



API/HPAPI CONTAINMENT SOLUTIONS

**ENGINEERING CONTROLS FOR
PHARMACEUTICAL MANUFACTURING**



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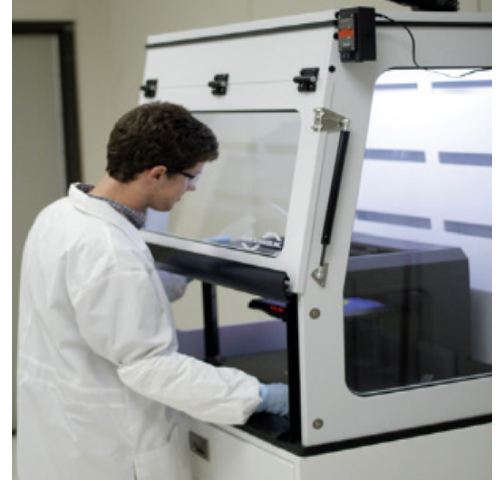
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“Solutions to containment challenges come from understanding the relationship between equipment, operator, and process.”

Ray Ryan, Flow Sciences Inc.
CEO/President

WHAT HAPPENS WHEN YOU CONSULT WITH FLOW SCIENCES?



BEFORE WE BEGIN DESIGNING, WE ESTABLISH THESE 5 CRITERIA:

1. PROCESS

Identifying the process performed inside and outside of the containment enclosure that requires personnel and/or product protection.

2. CPT

Containment Performance Target is a customer-defined level of acceptable exposure to personnel from potentially harmful materials handled during the process.

3. SCOPE

Defining expectations of all parties involved in the project in regards to budget, lead time, and complexity of the containment solution.

4. FACILITY

Documenting allowances and restrictions in the designated work space required for power, installation, and operation

5. EQUIPMENT

Citing specifications and parameters of the operating machines, instruments, and hardware required to complete the process.

FSI CULTURE

OUR HIGHEST QUALITY ENSURES YOUR EXCELLENT RESULTS



Engineering and Consulting firms' involvement in pharma and biopharma projects continues to grow every year. For these projects, the ability to provide effective and efficient safety protocols continues to be in high demand.

Safety and performance are of the utmost importance, as the pharmaceutical manufacturing companies rely on proper engineering controls to develop and produce consistent products and results, while keeping their personnel and/or product safe. At Flow Sciences, we pride ourselves in the ability to engineer solutions that contain applications properly while creating consistent results.

Versatility and flexibility are key to the most successful pharma and biopharma companies, which is why many of the top design and engineering firms in the world choose Flow Sciences as their trusted containment provider. With products ranging from convertible enclosures for different API toxicity levels to enclosures designed for specific tasks and equipment, FSI has the engineering and production capability to provide solutions throughout the entire manufacturing space.

Flow Sciences takes reproducibility seriously and we are ISO 9001:2015 certified in production quality. Every unique unit receives factory acceptance testing before leaving the facility. Our commitment to manufacture quality products results in the end user's ability to produce quality results. While there are many options available now, new enclosures and systems are being created every day to house the latest and most advanced equipment on the market. If you do not see your application or what you are looking for, please contact us.



HPAPI SYSTEMS

HIGH POTENCY API PREP SYSTEM

SIZE: 66" EXT. WIDTH | 39" EXT. DEPTH | 31" INT. HEIGHT

High Potency API (HPAPI) Prep System LFBC™ is designed as an enclosure suite with 2 Hybrid Isolators and a Glovebox Workstation connected for processing. Featuring a full transfer port system made of polypropylene for processing HPAPIs through the entire enclosure suite. The Glovebox Workstation features a lateral flow air filtration system with an ISO 5 or better interior environment. The Hybrid Isolators feature dual speed fans so the glove panels can be removed and operated with an open face as a modular feature. The dual speed fan automatically senses the removal or addition of the glove panel, and adjusts the fan speed accordingly to maintain proper face velocity.



