

- If a grouping strategy will be used, document that the design of equipment, and/or the characteristics of the products are sufficiently similar to scientifically justify the grouping rationale.
- If the cleaning evaluation is to address more than one active ingredient or API step, then justification for the scope should be included as well as the rationale for the selection of worst case materials if the process is to be validated.
- Consideration of removal requirements for microbiological organisms and cleaning agents (if used), including any non-active containing drug product materials such as granulating or film-coating solutions. A documented and approved risk assessment should be performed to determine if microbial acceptability limits are required for cleaning validation of non-sterile product contact equipment and considerations.

Any documentation used to describe and justify the cleaning validation approach should be subject to site change control procedures and be reviewed and approved by the site Quality Authority and Production Authority.

Figure1: [Guidance on item to be considered as part of the cleaning evaluation is given in the following table.](#)

Use of Quality Risk Management

Risk assessment tools may be useful in documenting the rationale supporting the cleaning program. For example, determining the residues that should be looked for:

- **Probability** of the residue/cleaning agent being a contaminant
Based on solubility in cleaning agents and amount present
- **Severity** of impact
Based on toxicity / minimum therapeutic dose

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 systems.

Completion of each significant cleaning cycle should be recorded either manually (initial, date, and time) or using a validated computerized system.

Such instruction-records should include or reference, at least, the following parameters, where applicable:

- Cleaning and sanitizing agents, including concentration, amount to be used and contact time;
- Quality of water or other solvents used;