Advanced Barrier Concepts, Inc. is the trusted resource of many of the world's leading pharmaceutical manufacturers. Their repeated confidence reflects our ability to continually set benchmark standards of quality and service. We invite you to review some of our completed projects for our valued clients.

AAI, Inc. (Wilmington, NC)

- Performed Factory Acceptance Testing and Site Acceptance Testing for a SKAN Bioburden Testing Isolator System / Sterility Test System.
- Performed the IQ, OQ, and developed the PQ testing protocols.
- H_2O_2 gas D-value determination of test carriers.
- Executed Cycle Development and Performance Qualification protocols for the decontamination process on both isolators.
- Developed the SOP for the set-up and operation of the sterilant generator to support the execution of a validated isolator decontamination cycle.
- Sterile challenge protocol development and execution support.

Abbott (Barceloneta, PR)

- Developed the User Requirement Specifications, Equipment Specifications, and Factory Acceptance Testing Specifications for a Bioburden Testing Isolator System.
- Reviewed / specified the facility's requirements for the isolated system.
- Developed the Validation Master Plan that determined the requirements for the qualification of the processes associated with the Bioburden Test Isolator System.
- Developed IQ, OQ, and PQ testing protocols.
- Executed Cycle Development and Performance Qualification protocols for the decontamination process.
- Developed the SOP for the set-up and operation of the sterilant generator to support the execution of a validated isolator decontamination cycle.

Acambis, Inc. (Canton, MA)

- Provided conceptual design support for a production aseptic processing fill/lyophilize manufacturing facility. The following three designs were explored for this project: conventional aseptic processing in a clean room, a totally isolated filling system, and an aseptic processing design that utilized the RABS (Restricted Access Barrier System) technology.
- Provided current technical information regarding the validation of an isolator and a RABS system.
- Provided input for the FDA's 2004 initiative, "Pharmaceutical CGMPs for the 21st Century", relative to how a specific aseptic processing design will impact the Agency's procedure regarding facility reviews.

Acambis, Inc. (Rockville, MD)

- Reviewed / revised the URS, DDS, mock-up procedures, and the FAT and SAT protocols for a la Calhéne lyophilizer interface isolator and an autoclave/depyrogenation oven interface isolator.
- Executed the mock-up, FAT, and the SAT for the two interface isolators.
- Developed the commissioning protocols for the two interface isolators and for an IsoTech filling isolator, three IsoTech transfer isolators, and two VHP1000 Biodecontamination systems.
- Executed the commissioning protocols.
- Reviewed / revised the SOPs for the set-up and operation of the equipment.

Acambis, Inc. (Rockville, MD)

- Qualification of a lyophilized aseptic filling isolator system consisting of a filling isolator (IsoTech), lyophilizer interface isolator (la Calhéne), autoclave/depyrogenation oven interface isolator (la Calhéne), and three transfer isolators (IsoTech) decontaminated using a VHP1000 Biodecontamination System
- IQ/OQ/CD/PQ protocol development and execution for the six isolators and two VHP1000 H_2O_2 generators. Equivalency testing was performed for two transfer isolators and the second VHP1000 generator.
- BI resistance testing using a transfer isolator.

Agracetus, Inc. / Auragen, Inc. (Middleton, WI)

- Sterile process development for Phase 1 Clinical DNA Product and system validation of an Isolation Technologies rigid wall isolator, sterile transfer systems, autoclave, and VHP1000 generator.
- Environmental monitoring of the isolator, laminar flow hoods, and the manufacturing area. Revalidation performed after equipment modifications.
- Participation in SOP development and reviews.

Allergan, Inc. (Waco, TX)

- Facility design review and optimization (HVAC air exchanges, temperature control).
- Validation protocol development and execution of a la Calhéne flexible wall sterility test isolator system and a VHP1000 generator.
- H_2O_2 gas D-value determination of test carriers.

Allergan, Inc. (Irvine, CA)

- IQ/OQ/CD/PQ protocol development and execution for an IsoTech HemiSphere half-suit isolator, an IsoTech IsoSphere isolator, and a VHP1000 Biodecontamination System.
- BI resistance testing using the IsoSphere isolator.
- Sterilant intrusion and residue effects protocol generation and execution to determine if H_2O_2 can penetrate into product containers and environmental monitoring supplies at levels that could lead to false negatives.

Amgen Limited (Juncos, Puerto Rico)

- Qualification of a Carlisle Barrier (Walker Barrier) sterility testing system that consisted of two rigid wall 3-glove transfer isolators, a rigid wall dual half-suit workstation isolator, and two STERIS VHP1000ED-AB generators.
- Validation master plan, URS, and operational SOP development.
- BI D-value resistance testing in a transfer isolator protocol development and execution.
- Advanced decontamination cycle development testing.
- IQ/OQ/PQ protocol development and execution.
- Sterilant intrusion and residue effects protocol generation and execution to determine if H_2O_2 can penetrate into product containers and environmental monitoring supplies at levels that could lead to false negatives.

