Simon Wigglesworth
Powder Systems Limited
Process Engineer

CONTAINED DRUM FILLING & CONTINUOUS LINER TECHNOLOGY

Introduction

Within the pharmaceutical, fine chemical and toxic chemical industries, containing the discharge of potent active powders into lined drums is required not only for product protection but also for Operator Exposure Levels (OEL) which must be controlled in order to guarantee operator safety. Process equipment must be kept in line with these containment requirements, be it through the design and installation of new contained filling systems or by retrofitting enhanced containment to existing process equipment.

The evolution of drug development in recent years resulting in the production of increasingly potent compounds is continually driving stricter OEL and containment requirements whilst demanding flexibility for cost effective multi-product process design. The drum filling process often involves differing drum sizes, varied product net weights in each drum (changing processes and cleaning solvents). Further design challenges include requirement for mobile systems to ensure process equipment can discharge to lined drums and also Flexible Intermediate Bulk Containers (FIBC's) for example.

OEL Requirement	Drum Filling Containment Solution
5-10 mg/m^3	Local Exhaust Ventilation
1-5 mg/m^3	Simple Filling Head Inflatable Seal
100-500 $\mu g/m^3$	Double "O" Ring Continuous Liner System
50-100 $\mu g/m^3$	Double "O" Ring Continuous Liner System with Cross Flow Extraction Booth
1-50 $\mu g/m^3$	Single Chamber Glove Box with Double "O" Ring Continuous Liner System
<1 $\mu g/m^3$	Double Chamber Glove Box with Double "O" Ring Continuous Liner System

Summary of various containment solutions designed to meet specific OEL requirements.

Background

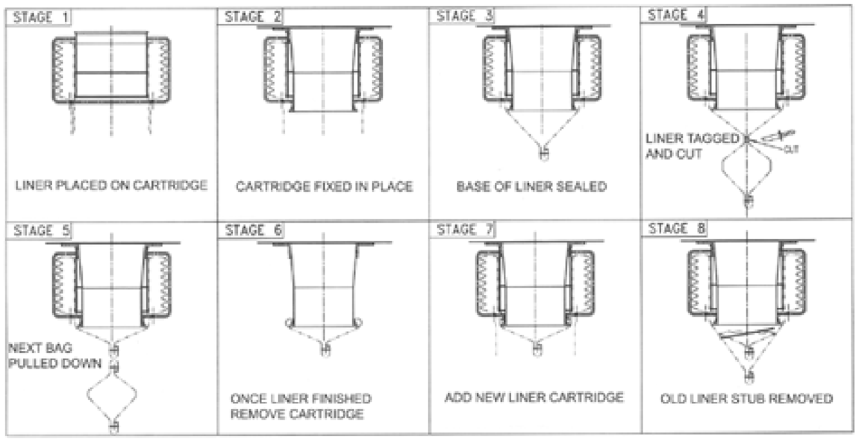
Since the introduction of the Control of Substances Hazardous to Health (COSHH) in 1988, emphasis moved from dependence on personal protective equipment to engineered solutions to contain potent powders at source and prevent emissions into the work area.
Traditional solutions involved each drum having its own individual liner and an inflatable seal or equivalent with perhaps local exhaust ventilation utilised. However after every fill the seal needs to be deflated to allow liner detachment, liberating dust from the liner and upstream process chute into the atmosphere. In addition to operator exposure issues, there are concerns over foreign body ingress into the product. For a multi-product plant there is also the concern of cross contamination to take into account. Containing materials at source can greatly simplify a process, as well as having cost benefits by removing, for example, the need for separation of rooms, enhanced cleaning regimes, more advanced HVAC systems with differing pressure regimes to prevent powder transfer, usage of airlocks and showering/changing personal clothing between key rooms. There is also the commercial loss of small, but potentially significant, quantities of material via dust emissions into the room.

By using continuous liner technology to fill a complete batch by discharge to drums, the product is contained and is not exposed to the room atmosphere, thereby protecting both the product and the operator.