HPAPI GLOVEBOX WORKSTATION

SIZE: 80" EXT. WIDTH | 32" EXT. DEPTH | 28" INT. HEIGHT

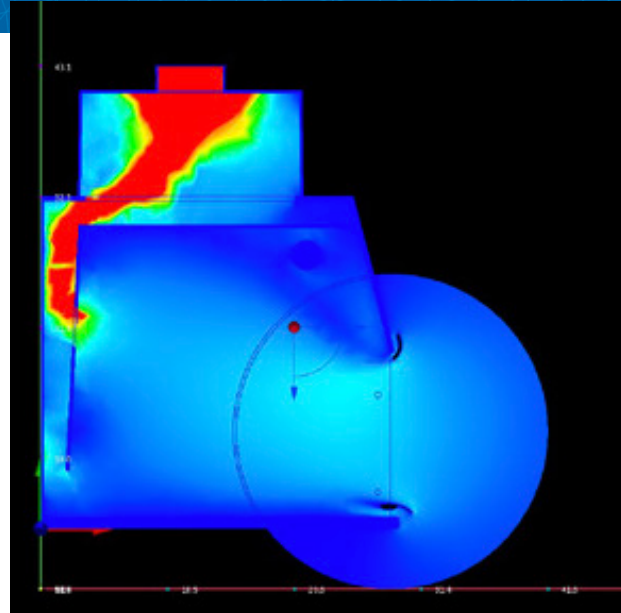
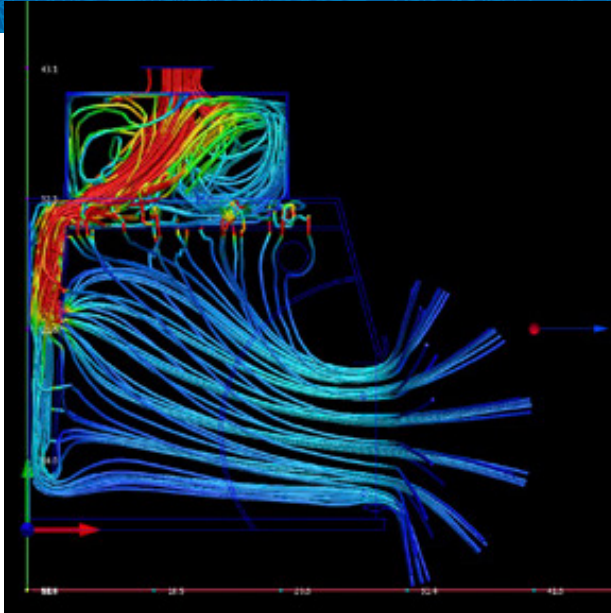


HPAPI Glovebox Workstation LFBC™ designed to house 2 balances and maximize both personnel and product protection while weighing powder and liquid APIs and HPAPIs. Units can be configured with many different transfer systems, including Ezi-Dock as shown here, as well as RTP ports from Getinge, continuous liners, and many more. 4 x 10" glove ports at the front of enclosure, pass through for data and power cables as well as access door to maximize operational flexibility. ISO 5 or better interior environment.



DESIGN & ENGINEERING

DESIGN PROCESS



Computational Fluid Dynamics (CFD) is the study of fluid dynamics using sophisticated computing technology. Computational Fluid Dynamics uses or solves the governing equations of fluid or gas flows to predict the characteristics and the structure of a flow field. The most important feature or advantage of using CFD in the design process is the ability to see airflow.

CFD allows the user to see the results of engineering design more effectively than in the real world. The effects of minute features in the designing process can be seen and compared using CFD which cannot be done in an otherwise efficient manner. Another added advantage of using CFD is the repeatability of the results.

Flow Sciences uses CFD in the design process to concentrate and study the effects of changes in airflow (large and small) in the enclosure design. Any changes to an enclosure's design affect the airflow structure inside the enclosure and FSI's goal is to maintain stable airflow that improves containment while also providing a low turbulent atmosphere that allows sensitive equipment to perform properly and minimize any potential product loss.

With CFD we have the advantage of evaluating the performance of the enclosure even before it is built, and then verify those results in our testing lab. This results in our clients receiving enclosures that have proven performance.

CONTAINMENT SOLUTIONS FROM RESEARCH TO PRODUCTION

Flow Sciences, Inc. provides engineered containment solutions from research to production. From Occupational Exposure Bands (OEB) 3 to 5, we build to suit your application. Whether in powder manipulation where balance stability is paramount, or using specific manufacturer equipment needing containment, or operating in a temperature and humidity controlled environment, Flow Sciences keeps your personnel and product safe.

