FLOW SCIENCES, INC.

PILOT PLANT / MANUFACTURING

PROCESS SOLUTIONS:

ACTIVES & EXCIPIENTS | BLENDING | MILLING & GRANULATING
DRYING & COMPRESSION | TABLET COATING & POLISHING

MADE IN THE USA

www.flowsciences.com · 1-800-849-3429 · Leland, North Carolina, USA

ISO 9001 2015 CERTIFIED

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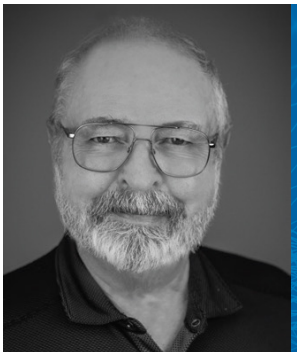


"Solutions to containment challenges come from understanding the relationship between equipment, operator, and process."

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

Contract manufacturing and research of pharmaceuticals consume an increasing percentage of budgets every year. The ability to be effective is both a challenge and an opportunity as contracts are processed and delivered. Safety, performance, and reproducibility are of the utmost importance to CMOs or CROs. They rely on their equipment to manufacture consistent products and deliver results while maintaining personnel and product safety.

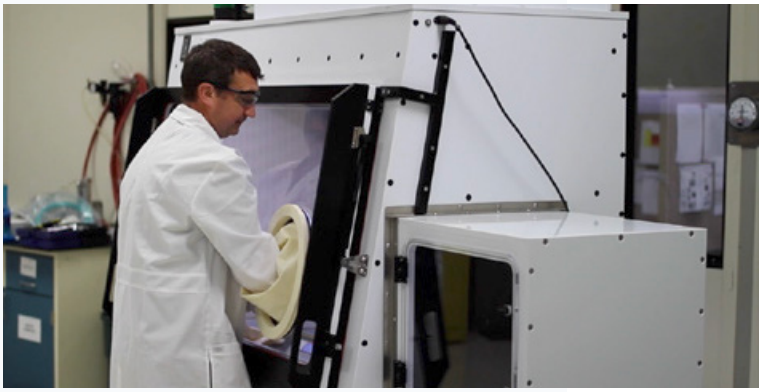
At Flow Sciences, we pride ourselves on the ability to engineer solutions that contain applications properly while creating consistent results. Versatility and flexibility are vital to successful CDMOs and CDROs, which is why many of the top contract manufacturing and research companies in the world choose Flow Sciences as their trusted containment provider. With products ranging from convertible enclosures for different API toxicity levels to options 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 is ISO 9001:2015 certified in production quality. Every unique unit receives factory acceptance testing before leaving the facility. Our commitment to manufacturing quality products results in the end user's ability to produce quality results. While there are many options available now, new enclosures systems are designed 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, contact us by phone or online.

