FLEXIBLE AND CONTAINED TRANSFER SOLUTION FOR SMALL POWDER QUANTITIES

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Marcel Buehrer

Industrial Hygienist & Safety Specialist
INTRODUCTION

of the presenter:

Marcel Buehrer

Organic Chemist 24 years
EH&S / Industrial Hygiene 7 years

Working for J&J 25 years
For other pharmaceutical companies 3 years
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1. INTRODUCTION

There are a lot of technical possibilities on the market which allow a safe transfer of solid chemicals and keep the risk of exposure very low.

- Isolators
- Twin valve systems
- Rotary valves
- Flanged connections
1. INTRODUCTION (2)

The price for their reliability and robustness is:

- High cost
- Complexity of application
- Intensive maintenance
- Low flexibility

→ Trend towards flexible solutions for certain activities
WHAT WE CANNOT EXPECT IS

... a miracle
2. PARTIAL SOLUTION

TransferBag

The flexible transfer solution for small quantities.
3. DESCRIPTION (1)

- The TransferBag solution in combination with the manual SafeSeal System

- Guarantees a high containment level \((\text{OEL} < 1\mu g/m^3)\).

- The bag system is available in various LDPE films and executions, also in antistatic versions.
3. DESCRIPTION (2)

- The connection to the TransferBag allows a change, free of contamination allows a safe handling.

- The head is available with a flange or a TriClamp connection.
3. DESCRIPTION (3)

Charging:

Discharging:
4. HOW IT WORKS (1)

- Prepare of the filled TransferBag above the connecting device.
4. HOW IT WORKS (2)

- Place the O-Ring on the discharge side onto the correct place of the connection device.

- Remove the remaining old bag.

- Establish the Triclamp-connection of the inner bag.
4. HOW IT WORKS (3)

- Remove the SafeStick and perform the powder transfer.
4. HOW IT WORKS (4)

• Remove the air from the TransferBag via the installed HEPA-filter by using a slight vacuum.

• Prepare the empty TransferBag for disposal.

• Disconnect the bag.
4. HOW IT WORKS (5)

The SafeSeal crimping system provides a clean cut and closure of the transfer parts.
5. IH SAMPLING (1)

- Sampling date: March 2013
- API-Assumption: OEL 1 μg / m³
- Simulation: Transfer of 10 kg (3 x)
- Sample time: 15 – 25 minutes
- Unit Operations: Charging and Discharging
- Three different operators
- Method LOQ / LOD: 0.5 ng / filter (IOM 2)
- Sample points: 1 personal / 2 area
5. **IH SAMPLING (2)**  

Results in μg / m³

C: Charging

C_P: Personal  
0.10  
0.18  
0.21

C_L: Left side  
0.10  
0.18  
0.10

C_R: Right side  
0.72  
0.62  
0.48

* Below LOD
5. IH SAMPLING (3)  

Results in $\mu g / m^3$

**D: Discharging**

- **D_P:** Personal
  - 0.13
  - 0.13 *
  - 0.07 *

- **D_F:** Front
  - 1.51
  - 0.13 *
  - 0.14

- **D_B:** Back
  - 0.08 *
  - 0.13 *
  - 0.07 *

* Underpressure not applied

* Below LOD
6. **PRO’S AND CON’S** (+)

- Low Cost
- Less Inventory
- Very flexible in terms of production planning
- Easier ergonomic situation for the handling
- No mechanical treated gaskets which may release particles to the product
- No cleaning and cleaning validation
- Almost no maintenance required
6. PRO’S AND CON’S

- Maximum quantities are approx. 20 kg
- Only qualified and well trained personnel should work with this system
- PE bags are mechanically sensitive; therefore need to be handled carefully and secondary packed for storage and transportation
7. CONCLUSION

- Schaffhausen will probably apply the Lugaia-System in the High Containment Plant HCP for substances with an OEL down to 1 μg / m$^3$ for API's and intermediates.

- Currently a prototype order of 50 bags is tested in different applications.

- Further IH-sampling is required with another surrogate (Paracetamol or Naproxene) to confirm lower exposure levels down to < 0.5 μg / m$^3$.

- The flexible TransferBag system is a valuable option for high potent solid transfers.
8. REFERENCES

Lugaia AG
Containment Solutions
Industriezone Basper 31
CH-3942 Raron
Switzerland

Phone: +41 (0) 27 948 45 55
E-Mail: anfrage@lugaia.ch
www.lugaia.com
QUESTIONS ?