Double “O” Ring Continuous Liner System

Double “O”Ring System

A unique double “O” ring design eliminates the need for complex and expensive inflatable seals. This system can achieve an OEL of 100microgrammes/m^3 based on a 1 hour operation over 8 hour time weighted average. The major advantage of this system is its inherent simplicity. The system consists of a stainless steel chute with a surrounding liner cartridge for storing loaded continuous liner sheet. This cartridge is easily attached via a “bayonet” type push and turn system. In addition an ergonomic continuous liner-loading table has been designed enabling quicker loading. The liner is fixed to the chute via a top and bottom “O”ring, both of which are outside the powder flow, these “O”rings therefore can be made of simple, inexpensive materials. This system also allows any thickness of liner to be used, this is of major benefit when product/liner stability data has already been established and compliance bodies prevent changes.



Liner filling technique using the double "O"ring

After filling the liner, the liner is gathered and twisted together and tied using bag ties twice very closely to each other. Then the liner is cut between the ties, the bottom tie then creates a sealed bag of powder and the top tie seals the base of the liner for the next filling operation

The liner is inflated prior to filling utilising air or nitrogen to open up the liner to receive the powder. At the end of the filling procedure, the liner is deflated to narrow the neck of the liner to make it easier for the operator to manually tie the liner

Following the safe change liner procedure, liners can be changed / replaced without needing to open up the chute to the atmosphere. The old liner is removed into another plastic liner tied and cut with one "O"ring lost at each liner change procedure.

Other Key Process Points

- Explosion Prevention. Dust explosions can be prevented by a controlled nitrogen purge. Typical requirements are < 5 % Oxygen levels, and lower levels can be achieved. This nitrogen purge may be either manual or automatic, depending on process requirements. The nitrogen and exhaust to the chute are balanced to allow a sweep of nitrogen through the chute.
- Cleaning. A wash tundish can be connected to the chute outlet via a triclamp connection without the need to attach to an inflatable seal.
- Material compatibility. Extensive solvents are often used and these can attack the typical silicone inflatable seal material. The double "O"ring continuous liner system allows for product contact surfaces to be uniquely metallic, giving considerable extra flexibility for solvent usage
- Weigh systems. A full range of weigh systems can be integrated with this continuous liner design. These range from simple scale with local indication to full autofill systems for a precise weight accuracy with set point control. Specialised low profile weigh systems can also be developed for retrofitting to existing equipment.
- Powder properties. Analysing material properties, bulk densities and material cohesion will enable suitable metering systems (rotary valves or screw feeders for example) to be best designed to integrate with continuous liner filling system
- Safety interlocks. Identifying a clear list of interlocks and output signals to the central control systems.

Sampling

The containment of the drum filling process needs to include any requirement for product quality sampling. No longer can the liner be opened up to take samples, as this would invalidate the contained continuous liner drum filling. Alternative methods include the usage of in-flight sampler screw augers for collecting samples out of the product chute. If this relates to a continuous liner system without any secondary containment then attention is needed on the de-coupling of the sample container.

A split butterfly valve can be used for containment during de-coupling. One half can be fixed on the sampler outlet and the other when un-docked remains with the filled sample container, this works on the principle that the inner surfaces never come in contact with the powder and hence when de-coupled remain clean.

Single Chamber Glove Box & Continuous Liner System with Horizontal Cross Flow Booth

PSL TubeFill

10-50 microgrammes/m^3 containment for a 1 hour operation over an 8 hour time weighted average can be achieved by enhancing the continuous liner chute. This involves the double "O"ring continuous liner system as the primary containment with an additional extraction cabinet around it for secondary containment.

Key design features include: -

- > 1 m/s inward air extraction across the open cabinet
- Extraction plenum for uniform air flow
- Sloping draining base, allowing full cleaning to one common lowest point drain

For the filtration of the air from the extraction cabinet, safe change filters can either be integrated into extraction cabinet or within separate housings.

Ergonomics are aided by the use of drum roller tracks with uniform height both within and external to the cabinet. Side discharge doors of various designs are utilised to allow easy removal of filled drum.