BULK POWDER SYSTEMS



BULK POWDER HYBRID ISOLATOR

SIZE: 60" EXT. WIDTH | 30" EXT. DEPTH | 27" INT. HEIGHT

Modular Hybrid Isolator with Dual Bag-In/Bag-Out HEPA filtration designed for weighing highly toxic powder APIs with balances and other processing equipment. Draftshield fitted with 4 x 8" glove ports is designed with airfoils to ensure laminar airflow across the work surface. Draft Shield can be removed and the dual speed fan will automatically adjust the power to maintain containment at the face opening. Rear plenums and top-mounted fans also work to maintain laminar airflow across the work surface. Chemically resistant Black Phenolic base incorporates 20" cutout for bulk powder processing. Constructed from static dissipative acrylic which allows for optimum ambient light transmission while built-in LED system provides additional lighting when necessary.

DRUM LIFT BULK POWDER ENCLOSURE

SIZE: 96" EXT. WIDTH | 36" EXT. DEPTH | 26" INT. HEIGHT

Bulk Powder enclosure with side mount EHS-Now Drum Lift System. Unit features top-mounted HEPA filtration system and is designed for personnel protection while working with powder substances. Unit designed to contain balance application. Enclosure features acrylic superstructure and side panels with hinged door. Also features waste chute.



TESTING

Flow Sciences possesses a laboratory capable of testing products for conformance to the relevant standards (ie. ASHRAE 110-2016 Tracer Gas Testing). Every unique enclosure or hood that is manufactured in the facility is tested to these standards to ensure quality and performance to the ISO 9001:2016 standard.

Additionally, the facility can be used to perform further testing, using surrogate materials to determine expected enclosure containment capabilities. This factory acceptance testing using surrogate materials is often accompanied by a third party industrial hygiene group, as well as the customer. This helps to replicate the end process exactly, and also to suggest SOPs and GLPs for best use of the equipment.



MANUFACTURING

We have a wide range of machines to manufacture and build our products in-house. We are an ISO 9001 certified facility and our products are fully inspected, lab tested, and certified before shipping to our customers.

Flow sciences takes pride in working closely with our customers to recommend task specific enclosures, to the best of our ability, that will contain the application and process.



STAINLESS STEEL



STAINLESS STEEL TABLET PRESS ENCLOSURE

SIZE: 82" EXT. WIDTH | 52"
EXT. DEPTH | 29" INT. HEIGHT

Stainless steel integrated containment solution for Huxley Bertram HB-100 model tablet press simulator. Unit designed to enclose API loading, die punch, actuator, and 50-slot carousel. ¾" acrylic front door fitted with inflatable seal to ensure operator safety as well as (4) 8" inch glove ports. Unit equipped with lateral flow fan, dual-HEPA filtration with BIBO option, and thimble connection to house exhaust.



STAINLESS STEEL HYBRID ISOLATOR

SIZE: 67" EXT. WIDTH | 31" EXT.
DEPTH | 30" INT. HEIGHT

Stainless steel hybrid isolator with pass through and dual, top-mounted HEPA filtration system with BIBO for personnel protection, designed to contain balance for work with powder substances. The unit features a stainless base, with glass viewing ports, and hinged door. Unit also features (3) 8" glove ports and built in LED lighting.



PERFORMANCE

PERFORMANCE

Performance is paramount in the safety industry, and through consistent quality design and expert manufacturing, Flow Sciences' units perform. With surrogate powder testing both in our facility as factory acceptance testing and at the customer facility as site acceptance testing, Flow Sciences consistently exceeds our customers' expectations with containment targets and goals.