Amgen (West Greenwich, RI)

- Qualification of a Walker Barrier sterility testing system that consisted of two rigid wall 3-glove transfer isolators, a rigid wall dual half-suit workstation isolator, and two STERIS VHP1000ED-AB generators.
- Provided a technical review (GAP Analysis) of the original validation and determined that the testing was not properly conducted (validation short-falls) to support repeatable and robust decontamination cycles.
- VHP1000ED-AB User Requirements Specifications (URS) development.
- VHP1000ED-AB IQ/OQ protocol development and execution.
- BI D-value resistance testing in a transfer isolator protocol development and execution.
- CD/PQ protocol development and execution.
- Sterilant intrusion and residue effects protocol generation and execution to determine if H_2O_2 can penetrate into product containers and environmental monitoring supplies at levels that could lead to false negatives.
- Maintenance of Asepsis within the Workstation Isolator protocol generation and execution to verify a 30-day hold time period between decontamination cycles.
- SOP development
- Operator training to provide an overall understanding of the capabilities and limitations of the equipment.
- Annual requalification of the Sterility Test System's decontamination cycles for all three (3) isolators located in Amgen's Microbiology Laboratory located in the West Greenwich facility.

Amgen (West Greenwich, RI)

- Validation of a SKAN Sterility Test Isolator system that consisted of a rigid wall, 4-glove PSI-M isolator with an airlock.
- Generation of Performance Qualification protocol and execution for the Sterility Test System. Decontamination cycles were developed for both a maximum and minimum load configuration. A single load configuration was used to develop a decontamination cycle for the airlock only.
- A Sterilant Intrusion and Residue Effects protocol was drafted and executed. A product container matrix was developed and then each type was bracketed in terms of size and then semi-quantitatively assayed for residual H_2O_2 after "back-to-back" production decontamination cycles. Then a representative from each container type was challenged microbiologically.
- Drafted a 7-day sterile hold time protocol.
- BI D-value resistance execution.
- Annual requalification of the Combined System (isolator plus airlock) Production Decontamination Cycle and the Airlock Decontamination Cycle.

Amgen (Thousand Oaks, CA)

- Validation Planning and Execution Support for two (2) Walker Barrier sterility test single half-suit isolators with adjoining airlock and two (2) VHP1000ED-AB Bio-decontamination systems.
- Equipment and facility final design reviews and optimization (HVAC air exchanges, temperature control, sterilant manifold).
- Process equipment and isolator User Requirements Specifications (URS) development.
- Mock-up evaluation and pre-FAT to properly assess the design, construction, and test plan.
- FAT and Commissioning protocol development and execution.
- IQ/OQ/CD/PQ protocol development and execution for the process equipment and isolator systems.
- SOP development and operator training.
- TOP (Turn Over Package) generation.

Amgen (Thousand Oaks, CA)

- Validation of two (2) SKAN Sterility Test Isolator systems that consisted of two (2) rigid wall, 4-glove PSI-M isolators with two (2) airlocks attached to the isolators.
- Generation of Cycle Development and Performance Qualification protocols and execution for System 1 and System 2. Decontamination cycles were validated for both a maximum and minimum load configuration for each isolator system.
- Assisted with Sterilant Intrusion and Residue Effects testing. A product container matrix was developed and then each type was bracketed in terms of size and then semi-quantitatively assayed for residual H_2O_2 after "back-to-back" production decontamination cycles. Then a representative from each container type was challenged microbiologically.

Apotex (Richmond Hill, ON)

- Validation Planning and Execution Support for an isolated vial filling system that consists of a la Calhéne Filling isolator, Accumulation isolator, Transition isolator and two (2) STERIS VHP1000 Biodecontamination systems.
- Validation master plan development.
- Facility design review and optimization (HVAC air exchanges, temperature control).
- Process equipment and isolator User Requirements Specifications (URS) development
- FAT/SAT protocol development and execution
- Process equipment and isolator system validation (IQ/OQ/PQ)
- Process development involving isolation and hydrogen peroxide gas decontamination.
- SOP Development

Apotex (Richmond Hill, ON)

- Provided technical support for the upgrade of a 1995 la Calhéne 4-isolator aseptic filling system to incorporate 21st century isolation and sterilization technologies, which included current system evaluation and viable upgrade design concepts.
- Designed and qualified a sterilant manifold system with controlled air flow through seven supply lines to decontaminate the 4-isolator system.
- Interfaced with equipment vendors to ensure that the proposed designs would provide the required operational parameters and could be easily integrated to provide a system that could be validated.

APP, Inc. (Grand Island, NY)

- IOQ and Validation protocol development and execution of a la Calhéne two half-suit flexible wall sterility test workstation isolator, two 3-glove flexible wall transfer isolators, and two STERIS VHP1000ED Biodecontamination systems.
- Successful revalidation of decontamination cycles and equivalency testing on second VHP1000ED-AB.
- Performed D-value testing on test Biological Indicators for validation testing.
- Developed the Cycle Development and Performance Qualification test protocols for a SKAN ARIS Sterility Test System.
- Executed Cycle Development and Performance Qualification protocols for the decontamination process.

AstraZeneca, Inc. (Westborough, MA)

- Facility design review and optimization (sterilant generator manifold).
- Validation protocol development and execution of a rigid wall sterility test isolator system, including autoclave-interface and VHP1000.
- H_2O_2 gas D-value determination of test carriers.
- SOP Generation.
- Annual revalidation services, including BI resistance testing.

