

Summary - Use of Sterilized Goggles within the Aseptic Processing Area

The FDA has supported the use of sterilized goggles as supported within its' Guidance document "Guidance for Industry – Sterile Drug Products Produced by Aseptic Processing", published in September 2004. This guidance indicates that gown articles worn within the aseptic processing area should be sterilized and further specifies goggles as part of this sterile ensemble.

Validation documentation of the sterilization of these goggles needs to be reviewed and is available from certified vendors.

Any vendor that supplies re-usable goggles will need to have complete validation data readily available for review to support the goggles throughout its' lifecycle if the goggles are cleaned and re-sterilized by the supplier. In some cases complete validation packages are available that document a sterilization compatibility program for their product, regardless of sterilization location, within specified sterilization parameters.

Goggles sterilized by ethylene oxide (ETO) must also have safety data available that verifies any remaining residual levels of ETO present in the goggles post sterilization is below established exposure limits for each sterilization cycle.

Re usable goggles are more cost effective over the long-term and numerous studies have been completed by goggle suppliers, evaluating the effects of repeat sterilization on goggle components.

While sterilization of the goggles is the focus of this bulletin, cleaning of the goggles is a potentially critical component for any re-usable goggle due to the direct ability to properly re-sterilize (e.g. ETO).

If reusable goggles are chosen, the decision to sterilize on site depends on the sterilization technology available, goggle component compatibility, and the commitment to develop, document and maintain an overall goggle sterilization program.

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