

Case Study: High Intensity bio-decontamination of an c. 8,500m³ pharmaceutical sterile production facility within 24 hours

Site:	<i>Major multinational pharmaceutical company</i>
Location:	<i>Northern Belgium</i>

The Challenge

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

Solution

Our client has contracted the BIOQUELL Room Bio-Decontamination Service (RBDS) to perform their shutdown bio-decontaminations for the next 5 years. In order to minimise production downtime, and thus the associated financial implications, two separate production lines are bio-decontaminated simultaneously in a single high intensity deployment. Upon completion of routine maintenance on the production facility BIOQUELL are contracted to bio-decontaminate and thus re-commission the facility enabling the client to go back into production. The two production suites have a combined volume of approximately 8,500m³ and have in excess of 60 rooms; due to the excellent materials compatibility of H₂O₂ vapour all the suites' equipment is able to remain

within the facility to undergo bio-decontamination in-situ.

To limit facility downtime BIOQUELL deploy a larger team to complete the bio-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 again the following Monday morning.

Previous bio-decontamination methods took over 60 hours to complete and left the arduous task of removing a harmful residue costing further production time.

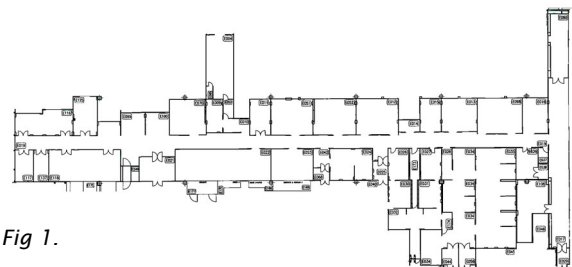


Fig 1.

The larger of the two production suites, 6,000m³

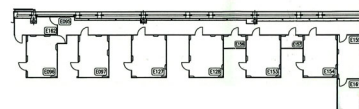


Fig 2.

The second sterile suite is 2,500m³

The deployment utilises 36 Clarus™ R generators along with a large team of engineers trained both in the operation of the equipment and also health and safety procedures.

Along 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 Hampshire head office and were on-site in Belgium within 48-hours of receiving confirmation, bio-decontaminating 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 cycle 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 12 hours incubation results are available. The preliminary results give a very good indication and on this basis the client is able to go into production upon acquisition of these results.

Results

The RBDS service has been deployed within the facility on >3 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. The Clarus™ R provides a rapid and effective bio-decontamination system, which combined with the rapid aeration method produces a minimal

complete cycle time. The total cycle time was less than 24 hours including equipment set-up and retrieval. The bio-decontamination cycle has now been validated across 3 deployments and thus the client is now able to go back into production immediately after completion of the cycle.



Clarus™ R generator

Background: Bio-decontamination within a room or chamber is achieved by depositing an even layer of 'micro-condensation' of H₂O₂ over all surfaces. The term 'micro-condensation' may be defined as a microscopic film of H₂O₂, which being at a sub-micron level is invisible to the naked eye. Scientific research has proven that it is this low temperature, residue-free deposit that rapidly deactivates micro-organisms during the gassing process.



The RBDS service is a rapid, highly flexible service that is able to bio-decontaminate 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 remote controlled by skilled engineers via a laptop computer and Siemens™ 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 bio-deactivation phase) is achieved throughout the target area. This, along with validation of each cycle using biological indicators provides an unparalleled bio-decontamination solution in terms of both speed and efficacy.