AstraZeneca, Inc. (Westborough, MA)

- Reviewed / revised the URS, FRS, DDS, and FAT for a new sterility testing isolator system that was comprised of two 3-glove la Calhéne soft-wall transfer isolators, a dual half-suit soft-wall workstation isolator and two STERIS VHP1000ED-AB Biodecontamination Systems.
- Reviewed / revised isolator and P&ID drawings.
- FAT execution team member for both isolator systems.
- Supervised isolator system installation at client facility.
- Designed VHP circuit to allow the decontamination of the complete isolator system using either of the two hard piped (stationary) VHP 1000 generators. The design included heat taping and insulation of the supply and return piping with a temperature feedback circuit.
- Designed a Dräger H_2O_2 gas monitoring system where the sensors when activated send a signal to a Dräger QuadGard controller to activate a warning strobe light and audible alarms, abort the decontamination cycle, and send an alarm signal to the security guard station.
- IQ/OQ/CD/PQ protocol development and execution for the three la Calhéne isolators and two VHP1000 generators.
- Sterilant intrusion and residue effects protocol generation and execution to determine if H_2O_2 can penetrate into product containers and environmental monitoring supplies at levels that could lead to false negatives.
- BI resistance testing using a transfer isolator.
- Developed the SOP for the set-up and operation of the equipment.
- Provided a one-day combined classroom / hands-on training session to provide an overall understanding of the capabilities and limitations of the technology.
- Annual revalidation services, including BI resistance testing.

Aventis Pasteur Clinical Manufacturing Area (Swiftwater, PA)

- FAT protocol development for clinical filling facility isolators.
- IQ/OQ/PQ protocol development and execution on VHP1000 and clinical filling facility isolators.
- H_2O_2 gas D-value determination of test carriers.
- Environmental qualification and monitoring plan development.
- Media fill / sterile challenge protocol development and execution support.

Aventis Pasteur Production Facility (Swiftwater, PA)*

- Validation planning and execution support for an isolated high speed vial filling system that consisted of a Despatch Industries MAFS® isolator designed with Infeed, Filler, and Outfeed sections and was decontaminated with a single STERIS VHP1000 Biodecontamination system.
- IQ/OQ protocol development and execution for the VHP1000 generator.
- CD/PQ protocol development and execution.
- BI resistance testing of spore suspension directly inoculated onto stainless steel carriers.
- UV D-value determination of test carriers.
- UV pass-through chamber Cycle Development and PQ protocol generation and execution.
- Media fill / sterile challenge assistance.
- Drafted Regulatory Licensing documents.
- Provided operator training on all process equipment in formal training program
- System annual revalidation testing.

*ONE OF THE INITIAL ISOLATED ASEPTIC FILLING LINE INSTALLATIONS (1997) IN THE USA.

Baxter Healthcare Corp. (Boulder, CO)

- STERIS VHPM1000 modular generator IQ/OQ, Cycle Development, and PQ protocol development and execution on a Metall + Plastic clinical filling isolator.
- VHP1000 and sterility testing isolator IQ/OQ and PQ protocol development and execution.
- H_2O_2 gas D-value determination of test carriers.

B. Braun, Inc. (Irvine, CA) *

- Validation planning and execution support for a sterile liquid and powder high speed filling process that consisted of an IMA 4-isolator filling system and two STERIS VHP1000 Biodecontamination systems.
- Isolator design consultation (e.g., sterilant port locations, generator/isolator control issues).
- CD/PQ protocol development and execution,
- CD/PQ protocol development and execution for the second sterile liquid and powder high speed filling process (duplicate of initial line).
- CD protocol development and execution for the third sterile liquid and powder high speed filling process (same design as lines 1 and 2).

*ONE OF THE INITIAL ISOLATED ASEPTIC FILLING LINE INSTALLATIONS (1997) IN THE USA

Biogen (Research Triangle Park, NC)

- Technical support and IOQ execution for an existing Metall+Plastic (M&P) Vial Filling Isolator System that underwent an extensive technical upgrade.
- Technical support provided to M&P representative to complete the automation checkout (ACO) and mechanical checkout (MCO) of the system prior to the initiation of the IOQ.
- IOQ support included detailed installation checklists, drawing reviews, input/output / mechanical / electrical verifications, and functional testing for each operational mode.
- Decontamination cycle development support.

Biogen (Research Triangle Park, NC)

- Process qualification for Sterilant Intrusion and Residue Effects for a SKAN sterility test isolator system.
- Product container matrix was developed, and each type was bracketed in terms of size and then semi-quantitively assayed for residual H_2O_2 after “back-to-back” decontamination cycles.
- A representative from each container type was challenged microbiologically.
- Residue Effects testing (False Negative determine Test) was performed with triplicate product and environmental monitoring samples in the isolator to rule out the possibility of false negatives due to sterilant residues in the isolator, on the samples, and/or in the supplies.
- Validated a “Sterile Hold Time” of 7 days that the isolator could be maintained under “germ-free” conditions.

Biopure, Inc. (Cambridge, MA)

- System specification and design review of a rigid wall IsoTech 2-glove IsoTransfer® sterility test isolator system.
- H_2O_2 gas D-value determination of test carriers.
- IQ/OQ and PQ protocol development and execution on VHP1000 and sterility testing isolators.
- Design review of hydrogen peroxide liquid, hydrogen peroxide spray/fog, hydrogen peroxide gas, and steam sterilization processes for a Form-Fill-Seal machine used for IV solution filling.

