



C A S E S T U D Y

Xenotransplantation Research Facility

Swine Barn Bio-Decontamination

Emergency Viral Outbreak Response with Triple-Clean Protocol & Dry Fog
Sterilization

57,880 ft³ | 6-Log Sterility Assurance | Zero Post-Service Recurrence

Sterile Science LLC

Critical Cleaning & Bio-Decontamination Services

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At a Glance

FACILITY TYPE	TREATMENT VOLUME	VALIDATION	OUTCOME
Swine Barn Xenotransplantation research	57,880 ft³ Full barn + HVAC system	6-Log Kill 14/14 BIs negative	Zero Recurrence No post-service infections

The Challenge

A biotechnology company pioneering xenotransplantation - the genetic modification of porcine organs for human transplant - faced an urgent biosecurity crisis at one of its research swine barns. A case of viral streptococcal pharyngitis (strep throat) had been identified in the pig population and was actively transmitting between animals, threatening both the health of the herd and the integrity of the company's research program.

The stakes were exceptionally high. These were not conventional livestock, each animal represented significant research investment and could not be easily replaced, with organs destined for human clinical application. An uncontrolled outbreak could compromise ongoing studies, delay transplant timelines, and potentially require the depopulation and replacement of genetically modified animals that cannot simply be re-sourced. The client needed a rapid, validated decontamination response that would eliminate the pathogen from the environment without disrupting their operational timeline any longer than necessary.

The barn environment itself presented unique challenges. Agricultural structures are inherently more difficult to decontaminate than controlled cleanrooms due to rough surfaces, porous materials, enclosed pens, feed systems, ventilation ductwork, and organic soil load all create harborage points where pathogens can persist and re-emerge if not fully addressed.

The Approach

Sterile Science deployed a comprehensive two-stage protocol designed to address both the accessible surfaces and the hard-to-reach spaces where the pathogen could persist: a full triple-clean manual process followed by validated dry fog bio-decontamination.

Stage 1: Triple-Clean Manual Protocol

With the animals temporarily relocated, Sterile Science technicians executed a rigorous three-pass manual cleaning sequence across all accessible surfaces in the barn - walls, floors, pens, equipment, feed systems, and fixtures:

Pass 1 - Surfactant Detergent: A surfactant-based detergent was applied to break down organic soil load, biofilms, and surface contamination. This critical first step removes the protective matrix that shields pathogens from chemical disinfectants, ensuring subsequent agents can make direct contact with microbial contaminants.

Pass 2 - Sporidical Disinfectant: A sporidical-grade disinfectant was applied to all cleaned surfaces with appropriate contact time. This agent targets the full spectrum of microbial threats-vegetative bacteria, viruses, fungi, and bacterial spores - providing the primary kill step against the streptococcal pathogen and any co-contaminants present in the environment.

Pass 3 - 70% Isopropyl Alcohol (IPA): A final IPA wipe removed residual chemicals and provided an additional bactericidal action. This pass ensures no disinfectant residue remains that could irritate animal mucous membranes or interfere with the facility’s operations upon reintroduction of the herd.

Stage 2: Dry Fog Bio-Decontamination

Following the manual triple-clean, the entire barn including HVAC ductwork, ceiling cavities, enclosed pen structures, and any spaces inaccessible to manual cleaning, was treated with Sterile Science’s validated dry fog system using Minncare Cold Sterilant (EPA Reg. No. 52252-4). The peracetic acid and hydrogen peroxide formulation was dispersed at a mean Sauter diameter of 7.5 microns, allowing the sterilant to behave as a gas and penetrate every reachable surface and airspace without condensation or corrosion risk.

Treatment Summary

Parameter	Value	Detail
Total Volume Treated	57,880 ft ³	Full barn including HVAC
Manual Protocol	Triple-clean	Detergent → Sporidical → IPA
Sterilant Used	Minncare Cold Sterilant	EPA Reg. No. 52252-4
Active Chemistry	Peracetic acid + H ₂ O ₂	7.5 µm dry fog particle size
Contact Time	10 minutes	Followed by 2-hour aeration
Target Humidity	≥80% RH	Achieved and maintained

Doors were sealed and taped to isolate the treatment zone, and equipment covers were opened to allow the sterilant to access all confined areas. Humidity and temperature sensors confirmed that the target concentration (≥80% RH) was reached and maintained throughout the treatment cycle.

Validation & Results

Biological indicators containing *Geobacillus stearothermophilus* spores (6-log challenge, 1.0×10^6 spores per carrier) were placed at 14 critical control points throughout the barn - proximal to ceilings, under equipment, and inside partially enclosed or obstructed areas. All BIs used 304 stainless steel carriers to avoid false results from hydrogen peroxide residuals.

Testing was performed in compliance with US FDA GMP regulations (21 CFR Parts 210, 211, and 820).

Biological Indicator Results

Indicator Type	Tested	Positive	Negative
Test Articles	14	0	14
Environmental Control	1	0	1
Media Negative Control	1	0	1
Positive Control	1	1	0

100% PASS RATE

All 14 biological indicators achieved full 6-log inactivation. The sterility assurance level of 1 in 1,000,000 was confirmed across every monitored location in the facility, a standard typically associated with pharmaceutical-grade cleanroom environments.

The Outcome

Following decontamination, the swine barn was returned to service, and the genetically modified pig population was reintroduced to the facility. The viral streptococcal outbreak was fully resolved with no recurrence of the illness was observed in the herd after the decontamination service. The client's xenotransplantation research program resumed without further biosecurity disruption, and the animals continued their development trajectory toward clinical organ sourcing.

The combination of the triple-clean manual protocol and dry fog sterilization addressed the pathogen at every level: the detergent pass removed organic harborage, the sporicidal pass delivered the primary kill, the IPA pass eliminated residue, and the dry fog reached every surface and airspace the manual team could not including the HVAC system that could have served as a vector for reinfection.

Why This Matters

This project illustrates Sterile Science's ability to operate beyond traditional cleanroom environments and deliver pharmaceutical-grade sterilization outcomes in non-standard facilities where the stakes are just as high. The client's genetically modified animals are irreplaceable research assets, the decontamination had to be both thorough enough to eliminate the pathogen and safe enough to allow the animals to return without risk.

Rapid Response: Sterile Science mobilized quickly to contain an active viral outbreak, minimizing the window of exposure and operational downtime for the client's research program.

Adaptable Protocols: The triple-clean approach was tailored to the unique challenges of an agricultural environment - organic soil load, porous surfaces, enclosed pens, where standard single-pass disinfection would be insufficient.

Full-Spectrum Coverage: Manual cleaning addressed accessible surfaces; dry fog decontamination reached the HVAC system, ceiling cavities, and every gap where airborne pathogens could persist and re-emerge.

Validated Results: A 100% BI pass rate (14/14) provided the client with documented, defensible proof that the facility met a sterility assurance level consistent with pharmaceutical-grade environments.

Proven Outcome: Zero post-service recurrence of the viral infection confirmed the real-world efficacy of the decontamination—not just a test result, but a measurable impact on animal health and research continuity.

Facing a contamination event? We respond 24/7/365.

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