Summary - Clean Process - External Vial Capping Operations

"Clean Process" Capping Operations may be considered for GMP sites where aseptic processing operations as part of sterile medicinal product manufacture occur. The EU GMP Annex 1 includes the following statements:

"The container closure system for aseptically filled vials is not fully integral until the aluminium cap has been crimped into place on the stoppered vial. Crimping of the cap should therefore be performed as soon as possible after stopper insertion".
(Paragraph 118)

"*Vial capping can be undertaken as an aseptic process using sterilised caps or as a clean process outside the aseptic core. Where this latter approach is adopted, vials should be protected by Grade A conditions up to the point of leaving the aseptic processing area, and thereafter stoppered vials should be protected with a Grade A air supply until the cap has been crimped.*" (Paragraph 120).

The air handler over the part of the capping operation where vials exit the aseptic area to the point of capping meet ISO 5 requirements for non-viable particulates.

Assessment of acceptable operation may be performed by routinely monitoring the physical parameters of the air handling system to supply Grade A quality air as outlined within EU GMP Annex 1.

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