Bristol Myers Squibb (Devens, MA)

- Validation execution support for a bioburden test isolator system that consisted of two Walker Barrier 3-glove flexible wall isolators and a portable STERIS VHP100S-P Biodecontamination system.
- CD/PQ protocol development and execution.
- Sterilant intrusion and residue effects protocol generation and execution.

Bristol Myers Squibb (New Brunswick, NJ)

- Validation planning and execution support for an isolated filling/lyophilization system that consisted of a SKAN Filling isolator, a SKAN Lyo Loading isolator, a Walker Formulation isolator, and a VHP1000 Biodecontamination system.
- Review and revise process equipment and isolator User Requirements Specifications (URS).
- VHP1000 cycle development testing for the Formulation isolator.
- IQ/OQ/PQ supplemental protocols to vendor qualification packages when required or in lieu of these packages when not provided by the process equipment manufacturers.
- Isolated equipment mock-up support.
- FAT/SAT protocol development and execution.
- Process equipment and isolator system validation (IQ/OQ/PQ)
- Process development involving isolation and hydrogen peroxide gas decontamination.

Covidien / Mallinckrodt / Guerbet (Raleigh, NC)

- Walker Barrier 4-glove rigid wall Sterility Test Isolator IQ/OQ protocol development and execution.
- VHPM100-ABX IQ/OQ, cycle development, and PQ protocol development and execution.
- BI resistance testing.
- Sterilant intrusion and residue effects protocol generation and execution to determine if H_2O_2 can penetrate into product containers and environmental monitoring supplies at levels that could lead to false negatives.
- Standard Operating Procedure (SOP) development.
- Operator training.
- Annual requalification of the decontamination cycle.

Evonik Industries (Birmingham, AL)

- FAT assistance for an Extract Technologies 2-glove Transfer isolator system that verified component operation, input/output operation, and alarm operation. Isolator interfaced with a STERIS VHP®1000ED-AB generator
- Transfer Isolator IQ and OQ protocol generation and execution.
- Cycle Development protocol generation and execution for an Extract Technologies 4-glove Sterility Test Isolator integrated with a STERIS VHP®M100-S generator.

Eyenovia (Redwood City, CA)

- Validation of a 4-glove NuAire Pharmagard production isolator interfaced with a STERIS VHP®1000ED-AB generator.
- IQ/OQ protocol generation and execution for the NuAire isolator and the STERIS generator.
- Cycle Development protocol generation and exécution.
- Performance Qualification protocol generation and exécution.
- Annual requalification of the decontamination cycle.

Genentech, Inc. (Hillsboro, OR)

- Validation execution support for an isolated aseptic liquid filling system that consisted of a SKAN Filling isolator; an isolated aseptic lyophilization system that consisted of a SKAN Filler isolator, Buffer isolator, and Loader isolator; and two SKAN ARIS sterility testing isolator systems.
- Smoke testing protocol generation and execution for the three isolation systems.
- BI resistance protocol generation and execution using a SKAN ARIS isolator.
- CD/PQ protocol development and execution for the two SKAN ARIS sterility testing isolator systems.
- CD/PQ protocol development and execution for the two SKAN aseptic processing isolator systems.

Genzyme (Framingham, MA)

- GAP analysis to verify that the VHP1000ED decontamination cycles developed for both an IsoTech IsoTransfer™ and Hemisphere™ Interface isolators incorporated regulatory and industry guidelines.
- VHP® Sterilization Technology training for Validation and Quality personnel.

GSK Biologicals formally Wyeth (Marietta, PA)

- Initially qualified the la Calhéne flexible wall isolator system consisting of one (1) autoclave interface isolator, one (1) workstation isolator, four (4) 3-glove Transfer isolators, and 2 STERIS VHP1000 bio-decontamination systems.
- Annual requalification testing support for the BI challenge D-value determination.

HTL Biotech (Boston, MA)

- Initial validation of 2 Germfree Production Isolators, 1 QC Isolator, and 12 modular laboratory rooms.
- IOQ protocol generation and execution for Purification Isolator, Fermentation Isolator, and a QC isolator.
- IOQ protocol generation and execution for the isolator integrated Decontamination Specialty Equipment (DSE) hydrogen peroxide generator.
- IOQ protocol generation and execution for the portable Decontamination Specialty Equipment (DSE) hydrogen peroxide generator for the modular room decontamination.
- Cycle Development and Performance Qualification protocol generation and execution for the three isolators.
- Cycle Development and Performance Qualification protocol generation and execution for Zone 2 modular rooms that consists of four (4) rooms with a total volume of 3,361 ft^3. Zone 1 consists of four (4) rooms with a volume of 3,334 ft^3 and Zone 3 consists of two (2) rooms with a volume of 1,860 ft^3 and Germfree qualified these zones using the operational parameters for the H_2O_2 generator that were developed for Zone 2.
- BI D-value protocol development for the side-by side evaluation of *Clostridium botulinum* spores and *Geobacillus stearothermophilus* spores. Generated spore preparation for the *C. botulinum* spores to be used in the D-value testing.

