Elexes

Post-Market Surveillance Audit-Readiness Checklist

PMS System Structure

- PMS plan is updated and reflects actual processes
- PMS activities are clearly defined (not generic)
- Roles and responsibilities for PMS are documented
- PMS is aligned with current regulatory requirements (FDA / EU MDR)

Data Completeness

- Complaint handling data is complete and structured
- Adverse event / vigilance data is integrated
- CAPA data is linked to PMS inputs
- Field service and return data are included in analysis

Trending & Analysis

- Trend analysis is performed at defined intervals
- Statistical or logical thresholds are defined
- Trends are distinguished from normal variability
- Data is analyzed across product families (not in isolation)

Signal Detection

- Signal detection criteria are clearly defined
- Signals are documented with justification
- No-signal decisions are also documented
- Escalation criteria are established and followed

Decision-Making

- Trend / No Trend decisions are documented
- Signal / No Signal decisions are justified
- CAPA / No CAPA decisions are clearly recorded
- Decisions are consistent across reporting periods

CAPA & Risk Linkage

- Complaint trends trigger CAPA when required
- PMS outputs are linked to risk management files
- Risk updates are documented and justified
- CAPA effectiveness is fed back into PMS

PMS Reports (PMSR / PSUR)

- PMS reports reflect actual data insights (not summaries)
- Trends and signals are clearly explained
- Decisions are traceable to underlying data
- Reports are consistent across cycles

Audit Readiness

- PMS decisions can be explained during audits
- Supporting data is easily traceable
- Documentation is consistent across PMS, CAPA, and risk files
- PMS outputs align with regulatory expectations