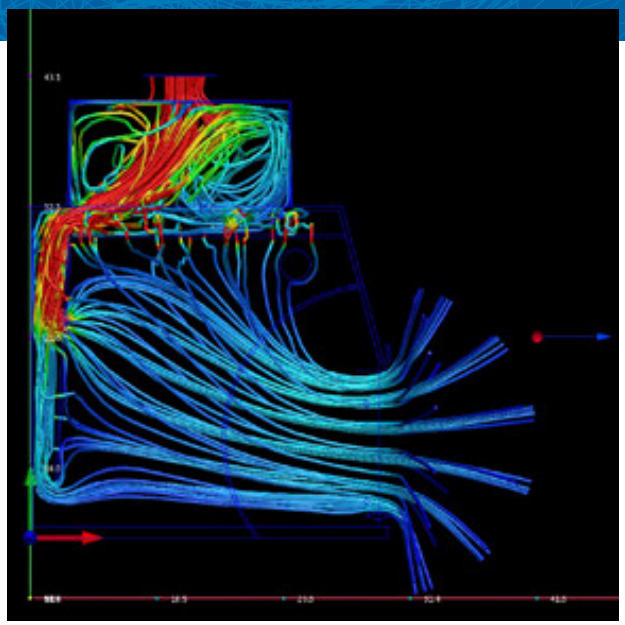
CONTAINMENT SOLUTIONS FROM RESEARCH TO PRODUCTION

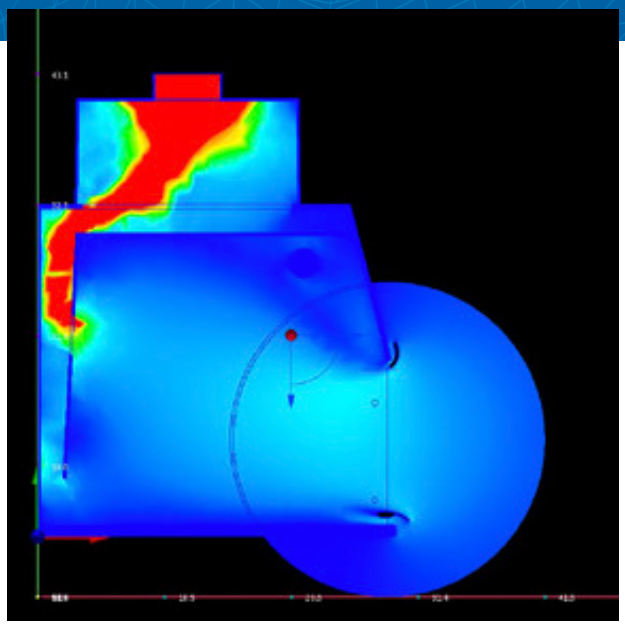
Flow Sciences, Inc. provides engineered containment solutions from research to production. From Occupational Exposure Bands (OEB) 3 to 5, we manufacture systems to suit your application. Whether in powder manipulation where balance stability is paramount, using specific manufacturer equipment needing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

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 manufacturing 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.



DESIGN PROCESS





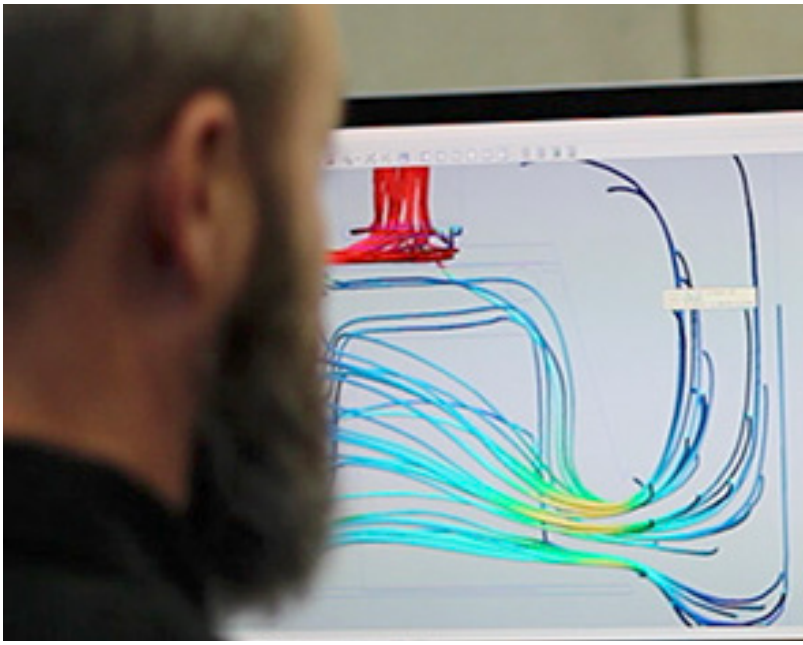
Computational Fluid Dynamics (CFD) is the study of fluid dynamics using sophisticated computing technology.

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.

