Pharmacovigilance –Specific SOP Master List

Pharmacovigilance Quality Management System (QMS) Documents
• Description of the company's Pharmacovigilance / Vaccine safety Drug Safety Policy • Description of the Pharmacovigilance / Risk Management System (Pharmacovigilance System Master File PSMF) o Working Instruction on the generation of a PSMF as appendix
• Pharmacovigilance (Vaccine Safety) Quality Manual:
1. ICSR Management
2. Product Complaint Handling
3. Generation of aggregate / Periodic Reports (DSURs, PSURs, PADERs etc.)
4. (safety relevant) Literature Search and Analysis (may be a shared one for entire R&D)
5. Set-up and maintenance of inventory of regulatory requirements (may be subset of R&D relevant ones, however due to the country specific PV requirements, a PV stand-alone one is highly recommended)
6. Interaction and communication with Regulatory Authorities
7. Communication with other stakeholders (press releases require a corporate SOP)
8. Generation / Maintenance of Risk Management Plans
9. Design, Conduct of Risk Minimization Programs / REMS and their evaluation
10. Signal Detection and Investigation
11. Design and Conduct of PASS
12. Collection of safety information in patient support programs and market research programs (or part of the Design and Conduct of PSPs and MR programs) -may not be applicable for pure vaccine companies
13. Safety Issue Management
14. Crisis Management (Corporate SOP)
15. Safety Governance
16. Management of internal safety databases
17. Access and analysis of external databases
18. Safety Data Exchange Agreements and management of safety relevant business partnerships
19. Generation and maintenance of the reference safety information (RSI)
20. Generation and maintenance of integrated summaries of safety (ISS) / safety profiles
21. Benefit-Risk Assessments / generation of clinical expert statements
22. Vaccine Safety and Risk Management Training (may not be presented as SOP but as a training matrix)
23. The QPPV and local / EU QPPV as applicable
24. MedDRA maintenance and coding principles
25. Vaccine safety Quality management planning, conduct and compliance monitoring
26. Management of Safety Advisory Boards / Drug Safety Monitoring Committees
27. Reconciliation of data sources with safety information
28. Health hazard assessments