



Extract Technology Delivers State-of-the-Art Sampling Facility to Big Pharma Company



Updating a Sampling Area with New Containment Technology

*Gary Partington
Technical Sales Manager
Extract Technology*

After multiple successful facility projects across the world, Extract Technology were approached by a major Pharmaceutical Company and given the challenge to update the older generation of containment equipment from 1990's technology to the advanced technology available today.

Replacing its predecessor which was installed by ETL in June, 1999, this state of the art facility covers 27m² with a large sampling area protected by independent personnel and material airlocks. This particular system was designed with the vision that maintaining operator and product protection would be of paramount importance. To achieve this, the tried and tested unidirectional airflow regime that is found within our range of downflow booths was used. To allow the facility to maintain regulatory compliance with ISO 5 conditions ensuring product protection, a positive to ambient pressure regime was used within the airlocks providing defined barrier between the external environment and the ISO 5 environment.



Rigid Barrier Screen within Facility

Technical process

The Sampling Booth operates with a single pass airflow regime whereby a clean vertical laminar airflow is supplied at a velocity of 0.5m/s +/- 10% directly into the top plenum. After the air has passed over the operators alleviating any airborne particulate from their breathing zone, it will be exhausted via the low level exhaust duct. In addition to the low level extraction a high level exhaust duct was also integrated into the rear bulkhead of the booth - this allowed any particulate at working height to also be removed from the internal environment. This specific project housed a local HVAC system which was used to supply the purified air to both the sampling booth and airlocks.

Challenged with providing an OEL of less than $1\mu\text{g}/\text{m}^3$ over the task duration, it was decided to integrate a Rigid Barrier Screen technology into the facility. The assembly is fitted with a transparent acrylic screen that houses two glove ports. To ensure ergonomic viability the screen is mounted on an articulating arm allowing 5 axis of movement. Nevertheless, to achieve the required OEL of less than $1\mu\text{g}/\text{m}^3$ over the task duration, set SOP's (Standard Operating Procedures) of the screen must be strictly adhered to. The operator must work behind the acrylic screen through the glove ports; by doing this a physical barrier is created to segregate the operator from the product yet still allowing access to perform their tasks.

The sampling facility housed a sophisticated control system which allowed for complex and specific manipulation of the equipment. The on-board PLC gives signals to the air handling unit informing the unit at what speed it should be supplying the air to aid in maintaining the required velocity in various filter



Facility Local Operator Panel

conditions. On-board hardware and systems such as valves, alarms and the operational sequence of the facility are all accessible by the integrated HMI. In addition to the PLC, the facility was fitted with a chart recorder allowing it to comply with CFR 21 Part 11 regulations. A multitude of monitoring is performed continuously by various on-board sensors, processed by the PLC and displayed on the HMI. The monitored parameters include: **booth supply flow, filtration condition, booth exhaust flow, booth pressure, oxygen levels, personnel and material airlock pressure.**

A hazardous analysis report supplied by the customer provided the required ATEX zoning. The unit was commissioned with both a dust and gas rating with: a 300mm zone around the product was rated to ATEX Zone 2 IIB T4 and within the exhaust ducts a rating of Zone 22 IIIB T4.



Material Airlock Featuring Client's Transportation Device

Operational Process

To correctly, safely and efficiently use the sampling facility the following SOP's (Standard Operating Procedures) are utilized:

- Operator starts the facility via the HMI located outside the airlocks.
- To ensure the facility is in good health all measured parameters are checked.
- Pallet is placed on rail track transport truck.
- Operator activates external material airlock roller shutter door (door opened)
- Operator remotely drives the truck into the material airlock, following the truck into the airlock to perform the clean down procedures.
- Once preformed the operator exits the material airlock and de-activates the external roller shutter door (door closed)
- Operator enters personnel airlock.
- Changing procedures take place.
- Operator exits the personnel airlock and enters the sampling booth.
- Once again the condition of the booth is checked via the internal magnehelic gauges to ensure containment is being achieved.
- After this the operator then activates the internal material airlock roller shutter door. (Door opened)
- The transport truck is driven in via the operator's remote control unit.
- Once in place the operator de-activates the roller shutter door (Door Closed)
- Utilizing the installed work bench and rigid barrier screen, the operator begins their samplings tasks.

Note: clients transport truck will remain in the material airlock until the set working pressure is once again achieved.



Front View of Facility 1

Benefits

- ISO 5 processing conditions
- cGMP finish
- Ergonomic workflow
- Turnkey package
- Custom design to suit client's process
- Hazardous compliance
- Internal furnishings
- Battery backup LED lighting in airlocks
- PLC control with touch screen HMI interface
- Rapid roller shutter doors for material entry/exit
- Single Pass airflow for liquids/powder handling, complete with full air handling packages
- Cascading pressure regime

Conclusion

Close collaboration with the customer ensured that the equipment was engineered to suit their specific needs and safety requirements. The advanced technology integrated into the facility provided a more efficient way to handle highly potent substances. By using a PLC control system and various conditions monitoring safe 24 hour production within the facility was made possible, allowing the customer to increase their production rate without the risk of faulty machinery compromising the ISO 5 processing conditions.

Learning from previous experience, Extract Technology were able to add onto the innovative and educational values of the new facility project.

Although the previous facility was decommissioned and removed, having its presence on site for 15 years re-assured the customer that undertaking projects with Extract Technology will lead to a successful long term solution.