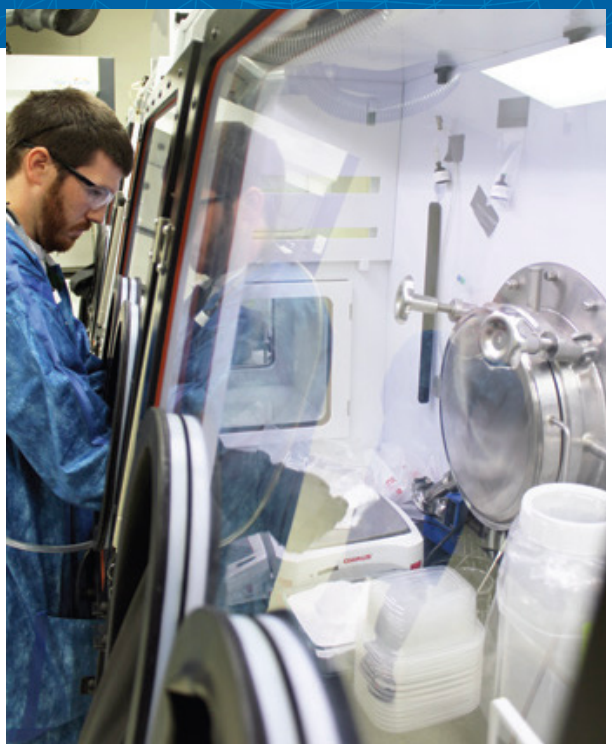
CFD allows the user to see the results of engineering design more effectively than in the real world. The effects of minute features in the designing process can be seen and compared using CFD which cannot be done in an otherwise efficient manner. Another added advantage of using CFD is the repeatability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

