Regulatory Basis:
FDA Quality Systems Regulations

Reference: FDA CFR - Code of Federal Regulations Title 21

General Discussion
This document will discuss the requirement for goggle use within Aseptic Processing Areas (APA) as well as products and processes that are available to assist sites in complying with established requirements. Suggested elements of a sterile goggle program are also considered.

This guidance provides background information forming the basis for the requirement for sterilized goggles and discusses goggle availability, sterilization compatibility, and program considerations.

United States based APA sites first encountered regulatory concern from the Medicines and Healthcare products Regulatory Authority (MHRA) requiring the use of sterilized goggles within APA manufacturing operations for any aseptically manufactured product exported for use in Europe.

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.

FDA 483 citations have been issued to aseptic pharmaceutical sites where goggles have been sanitized with isopropyl alcohol prior to use as opposed to being sterilized.

As with every other article that comprises the sterile gown, it is interpreted that use of a newly sterilized pair of goggles would need to be donned with every gowning. As the human element is the greatest contamination contributor, the aseptic quality of the garments meant to act as the particulate barrier between human and environment must be maintained at the highest levels.

Goggles should be chosen, in part, based on their ability to contain particles shed by the wearer as well as not release any contaminating particles or fibers from the goggle itself. The need for goggles to be sterile within the APA is supported by the following principles. First and foremost, the criticality of the aseptic filling environment requires every other gown component to be sterile at the time of donning, including boots that touch the floor and are maintained well below line surfaces.

The proximity of the goggle area, being above the filling line, places the goggle surfaces in the air path upstream of objects at working height. These objects include tools and implements that may come into contact with critical line surfaces, as well as product or product components.

While it is relatively easy to understand the premise behind the requirement for goggle sterilization, meeting that requirement can be challenging.

Appendix 1: Examples

Goggle Name	Manufacturer/ Supplier	Material of Construct	Sterilization Methodology	# Times Re-sterilizable
Jones Visorgogs	Aramark	Cellulosic plastic	Gamma (manufacturer also claims autoclavable)	4-5 irradiation
Centurion Goggle 40300-00000	Aramark	Duralite® Polycarbonate	Gamma (recommended) or EtO	Replaced after eight irradiation cycles when maintained by Aramark.
VWR Sterile Disposables 46600-610 69100-210	VWR	Polycarbonate coated with Exxene anti-fog	EtO	Disposable/ single use
A-50B-IR	Benchmark/ VWR	Polycarbonate lens, PVC Strap	Irradiation	Sold as Disposable/ single use, but may be re-sterilized
Univet Sterilizable Goggle Model 611 (Brazil, Dublin)	General Econopak	Polycarbonate lens	Steam, radiation, EtO	Approximately 50 (Steam)

