

Summary - Cleaning Evaluation Documentation & Records for Cleaning Activities

All cleaning practices requiring validation should first be evaluated and the results of the evaluation documented and approved. Every aspect of the cleaning practice should be reviewed including all materials and methods involved.

The cleaning program requires that cleaning is conducted and the cleaning activities documented following written instruction-records, or SOPs with attached checklists.

Cleaning instruction-records or SOPs with attached checklists, should include all relevant cleaning parameters and confirmation that significant steps have been completed.

Cleaning Evaluation Documentation

In order to appropriately document the development of the cleaning requirements for a material and/or equipment train, it is recommended that a cleaning evaluation report be prepared. Risk assessment tools may be useful in documenting the rationale supporting the cleaning.

Cleaning Instruction-Records

Equipment Cleaning Instruction-Records should be written in a detailed stepwise format for manual cleaning methods and in a defined sequential operation for automated cleaning contact time;

- Start and end times of each critical cleaning cycle or step;
- Method for indicating equipment cleaning status;
- Method for protecting clean equipment from contamination;
- Maximum time intervals for between use and cleaning;

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