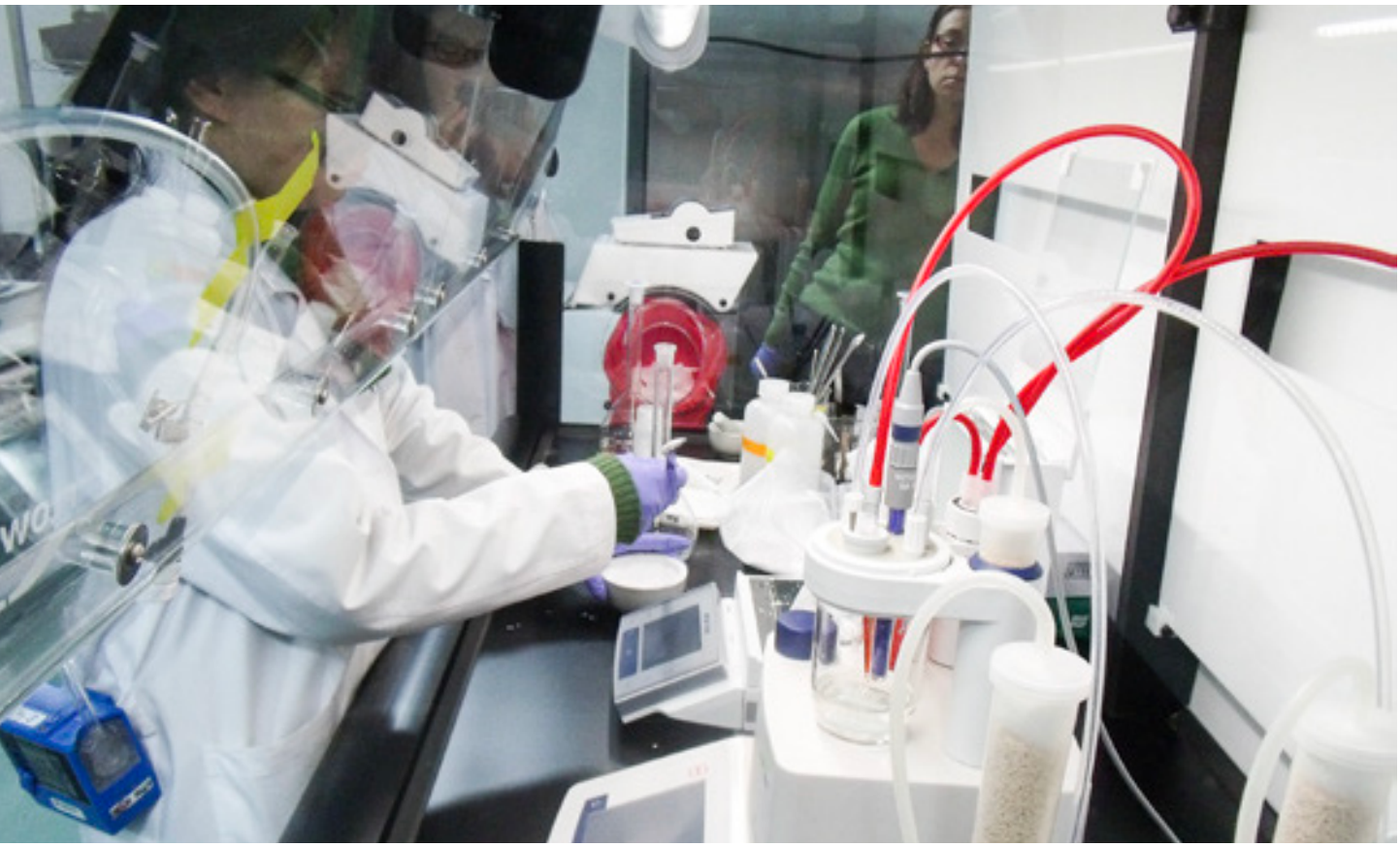


TESTING



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 hygene 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.



PILOT PLANT/ MANUFACTURING CONTAINMENT SOLUTIONS

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 ceritified 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.

PRODUCTS BY MANUFACTURING PROCESS STAGE

ACTIVES & EXCIPIENTS

QUALITY CONTROL

BLENDING

MILLING & GRANULATION

DRYING & COMPRESSION

TABLET COATING & POLISHING

ACTIVES & EXCIPIENTS

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 epuipment. 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.

ACTIVES & EXCIPIENTS

BULK POWDER VENTED ENCLOSURE

SIZE: 71” EXT. WIDTH | 30” EXT. DEPTH | 27” INT. HEIGHT

Bulk Powder Vented Enclosure designed to provide personnel protection while working with powder substances. The Pictured unit is designed specifically for a Hicoflex Disposable Containment System by GEA. The enclosure features include antistatic acrylic superstructure, hinged door style, acrylic viewing panels, LED lighting, 20” bulk powder cutout with cover, BIBO (Bag–In/Bag–Out) dual HEPA filtration, velocity alarm, right side waste chute, left side blanked optional pass–through port, 2” sanitary valve, reducing coupling, tri–clover clamp with gasket and cap, and 316 stainless steel cart. Acrylic viewing panels and LED lighting maximize lighting across the workspace. Alarm mount and printer stand optional.

STAINLESS STEEL BULK POWDER HOOD

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

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

QUALITY CONTROL

MALVERN MASTERSIZER 3000 SYSTEM

SIZE: 36” EXT. WIDTH | 40” EXT. DEPTH | 36” INT. HEIGHT

Malvern Mastersizer 3000 with Aero S and Hydro MV Enclosure designed to provide personnel protection while working with powder substances. The enclosure features include a polypropylene frame, acrylic panels, black phenolic base, top mount fan, HEPA filtration, sliding sash, side access doors, iris ports on both sides, minihelic gauge, and a white steel cart with cover panels and doors that docks into the enclosure. Cart is fitted with lock–down casters. Acrylic viewing panels and LED lighting maximize lighting across the workspace.

PARTICLE ANALYSIS SUITE

SIZE: 206” EXT. WIDTH | 48” EXT. DEPTH | 100” EXT. HEIGHT

Dual section Balance enclosure with Bag in Bag out filtration for containment of <100ng/m during vacuum filter change. This unit is designed to be compatible with a compressed air cleaning system and lower section to house the Nilfisk Vacuum unit. Enclosure for Sympatec HELOS/BF: This enclosures houses a Sympatec – for Lazer Diffraction Particle Analysis. The Lower Section will allow a Midas to sit on a shelf outside of containment.

