PSMF Inspection Readiness Checklist

This checklist supports inspection readiness by outlining the key governance elements inspectors typically verify when reviewing the Pharmacovigilance System Master File (PSMF).

- PSMF reflects current pharmacovigilance organizational structure
- Clear definition of QPPV oversight and escalation pathways
- Documented governance for outsourced pharmacovigilance activities
- Controlled change management and version history for the PSMF
- Traceability between PSMF descriptions and operational evidence
- Alignment between safety governance narratives and inspection records
- Regular management review of pharmacovigilance system governance