Appendix: updates to the document

The Q&A for Special manufacturers was first published in September 2013, and provides GMP guidance where unlicensed medicines for an individual patient's special clinical need are manufactured under a Manufacturing Specials (MS) license. Following inspectorate experience and stakeholder feedback it has been reviewed and updated.

Areas where changes have been made are as follows:

3.1.3 – capacity planning
3.3.1 and 3.5.22 – use of Sporicides for surface sanitisation
3.3.6 – cleaning validation
3.5.12 – use of bar coding of materials in compounding
3.5.13 – second person verification of micro volume additions to compounded products
3.5.17 – design of aseptic processes
3.5.18 – use of ampoules
3.5.19 – pooling of pre-sterilised starting materials
3.5.20 – sanitisation of components and equipment for aseptic compounding
3.5.21 – periodic verification of surface sanitisation
3.5.24 – requirement for use of face protection / goggles in aseptic compounding
3.5.27 – compounding of eye drops
3.6.5 – application of 90 day expiry periods and prospective sterility testing
3.6.7 – application of media fill simulation to starting material pooling processes
3.6.8 – matrix approach to process validation
3.6.9 – identification of microbial growth in Grade A and B areas
3.6.14 – use of FTIR analysis of starting materials
3.6.16 – consideration of new technologies in finished product testing
3.12.10 – regulatory aspects of compounding in a registered pharmacy, in anticipation of a prescription
4 (Glossary) – definition of 'closed system'

It is recognised that some changes may have an operational impact on sites and therefore there will be a grace period to allow implementation of the changes.

It is expected that most changes should be implemented within 3 months of publication of this document. However due to the significance of the following changes these should be implemented within 6 months of publication of this document.

3.3.6 - Cleaning validation.
3.5.19 – Pooling (except the requirements for pooling batch records and conduct of media fill studies reflective of the process, which should be implemented within 3 months)
3.5.20 – Disinfection using sporicidal agents.
3.5.27 – Eye drop manufacture
3.6.9 – Identification of Microorganisms

Due to the significant impact of these changes on sterility assurance, licence holders should ensure that, where relevant, interim risk reducing actions are considered during the 3/6 month implementation phase.


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