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High-intensity fumigation of a c. 8,000m^3 pharmaceutical sterile production facility within 24 hours

Major Multi-national Pharmaceutical Company, Belgium

The Challenge

Our client, a major multinational pharmaceutical company required, as an integral part of the bi-annual production shutdown, their production lines within a European manufacturing facility to be sterilised. Due to the costs in lost revenue incurred with each shutdown, our client required a rapid and reliable decontamination solution.

Solution

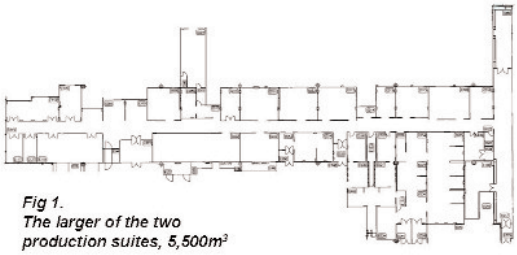

Fig 1.
The larger of the two production suites, 5,500m^3

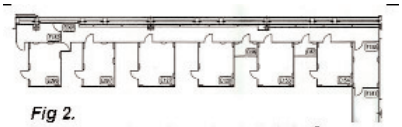

Fig 2.
The second sterile suite is 2,500m^3

Our client has contracted Bioquell's Room Bio-Decontamination Service (RBDS) to perform their shutdown fumigations for the next 5 years. In order to minimise production downtime, and thus the associated financial implications, two separate production lines are fumigated simultaneously in a single high intensity deployment. Upon completion of routine maintenance on the production facility, Bioquell are contracted to fumigate and thus re-commission the facility enabling the client to re-enter production. The two production suites have a combined volume of approximately 8,000m^3 and have in excess of 60 rooms. Due to the excellent materials compatibility of Hydrogen Peroxide Vapour (HPV), all of the suites' equipment is able to remain within the facility to undergo the decontamination procedure in-situ.

To limit facility downtime, Bioquell deploy a larger team to complete the decontamination in <24 hours; and the residue free nature of the process allows the facility to go back online immediately. At the clients' convenience the cycle is run over the weekend allowing production to begin the following Monday morning. Previous fumigation methods took over 60 hours to complete and left the arduous task of removing a harmful residue costing further production time.

The deployment utilises 40 Clarus R generators together with a large team of engineers who are trained both in the operation of the equipment, plus health and safety procedures.

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A long with the 6-monthly scheduled service, our client has contracted Bioquell to reserve the capacity to react rapidly in the event of accidental contamination within the facility. Such an occasion arose in August 2005 and a Bioquell team were dispatched from BQ's UK Head office and were on-site in Belgium within 48-hours of receiving confirmation, fumigating the larger suite, again within 24-hours.

Gassing Cycle Verification

The facility is used to manufacture intravenous medicine and as such the highest degree of sterility is essential. The process is verified using commercially available biological indicators. The BIs are inoculated with *Geobacillus stearothermophilus* spores and are placed throughout the facility and exposed to the cycle. Upon completion of the cycle, the BIs are immediately transferred to tryptone soya broth (TSB) and incubated at 60°C. The recognised incubation protocol states that the BIs should undergo incubation for 7 days, however the organism characteristics are such that after 24 hours incubation initial results are available. The preliminary results give a very good indication of the final anticipated result and on this basis the client is able to go into production. The client also used settle and contact plates to verify the process.

Results

Bioquell's RBDS has been deployed within the facility on >6 occasions and after each deployment full bio-deactivation of the BIs has been achieved.

Conclusion

The full bio-deactivation of *G. stearothermophilus* spores was demonstrated in each room within both target facilities. RBDS provides a rapid and effective fumigation service, which combined with new and unique rapid aeration methods produces a minimal complete cycle time. The total cycle time was less than 24 hours including equipment set-up and retrieval. The fumigation cycle has now been validated across three deployments and thus the client is now able to go back into production immediately after completion of a cycle.

The RBDS service is a rapid, highly flexible service that is able to fumigate any sealable area from ranging in size from an ambulance to a whole building due to ability of the units to be 'daisy-chained' together. The system is completely controlled by skilled engineers via an external computer and dedicated control software.

The engineers use a real-time data feed from sensors placed within the area to ensure that the micro-condensation (and thus the rapid decontamination phase) is achieved throughout the target area. This, along with validation of each cycle using biological indicators, provides an unparalleled fumigation solution in terms of both speed and efficacy.

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