

Pharmacovigilance (Pv) Audit Checklist

The newly-revised pharmacovigilance regulations shift the emphasis of the audit process to the marketing authorisation holder. Use this checklist to help you assess your own pharmacovigilance systems – using the prescribed risk-based approach.

The aim of a pharmacovigilance audit is to use objective evidence to assess the appropriateness and effectiveness of the implementation and operation of a pharmacovigilance system. The audit must be clearly documented and can only rely on verifiable evidence, such as written records and statements.



Strategic Risk Planning

Your strategic risk planning should include:

- All Pv processes and tasks – including those conducted by affiliates or delegated to another organisation
- The quality system in place for Pv activities
- Any interactions with other departments

The following are typical of the factors that you should consider at a strategic planning level.

1 – Changes in staffing, company structure etc:

- Changes to key managerial function(s)
- Changes in the number and availability of adequately trained and experienced Pv staff. Causes include high staff turnover, gaps in formal training processes, increased volume of products etc.
- Changes to the structure of the Pv system that result from mergers, major company re-organisation etc. Such changes may, for example, lead to an increase in the number of products for which the system must cater.
- Changes to the organisation that could negatively impact on the area/process, e.g. IT support.

2 – The Pv system and the products it covers:

- Changes to the Pv system since the previous audit, e.g. introduction of a new or upgraded database, or changes to processes and activities to address changing regulatory requirements.
- The critical nature of the process being audited to the Pv system. This must be carefully considered when deciding when an affiliate or third party should be audited. In addition to all other factors, the MA holder should consider the nature and critical nature of the Pv activities that are being performed by the affiliate or third party on its behalf.
- The outcome of previous audits. Some areas or processes may never have been audited and so may need to be prioritised. Alternatively, an audit may have highlighted shortcomings or gaps in procedures and recommended changes in an area or process.
- The first medicinal product reaching the market – probably the most significant influence on the Pv system.
- Any medicinal products on the market that are subject to specific risk-minimisation measures or other safety conditions.

3 – External factors:

- Changes in legislation and guidance
- Other compliance-related factors, relating to legislation and guidance, e.g. information from compliance metrics, inspections, complaints, and other external sources (such as audits).

Tactical Risk Planning

The following are typical of the factors that should be focussed on at tactical planning level.

- The quality measures in place for the Pv system
- Critical processes within the PV system
- High-risk areas – especially to monitor the effectiveness of controls and curative actions
- Areas that may have received inadequate examination in past audits

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