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Qualification of Vaporised Hydrogen Peroxide (VHP) Gassing Cycles for Decontamination of Critical Zones & Material Transfer in Aseptic Facilities

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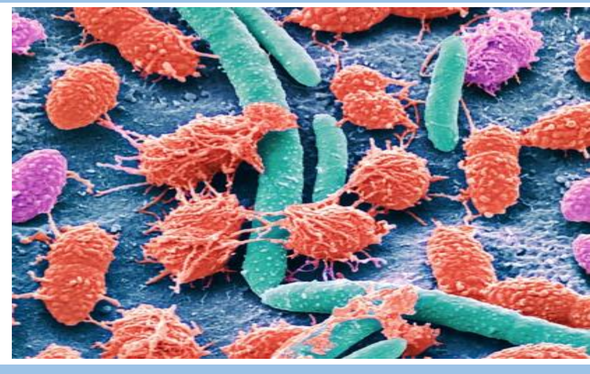
INTRODUCTION

Aseptic processing to produce Ready to Administer (RtA) therapeutics is a high-risk process which requires a robust transfer disinfection process for all materials and consumables, to mitigate the risk of microbial transfer.

VHP is a broad spectrum bactericidal and sporicidal agent that has been shown to demonstrate a considerable reduction in contamination instances in comparison to traditional four stage transfer disinfection.



CHALLENGES

Facilities & Finance

- Ageing facilities
  - Spatial disadvantage for the implementation of VHP compatible gassing isolators
  - Infrastructure changes may be required
- Financial burden
  - High cost associated with VHP compatible isolators
  - Business cases may be required to support a change to existing facilities or build a new facility
  - Financial resource required for the IOQ/PQ process
  - Regular PPM requirement for VHP generators and isolators & Analytical Equipment
  - Regular cost of Biological Indicators & Enzyme Indicators

Capacity & Workflow

- Capacity impact on facilities:
  - Reduction in production output during installation & the initial IOQ/PQ validation process
  - Capacity to train staff
- Process workflow considerations:
  - Timing to transfer materials if intended for material transfer
  - Decontamination schedules & workflow patterns
  - Potential impact on production output
  - Are changes to procedures required? Who is the expert?

METHODS

Identification of Efficient VHP Gassing Cycle Parameters

Phase I
Dehumidification

Phase II
Conditioning

Phase III
Decontamination

Phase IV
Aeration

Identification of Worst Case Loading Patterns

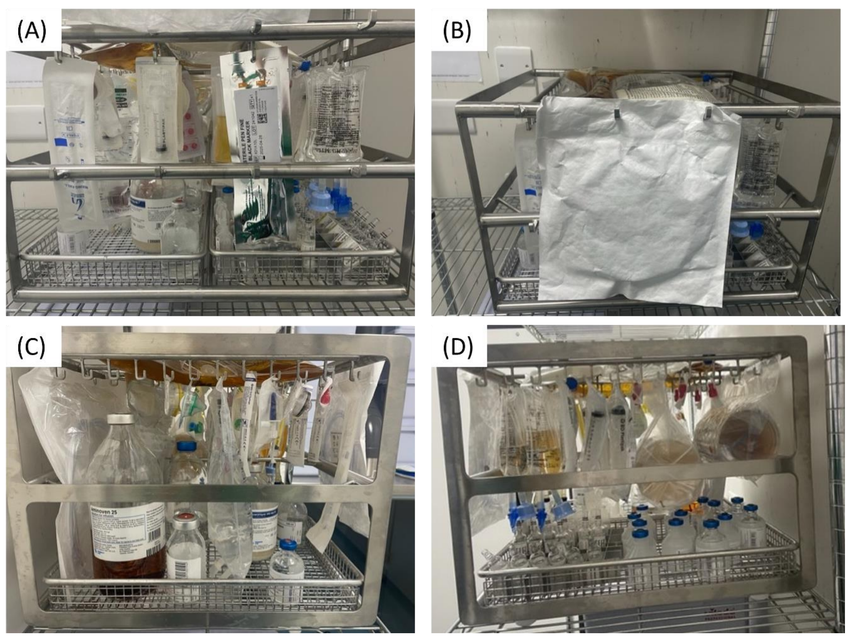


Figure 1: Illustrations (A-D) represent the final worst-case loading pattern for VHP qualification.

