

Can you effectively fulfil your regulatory obligations?

WCI's holistic Pharmacovigilance Audit

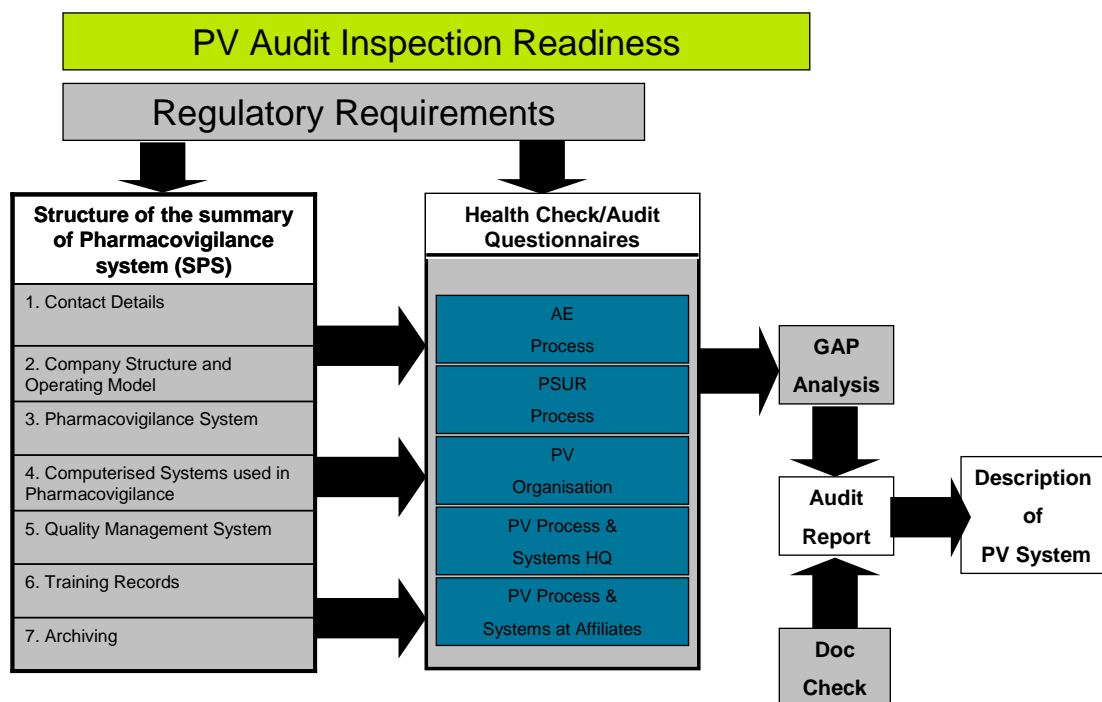
Why this is important

Increased regulatory focus and the need for proactive pharmacovigilance reconfirm the significance of product safety to the value of the Life Science organisation. In the context of today's market and increasingly complex regulatory environment there is a growing momentum and structure behind PV inspections across Europe; inspections that require more prescriptive action. Following the announcement of an inspection, companies have six weeks in which to provide the required detailed description of their PV system. Yet, organisations are often not well placed to deal with the new regulatory requirements and inspections.

Companies often cannot prove compliance because they lack a detailed description of the PV system and/or a summary of the PV systems (as named by MHRA). It is also evident that companies are not always aware of the requirements of the inspectors and are unable to meet their growing expectations. The result? An organisation left open to a serious risk of critical findings during inspection.

In response, WCI have developed the holistic Pharmacovigilance Audit. Working with global law firm Sidley Austin LLP, with whom WCI have a strategic alliance, the Audit offers an unparalleled understanding of pharmacovigilance regulations. So, how can you ensure that your organisation will get a clean bill of health following your next Pharmacovigilance Inspection?

Model for Success



Simplify what you do



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Completed within a timeframe of ten days, the Pharmacovigilance Audit maps against regulatory requirements so that compliance risks, issues and root causes can be clearly identified, together with an action and implementation plan to permanently resolve underlying causes of audit findings.

The holistic approach includes:

- defining stakeholders, the plan and scheduling meetings
- conducting interviews and workshops with selected staff
- mapping single case handling, PSUR and signal detection processes
- creating a high level systems map
- reviewing Risk Management processes
- reviewing a sample of expedited case reports to validate information and SOP compliance, metrics for single cases, PSUR and signal reporting
- reviewing Licence Agreements with third parties
- reviewing Quality Management systems, training records and archiving
- identifying interfaces with other functions and departments
- feeding back findings and prioritising activities
- documenting Audit findings and recommendations
- presentation of findings to stakeholders

Benefits

- a structured proactive approach performed by experts
- the rapid identification of areas of greatest risk
- the ability to focus resource on solving key areas
- the development of practical and proven solutions
- an opportunity to develop a detailed and structured description of the Pharmacovigilance system
- the identification of opportunities to eliminate non-value adding activities and reduce costs.

Proof of Solution

“Your assessment is pragmatic, down to earth and has given us the reassurance of the legal perspective provided by your partners. We felt all along that you placed yourselves in our shoes and see things from our perspective, which is why the assessment has been so pragmatic and useful.”

Irene Rebollo, Manager of Drug Safety, Alcon



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