Flexibility is Critical

PSL DrumBox

Flexibility is a key issue, in particular for multi-purpose plants which often utilise one containment system to operate at different containment levels and to multiple drum sizes. A flexible design can allow operators utilise simpler systems with easy access to the drums when handling less potent powders, by using gloveboxes as a barrier between the operator and the drum when required by specific product OEL.

When enhanced containment now to 1microgramme/m^3 is required, previously a double chamber glovebox would have been required. However, now a special design using a single chamber glovebox (secondary containment) with the primary containment of a double “O”ring can be utilised at three different containment levels. This flexible design can achieve an OEL performance from 1 to 50 microgrammes/m^3. Air is introduced at low level via a slot whose height can be varied and air is extracted via HEPA filters at the back of the top of the glovebox. This ensures any small dust releases during bag tieing and cutting are safely carried away into the extract.

Different levels of usage include: -

- Level 1 Cabinet with open top window – 50 microgrammes/m^3
- Level 2 Cabinet with window in place with open gloveports, no gloves – 10 microgrammes/m^3
- Level 3 Cabinet with sealed window and gloveports complete with gloves – 1 microgramme/m^3

This flexibility is achieved via the top section of the cabinet having a simple lift off window (to allow Level 1 solution). The gloves can be removed easily for Level 2 solution. The glovebox can be fully cleaned via internal wash hoses with a drainage base. These systems have been successfully proven to guarantee the 1-microgrammes/m^3 containment requirement when used at Level 3.

Double Chamber Glove Box - Containment to <1 microgrammes/m^3

PSL FlowBox

Continuous Liner

When higher containment to <1 microgrammes/m^3, for a one hour operation over 8 hour time weighted average is required, a double chamber glovebox design, utilising double "O"ring continuous liner system as the primary containment can be used. These systems can also allow for flexibility of drum sizes up to 220 Litres in volume.
An aperture between top and bottom chamber is designed to allow an engineered gap around the perimeter of the drum enabling air flow in from the front of the glovebox at low level and out behind the bag at high level. The engineered air gap between the drum and the horizontal shelf maximises local air velocity at this point ensuring that even if tiny dust particles were released during bag tieing and cutting in top chamber these are extracted and can never enter the lower chamber. There is also a fixed minimum pressure drop between top and bottom chamber ensuring a minimum air flow velocity across this gap up into the top chamber.

Optional features of the double chamber solution include: -

- Drum positioner to ensure drum is situated correctly relative to aperture to allow correct gap around drum and hence air flow system as discussed.
- Mechanical hinged plate which seals chute and residual liner from rest of glovebox after each fill operation , to prevent any tiny dust releases when exit door is opened.
- Glove position interlock with exit door. This ensures glove is pulled out temporarily of glovebox chamber when door is opened , again this helps to stop any tiny dust on gloves becoming airborne at the stage when door is opened.

Such advanced systems have been developed with pharmaceutical active handling in mind. These have been successfully validated at <1 microgrammes/m^3 and in fact at non-detectable levels, after dust and OEL monitoring studies.

Conclusion

Containment solutions for drum filling can be achieved without excessive cost and allowing simple and easy to operate techniques like double “O”ring technology. Clear initial thinking on OEL’s required, product protection needs, cleaning regimes and powder properties can allow the optimum continuous liner system to be chosen to suit the process application.
The usage of one system like the single chamber drum filling glove box for multiple containment levels can allow greater flexibility in production, utilising a common containment system for powders of varying potency.
Mobile systems further enhance the ability to charge filling regimes for example IBC‘s and FIBC’s. Such systems give proven containment performance based on validated airborne dust monitoring with good ergonomic solutions. These designs can also be retrofitted to existing equipment.

Simon Wigglesworth has been a *Process Engineer* at **Powder Systems Limited** for 6 years, developing contained process solutions for the pharmaceutical industry. Prior to this Simon spent 10 years at Eli Lilly as a containment specialist.