THE BAKER COMPANY

Intro To Custom Products

Because of our vast expertise in the fields of HEPA filtration, laminar flow technology, microbiology, containment and stainless steel manufacturing, The Baker Company has routinely been called upon to build specialty containment and clean air equipment for very specific or unique applications since the 1960's.

With a philosophy of developing unique products that will eventually fit the needs of many, The Baker Company has manufactured hundreds of products including:

- Class III biological safety cabinetry to contain the world's most deadly viruses.
- Aseptic filling line isolators for the manufacturing of parenteral drugs.
- Containment isolators for the handling of potent drug compounds.
- Restricted access barrier systems for aseptic processing.
- Walk-in size biological safety cabinets to house large automated liquid handling systems and other potential aerosol generating equipment.
- Customized fume hoods for cGMP manufacturing requirements.
- HEPA filtered laminar down flow modules.
- Aseptic clean air enclosures for food processing.
- Vapor phase hydrogen peroxide compatible systems.

To meet the varied needs of researchers and industry, The Baker Company can apply the in-house expertise of professional and experienced mechanical engineers, microbiologists, HEPA filtration and airflow specialists, containment specialists, project managers, industrial hygienists, NSF Accredited equipment certifiers, sheet metal designers as well as a base staff of stainless steel manufacturing craftsmen skilled in cGMP manufacturing requirements.

Since every aspect of a custom project is handled in-house, Baker maintains direct control over every design, manufacturing and testing aspect of your project to assure complete customer satisfaction.

Baker Custom Engineered Solutions

Class III Biological Safety Cabinetry and Pharmaceutical Isolators

IsoGARD®

The Baker Company has developed a standard line of gloveboxes that have been designed to meet the very stringent performance and leak testing requirements of Class III biological safety cabinetry, as defined by the US Federal Register.

IsoGARD®

The IsoGARD® series is designed with an integral full-size pass-thru chamber with a unique front opening glass panel door that allows a user to introduce samples into the main working chamber with ease. The cabinets are built using heavy 11-gauge, highly corrosion resistant 316L stainless steel in a unibody type construction to eliminate cracks and crevices. Designed to handle deadly microbiological agents and pharmaceutical potent compounds under contained conditions, IsoGARD® units are supplied with full coverage supply HEPA filters to insure an ISO Class 5 (Class 100) operating environment as well as easily removable specially designed cartridge style exhaust HEPA filters.

Other features such as an ergonomic 10° tilt to the viewing windows, oval gloveports, and an exhaust plenum built to the rear of the cabinet make it much easier and comfortable to work in.

The IsoGARD® is designed in four standard models offering two, three, four and five glove primary working chambers along with a host of options that will allow a user to tailor a cabinet to meet most standard requirements.

Specialty Class III Gloveboxes and Isolators

In addition to the standard IsoGARD® series, The Baker Company designs and manufactures Class III gloveboxes and isolators to meet very specific user applications. Unique requirements for aerosolization studies, vaccine research, and the handling of potential biological or chemical agents are all projects that our Custom Products Division deals with on a routine basis.

The Baker Company is unquestionably the most experienced Class III glovebox manufacturer in the world. All equipment is manufactured and tested to exacting standards to assure the integrity of your research and safety. Our applications engineers are always ready to discuss your unique requirements. Drawing on the company's past experiences with hundreds of special applications, many times we can make specific recommendations in minutes, as well as providing drawings and quotations.

Receiving Isolator

Working directly with governmental agencies, and public health laboratories, The Baker Company has developed this specially designed Class III receiving glovebox to accommodate the handling of incoming samples of a suspicious nature. Designed to handle either biological or chemical agents, the cabinet is equipped with an oversized pass-thru chamber with a hinged work surface to ergonomically manipulate different sized coolers, boxes or cans that may come in from the field. A 6' working chamber with a built in disinfectant dunk tank is used to analyze and identify the unknown sample. Like all Class III equipment, the cabinet runs under a negative pressure in relation to the laboratory and is equipped with various alarms and interlocks to assure safe operation.

Gloveboxes

Class III Biological Safety Cabinet Line

A major university commissioned The Baker Company to build a custom Class III containment line to handle their research and work with a biosafety Level 4 pathogen. Working together with the end users and a group of architects that specialize in the design of high containment laboratories, Baker built a fully integral line of Class III cabinetry. The line consisted of cabinets integrated with an ultracentrifuge, laminar flow work stations, microscopes with remote viewing screens, incubators, well type refrigerators and freezers, dunk tanks and an autoclave.

Robotic Clean Air and Containment Equipment

In order to speed throughput and improve accuracy, laboratories are increasingly employing automatic liquid handling systems and other large potential aerosol generating equipment. The Baker Company has responded with the BioPROtect II series of walk in clean air and containment hoods offering Class II biological safety cabinet containment performance as well as a line of laminar flow downflow enclosures offering ISO Class 5 (Class 100) air conditions.

Laminar Downflow Unit

Pharmaceutical Manufacturing Equipment and Specialty Isolators

Examples of The Baker Company's work in the pharmaceutical manufacturing area are described below. In both cases, Baker engineers worked directly with engineers from major pharmaceutical companies to design and validate specialized isolators to meet the specific manufacturing requirements.

ParenteralGARD™

This innovative concept provides many of the benefits of a complete barrier isolation system, but without the rigorous and risky validation requirements, at a very attractive price. Dramatic improvements in sterility assurance levels up to one hundred times cleaner when compared to a conventional ISO Class 5 (Class 100) cleanroom with a gowned operator are readily achieved.

The ParenteralGARD™ integrated system in combination with aseptic filling machines, is designed to provide significant, reliable reduction in both total airborne particulates and viable counts in the critical zones of your aseptic process.

ParenteralGARD™

Sterile Potent

In this case, the manufacturer of a highly potent, injectable chemotherapy drug required an isolator to enclose its filling line. The Baker Company responded by building the country's first three-chamber negative pressure filling line isolator that offered personnel, product and environmental protection. Our client also required integration with a UV tunnel for vial entry and an active exit "mousehole" for the continuous exiting of filled and stoppered vials.

Sterile Potent Compound Filling Line Isolator

This groundbreaking isolator gained quick FDA approval and has been in continuous operation since 1996.

Classed Capping Isolator

Classed Capping Isolator

Working closely with our client, the filling machine manufacturer, the conveyor system fabricator and the capping machine vendor, The Baker Company managed all aspects of equipment integration. The result was a complete synergistic system that provided a sensible and seamless process flow. The Classed Capping Isolator provides a physical barrier between the operators and the product during filling and capping operations while insuring ISO Class 5 (Class 100) conditions. The Baker Company specially designed a "point of source" exhaust plenum at the capper crimping rail to capture particles. This technique captures contamination as it is generated and prevents upstream migration of viable and nonviable particulate. The vial exit mousehole is configurable to allow the fine-tuning of exiting air with different vial sizes. The isolator is equipped with 22 gloveports so that all interior surfaces are reachable with a gloved hand.

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P.O. Drawer E, Sanford, Maine 04073 (207) 324-8773 1-800-992-2537 FAX (207) 324-3869 www.bakerco.com