

Reducing cycle duration of VPHP biodecontamination

Decreasing the time needed for biodecontamination cycles impacts H₂O₂ consumption and productivity. The knock on benefits on the bottom line have meant increased efforts by suppliers to provide equipment that allows this

In environments sensitive to microbiological contamination, the presence of pathogens or other microorganisms can compromise product safety and quality. It is therefore mandatory to restore periodically the sterility conditions needed to perform production activities in order to guarantee efficiency, quality and safety parameters required by regulation and business goals. Eliminating contamination in pharmaceutical companies is essential and to maximise production efficiency, it is also key to reduce biodecontamination cycle duration even in areas with complex layout.

Two series of tests were performed in Amira ToTech that proved the possibility of reducing VPHP cycle duration by 50% in a volume of about 160 m³ using Turboflow.

Based on the geometric layout of the volume to be decontaminated – which included a cleanroom, two dressing rooms and a laboratory – the following items have been positioned:

- A Bioreset PLUS V-PHP generator
- Environmental control probes to monitor temperature and humidity conditions during all phases of the biodecontamination cycle in order to avoid the dew point
- 25 biological and chemical indicators to prove that all critical points have been reached; chemical mapping allows to verify the correct gas distribution while microbiological mapping, done with bioindicators loaded 10⁶ with *Geobacillus stearothermophilus* spores, allows to demonstrate the effective sterilisation (>6 log).

The first

The first test series aimed to identify the shortest recipe without the use of any equipment to help biodecontaminating gas distribution, defining specific parameters for diffusion and aeration time of the biodecontamination cycle. Suitable for the reduction of a wide spectrum of microorganisms and viruses, vapour-phase hydrogen peroxide has by nature a perfect diffusion in the environment, assuring the 6 log reduction of the microbial load on all exposed surfaces. In case of complex layout, it may require a longer distribution time to reach even the most difficult points.

The tests confirmed that the area was biodecontaminated with a cycle of about five hours (total duration, from the distribution phase

to the aeration phase to reach the threshold <1 ppm) with a reduction of the microbial load of >6 log in each of the mapped points.

The second

With the second test series, it was possible to speed up the biodecontamination cycle by positioning Turboflow central unit and satellites in strategic points of the area to be treated, leaving all other elements unchanged. The result of the tests confirmed that the overall cycle time has been significantly reduced: the >6 log reduction in each of the mapped points was reached in about 2 hours and 30 minutes.

For production companies, the reduction of biodecontamination duration is an important added value to plan and carry out cycles more frequently (even daily) according to specific business needs and to optimise management costs thanks to lower H₂O₂ consumption.

Turboflow is a distribution system that can be used with any VPHP generator. It consists of a central unit that can be equipped with five satellite units to empower its action range, satisfying biodecontamination needs and simplifying preparation and repeatability of the cycle.

Although based on a simple operating process - central unit and satellites collect the air from below and move it upwards, generating an optimal flow in the area under treatment - the flow angle is specially designed to optimise distribution in environments with extremely complex layout. Made in ABS and AISI 316 steel, it meets even the most stringent regulations in the pharmaceutical sector. It is also easy to move (wheeled central unit) and simple to store after use (satellite units and power cables housed in the central unit) for the operator.

Amira is a reference partner for many companies in the pharmaceutical and life science sectors, and has been operating for years in VPHP (Vapour-Phase Hydrogen Peroxide) biodecontamination market. The company offers a wide range of products and solutions for the reduction of contamination.

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For production companies it is an added value to plan and carry out cycles more frequently

