

## Pharmacovigilance Audit Checklist

*An introduction to PV audits, including the discussion of a PV audit checklist was presented at the DCVMN webinar on Vaccine Safety Monitoring and Pharmacovigilance Tools from March 16-18, 2020 – Proposal for a PV audit checklist for facilitating internal PV System gap analysis (PV audits).*

Pharmacovigilance (PV) audit activities should verify by examination and evaluation of objective evidence, the appropriateness and effectiveness of the implementation and operation of a PV system, including its quality system for PV activities.

A Pharmacovigilance Audit includes (but not limited) the evaluation of the following:

- 1) Oversight Marketing Authorization Holder, including Safety Governance
- 2) Roles and responsibilities of QPPV
- 3) Responsibilities and organization of local Pharmacovigilance Department
- 4) Back-up procedures
- 5) Quality Management Systems
  - i) Procedures
  - ii) Quality Assurance
  - iii) Quality Control
  - iv) Record retention
- 6) Staff:
  - i) Training and training records
  - ii) Job descriptions
  - iii) Qualifications
  - iv) PV experience
  - v) Staff not directly involved in PV activities
- 7) SOPs including cross-functional SOPs
- 8) Case processing of individual AEFIs incl. regulatory submission of AEFIs
- 9) Aggregate reports
  - i) PSURs / Annual Reports
  - ii) Timely submissions to NRA
- 10) Signal identification and evaluation
- 11) Risk Management Plans and updates

- 12) Handling of urgent safety issues / crisis management
- 13) Responses to safety inquiries from NRA
- 14) Safety database
- 15) Literature searches
- 16) Medical information
- 17) Compliance metrics
- 18) Labeling:
  - i) Company Core Data Sheet (CCDS)/ Company Core Safety Information (CCSI)
  - ii) Summary of Product Characteristics (SPC)
  - iii) Patient Information Leaflet (PIL)
  - iv) Process of updating and implementation of changes
- 19) Contracts for external services
  - i) Contents and management
- 20) Contracts with co-marketing, co-development, co-manufacturing
- 21) Archiving

Endorsed by the DCVMN PV Working Group September 9, 2020