Janssen Biologics BV (Leiden, Netherlands)

- Determined the cause(s) for H_2O_2 gas concentration reduction and provided a recommended corrective action plan for a Getinge flexible wall workstation isolator integrated with a VHP®1000ED generator.

Jubilant HollisterStier Corp. (Spokane, WA)

- Validation planning and execution support for a Walker Barrier rigid wall 4-glove aseptic filling isolator integrated with a Bioquell IG-1 hydrogen peroxide generator system.
- H_2O_2 cycle development protocol generation and execution for the FAT and SAT (triplicate testing of cycle defined during the FAT), which included aeration studies to ≤1.0ppm.
- BI resistance protocol development and execution.

Lancaster Labs (Lancaster, PA)

- IQ/OQ/PQ protocol development and execution of a la Calhéne flexible wall sterility test isolator system.
- Facility design review for isolator external exhaust optimization and room control (# air exchanges, temperature).
- Successful revalidation of decontamination cycles and equivalency testing on second VHP1000.
- New laboratory design review, exhaust system design/qualification and post-relocation equivalency revalidation studies of the sterility test isolator suite.
- H_2O_2 gas D-value determination of test carriers.
- IQ/OQ and PQ protocol development and execution of a double-door autoclave and adjoining interface isolator.

Lantheus / Progenics / Sofie / Zevacor (Somerset, NJ)

- Initial decontamination cycle qualification for a Tema Sinergie dispensing DHC hot cell chamber (Suite 2) integrated with a portable remote located STERIS VHP®M100-S generator.
- Cycle Development and Performance Qualification protocol development and execution.
- Developed a Standard Operating Procedure (SOP) for the operation of the H_2O_2 decontamination system.
- Provided design guidance for the minimization of the Aeration Phase of the decontamination cycle.
- Annual revalidation of the decontamination cycle.

Lantheus (Somerset, NJ)

- Initial decontamination cycle qualification for a Tema Sinergie dispensing Flex Cell chamber (Suite 3) integrated with a portable remote located STERIS VHP®M100-S Bio-decontamination system.
- Cycle Development and Performance Qualification protocol development and execution.
- Provided design guidance for the minimization of the Aeration Phase of the decontamination cycle.
- Annual revalidation of the decontamination cycle.

Lantheus / Progenics (Idaho Falls, ID)

- Initial decontamination cycle qualification for a Tema Sinergie dispensing DHC hot cell chamber integrated with a portable remote located STERIS VHP®M100-S Bio-decontamination system. This system was identical to the Somerset DHC installation.
- Cycle Development and Performance Qualification protocol development and execution.

Lifecore Biomedical (Chaska, MN)

- Initial qualification of a 4-glove unidirectional air flow rigid wall Aseptic Powder Feed Isolator with a remote mounted hydrogen peroxide generator in the mezzanine.
- H_2O_2 gas D-value determination protocol development and execution.
- IQ/OQ protocol development and execution for the isolator system and the hydrogen peroxide generator.
- Cycle Development/Performance Qualification protocol development and execution.
- Sterilant intrusion and residue effects protocol development and execution.

Merck & Co., Inc. (Elkton, VA)

- Design consultation and process development including sterilant manifold systems into the production areas for a sterile bulk powder filling application in rigid wall isolators (Total Process Containment) decontaminated using STERIS VHP1000 Biodecontamination systems.
- Sterilizable transfer system development assistance for bulk powder transport and delivery in disposable bags.
- VHP1000 IQ/OQ and FAT cycle development.
- H_2O_2 gas D-value determination of test carriers.
- PQ protocol development and execution on 5 isolators and 5 VHP1000s, including successful equivalency studies on the multiple generator system.

Merck & Co., Inc. (Elkton, VA)

- Generated a *Conceptual Design Study* that explored the viability of three different concepts that incorporated only available technology that would convert an existing sterile powder filling operation inside isolators, which had product packaging manufacturing stages that did not support asepsis operations, into a completely closed aseptic process from fill through final bulk product packaging.
- Identified all the equipment and components required to implement each viable design.
- Performed a risk analysis for each of the viable designs.
- Provided cost estimate for each of the viable designs.

Merck & Co., Inc. (West Point, PA)*

- Barrier technology prototype research, development, and feasibility testing.
- Peroxide Plus™ (steam/H_2O_2) sterilization methods development and testing.
- Factory Acceptance Testing, IQ, and OQ protocol development and execution of an isolated (Despatch Industries isolator system integrated with a Peroxide Plus sterilization process) high speed TL filling system that consisted of a vial washer, depyrogenation tunnel, filler, stoppering and capping systems, and related systems (i.e. isolator CIP, product pathway CIP/SIP, sterilizable transfer ports, stopper lift system).

***One of the initial isolated aseptic filling line installations (1997) in the USA**

Merck, Sharpe & Dohme, Inc. (Clermont-Ferrand, FRANCE) *

- Design consultation and process development for a sterile batch ophthalmic isolated filling line that consisted of three la Calhéne rigid wall isolators, a flexible wall transfer isolator, and three STERIS VHP1001 Bio-decontamination systems.
- VHP1001 FAT cycle development testing on filling line isolators at la Calhéne (France) and IMA (Italy).
- IQ/OQ and PQ protocol development and execution for three (3) rigid wall isolators, one (1) soft wall isolator and three (3) VHP1001s.
- H_2O_2 gas D-value determination using spore suspension inoculated on test carriers manufactured from the system's materials of construction.
- Successful revalidation of decontamination cycles.