QUALITY CONTROL

SYMPATEC INHALER 2000 ENCLOSURE

SIZE: 62” EXT. WIDTH | 49” EXT. DEPTH | 36” INT. HEIGHT

Designed to provide personnel protection working with powder substances. Designed specifically for use with a Sympatec Inhaler 2000. This enclosure features include a polypropylene superstructure, removable sliding sash, dished black phenolic base with base cutout 37.25” W x 36” D, BIBO (Bag–In/Bag–Out) dual HEPA filtration, access doors on both sides, left side waste chute, minihelic gauge, 4x right side iris ports, monitor mount, B.A.S. current monitoring system with velocity alarm, ADA lift table with lock–down casters, cart for Sympatec Inhaler 2000 loading/unloading, and acrylic viewing panels. Acrylic viewing panels and LED lighting maximize lighting across the workspace.

MAXIBLEND V–BLENDER SYSTEM

SIZE: 72” EXT. WIDTH | 34” EXT. DEPTH | 39” EXT. 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.

BLENDING

SIEVING SUITE

SIZE: 109” EXT. WIDTH | 36” EXT. DEPTH | 29” INT. HEIGHT

Sieving Suite Hybrid Isolator designed to house Retsch AS–200 TAP Sieve Shaker and Hirschmann Laborger te Jolting Volumeter STAV–II with Water bath cart. Airfoils and plenums coupled with a BIBO (Bag–In/Bag–Out) dual HEPA filtration system control airflow across the workstation and maximize personnel protection while working with powder APIs. Stainless steel construction with inset acrylic paneling allows for ambient light transmission. Size

VORTI–SIV BULK POWDER ENCLOSURE

SIZE: 95” EXT. WIDTH | 62” EXT. DEPTH | 62” EXT. HEIGHT

Vorti–Siv Bulk Powder Station with dual, BIBO (Bag–In/Bag–Out) dual HEPA filtration 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 a built–in LED system to provide both ambient and additional lighting.

BLENDING

MAXIBLEND V–BLENDER SYSTEM

SIZE: 69” EXT. WIDTH | 36” EXT. DEPTH | 36” INT. HEIGHT

Enclosure built for personnel protection and containment of Maxiblend V–Blender while loading, sampling, and unloading powder substances. Enclosure fitted with a single HEPA filter and dual–speed, top–mounted fan with dual speed to accommodate operations/containment and cleaning. Stainless steel sink in base contains sanitary fitting for drain. Additional cleaning features include an interiorly mounted misting wand and vacuum ports on both sides of the enclosure. Clean in Place CIP Wand and hose installed for misting inside of the enclosure.

SENTRONIC SENTRO BLENDER ENCLOSURE

SIZE: 47.75” EXT. WIDTH | 44” EXT. DEPTH | 42.4” EXT. HEIGHT

Sliding sash and polypropylene construction allow for versatility and protection while working with a Sentronic Sentro Blender, a blended system for NIR method development using the SentroPAT BU TL system. The enclosure has a sliding sash for ease of equipment loading and operation. LED is included inside of the enclosure to illuminate the work surface for the optional process view.

MILLING & GRANULATION

FREWITT FREDRIVE MILL ENCLOSURE

SIZE: 43” EXT. WIDTH | 49” EXT. DEPTH | 50” INT. HEIGHT

Fluid Bed Dryer enclosure designed to maximize personnel protection. Top Mounted HEPA Unit features a complicated structure with an aluminum frame and removable acrylic panels and hinged doors to allow the enclosure to contain Freund Vector VFC–LAB 1 application while not limiting operator access or protection. The Iris port on the right of the enclosure allows additional operator access. The unit is equipped with a mesh–top fan with HEPA filtration. Clean in Place CIP Wand and hose installed for misting inside of the enclosure.

