Change Control Dossier CCD-2287

1. Scope and applicability

This dossier records the assessment of change request CCD-2287 against the validated state of the aseptic filling line FL-02. It covers equipment qualification, cleaning validation and the sterility assurance rationale[i] for the affected product family.

1.1 Validated state

The line was last requalified under protocol PQ-114[1]. Operating limits are recorded in the equipment master file and are unchanged by this request.

1.2 Impact assessment

The requested modification replaces the sterilising grade filter housing. Risk ranking used the site FMEA tool[2]; no critical quality attribute[ii] was scored above the action threshold.

Deviation DEV-9931 remains open and is tracked separately. Closure is not a prerequisite for this change.

Cross-reference check: see section 1.1 Validated state on page 1.

Inserted during review: the filter integrity test method is unchanged.

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[i] Sterility assurance level target 1E-6, per Annex 1.

[ii] The CQA list is maintained in the product control strategy, table 4.

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[1] PQ-114 rev. 3, approved 14 March 2024 by Quality Assurance.

[2] FMEA scoring matrix SOP-QA-118: severity x occurrence x detectability.