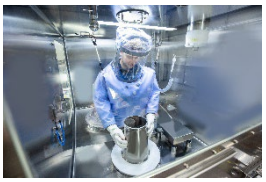

Case Study

Contained HPAPI Sampling

Overcoming containment challenges during sampling of HPAPI materials from a wide range of containers including IBC's (Intermediate Bulk Containers) and traditional product drums within multi-product facilities.

Challenge

Creating effective HPAPI and API samples within a pharmaceutical facility involves meeting stringent technical and regulatory standards to ensure safety, compliance, and operational efficiency. Some of the key requirements based on industry best practices and regulatory guidance as follows:

-Regulatory Compliance: Alignment with global pharmaceutical regulations and GMP standards.

-Scientific and Technical Accuracy: Use representative chemical structures, batch data, and impurity profiles.

-Documentation Standards: Clear Data and Audit Trails

-Integration with Facility Systems: Compatibility with Digital Batch Records and Automation Compatibility

-Safety and Containment: Hazard Identification and Contamination Control

-Scalability and Flexibility: Samples should be adaptable to different production scales

Solution

Howorth applied its proven expertise in complex, task-based containment for highly potent compounds, to develop a customised and integrated Total Containment Solution. This ensured all sampling operations were conducted within a fully enclosed and controlled system.

Half Suit technology was selected over traditional glove ports to significantly improve operator flexibility and provide superior ergonomic access to IBCs and drums. This ensures safe, precise, and ergonomic sampling—particularly when using industry-standard segmented sampling systems to obtain representative samples.

Outcome

Howorth's tailored, ergonomic approach to HPAPI sampling delivers a safe, compliant and efficient solution, enabling the client to handle potent compounds with confidence. Key benefits included:

-OEB 5 containment achieved throughout sampling operations.

-Enhanced ergonomics, reducing operator fatigue and improving task accuracy.

-Regulatory compliance with GMP and occupational exposure standards.

-Minimized downtime through seamless system integration and user-friendly design.