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Informazione aziendale

Biodecontaminazione V-PHP
un alleato per essere conformi all'Annex 1

V-PHP BIO-DECONTAMINATION

an ally for Annex 1 compliance

The new draft version of Annex 1, the EU GMP section providing specific guidance on the production of sterile drugs, focuses on risk management by requiring manufacturers to have a clear strategy to prevent contamination of final products.

The document highlights how RABS (Restricted Access Barrier System) and isolators are useful in ensuring the required conditions and minimising microbial contamination associated with human interventions in sterile areas (grade A). It also offers interesting insights into the topic of bio-decontamination of aseptic filling lines and clean rooms.

In particular, Chapter 4 emphasises that:
- RABS gloves used in Grade A areas must be sterilised before installation and sterilised (or effectively decontaminated by a validated method that achieves the same objective) before each batch production;
- for RABS and isolators, decontamination methods must be validated and controlled within defined cycle parameters;
- fumigation or disinfection with vapour (e.g. hydrogen peroxide in vapour phase) of clean rooms and their surfaces can be useful to reduce microbial contamination in inaccessible places.

The advantages of V-PHP technology

The above highlights how V-PHP biodecontamination is an excellent ally for sterile drug manufacturers. This technology, using hydrogen peroxide in vapour form (Vapour-Phase Hydrogen Peroxide), enables the rapid and effective elimination of a broad spectrum of microorganisms, offering the same levels of microbial load reduction as sterilisation (6 Log) and a perfectly uniform gas diffusion to reach even the most difficult places such as the gloves of a RABS.

Bioreset®, the patented line of V-PHP generators, not only complies with current regulations (e.g. 21 CFR Part 11), but thanks to its portability, efficacy and ease of use is particularly suitable for the decontamination of cleanrooms, isolators and RABS and fulfils the requirements of Annex 1.

In fact, cycles performed with Bioreset® generators are:
- officially validated through the use of chemical indicators and 6 Log biological indicators loaded with Geobacillus *stearothermophilus* (also used to validate autoclave sterilisation)
- monitored, repeatable and reproducible over time thanks to PPM (H_2O_2 gas concentration) and Temperature and Relative Humidity (T/RH) probes, as well as scale to control the consumption of liquid H_2O_2 at 35%.
The reports, showing all data related to the biodecontamination cycle, can be exported directly to different devices for perfect traceability of the production batch.

Single user interface, infinite connection modes

Continuous focus on customer and market guided Amira to introduce important innovations on a number of Bioreset® models, simplifying the user access modes. The new models, equipped with proprietary software, a removable tablet and a Wi-Fi signal generation module, offer the operator a single user interface that can be accessed from any device via direct connection, Wi-Fi or via a corporate network connection.