CPT: $.05 \mu\text{g}/\text{m}^3$

Result: $.0004 \mu\text{g}/\text{m}^3$

Equipment: Balances

Operation: Weighing/
Transferring

CPT: $.05 \mu\text{g}/\text{m}^3$

Result: $.0001 \mu\text{g}/\text{m}^3$

Equipment: Funnel balance

Operation: Weighing/
Transferring



PERFORMANCE



CPT: $.1 \mu\text{g}/\text{m}^3$

Result: $.008 \mu\text{g}/\text{m}^3$

Equipment: Nilfisk

Operation: Sympatec
simulation, cleaning

CPT: $.05 \mu\text{g}/\text{m}^3$

Result: $.001 \mu\text{g}/\text{m}^3$

Equipment: Sieve shaker

Operation: Sieve shaking



PERFORMANCE



CPT: $.1 \mu\text{g}/\text{m}^3$

Result: $.003 \mu\text{g}/\text{m}^3$

Equipment: Balance

Operation: Weighing

CPT: $.2 \mu\text{g}/\text{m}^3$

Result: $.009 \mu\text{g}/\text{m}^3$

Equipment: Balances,
mortar & pestle

Operation: Weighing,
grinding





TOP MOUNT SERIES

- Available in many exhaust configurations with single 4" HEPA filter or dual 4" HEPA filters with BIBO filter change technology
- Reproducibility and accuracy of weighing is achieved by engineering controls that create laminar air flow



BULK POWDER

- Most effective and efficient containment for bulk powder applications and large drum loading and unloading
- Prevent the loss of containment with the three membrane safety system for securing the drum into the inside of the enclosure



GLOVEBOX WORKSTATION

- Designed for work with anti-cancer drug on conjugate processing and other sensitive applications
- HEPA inlet provides interior laminar airflow that meets or exceeds ISO 5 environment



HYBRID ISOLATOR

- At or near isolator containment levels for a fraction of the cost
- For applications that require containment of less than 50 ng/m³



LEV III

- Save energy and lab space by moving the process applications out of fume hoods
- Most effective and efficient containment for flash chromatography, rotovaps, and more



FUME HOOD SERIES

- Overlapping sash bypass provides better containment and does not require changes if VAV is installed
- Save over 60% of energy with the SAF-T Flow™ Fume hood series



NITROGENEMA II

- Achieve and maintain low humidity or oxygen levels
- HEPA filtration to house exhaust with one way check valve

TASK MATCH

BY *FLOW SCIENCES, INC*

A SEARCH TOOL TO MATCH YOUR TASK OR PROCESS
WITH PREVIOUS ENCLOSURES ENGINEERED AND
DESIGNED BY FLOW SCIENCES TO FIT SIMILAR TASKS.

WWW.FLOWSCIENCES.COM/TASKMATCH

TASKMATCH APPLICATIONS

BUCHI SPRAY DRYER SYSTEM

SIZE: 149" EXT. WIDTH, 46" EXT. DEPTH, 105" EXT. HEIGHT

Left side encloses a Buchi Spray Dryer, Model B290 and includes a tapered, covered sink and drain as well as an integrated alarm, bag in-bag out hepa filtration, minihelic gauge, and iris ports. Right side floor-mounted enclosure houses Inert Loop B295 with Dehumidifier B296 sitting on top and includes bag in-bag out hepa filtration, an integrated alarm, minihelic gauge and an LED light. This enclosure is designed to work with liquids and aerosols.



MALVERN SPRAYTEC ENCLOSURE

SIZE: 72" EXT. WIDTH, 34" EXT. DEPTH, 39" INT. HEIGHT

Dual, top-mount HEPA filtration system and BIBO to maximize personnel protection while working with powder/aerosol application. The enclosure features a sliding sash door with black phenolic base, polypropylene structure, and acrylic sides. Enclosure is also equipped with built-in LED lighting system that can be adjusted to provide additional light for viewing and working with application.



PROVERIS SPRAYVIEW ENCLOSURE

SIZE: 50" EXT. WIDTH, 66" EXT. DEPTH, 46" INT. HEIGHT

Designed to provide personnel protection when using a Proveris SprayVIEW with dimensions of 35" W x 33" D x 28" H for measuring spray pattern and plume geometry of orally inhaled and nasal drug products (OINDPs). This enclosure features include a black phenolic base, aluminum superstructure, acrylic panels, top-mount fan, bag-in/bag-out filtration with dual HEPA filters, right side access door, minihelic gauge, right side iris port, and hinged doors. Acrylic viewing panels maximize lighting across the workspace.





