

# What elements should be included in a software validation periodic review?



## System Documentation

Includes validation master plan, user requirements, functional specifications, and validation protocols



## Change Control Records

Documentation of all modifications made to the system since the last review



## Performance Metrics & Incidents

System performance metrics alongside incident reports flagging operational issues



## User Access Controls & Security

Verification of access permissions and security measures protecting the system



## Audit Trails & Data Integrity

Confirmation that audit trails are intact and data integrity controls function as intended



## Training Records

Evidence confirming users remain qualified and current on system procedures



## Supplier Assessments

Review of supplier assessments and vendor updates affecting the validated system



## Related SOPs

Standard Operating Procedures tied to the system, checked for continued accuracy



## Backup & Recovery Processes

Testing of backup procedures and recovery processes to confirm they hold up under use



## Regulatory Requirements & Industry Standards

Current regulations and industry standards reviewed to identify any compliance gaps