1) Established the maximum number of ingredients and consumables, required for transfer.

2) Established the challenge locations.

3) Analysis of VHP exposure and efficiency using Enzyme Indicators (EI's) and Biological Indicators (BI's).

4) Loading pattern validated and documented for future requalification's.

Qualitative & Quantitative Analysis

Biological Indicators: BI's were added to Spordex broth and incubated as required. A colour change (purple → yellow) or turbidity in the samples suggests BI growth and a potential ineffective gassing cycle.

Enzyme Indicators: EI's were analysed using PR2A Luminometers to identify residual 'live' enzyme *via* luminescence photometry, generating a log kill value.

Figure 2: (A) PR2A Luminometer for EI analysis, (B) Spordex Broth & BI strips pre- VHP exposure.

RESULTS

- Drager sensors were used to successfully monitor the temperature, humidity and hydrogen peroxide concentration during VHP cycles. This enables assurance on cycle efficacy, or conversely enables identification of discrepancies that may suggest inefficient decontamination (Figure 3).
- Successful pass rate for EI's and BI's at all challenge locations for the initial and consequent requalification was achieved. Successful qualification of VHP decontamination for full Isolator chamber cycles of 2x2 glove isolators, 4 glove isolators and RGC transfer chambers was achieved (for example EI data, refer to Figure 4).
- Worst-case material transfer loading patterns have been identified.
- A subsequent periodic revalidation protocol embedding critical control parameters has been implemented at the RLUH Aseptic Manufacturing facility demonstrating effective and repeatable VHP decontamination

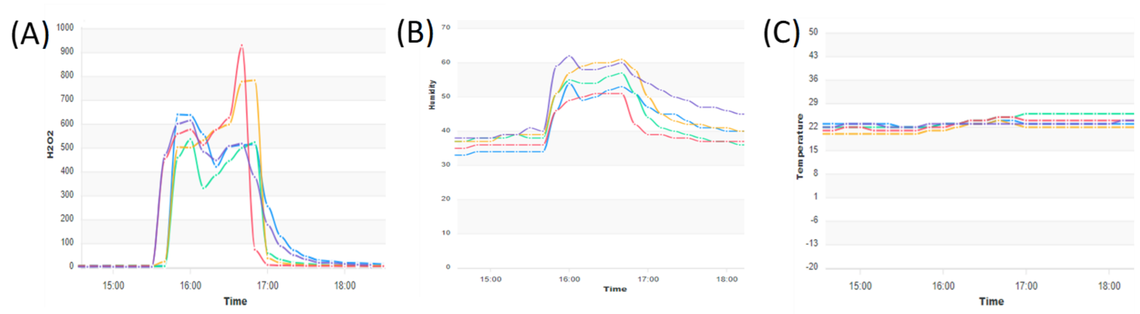


Figure 3: (A) H_2O_2 concentration (ppm) throughout the gassing cycle, (B) Humidity in the chamber throughout the cycle, (C) Temperature throughout the chamber for the duration of the gassing cycle.

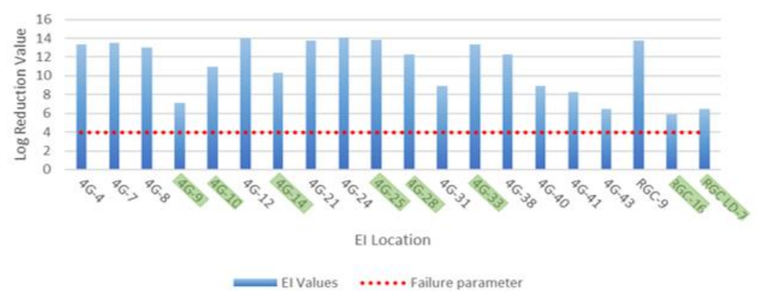


Figure 4: Example data obtained from (A) quantifiable EI Log Kill values, where location references highlighted in green symbolizes a BI location

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