***La Calhéne's First Production Isolator Installation.**

Merck, Sharpe & Dohme, Inc. (Clermont-Ferrand, FRANCE)

- Design consultation and process development for an isolated sterile filling/lyophilization line that consisted of three (3) rigid wall la Calhene filling isolators, six (6) rigid wall lyophilizer isolators, one (1) rigid wall inspection isolator, one (1) rigid wall capping isolator and ten (10) Steris VHP1001 Biodecontamination systems. The filling line was supported by two (2) la Calhene flexible wall transfer isolators, decontaminated using an eleventh STERIS VHP1001 generator, to aseptically transfer presterilized supplies, tools, and/or machine components required for the manufacturing process. The filling line was also supported by a sterility testing suite that consisted of a la Calhene flexible wall workstation isolator, a flexible wall transfer isolator and a twelfth STERIS VHP1001 generator.
- VHP1001 cycle development protocol generation and execution for the three filling/lyophilization line isolator systems, the two support transfer isolator systems, and the sterility test isolator system.
- VHP1001 equivalency testing using the Guided Wave NIR sensor technology protocol generation and execution.
- IQ/OQ and PQ protocol development and execution for the three filling/lyophilization line isolator systems, the two support transfer isolator systems, the sterility test isolator system, and the twelve (12) STERIS VHP1001 generators.
- Sterilant intrusion and Residue Effects protocol generation and execution.

MilliporeSigma (Kankakee, IL)

- Initial qualification of an Extract Technologies bottle filling Isolator system consisting of a rigid wall 3-section (Loader, Buffer, Filler) unidirectional (Filler) and turbulent flow production isolator with an integrated STERIS VHP®M100-AB generator.
- IOQ protocol generation and execution for the loader, buffer, and filler isolators.
- IOQ protocol generation and execution for the STERIS VHPM100-AB generator.
- Troubleshooting support to enable the system to operate properly prior to the initiation of the qualification testing.
- H_2O_2 gas D-value determination protocol development and execution.
- Cycle Development protocol development and execution.

MilliporeSigma (Rockville, MD)

- Initial qualification of an Extract Technologies Sterility Test Isolator System consisting of a rigid wall dual half-suit isolator with an attached airlock integrated with a STERIS VHP®M100-AB generator.
- IOQ protocol generation and execution for the isolator and the STERIS generator.
- Apex BI D-value determination protocol development and execution
- Cycle Development and Performance Qualification protocol generation and execution for the half-suit isolator and attached airlock.
- Sterilant Intrusion and Residue Effects protocol generation and execution.
- Annual requalification of the decontamination cycles.

Millennium Pharmaceutical (Cambridge, MA)

- Designed and oversaw fabrication of an isolated integrated mammalian cell culture and purification system.
- Integrated process equipment with isolators.
- Developed and executed environmental monitoring plans.
- Validated (IQ/OQ/PQ) all process equipment and decontamination processes.

Monsanto (Augusta, GA)

- Design consultation and process development for an isolated sterile syringe filling line and support processes that consisted of a Carlisle (Walker) Barrier rigid wall filling isolator with integrated STERIS VHP M1000 modular Biodecontamination system, a rigid wall combination isolator with integrated STERIS VHP M1000, and five (5) rigid wall support isolators including a sterility test isolator that were individually decontaminated using a STERIS VHP1000 mobile generator.
- Facility design review for isolator external exhaust optimization and room control (# air exchanges, temperature).
- FAT protocol execution at isolator vendor.
- H_2O_2 gas D-value determination of test carriers.
- IQ/OQ and PQ protocol development and execution for the seven (7) filling and support isolator systems, the two (2) modular STERIS VHP M1000 generators and the multiple VHP1000 mobile generators.
- IQ/OQ and PQ protocol development and execution for the IC Technologies UV transfer port for the syringe barrels.
- UV D-value determination.

Novex Pharma, Inc. (Richmond Hill, Ontario)

- Hydrogen peroxide gas manifold system development for a production ophthalmic barrier filling system.
- Hydrogen peroxide gas manifold system for a clinical injectable barrier filling system.
- Protocol development and execution for VHP1000 cycle development on three (3) rigid wall isolators comprising the injectable barrier filling system with oven and autoclave interface.
- H_2O_2 gas D-value determination of test carriers.
- Design review, protocol development, and execution H_2O_2 gas cycle development studies on a high-speed injectable filling line interfaced to 2 VHP1000's in parallel.

Ology Bioservices (Alachua, FL)

- Initial qualification of a 4-glove turbulent air flow Getinge Isoflex Sterility Testing Isolator System with an integrated Steritrace II Hydrogen Peroxide Vapor (HPV) decontamination system.
- H_2O_2 gas D-value determination protocol development and execution.
- Cycle Development/Performance Qualification protocol development and execution.
- Sterilant intrusion and residue effects protocol development and execution.