QUADRO COMIL 197S MILLING ENCLOSURE

SIZE: 60” EXT. WIDTH | 40” EXT. DEPTH | 70” EXT. HEIGHT

Quadro Comil 197S Milling Enclosure designed to provide personnel protection while working with powder substances. Specifically designed for using the Quadro Comil 197S. The enclosure features include polypropylene superstructure, sliding sash door style, top mount fans, BIBO (Bag–In/Bag–Out) HEPA filtration, right side waste chute, and dished black phenolic base. Acrylic viewing panels maximize lighting across the workspace.

MILLING & GRANULATION

FITZMILL L1A & QUADRO COMIL GLOVEBOX

SIZE: 69” EXT. WIDTH | 36” EXT. DEPTH | 36” INT. HEIGHT

Negative pressure unit designed to contain Fitzmill L1A or Quadro Comil U5 R&D mills for operator protection while working with powder substances. Enclosure equipped with a pass–thru interlocking chamber for loading and unloading materials on the left side of the unit as well as five 10” glove ports on front and back of enclosure for working with specified application. Enclosure equipped with top–mount BIBO (Bag–In/Bag–Out) HEPA filtration. Features stainless steel base, polypropylene structure, and acrylic sides. Clean in Place CIP Wand and hose installed for misting inside of the enclosure.

WITH COMIL

WITH BLANK PLATE

DRYING & COMPRESSION

MEMMERT VO 200 VACUUM OVEN ENCLOSURE

SIZE: 34” EXT. WIDTH | 34” EXT. DEPTH | 33” INT. HEIGHT

Memmert VO 200 Vacuum Oven Enclosure designed to provide personnel protection while working with powder substances. Enclosure features include polypropylene superstructure, black phenolic base, acrylic viewing panels, hinged door style, BIBO (Bag–In/Bag–Out) dual HEPA filtration, top mount fan, Go/No Go Red and Green Signal Light, removable draft shield with 2x 8” oval glove ports, integrated alarm, LED lighting, vent kit, thimble connection, a right side pass–thru with interlock doors, and right side iris port. LED lighting and Acrylic viewing panels maximize lighting across the workspace.

LINDBERG/BLUE M VACUUM OVEN HOOD

SIZE: 252” EXT. WIDTH | 30” EXT. DEPTH | 101” EXT. HEIGHT

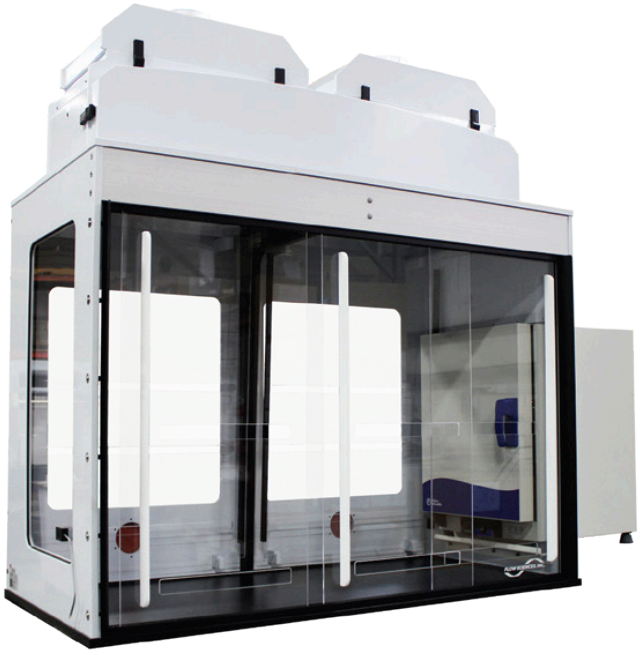
API Process Development System designed to provide personnel and product protection while working with powder and liquid substances. Designed to house a Mettler Toledo Easy Max 102, Vacuum Oven, and IKA LR 1000. System features include acrylic superstructure for Isolators, polypropylene superstructure for Glovebox Workstation with clear opening pass–thru on left and right side, inlet HEPA filtration, black phenolic base, acrylic viewing panels, hinged door style, BIBO (Bag–In/Bag–Out) dual HEPA filtration, top mount fan, vent kit, 5x thimble connections, acrylic left side pass through, polypropylene right side pass–thru, removable draft shields with 12 x 8” oval glove ports on isolators, 2 x 10” glove ports on the glovebox, minihelic gauges, LED interior lighting, 6” solid waste port with continuous liner, 3x tables, 2x vacuum pump cabinets with power switches, and main electrical box for fans and on/off switch for lighting. LED lighting and Acrylic viewing panels maximize lighting across the workspace.

