

## **CONCURRENT SESSION 4 – COVID-19 DECONTAMINATION RESEARCH EFFORTS**

### **Decontamination of Covid-19 Vaccine Production Facility**

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A pharmaceutical company in the United Kingdom previously produced cephalosporins and contained possible residuals within their facility. Beta lactams derived from cephalosporin production within their facility would need to be inactivated prior to any other non-beta lactam containing products being produced.

The United States Food and Drug Administration (FDA) requires a separation in manufacturing of non-beta-lactam containing drugs and beta-lactam containing drugs. This is due to the danger initiating in the sensitizing effect and the possibility of a patient's allergic shock reaction if an individual were to be exposed to a beta-lactam containing product. It is estimated 3%-10% of all adults in the United States have experienced an allergic response to penicillin (CDC, 2006). Reactions to these allergies can range from rashes to life-threatening anaphylaxis (Romano et al., 2002). This includes blood pressure dropping to dangerous levels, causing lightheadedness and loss of consciousness (Barza, 1985).

Due to the strict requirements set forth by governing bodies, many pharmaceutical firms resort to demolishing buildings or ridding themselves of equipment used during beta-lactam production. However, a study completed within the United States Pharmaceutical Industry alongside ClorDiSys Solutions, Inc established evidence that chlorine dioxide gas has the capacity to inactivate beta-lactams. The tests consisted of nine inactivation cycles, with five passing the acceptance criteria of achieving a 3-log reduction of the eight beta-lactams to beneath U.S. Food and Drug Administration (FDA)-required 0.03 ppm residue detection level. Successful inactivation cycles that achieved a 3-log reduction of all eight beta-lactam compounds all had cumulative exposures of over 7,240 ppm-hours. These results can conclude that to achieve a 3-log reduction of beta-lactams, an inactivation cycle consisting of a 30-minute conditioning phase at 75% relative humidity, followed by an exposure to chlorine dioxide gas of at least 7,240 ppm-hours, is required. Chlorine dioxide destroys the beta-lactam ring and inactivates the compound, in similar fashion to the manner in which penicillin-resistant organisms act.

With the urgency to increase Covid-19 vaccine production, the facility in the United Kingdom realized the necessity to shift focus towards this effort. The facility needed to be repurposed to begin vaccine production and storage to address world-wide concerns. However, due to the previous production of beta-lactams, the firm was required to ensure inactivation of cephalosporins or any other residues that may possibly be present. To allow for that assurance, the initiation of a chlorine dioxide gas decontamination of the facility was implemented. Once successful, production in the plant could then begin to turn towards producing and storing the vaccine.

The chlorine dioxide gas inactivation of beta-lactam ring antibiotics consists of exposing the target beta-lactam to Chlorine dioxide gas at a concentration of 5mg/L with a contact period of 7,240 ppm-hrs where the target is exposed to the gas. The facility contained a total volume of 247,203 cubic feet and was decontaminated with chlorine dioxide gas generated utilizing 120 chlorine gas cylinders with proprietary CD generating cartridges produced by ClorDiSys. The gas was generated on demand and fed into the space via tubing injected in various locations which, alongside sample tubing, was pre-determined to ensure the entire area was evenly distributed to. Sample tubing allows for continuous monitoring and control of the gas concentration. The EMS

monitors the concentration by utilizing a calibrated photometer which can accurately read Chlorine dioxide gas concentration. The continuous monitoring ensures a successful cycle and that the desired dosage is achieved throughout. During the entire exposure, personnel are able to secure a safe environment by utilizing an ATi Portasens that can monitor chlorine dioxide levels and determine if there are any leaks present. Once the entire gassing area reached the desired dosage of 7,240 ppm-hours, the space could then be aerated by exhausting through carbon scrubbers to eliminate the gas. Once aerated, personnel then use the ATi Portasens to ensure the final internal and external chlorine dioxide concentration levels are below the HSE TWA of 0.1ppm. Once verified, the production facility was safe to reenter and the company could again resume operations.

Due to the success of the inactivation, the plant could venture forward with utilizing the building to manufacture and store the Covid-19 vaccine. Repurposing the space thanks to the chlorine dioxide gas decontamination expedited the logistical and practical distribution of the vaccine to those in the United Kingdom and throughout the world.

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