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