DRYING & COMPRESSION

API PROCESS DEVELOPMENT SYSTEM

SIZE: 78” EXT. WIDTH | 50” EXT. DEPTH | 27” INT. HEIGHT

For containing vacuum oven where pressure and heat must be controlled for drying, curing, vacuum embedding, and plating applications. The enclosure features an aluminum frame, black phenolic base, two Ezi–Dock systems, and acrylic walls with an access door for viewing and working with the specified application. Dual top–mount filter and fan with BIBO and alarm system for monitoring laminar flow.



SMALL OVEN AND FTIR ENCLOSURE

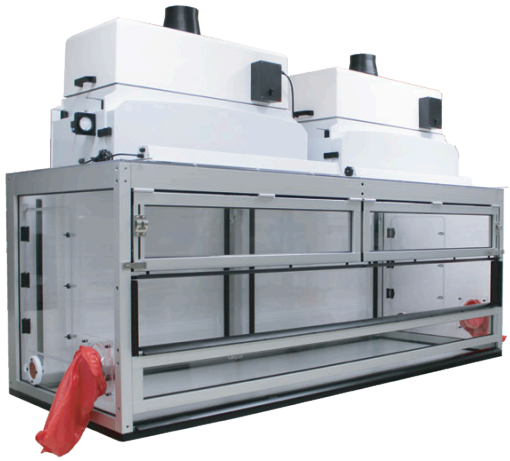
SIZE: 64” EXT. WIDTH | 32” EXT. DEPTH | 45” EXT. HEIGHT

Small Oven and FTIR Enclosure designed specifically for a ThermoFisher Heratherm™ General Protocol Mechanical Convection oven with specifications of 22.2” W x 25.2” D x 32.3” H and FTIR (Fourier Transform Infrared Spectroscopy) equipment with specifications of 15” W x 15” D x 8” H. Features include a vent kit with Bag–In/Bag–Out filtration, Dual HEPA filters, a black phenolic base, removable sliding doors, and acrylic panels. Two (2) minihelic gauges monitor filter status and face velocity. Acrylic viewing panels maximize lighting across the workspace.

TABLET COATING & POLISHING

CARVER PRESS & RPA CUTTER ENCLOSURE

SIZE: 100” EXT. WIDTH | 40” EXT. DEPTH | 35” INT. HEIGHT

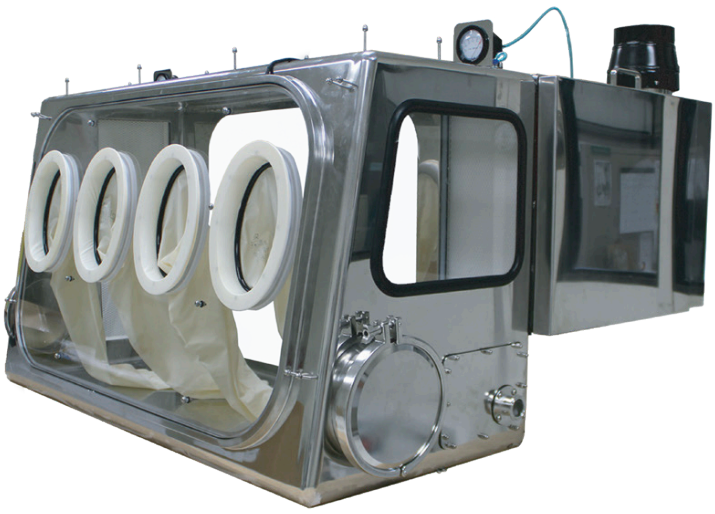


Enclosure designed to maximize personnel protection during dye preparation and sample cutting operation. Unit built to fit multiple instruments: balance, guillotine cutter, sample cutter, and hydraulic press curer while also providing equipment stability with a bolt–down on the base. Designed so that 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 grey trespa base. Top–mount fan and HEPA filtration system.