RAW MATERIAL INSPECTING SYSTEM

SIZE: 84" EXT. WIDTH, 36" EXT. DEPTH, 26" INT. HEIGHT

Bulk powder containment unit for personnel protection while inspecting powder substances. Enclosure features black phenolic base and polypropylene structure with acrylic sides and hinged doors for access to application and loading bulk powder. Also features mesh top fan with BIBO. Unit equipped with minihelic gauge for monitoring pressure, iris ports on both sides of enclosure to assist in cleaning, and LED lighting for added visibility of application. Removable divider separates bulk powder storage from application.



PARTICLE ANALYSIS SUITE

SIZE: 206" EXT. WIDTH, 48" EXT. DEPTH, 100" EXT. HEIGHT

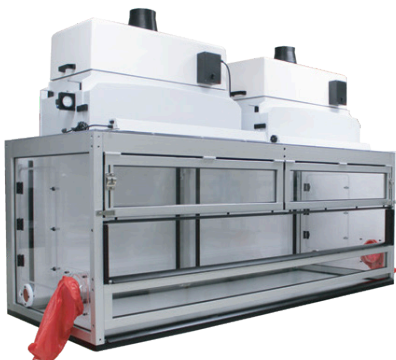
Dual section balance enclosure with BIBO filtration for containment of $<100\text{ng}/\text{m}^3$ during vacuum filter change. This unit is designed to be compatible with compressed air cleaning system and lower section to house Nilfisk Vacuum unit. Enclosure designed for the Sympatec HELOS/BF for Laser Diffraction Particle Analysis. The lower section will allow a Midas to sit on shelf outside of containment.



VORTI-SIV BULK POWDER ENCLOSURE

SIZE: 95" EXT. WIDTH, 62" EXT. DEPTH, 62" INT. HEIGHT

Vorti-Siv Bulk Powder Station with dual, BIBO HEPA filtration system designed to house a VORTI-SIV® RBF-12 Small Batch Sieving Machine. Enclosure equipped with stainless steel lift cart and fitted with 20" bulk powder cutout for loading bulk powder APIs into Sieving Station. Hinged front and lower doors allow for loading/unloading of equipment and samples. Airfoils, rear plenums, and top-mounted fans maintain laminar airflow across the workspace and optimum face velocity to ensure full protection from exposure to hazardous powder APIs. Polypropylene enclosure fitted with acrylic panels and built-in LED system to provide both ambient and additional lighting.



CARVER PRESS & RPA CUTTER ENCLOSURE

SIZE: 95" EXT. WIDTH, 62" EXT. DEPTH, 62" INT. HEIGHT

Enclosure designed to maximize personnel protection during die preparation and sample cutting operation. Unit built to fit multiple instruments: balance, guillotine cutter, sample cutter, and hydraulic press curer while also providing equipment stability with a bolt-down on the base. Designed so the operator can complete multi-stage application with access to multiple devices without removing hands from the enclosure during the process. The enclosure features a hinged door, an aluminum frame with acrylic sides, and a black phenolic base. Top-mount fan and HEPA filtration system.



Flow Sciences' team of industrial engineers design workstations and enclosures that reduce product contamination and maximize protection for professionals who work with toxic substances and uncertain risks. All of our products are engineered and manufactured at our corporate headquarters in Leland, NC and are backed by our sophisticated design process and award-winning excellence in engineering, including 11 U.S. Government patents. We have worked with pharmaceutical companies, research and development laboratories, manufacturing, and production facilities for 30 years. Our task-specific designs are dynamic solutions that are adaptable to our clients' workflow and specific needs.

Flow Sciences was one of the first companies in the U.S. to use computational fluid dynamics (CFD) in drafting our enclosures to ensure optimum airflow. Our engineers use CFD algorithms to simulate fluid flows and interactions within contained spaces. This enables us to predict and control airflow through design, which we then test in our state-of-the-art laboratory. Working closely with our clients to mimic real-world applications, we develop testing protocols based on the intended use of our enclosures and measure them against industry-accepted standards to ensure proper containment. We have designed, manufactured, and tested over 13,000 enclosures, generating a wealth of data on situational flow dynamics, which allows us to control for consistency, safety, efficacy, and overall quality.