Pharmacia (Kalamazoo, MI)

- Hydrogen peroxide gas process development, validation strategy consultation, and cycle development on a high-speed barrier filling system.
- Joint project management of clinical filling facility incorporating isolation technology.
- Development of validation master plan for all new equipment.
- IQ/OQ/PQ protocol development and execution of equipment, filling system isolators and VHP1000.
- Design consultation and process development for a sterile bulk powder filling operation that included a centrifuge, two Fitzmills, one powder cooler, and an exit chute using hydrogen peroxide gas decontamination.
- VHP1000 cycle development testing.

PSGA / Johnson & Johnson (Buenos Aires, Argentina)

- Facility design review for isolator external exhaust optimization and room control (# air exchanges, temperature).
- IQ/OQ/PQ protocol development and execution for a Carlisle (Walker) Barrier rigid wall sterility testing isolator, a rigid wall transfer isolator, and a STERIS VHP1001 Biodecontamination system.
- H_2O_2 gas D-value determination protocol development and execution.
- Sterilant intrusion and residue effects protocol development and execution.
- SOP Generation.

PSGA /Janssen Cilag (Mexico)

- Facility design review for isolator external exhaust optimization and room control (# air exchanges, temperature).
- IQ/OQ/PQ protocol development and execution for a Carlisle (Walker) Barrier rigid wall sterility testing isolator, a rigid wall transfer isolator, and two (2) STERIS VHP1001 Biodecontamination systems.
- H_2O_2 gas D-value determination protocol development and execution.
- Sterilant intrusion and residue effects protocol development and execution.
- SOP Generation.

The Ritedose Company (Columbia, SC)

- Initial qualification of a 5-glove rigid wall unidirectional air flow API dispensing isolator with an air lock decontaminated with a portable hydrogen peroxide generator.
- Isolator IQ/OQ development and execution.
- Cycle Development and Performance Qualification protocol development and execution.
- Annual requalification of the two (2) decontamination cycles for the main chamber/airlock and the air lock only cycles.

SAIC (Fredrick, MD)

- Process development involving isolation and hydrogen peroxide gas decontamination.
- CD and PQ protocol development and execution for an isolated pilot filling process that consisted of a Walker Barrier rigid wall filling isolator, a rigid wall oven interface isolator, a rigid wall 4-glove transfer isolator, two (2) rigid wall 3-glove transfer isolators , two (2) STERIS VHP1000ED Biodecontamination systems, and one (1) STERIS VHP1000 Biodecontamination system.
- H_2O_2 gas D-value determination protocol development and execution.
- Sterilant intrusion and residue effects protocol development and execution.

SAIC (Fredrick, MD)

- FAT and SAT protocol development and execution for a Walker rigid wall sterility testing isolator/airlock system integrated with a STERIS VHPM100-ABX generator.
- IQ/OQ protocol development and execution for the VHP M100-ABX generator.
- H_2O_2 gas D-value determination protocol development and execution.
- CD/PQ protocol development and execution for the isolator's main chamber only decontamination cycle and the airlock only decontamination cycle.
- Sterilant intrusion and residue effects protocol development and execution.

Samsung Biotech (Incheon, Korea)

- IQ/OQ protocol development and execution for a STERIS VHP M100-S Biodecontamination system integrated with Comecer rigid wall 4-glove isolator with an adjoining pre-chamber.
- H_2O_2 gas D-value determination protocol development and execution.
- CD and PQ protocol development and execution for the combination isolator main chamber and pre-chamber decontamination cycle and the pre-chamber only decontamination cycle.
- Sterilant intrusion and residue effects protocol development and execution.
- Aseptic Maintenance protocol development and execution to verify that the isolator will remain germ-free and under ISO Class 5 conditions following the execution of the previously validated combined enclosure decontamination cycle for a minimum period of seven (7) days.

Shandong Luye Pharmaceutical Co. (Yantai, China)

- Initial qualification of an Extract Technology rigid wall 2-section (Accumulator and Filler/Stopper) unidirectional air flow M&O Perry powder filling isolator with an integrated hydrogen peroxide vapor generator.
- Isolator IQ/OQ protocol development and execution.
- Hydrogen peroxide vapor generator IQ/OQ protocol development and execution.

SOFIE (Totowa, NJ)

- Participated in the design with decontamination Specialty Equipment (DSE) of a H_2O_2 decontamination system that serviced four (4) TEMA hot cells. The system can be programmed to decontaminate two hot cells consecutively. When the first hot cell advances to the aeration phase the system will initiate the decontamination phases (dehumidify, condition, decontaminate) for the second cell. The system also has an independent auxiliary aeration blower that uses fresh air from the technical corridor to minimize the aeration time required to achieve a 1.0 ppm H_2O_2 residual.
- IOQ protocol generation and execution for the Decontamination Specialty Equipment (DSE) H_2O_2 generator.
- Cycle Development/Performance Qualification protocol development and execution for the TEMA DHC hot cell.
- Cycle Development/Performance Qualification protocol development and execution for the TEMA DTC-SAS hot cells.
- Initial qualification of a Tema Sinergie hot cell chamber with a portable remote located hydrogen peroxide generator.
- Participated in an on-site training video for potential operators.
- Annual requalification of the two decontamination cycles.

Steri-Pharma (Syracuse, NY)

- Sterilant Intrusion and Residue Effects protocol generation and execution for a Getinge Isoflex UDAF Sterility Test Isolator System.
- Drafted a Sterile Hold Study PQ protocol.

