Checklist: Is Your Pharmacovigilance System Audit-Ready?

Use this checklist to assess whether your pharmacovigilance system is ready for regulatory audits. Ensuring compliance and operational efficiency is critical for successful audits and maintaining trust in your products.

Process Compliance

- ☐ Are adverse event reporting timelines consistently met?
- ☐ Are standard operating procedures (SOPs) up-to-date?
- ☐ Are Risk Management Plans (RMPs) aligned with regulatory requirements?

System Preparedness

- ☐ Is your pharmacovigilance system validated and secure?
- ☐ Are backups and disaster recovery plans in place?
- ☐ Are electronic submissions compliant with global standards (e.g., E2B)?

Team Readiness

- ☐ Has your team received recent pharmacovigilance training?
- ☐ Are roles and responsibilities clearly defined?
- ☐ Is there a dedicated point of contact for audits?

Documentation and Reporting

- ☐ Are Periodic Safety Update Reports (PSURs) submitted on time?
- ☐ Are Pharmacovigilance System Master Files (PSMFs) up-to-date?
- ☐ Are safety narratives and adverse event data well-documented?