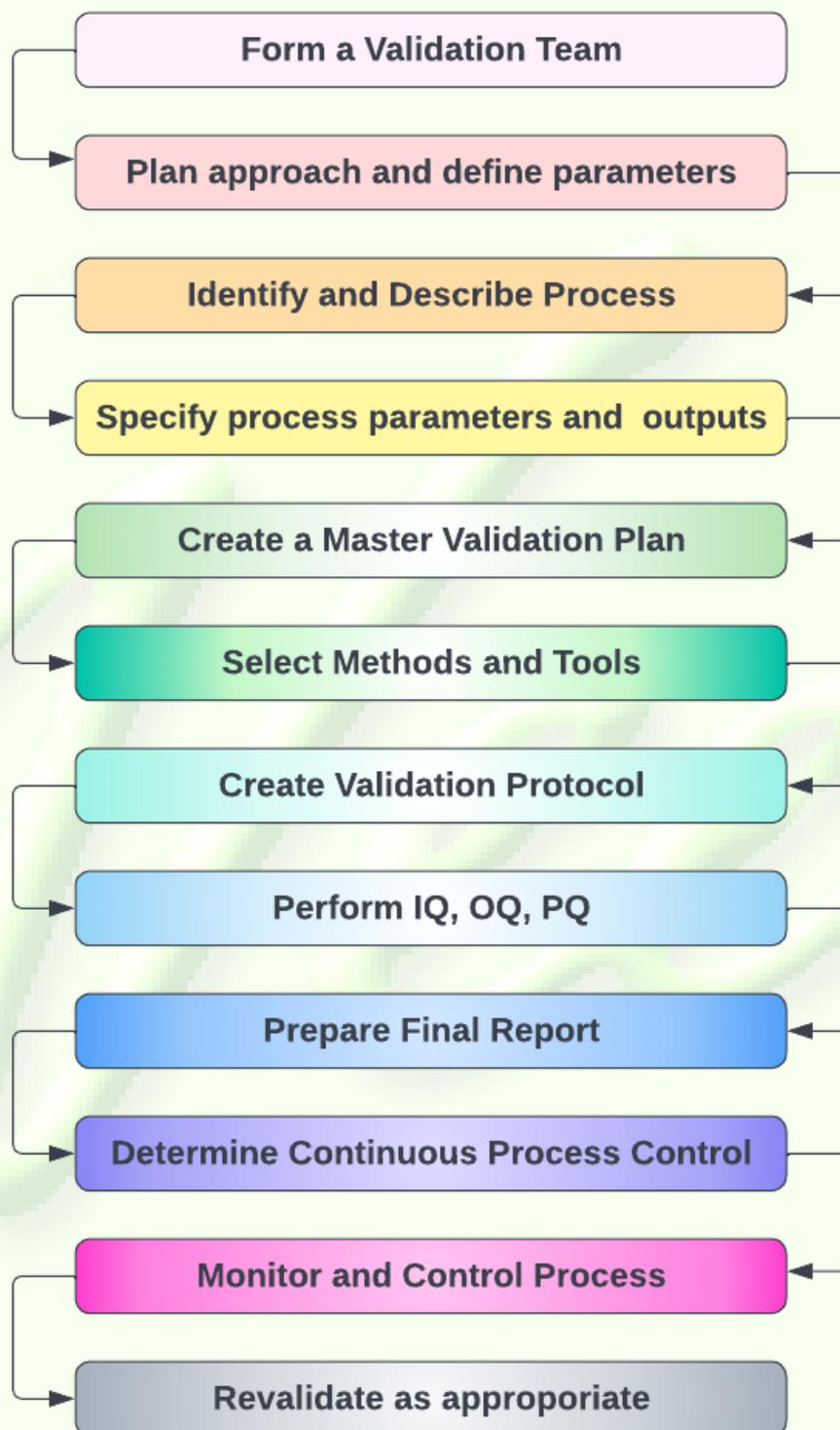


PROCESS VALIDATION PROCESS



PROCESS VALIDATION DOCUMENTATION

1. Validation Plan

- Process Objectives
- Process Descriptions (Flow Chart)
- Process Inputs
- Process outputs
- Process Equipment Identification
- Process Personnel
- Validation Frequency
- Validation Inspector
- Validation Plan approval

2. Installation Qualification report

- Validation Date and Personnel
- Process Equipment Descriptions
- Installation Conditions
- Calibration Schedule
- Operation work instruction
- Critical Process Parameters
- Maintenance Schedule and Procedure
- Training Records
- Validation Conclusion

3. Operational Qualification Report

- Validation Date, Batch, Batch Size and Personnel
- Process Parameters & Specifications
- Sampling Plan and Justifications for Trial Batch Size
- Process output Test Methods
- Test method(s) for output parameter(s)
- Process Outputs Range
- Upper Limits
- Lower Limits
- Critical Process Parameters & Control Limit
- Validation Conclusions

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4. Performance Qualification Report

- Validation Date, Batch, Batch Size and Personnel
- Critical Process Parameters (Medium or Average Value)
- Sampling Plan and Justifications for Trial Batch Size
- Process Output Results
- Batch 1 Output Results
- Batch 2 Output Results
- Batch 3 Output Results
- Validation Conclusion