TEVA Pharmaceutical Works (Gödöllö, Hungary)

- Decontamination cycle development (CD) and PQ protocol review and execution support for an IMA filling cRABS (closed RABS) and a Lyo/Capping cRABS with integrated STERIS VHPM100-SX Biodecontamination systems.
- Generated final reports.
- FDA audit support.

TriRx Pharmaceutical Services (Shawnee,KS)

- Initial qualification of an Extract Technologies 8-glove isolator with an integrated Decontamination Specialty Equipment (DSE) hydrogen peroxide decontamination system.
- IOQ protocol generation and execution for the Decontamination Specialty Equipment (DSE) H_2O_2 generator.
- IOQ protocol generation and execution for the Extract Technologies isolator.
- Cycle Development/Performance Qualification protocol development and execution for the H_2O_2 decontamination cycle.
- H_2O_2 gas D-value determination protocol development and execution.

University of Iowa Pharmaceuticals (Iowa City, IA)

- Design, construct, and qualify a fully automated manifold design for the hydrogen peroxide vapor decontamination of a 10-isolator aseptic processing system.
- The manifold system has twenty (20) VHP controlled inlets to service the isolator system providing ten (10) specific isolator combinations for decontamination.
- Generated P&IDs, FRS, and the PLC External Interface Procedure,
- FAT/SAT/IOQ protocol development and execution,
- Cycle Development protocol development and optimization execution for each of the 10 decontamination configurations.
- Operator training.

Wyeth (Carolina, Puerto Rico)

- Facility design review and optimization for a sterility test suite that consisted of a Carlisle (Walker) Barrier rigid wall single half suit autoclave interface isolator, a rigid wall two half-suit workstation isolator, two (2) rigid wall 3-glove transfer isolators, and two (2) STERIS VHP1000ED Biodecontamination systems.
- Validation master plan development.
- FAT/SAT protocol review and execution for the four isolator systems.
- IQ/OQ protocol development and execution for the four (4) isolator systems and the two VHP1000ED generators.
- CD/PQ protocol development and execution.
- H_2O_2 gas D-value determination protocol development and execution.
- Sterilant intrusion and residue effects protocol development and execution.
- Operational SOP Development.

Wyeth (Pearl River, NY)

- Design consultation, process development, and validation planning for an isolated containment clinical filling line that consisted of a vial washer; a depyrogenation tunnel; a Carlisle (Walker) Barrier isolator system that enclosed the vial accumulator, filler, lyophilizer loading/unloading system, capper, and the external vial washer that was decontaminated using two (2) Bioquell Clarus “C” hydrogen peroxide generators.
- Validation master plan development.
- URS (User Requirement Specification) and FS (Functional Specification) development for the isolator system.
- FAT and SAT support for the isolator system and selected process equipment.
- Designed a sterilant manifold system to allow isolator decontamination in a variety of combinations or separately.
- IQ/OQ/CD/PQ protocol development and execution for the isolators and sterilant generators.
- Operational SOP development for the isolators and sterilant generators and operator training.

Wyeth (Marietta, PA)

- Facility design review and optimization for a sterility test suite that consisted of a la Calhéne flexible wall single half suit autoclave interface isolator, a flexible wall two half-suit workstation isolator, four (4) flexible wall 3-glove transfer isolators, and two (2) STERIS VHP1000 Biodecontamination systems.
- IQ/OQ protocol development and execution for the seven (7) isolator systems and the two VHP1000 generators.
- CD/PQ protocol development and execution.
- H_2O_2 gas D-value determination protocol development and execution.
- Sterilant intrusion and residue effects protocol development and execution.
- Operational SOP development for the isolators and sterilant generators and operator training.

Wyeth (West Chester, PA)

- Process development, feasibility testing, and validation of surface decontamination of a centrifuge / rotary vacuum dryer system using a single STERIS VHP1000 Biodecontamination system that incorporated a ABC designed sterilant delivery manifold.
- IQ/OQ protocol development and execution for the VHP1000 generator.
- CD/PQ protocol development and execution for the VHP1000 generator connected to the centrifuge / rotary vacuum dryer system.
- H_2O_2 gas D-value determination protocol development and execution using a transfer isolator.

Wyeth Biotech (Sanford, NC)

- CD/PQ protocol development and execution for a sterility test system that consisted of la Calhene flexible wall single half suit workstation isolator, a rigid wall 2-glove transfer isolator and a STERIS VHP1000 Biodecontamination system.
- H_2O_2 gas D-value determination protocol development and execution using the transfer isolator.
- Sterilant intrusion and residue effects protocol development and execution.

Wyeth Biotech (Sanford, NC)

- Validation support for a sterility testing suit that consisted of two (2) CPS (Walker) Barrier rigid wall 4-glove sterility testing isolators and two (2) STERIS VHP1000ED-AB Biodecontamination systems.
- IQ/OQ protocol development and execution for the two isolator systems and the two VHP1000ED generators.
- CD/PQ protocol development and execution.
- H_2O_2 gas D-value determination protocol development and execution using the transfer isolator.
- Sterilant intrusion and residue effects protocol development and execution.
- SOP development and operator training.