Elexes

Medical Device Process Validation & Cleaning Validation Checklist

A practical review of critical parameters, IQ/OQ/PQ, process changes and revalidation.



1 Process definition & scope

- [ ] Define the process and its purpose.
- [ ] Clearly state the intended output.
- [ ] Identify equipment and utilities (e.g., HVAC, compressed air, water, etc.).
- [ ] Establish acceptance criteria for the process.

2 Critical parameters

- [ ] Identify critical process variables (e.g., temperature, pressure, time, concentration).
- [ ] Define operating limits for each critical parameter.
- [ ] Verify alarms and interlocks are in place.
- [ ] Establish monitoring methods and frequency.

3 IQ/OQ/PQ evidence

- [ ] Installation Qualification (IQ) completed and documented.
- [ ] Operating ranges challenged during Operational Qualification (OQ).
- [ ] Consistent and acceptable performance demonstrated during Performance Qualification (PQ).

4 Cleaning validation

- [ ] Define the cleaning method and procedures.
- [ ] Assess potential residues and contamination risks (e.g., product, cleaning agents, bioburden).
- [ ] Document sampling and testing approach (e.g., locations, methods, analytical techniques).
- [ ] Justify and establish acceptance limits (e.g., based on toxicological assessment).

5 Change control & revalidation

- [ ] Assess the impact of changes to equipment, materials, suppliers, software or process parameters.
- [ ] Evaluate the need for revalidation based on the change impact.
- [ ] Document revalidation triggers and criteria.

6 Records & ongoing control

- [ ] Maintain approved protocols and reports.
- [ ] Review and investigate deviations.
- [ ] Ensure personnel training is complete and up to date.
- [ ] Implement ongoing monitoring and periodic review of process performance.

Use this checklist as an initial screening tool. A detailed validation assessment may be needed based on the process and risk profile.