STERIS
Life Sciences

Biodecontamination Project: BSL3 Research Facility

Case Study

Project:

BSL3 Research Facility

Location:

Birmingham, AL – USA

Requirements:

6-log Biodecontamination of 65,000+ft^3, multiple room research facility

Products:

VHP® *VICTORY-PRO*™ Biodecontamination Unit

VHP *TS1000* Tri-Scale Sensor

Vaprox® 59 Hydrogen Peroxide Sterilant

Steraffirm™ Process Indicator (PCC051)

The Challenge:

There are many methods of biodecontamination available on the market today. Each method has its advantages and disadvantages depending upon the scope of the project and desired level of bioburden reduction. In this particular case, a very high standard was set. The Customer wanted to have the entire 65,000+ ft^3 facility and equipment within it biodecontaminated with a validatable process that delivered a wide range of efficacy, a high level of material compatibility, the least amount of downtime possible, and a minimum of a 6-log reduction in bioburden.

Facing this challenge, a prominent BSL3 research facility in Birmingham, AL turned to STERIS Life Sciences Biodecontamination Services to help with their biodecontamination needs.

The Solution:

The STERIS Life Sciences Biodecontamination Services Team worked together with the Customer's safety, scientific, and engineering teams to put together a comprehensive biodecontamination process for the research facility and equipment within it using a combination of STERIS Life Sciences technology and products including ten VHP *VICTORY-PRO* Biodecontamination Units; ten VHP *TS1000* Tri-Scales Sensors; Vaprox 59 Hydrogen Peroxide Sterilant; Steraffirm Process Indicators (PCC051); 6-log *Geobacillus stearothermophilus* biological indicators; and 24-hour biological indicator media.

The Result:

In less than 24 hours, the research facility (65,000+ft^3) and equipment within it were successfully treated with STERIS's proprietary VHP process technology. Sensors and Process Indicators confirmed that a 6-log bioburden reduction was achieved throughout the facility. By using STERIS Life Sciences Biodecontamination Services, the facility was able to create an effective biodecontamination cycle and fumigation management plan for proof of biodecontamination and confirmation of adequate safety standards in support of regulatory compliance.

STERIS Life Sciences Biodecontamination Technologies:

STERIS's patented, world renowned VHP Process Technology was introduced in 1991 by AMSCO® and utilizes hydrogen peroxide vapor sterilant, which is highly effective against a wide range of microorganisms and compatible with a wide range of materials including sensitive electronics and other lab equipment often found in laboratory environments. The process is non-carcinogenic and environmentally friendly, breaking down into water vapor and oxygen.

STERIS's VHP *VICTORY-PRO* Biodecontamination Unit with its high output, shortened cycle time, and easy operation, establishes a new standard for room and facility decontamination.

STERIS's VHP *TS1000* Tri-Scale Sensor Boosts VHP *VICTORY-PRO* biodecontamination system cycle efficiency and effectiveness by ensuring that hydrogen peroxide vapor sterilant is adequately distributed.

STERIS's Vaprox 59 Hydrogen Peroxide Sterilant is a United States Environmental Protection Agency registered product (EPA. Reg. No. 1043-123) compatible with STERIS VHP Biodecontamination Units.

The Biodecontamination Process

After an evaluation of the research facility and equipment, a project proposal was presented and agreed upon.

Upon arrival, a STERIS Life Sciences Biodecontamination Services Representative assessed the area and began preparing the facility for successful biodecontamination by ensuring that all surfaces were dry and clean; items within the facility were set-up for biodecontamination; and potential hazardous materials were removed from the facility. The VHP Units, tri-scale sensors, 6-log *Geobacillus stearothermophilus* biological indicators and Steraffirm process indicators were placed throughout the facility in accordance with the Customer's fumigation management plan. Vaprox 59 Hydrogen Peroxide Sterilant was loaded into the *VICTORY-PRO* Biodecontamination Units. A last walk-through was conducted before sealing the room and performing the biodecontamination cycle.

The biodecontamination cycle was initiated from outside the enclosure. The *VICTORY-PRO* Biodecontamination Units and *TS1000* tri-scale sensors were operated remotely, utilizing RealVNC® software via laptop with a wireless Ethernet connection. The biodecontamination cycle was monitored by utilizing the *VICTORY-PRO* and *TS1000* tri-scale sensors (measuring temperature, percent relative humidity and hydrogen peroxide vapor concentration) to ensure a minimum of a 6-log bioburden reduction. The facility was conditioned to a minimum of 400 ppm and held for a minimum of 30 minutes in accordance with Vaprox 59 Hydrogen Peroxide Sterilant EPA labeling. Aeration was conducted utilizing the facility's air handling system overnight down to a residual hydrogen peroxide vapor concentration of ≤ 1 ppm.

The facility was unsealed and checked with a Dräeger® hydrogen peroxide monitor for ≤ 1ppm hydrogen peroxide vapor concentration. Biological and Steraffirm process indicators were collected. All biodecontamination equipment and accessories were removed from the facility. The facility was then released to the Customer pending results from the biological and process indicators.

All Steraffirm process indicators showed color change indicating exposure to hydrogen peroxide vapor. The biological indicators were checked for growth analysis using a 24-hour biological indicator media with all reporting negative for growth after 24-hours.

A final report and Certificate of Successful Biodecontamination was prepared and presented to the Customer.

About STERIS Corporation

STERIS Corporation is a leading provider of infection prevention and surgical products and services, focused primarily on critical healthcare, pharmaceutical and research markets around the world. The Company supplies a broad array of equipment, consumable and service solutions that help assure productivity and quality. STERIS is listed on the New York Stock Exchange under the symbol STE. For more information, visit www.steris.com.

STERIS has a comprehensive offering of detergents, disinfectants, skin care products and sterility assurance products that support your needs. We also have world class technical support to design the most effective cleaning program for your facility.

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