Sterile Science
A Promera Company

C A S E S T U D Y

B-Lactam Pharmaceutical Facility

Decommissioning & Decontamination

Validated Dry Fog Bio-Decontamination & Chemical Denaturation

42,500+ ft² | 6-Log Sterility Assurance | Full Regulatory Clearance

Sterile Science LLC

Critical Cleaning & Bio-Decontamination Services

www.sterilescience.com | 800-758-4450

At a Glance

FACILITY SIZE	SERVICE TYPE	VALIDATION	OUTCOME
42,583 ft²	**Decommissioning**	**6-Log Kill**	**Certified Safe**
924,552 ft³ volume	B-Lactam denaturation	Geobacillus stearothermophilus	Full re-occupancy cleared

The Challenge

A pharmaceutical manufacturer operating two connected buildings in California needed to fully decommission a facility previously used for β-lactam (penicillin-class) antibiotic compounding. The site was being transitioned to non-pharmaceutical use, and the property owner required documented proof that all β-lactam residues had been chemically neutralized and the facility was safe for general re-occupancy including by individuals with penicillin allergies.

The project posed several technical challenges. β-lactam compounds are potent allergens even at trace levels, so physical removal alone was insufficient, chemical denaturation was required. The facility spanned over 42,000 ft² across cleanrooms, warehouses, offices, mezzanines, and HVAC systems. Prior to Sterile Science's engagement, the site had undergone partial demolition, which redistributed dust and potentially spread residual contaminants. Additionally, a lingering odor in certain areas needed to be assessed and explained in a way that satisfied the client's concerns.

The Approach

Sterile Science designed a two-phase decontamination protocol that combined targeted manual chemistry with facility-wide dry fog deployment, ensuring both chemical denaturation and biological sterilization across the entire site.

Phase 1: Manual Chemical Denaturation

In the first phase, all known β-lactam production and handling zones, including cleanrooms, production suites, HVAC registers, and equipment enclosures, received a targeted manual wipe-down using 1% sodium hypochlorite solution. This concentration was selected specifically for its proven ability to oxidize and hydrolyze the β-lactam ring structure, breaking the amide bond that gives these compounds their pharmacological and allergenic activity. The bleach treatment also oxidizes thioether side chains common in many β-lactam structures, converting them to inert sulfoxides.

A minimum 10-minute contact time was maintained on all surfaces, followed by a DI water rinse to prevent corrosion and remove residual bleach. Lower-risk areas such as offices and warehouses were HEPA-vacuumed and wiped with 70% IPA.

Phase 2: Validated Dry Fog Bio-Decontamination

Following manual cleaning, the entire facility including offices, warehouses, restrooms, mezzanines, and HVAC supply and return ducts, was treated with Sterile Science's validated dry fog system. The sterilant used was Minncare Cold Sterilant (EPA Reg. No. 52252-4), a peracetic acid and hydrogen peroxide formulation dispersed at a mean Sauter diameter of 7.5 microns. At this particle size, the chemical behaves as a gas, reaching all surfaces including the interiors of HVAC ductwork, equipment cavities, and hard-to-reach areas, without the corrosion risk of liquid oxidizers.

Each room was individually calculated for chemical volume based on temperature, humidity, and cubic footage. Humidity and temperature sensors verified that target conditions (≥70% RH) were achieved and maintained for a minimum 1-hour contact time in every treated zone.

Treatment Summary

Parameter	Value	Detail
Total Area Treated	42,583 ft²	924,552 ft³ volume
Sterilant Used	Minncare Cold Sterilant	EPA Reg. No. 52252-4
Active Chemistry	Peracetic acid + H_2O_2	7.5 µm dry fog particle size
Contact Time	≥1 hour per zone	Monitored via T/RH sensors
Target Humidity	≥70% RH	Achieved in all zones

Validation & Results

Biological indicators (BIs) containing *Geobacillus stearothermophilus* spores, one of the most chemically resistant organisms used in sterilization validation, were placed throughout the facility in challenging locations: near ceilings, under equipment, inside partially enclosed spaces, and within HVAC ductwork. Each BI carried a minimum 1.0×10^6 spore population (6-log challenge).

Biological Indicator Results

Indicator Type	Tested	Positive	Negative
Test Articles	19	0	**19**
Environmental Control	1	0	**1**
Media Negative Control	1	0	**1**
Positive Control	1	1	0

The successful 6-log kill of *G. stearothermophilus* spores confirms that the dry fog achieved sufficient concentration, spatial distribution, contact time, and environmental conditions to destroy even the most resistant biological organisms. Since β-lactam molecules are chemically less resilient than bacterial spores, this result provides scientifically grounded assurance that all β-lactam residues were denatured through oxidation of the β-lactam ring and thioether side chains.

Regulatory & Safety Compliance

All work was performed under Sterile Science's ISO-certified Quality Management System and in compliance with US FDA GMP regulations (21 CFR Parts 210, 211, and 820). The sterilant decomposes into non-toxic byproducts- acetic acid, water, and oxygen- generating no hazardous waste and requiring no post-project environmental monitoring.

A thorough odor assessment determined that a mild scent detected near facility entryways was attributable to absorbed volatile organic compounds in porous acoustic ceiling tiles, consistent with general laboratory use, and not residual β-lactam contamination. This finding was documented and communicated to the client to provide full transparency.

O U T C O M E

The facility was certified as safe for general re-occupancy, including by individuals with penicillin allergies. No further remediation, environmental monitoring, or regulatory oversight is required.

Why Sterile Science

Validated Process: EPA-registered chemistry with 6-log biological indicator validation, providing documentation that satisfies FDA, EPA, and municipal expectations.

Multi-Layered Assurance: Combined manual chemical denaturation with facility-wide dry fog deployment- two independent mechanisms of action confirming complete β-lactam inactivation.

Scalable Capability: Single mobilization covered 42,500+ ft² across cleanrooms, warehouses, offices, mezzanines, and HVAC systems.

ISO-Certified QMS: All procedures executed under documented quality standards with full traceability and reporting.

No Hazardous Waste: Sterilant chemistry biodegrades to acetic acid, water, and oxygen. No special disposal, environmental monitoring, or O&M plan required.

Ready to discuss your facility's decontamination needs?

Contact Sterile Science | 800-758-4450 | www.sterilescience.com