Hosokawa Containment meet <30ng/m³ Containment Levels for Mexican API Manufacturer

As modern API's (Active Pharmaceutical Ingredients) become increasingly potent and more stringent operator exposure levels are enforced, the need for containment has become of greater importance. Where typically 5-10 years ago containment equipment manufacturers were being requested to provide equipment to OEL's (operator exposure levels) of <100mg/m³, today's OEL's are more frequently in the range of <50ng/m³.

These factors have influenced a major API manufacturer to include high containment of <30ng/m³ for their new state of the art manufacturing plant in Mexico. The design brief incorporated containment equipment throughout the facility including packing from dryers in intermediate and final steps production, consolidation/sub-division of material and milling/micronising of finished powder together with associated packing and finishing.

Hosokawa Containment (A Division of Hosokawa Micron Ltd) in conjunction with their sister companies Hosokawa Micron Powder Systems (HMPS) of the USA and Hosokawa Alpine AG (HAAG) of Germany were awarded the contract in April 2005 with the delivery of equipment phased in line with site building and fitting requirements. Designed, engineered and project managed in the United Kingdom this installation has been the result of a strong partnership between all those companies involved. Phase 1 incorporated a total of 6 dryer pack-off isolators, 5 of which are identical static units permanently sited below the associated dryer, each incorporating a high containment removable discharge duct. The sixth unit is mobile allowing the isolator to be moved while the dryer is rotated during processing. These units have been successfully completed and delivered on time for immediate installation.

Design Concepts

A central consideration in the initial design of the dryer pack-off isolator was the incorporation of the clients preferred method of materials handling. It was important that material packed from the dryers could then be further processed in both the consolidation and milling/micronising isolators. This was achieved using Rapid Transfer Ports (RTP's) throughout the project.

Each dryer pack-off isolator whether static or mobile had to be designed such that it would enable an operator to fill a suitably sized RTP canister in a contained safe manner and provide assistance with docking and undocking. Material from the dryer was to be dosed vertically into each isolator and a means of dosing control was also to be included. Primary containment was envisaged as using a continuous liner with secondary containment provided by a once through negative pressure isolator. An additional RTP was also required for the movement of accessories.

In order to better understand and visualise final operability, the concept design was developed using 3D software. This allowed, at a very early stage in the project, the opportunity for operators and other personnel to assess the design.

The use of simple viewing software also allowed the client to review the model in 3D on their own screens, which proved invaluable during teleconferences in the early stages of design.

Addressing the primary requirements very quickly led the Hosokawa Containment engineers to a basic concept. The alpha port of the Ø350mm RTP was to be fitted in the base of the isolator, this would allow the support legs to be further utilised for a drum-lifting device. Dosing of the material would be via a star valve mounted directly under the dryer outlet valve and control would be from a local operator panel mounted to the isolator. With the single inlet and double extract HEPA filters positioned for optimum flow across the packing head, enough space for a smaller Ø190mm RTP was available on a side wall.

Wooden Mock-Ups & Ergonomic Assessments

Once the basic design had been agreed, the next stage was to create a wooden mock-up in order to physically assess the ergonomic impact of the design.

Protocols were prepared in conjunction with the client to ensure that all aspects of operation would be tested. Both the glove port carrier and filling chute were designed to be fully adjustable to achieve the optimum working position during the assessment.

Hinged plywood covers were included to simulate both the Ø350mm & Ø190mm RTP's, although these were lighter than the actual units they provided a good idea of the arc of operation that would be needed via the glove ports and the viewing area available to the operator during the operation.

After final positioning of the main items it was then possible to determine the ideal position for ancillary items such as the CIP spray devices and hand lance.

The use of wooden mock-ups for all aspects of the project was so successful that the client is using them to train operators prior to the arrival of the actual equipment.

Final Design & Build

From the findings of the ergonomic assessment the final designs were developed. These developments included incorporating the extract fan, process instrumentation and pneumatic controls for the drum lifter in a GMP technical area cabinet located directly under the local operator panel.

In doing so, this reduced the associated piping and wiring and allowed Hosokawa Containment to bring all terminations to a central point resulting in a neat and compact unit that requires minimum installation. The local operator panel was manufactured by HMPS in America and fully conforms to the hazardous area ratings required even though each panel contains not only control equipment but also the extract fan variable speed drive and system PLC. This was achieved by positively purging the panel at all times when the equipment is live.

Control of the entire packing procedure is by PLC via an operator interface also mounted on the front of the local operator panel. Start-up and shutdown sequences are fully controlled by the PLC ensuring that the pack-off system operates in a controlled and defined manner. The system is fully interlocked with the dryer controls and alarms/warnings are available both visually at the OIT and flashing beacon and audibly via a warning siren.

The drum lift system is entirely pneumatic and is operated via pushbuttons mounted to the front of each technical area panel. The drum is manually inserted into the shaped carrier, which automatically positions the drum for docking. Using pneumatic cylinders of a defined length, the drum is raised to the required height. Docking into the alpha port is then a simple twist of the drum by the operator. Once the drum is filled, the system operates in reverse ensuring that the cylinders and not the operator take the weight, fully complying with manual handling regulations. Removal of the drum is a straightforward slide out onto a pallet.

Internal to the isolator is shown the arrangement for CIP. A further consideration in the design was to ensure that solvents used in the cleaning of the dryer could be safely discharged. This was done by incorporating a washdown plate (show fitted) which is connected to a drain nozzle inside the isolator. This nozzle passes through the wall of the isolator to the clients solvent drainage system. When not in use, the washdown plate can safely be removed using the Ø350mm RTP canister.

Cleaning of the isolator itself is undertaken either using the spray balls mounted on the rear wall which rotate to give improved impact and cleaning or with a small hand lance which is tucked neatly away at the top of the isolator.

The feed chute is also shown with the continuous liner cage fitted. During production, the cage is prepared with the required quantity of liner and installed using the Ø350mm RTP canister, further maintaining the required OEL. Once the canister is docked to the alpha port and the cover opened, the cage is easily removed and simply hooked onto the packing head chute. Smaller items such as the 'O' ring seals can be introduced into the isolator via the Ø190mm RTP.

The packing head features internal filters which both purify the incoming nitrogen gas during inerting of the liner and prevents migration of powder during extraction of the liner. These filters are automatically cleaned using the reverse jetting of the incoming nitrogen.

Both inlet and extract filters are of a safe change design which can be capped off inside the isolator prior to removal.

Testing & Despatch

Prior to despatch each isolator was subjected to rigorous testing, again to strict protocols developed in conjunction with the client. Testing included both negative and positive pressure decay tests which each unit passed with an average decay for all units of only 13 Pascals over a 5 minute period. All six isolator are shown here having successfully completed the tests and awaiting packing and despatch.

Phase 2

The second phase of equipment which incorporates the consolidation/sub-division isolator, milling/micronising system and isolator, product collection filter and mobile pack-off isolator is currently under manufacture and due for delivery in March 2006.