STAINLESS STEEL TABLET PRESS ENCLOSURE

SIZE: 82” EXT. WIDTH | 52” EXT. DEPTH | 29” EXT. 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. ” acrylic front door fitted with an inflatable seal to ensure operator safety as well as (4x) 8–inch glove ports. Unit equipped with a lateral flow fan, dual–HEPA filtration with BIBO option, and thimble connection to house exhaust.



KRAEMER DEDUSTER ENCLOSURE

SIZE: 43” EXT. WIDTH | 31” EXT. DEPTH | 26” INT. HEIGHT

For containing vacuum oven where pressure and heat must be controlled for drying, curing, vacuum embedding, and plating applications. The enclosure features an aluminum frame, black phenolic base, two Ezi–Dock systems, and acrylic walls with an access door for viewing and working with the specified application. Dual top–mount filter and fan with BIBO and alarm system for monitoring laminar flow.

PERFORMANCE

PERFORMANCE

Performace 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.

POLYPROPYLENE BULK POWDER ENCLOSURE

Containment Target: 40 µg/m^3

Result: 3.82 µg/m^3

Equipment: Balance, Scoops

Operation: Weighing, bulk powder dispensing

Test: Lactose – 3 x 25kg

VORTI–SIV BULK POWDER

Containment Target: 19 µg/m^3

Result: 0.307 µg/m^3

Equipment: Sieves, Balances

Operation: Sieving, weighing

Test: Lactose – 7kg

PERFORMANCE

N15 WEIGHT SORTING ENCLOSURE

Containment Target: 50 ng/m^3
Result: Non–detect
Equipment: Trays
Operation: Pill sorting
Test: Naproxen Sodium – 3 x 400 pills (220g)

HIGH POTENCY API PREP SYSTEM

Containment Target: .200 ng/m^3
Result: 9 ng/m^3
Equipment: Balance, mortar & pestle
Operation: Weighing, grinding
Test: Lactose – 3 x 500g

PARTICLE ANALYSIS SUITE

Containment Target: 100 ng/m^3
Result: 8 ng/m^3
Equipment: Nilfisk, Sympatek
Operation: Sympatec simulation, cleaning
Test: Naproxen Sodium – 30 x 0.1g

PERFORMANCE

CYTOTOXIC DRUG DEVELOPMENT GLOVEBOX

Containment Target: 5 ng/m

Result: 0.12 ng/m^3

Equipment: Balance

Operation: Weighing, dissolution

Test: Naproxen Sodium – 3 x 10g

HIGH POTENCY GLOVEBOX SYSTEM

Containment Target: 50 ng/m^3

Result: .4 ng/m^3

Equipment: Balances

Operation: Weighing, transferring

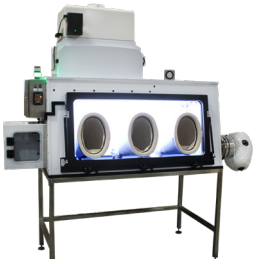
Test: Naproxen Sodium – 3 x 500g

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/m^3

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

CASE STUDY: TABLETING SUITE

Bulk powders are dispensed in aliquots and transferred to a high shear granulator, fluid bed dryer, and blender. The process concludes in the final enclosure containing the tablet press. The two larger enclosures use interchangeable carts to allow the addition and removable of equipment as dictated by the process. Units include dual Bag In/Bag Out HEPA filtration for maximum containment. Surrogate sampling showed containment results of 1 to 5 mg/m3.

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.