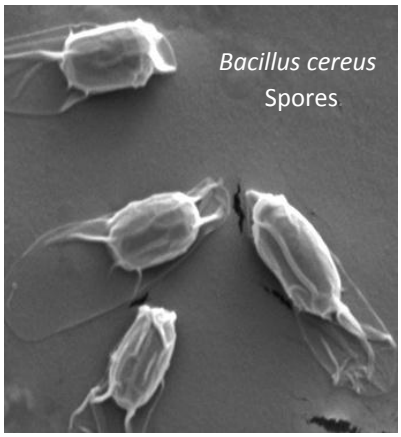
NHS PhQAC Advice Note

Sporicides in the Aseptic Transfer Process



Introduction

In 2014 there were a number of instances in UK hospitals where the apparent contamination of aseptically prepared products with spore-forming micro-organisms was linked with the death of vulnerable patients.

The most notable of these events triggered an investigation by the MHRA and the findings of which led to a revision of the MHRA 'Guidance for Specials Manufacturers' issued on 31st January 2015. This guidance requires a reconsideration of transfer decontamination processes for aseptic preparation of injectable medicines. A review of some related incidents and the observations of the survival of both spores and vegetative bacteria after application of existing transfer decontamination in many aseptic units in the NHS, shows this to be important and necessary.

The NHS Pharmaceutical Micro Protocols Group (MPG) was asked to investigate the issues, particularly concerning the incorporation of routine sporicidal agent use, and provide suitable guidance for NHS aseptic preparation services. This investigation resulted in the publication of the comprehensive and detailed NHS PhQAC 'yellow cover document' that accompanies this Advice Note.

"*Guidance for Aseptic Transfer Processes in the NHS: Addressing Sporicidal Issues*" 1st Edn. July 2015.

From the findings of the work of the Micro Protocols Group, **the most important thing to note is that the presence of any viable organisms in the Grade A environment, and bacterial spores in particular, poses a very real risk of contamination for aseptically prepared products and a significant potential for patient harm.**

In practice, with the diligence of operators, the use of 'closed systems' and the application of good technique, the likelihood of product contamination is low, but the consequences can be severe.

The Micro Protocols Group has concluded that it is necessary for all NHS aseptic units to heed the warnings and apply the MHRA Guidance, improve technique and incorporate additional measures to enhance the sterility assurance of aseptic preparation.

A first consideration should be to look at the use of double or triple wrapped materials as a way to reduce reliance on the operator dependent wipe-spray processes. Where this proves to be impractical, the MHRA Guidance (2015) requires a 2-stage disinfection process, each with a wipe and spray combination, with the incorporation of a sporicidal agent into the first stage.

Whatever approach is taken there will be an impact upon existing services and this will need to be carefully assessed.

The "Guidance for Aseptic Transfer Processes in the NHS: Addressing Sporicidal Issues" document has been written to assist in the conduct of impact and risk assessments and to suggest some best practice options.

In order for this advice to be as practical as possible, a comprehensive survey of cleanroom disinfectants suppliers was undertaken, and the detail was incorporated into the Guidance document.

Key Points:

- Only **sporicidal** agents are considered suitable; sporistatic agents are not.

  The acceptable sporicidal agents are Chlorine, Hydrogen Peroxide and a combination of Hydrogen Peroxide and Peracetic Acid.

- Although spraying is the most effective method of application, evaluation of best practice recommends that the sporicide is applied as an **impregnated wipe** in order to limit health and safety and corrosion effects.

- There were no fully applicable standards that could be used to evaluate sporicidal effectiveness for the in-use conditions, but some could be used for supportive information.

  Caution must be used in the interpretation of data presented by suppliers.

- The NHS Pharmaceutical Micro Protocols Group has stated that the minimum sporicidal efficacy required should be greater than a log 2 kill within 2 minutes. This means that if 1000 spores are present, this count must be reduced to less than 10 within 2 minutes.

- When published, the 'guidance' noted that all commercially available products were aqueous based. This has significant implications in use, for example evaporation or drying times are longer than an alcohol-based product and the integrity of paper backed packaging could be adversely affected. It will be important to get the balance between having sufficient disinfectant liquid on the item so that it will stay wet for the full contact time and having too much, which might weaken paper areas and allow tears or holes to form.

What to do with this document:

- This should be used to guide and assist a careful and detailed review of the current transfer disinfection processes for each aseptic unit and to decide what changes are needed.

- This should include an assessment of the impact of the changes needed to introduce
  a) a four step process incorporating two wipe stages *and*
  b) the routine use of a sporicidal agent

- It should also be used to help determine the 'best fit' of a revised transfer disinfection process. This will need to be formally documented and defined.

- The guidance contains information on most of the cleanroom products currently available in the UK.

- **IMPORTANT: Any changes to the transfer disinfection process should be implemented via a robust change control system that includes an assessment of health and safety issues in addition to those factors that could affect product quality.**

Further Advice may be issued as and when the 'Guidance for Aseptic Transfer Processes in the NHS' document is updated.

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