Pharmacovigilance inspection checklist

1. System & documentation readiness

- [ ] PV PSMF is complete, up-to-date and readily accessible
- [ ] SOPs/work instructions: all current versions, in controlled format and referenced in the PSMF
- [ ] Organisational charts, roles and responsibilities are clearly defined and key staff changes are logged (if there's a change in key personnel, this should be noted for an inspector)
- [ ] Key metrics dashboards and trends documented (e.g. case-processing KPIs, signal-detection metrics)

2. Case-processing quality

- [ ] ICSR intake, triage and data entry procedures validated and applied
- [ ] Sample of recent ICSRs quality controlled and any deviations documented with CAPAs
- [ ] Standard safety database listings quality checked and available for inspection

3. Signal detection & risk management

- [ ] Current signal-detection methodology and plan plus reports documenting results (incl. periodic safety review reports, signal logs)
- [ ] RMPs/PBRERs updated per latest regulatory guidance
- [ ] Evidence of cross-functional review and approval of signal-management activities

4. Regulatory reporting compliance

- [ ] List of all applicable reporting requirements and timelines by region
- [ ] Documentation of expedited (7-, 15-, 30-day) reports and line listings
- [ ] Evidence of timely submissions to health authorities (e.g. e-reporting acknowledgements)

5. Vendor & partner oversight

- [ ] Up-to-date PV agreements with CROs, distributors, affiliates
- [ ] Vendor qualification/audit reports and corrective-action status tracked
- [ ] Evidence of periodic vendor performance reviews

6. Training & competency

- [ ] Current training matrix for all PV staff (initial, refresher, role-specific)
- [ ] Training records available and signed off
- [ ] Documented proof of competency assessments (e.g. on-the-job evaluations)

7. CAPA & continuous improvement

- [ ] CAPA log with open and closed actions, deadlines, owners
- [ ] Evidence that previous inspection findings have been addressed
- [ ] Trend analysis of deviations and complaints to drive system improvements

8. Quality assurance & internal audits

- [ ] Audit schedule and recent audit reports (internal and vendor audits)
- [ ] Follow-up on audit findings documented with CAPAs
- [ ] Management review minutes demonstrating oversight (particularly QPPV oversight of MAH's QMS and the PSMF)

9. Inspection logistics & readiness

- [ ] Inspection team roles assigned (SME contacts, room host, document coordinator)
- [ ] 'War-room' setup: secure file repository, printing/scanning resources, IT support plan
- [ ] Pre-inspection briefing materials for team (agenda, FAQ, mock Q&A)

10. Mock inspections & drills

- [ ] Conducted at least one full mock inspection in the last 12 months
- [ ] Action items from mock inspection tracked and closed
- [ ] 'Interview readiness' drills for SMEs (key PV processes, non-conformity handling)
- [ ] Ensure MAH has SOP for inspection/audit procedures (and has practiced these)

Glossary

CAPA = corrective and preventive action

ICSR = individual case study report

MAH = marketing authorisation holder

PBRER = periodic benefit-risk evaluation report

PSMF = pharmacovigilance system master file

PV = pharmacovigilance

QMS = quality management system

QPPV = qualified person for pharmacovigilance

RMP = risk management plan

SOP = standard operating procedures