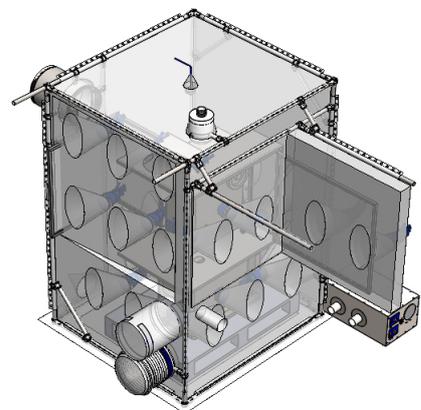


## Solution

ONFAB's answer was a flexible, negative pressure isolator, working at -15pascals, increasing operator protection whilst maintaining its shape.

The air handling unit featured H14 HEPA rated filters and ONFAB's automated fan control system, which helps maintain the pressure for long periods of time. The isolator was supported by a stainless steel frame that is easily dismantled when the client is not processing potent compounds, keeping the press accessible when the isolator is not in use. It allowed the operator to access the localised press area, by accommodating the doors of the press.

The finished product was recovered from the isolator via a continuous liner bag-in/bag-out port. This enabled the safe removal and incorporated safe removal of samples, to allow the standard in-process control to take place, again ensuring validity of the batch.





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## Solution (continued)



The finished solution was delivered four weeks after the first site visit, and installation took just 4 hours.

Tablet production was able to commence immediately, with our client commenting:

**"We had a short timeline to ensure we were able to press the OEB4 compound. ONFAB's solution ensured that we met our client's deadline and meant that we are also able to use the press on our non-potent product range.**

**Our operators were able to quickly start using the system and move forward with the product development phase. "**