ANDOCKSYSTEME

APRIL
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# CASE STUDY

## CONTAINED TABLET CHARGING FOR HIGH-POTENCY VETERINARY PHARMA APPLICATIONS

### Application Context

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|---|---|
| Industry: | Veterinary Pharmaceutical |
| Process Step: | Tablet coating pan charging and discharge |
| Product Handled: | High-potency veterinary actives (lotilaner, praziquantel) |
| Exposure Category: | OEL <1.0 µg/m³ |
| Location: | France |

### Project Requirements

The interface between transport vessels and the coating drum represented a critical containment vulnerability. Operational efficiency was restricted by the limitations of open-transfer methods and the logistical burden of multi-use equipment.

**Primary Engineering and Operational Challenges:**

- **Cleaning Validation Hold Times:** The site operated traditional multi-use stainless steel IBCs for tablet charging. Each campaign required a defined cleaning validation hold period before release for subsequent use. This created a persistent bottleneck that reduced the overall equipment effectiveness (OEE) of the coating line, decoupling production scheduling from the physical capacity of the equipment.
- **Aerosolised Dust Liberation:** High-energy tablet charging events liberated fine potent dust at the transfer point. Existing local exhaust ventilation (LEV) proved insufficient to achieve OEB 4-level primary containment at source, leaving the operation exposed to exceedances during charging cycles.
- **Reliance on PPE:** In the absence of adequate primary engineering controls, operators were required to use extensive PPE during charging sequences. This increased the risk of procedural error during docking and impacted ergonomic performance over multi-shift operations.

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## *Selected Product: ACUBE™ DL (Double Liner) Flexible Containment System with AVAX Single-Use Valve Interface*

The engineering objective was to replace the open charging process with a closed, repeatable, and validated SUT interface. The selected configuration utilizes the **Andocksysteme ACUBE™ DL (Double Liner)** system with a **Hybrid AVAX™** docking interface.

• **Hybrid Valve Configuration:** To maximize the lifecycle of existing capital assets, a permanent Stainless Steel AVAX™ Active Valve was installed on the coater's charging port. This docks with a Single-Use Plastic **AVAX™ Passive Valve** integrated into the ACUBE™. This ensures mechanical precision at the machine interface while leveraging the agility of single-use components.

• **Electrostatic Safety:** The ACUBE™ DL utilizes a dissipative PE grid film liner with a surface resistivity of **≤ $10^7$ Ω.** This specification is critical for preventing electrostatic discharge (ESD) risks during high-velocity flow in ATEX-rated zones.

• **Regulatory Compliance:** All product-contact materials are compliant with **FDA CFR Title 21 and USP Class VI standards**. The transition to SUT was achieved without introducing new extractable or leachable risks to the veterinary formulations.

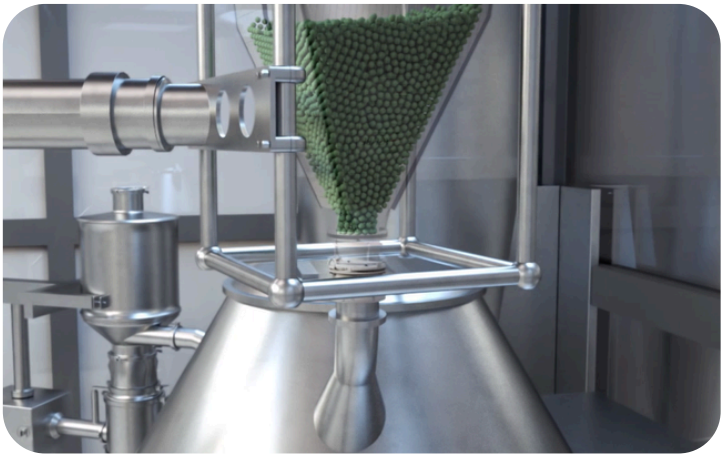
*ACUBE being Docked*

## *Benefits and Operational Performance*

The system was integrated as a plug-and-play solution within the site's existing lifting column infrastructure, requiring no structural modifications to the coating room.

- **Containment Performance:** SMEPAC-validated containment at OEL < 1.0 µg/m³ was confirmed across transfer operations. Engineering control requirements for OEB 4 pharmaceutical standards were met without reliance on secondary PPE.
- **Campaign Changeover:** By replacing multi-use IBCs with single-use liners, the site eliminated cleaning validation hold periods between campaigns. Changeover was reduced to liner replacement, visual inspection, and release, substantially shortening non-productive time between batches. This structural change decoupled production scheduling from cleaning laboratory timelines.
- **Regulatory Audit Readiness:** Compliance with FDA CFR Title 21 Part 211 and USP Class VI was achieved via pre-validated liner supply with full material traceability documentation. This eliminated the need for site-specific cleaning validation studies and simplified the regulatory file for new product introductions.
- **Production Throughput:** The removal of cleaning-related downtime increased coating line availability. Additional batches were processed within the same calendar period on existing equipment, improving return on installed capital without capital expenditure.
- **Cost of Ownership:** The transition to a single-use model reduced the cost and labour associated with each changeover cycle. By eliminating multi-step cleaning procedures and the associated

ACUBE next to the Tablet coating



Animation, ACUBE dropping Material

ACUBE, on storage

## Conclusions

This installation demonstrates that Single-Use Technology (SUT) is a viable engineering strategy for high-potency manufacturing where cleaning validation timelines are the primary constraint on throughput.

By focusing on interface management rather than room-level containment, the facility decoupled its production schedule from multi-use cleaning cycles. The ACUBE™ DL system provides an ATEX-compliant, high-integrity barrier that performs reliably across repeated campaigns. The Hybrid AVAX™ configuration allowed the site to retain robust stainless steel active valves on process equipment while gaining single-use flexibility at the container interface.

The outcome was a safer working environment for operators, a predictable and lower cost model for changeover, and higher utilization of existing coating equipment.

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