Field Guidance and Lessons Learned from the Decontamination Front Lines
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Increasingly, pharmaceutical manufacturing facility managers and engineers are being directed to develop contingency plans for large-scale gaseous decontamination of production facility cleanrooms and associated areas where potential future contamination outbreaks may occur and where conventional cleaning and disinfection protocols may prove inadequate. Such plans most typically include the selection of a gaseous decontaminant which offers an efficacious, practical and reasonably safe means of microbial contaminant eradication, while minimizing the inherent disruption such a process presents to normal facility operations. For those facilities without an internal capability, the most widely available gaseous decontaminant contract service options include formaldehyde gas, hydrogen peroxide vapor and chlorine dioxide gas. For a variety of reasons, hydrogen peroxide vapor is frequently the material of choice for large-scale pharmaceutical production area decontamination.

In an effort to provide practical field guidance to those charged with the development of contingency decontamination plans, this article outlines lessons learned in the field from the delivery of hundreds of large-scale gaseous decontamination projects. While many of the lessons outlined below may be broadly applied to the use of any gaseous decontaminant, the discussions herein seek to highlight some common pitfalls and areas of focus which may be helpful to planners who have selected or are considering the selection of hydrogen peroxide vapor as their decontaminant of choice. From a technical and disclosure context, it is important to note that lessons discussed by the author draw from field experiences utilizing (Continued on Page 3)
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STERIS Corporation vapor generation technology and consumables. This process maintains the hydrogen peroxide vapor level below its condensation or dew point.

Lesson 1: Build a Functional Multi-Disciplinary Project Team
To be successful in executing a large-scale decontamination, an empowered project leader must pull together a cross-functional team of players to work in concert with a competent decontamination services vendor. Build your project team and devote adequate time to plan and thoroughly address the full range of project issues. Identify the team players including stakeholders and support personnel including manufacturing, facilities engineering and support, environmental health and safety, quality control, security, and communications departments.

Lesson 2: Give Your Project Team Clear Roles and Responsibilities
A successful decontamination plan requires the assigning of clear roles and responsibilities for a host of project issues including but not limited to:
- Reviewing site schematics, performing site visit, evaluating HVAC and electrical capabilities to support project equipment (see more on HVAC below)
- Reviewing personnel/authority notification, site control and security, site signage, permit issues as applicable
- Reviewing area preparation: pre-cleaning, material/equipment transfer, HVAC control/support, smoke detector disengagement responsibilities, sealing of space
- Establishing safety buffer zone, project safety plan and external monitoring plan
- Reviewing post decontamination area clearance and equipment/material retrieval procedures
- Establishing biological indicator (BI) locations/mapping
- Establish acceptance criteria
- Establishing the final project schedule, task sequencing and responsibilities

Lesson 3: Equipment and Area Preparation
During the project planning phase, perimeter areas should be surveyed to identify and seal any leaks at the target decontamination area boundary. Smoke testing can be utilized to help ensure the proper sealing of any identified leaks. Prior to executing hydrogen peroxide decontamination, target decontamination area surfaces should be pre-cleaned and equipment within the project scope--i.e. refrigerators, cold rooms, warm rooms, incubators--brought to room temperature with all standing water removed. Surface temperature uniformity is important to avoid the condensing of the peroxide during the decontamination process. For sensitive equipment and materials, consult with manufacturers on compatibility with hydrogen peroxide vapor and take any necessary precautionary steps.

Lesson 4: Know Your HVAC System
In most cases, the HVAC system will play a critical role in the execution of your decontamination plans. Depending on initial environmental conditions, for hydrogen peroxide vapor decontamination, it may be desirable to utilize the HVAC system to dehumidify the decontamination zone (typically target to < 50% Rh) just prior to commencement of vapor injection. During the injection and dwell phase of the decontamination, the HVAC system will typically be neutral or under slightly negative pressure to surrounding areas to contain the decontaminant. Where desirable and appropriate, HVAC recirculation fans may be engaged to facilitate distribution of the vapor throughout the target area including through ceiling HEPA filters. Before engaging recirculation fans, confirm that doing so will not result in distribution of vapor outside of the target decontamination zone. Following completion of vapor injection and dwell time, aeration is most typically facilitated by re-activating the HVAC system. Regardless