# A Quick Guide to ace Pharmacovigilance audits

***Presented by***

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# Eliminate major Audit findings in PV with these simple tips!

# Major areas for audit findings:

- SOPs and WIs
- Training
- Compliance Monitoring
- Solutions for audit challenges

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**PREPAREDNESS AND READINESS WELL AHEAD OF TIME IS THE KEY!!**

# Standard Operating Procedure (SOP) & Work Instructions (WI)

- **SOPs and WIs are the main and integral part of any process which defines the structure and Quality management system (QMS) of the organisation.**

- **SOPs and WIs gives the auditor an idea and complete outline about how organised is your process.**

- **During auditing, the above documents are the major part which are verified against the procedure followed or to note any observations for any deviations etc.**

# Common findings with SOPs/WIs

- Master SOP does not exist
- No proper numbering of SOPs or the system
- SOPs and Wis are not linked to any reference documents
- Drafting, review and approval process is not well defined
- Revision, distribution and training process not in place
- Lack of process to ensure that training on SOPs are effectively conducted or just read & acknowledged
- Absence or improper “Change management” workflow process

# Training:

- Training is one of the most critical part of any organisation and especially in pharmacovigilance due to the dynamic environment where there are updates in regulation on a regular basis.

- A proper training process in place helps the auditor to gives an opinion that the members are professionally trained on every aspect to ensure good quality.

- Improper and inadequate training to professionals not only leads to huge quality issues but also impacts clients up to an extent that they might take away/shut down the projects.

# Training process: Observations

- A detailed SOP on training process is missing
- Trainers hired are not qualified and experienced
- Annual training schedule/plan & curriculum is not available
- No knowledge assessment conducted after training to measure and document the training effectiveness
- "Train the trainer" process is not defined
- Lack of process in maintaining and storing of training records

# Compliance monitoring:

- **One of the most important and significant check point for any PV project. This is the determining factor with direct business impact, compliance, client satisfaction and retention of business.**

- **If the process of internal monitoring is not explicit and established, numerous observations mainly related to Turn around time (TAT), Service Level Agreements (SLA) and Key performance Indicators (KPI) may arise which in turn may result in penalties due to non-compliance/non conformity.**

# Usual and common findings related to Compliance monitoring:

- Major communication gaps observed between Project managers & QA team
- Deviations identified by team members are not shared with QA team or clients and failing to file on time
- The QA team do not oversee the process on regular basis as the internal audit is done mostly once a year or solely based on client requirement
- The annual audit schedule/plan is not in place or not available
- The Project managers do not have sufficient knowledge of deviations and CAPA.

# Prepare in advance and avoid these findings:

# SOLUTION - 1

**The following mentioned below if implemented and practiced will eliminate major findings in most of your audits:**

- ✓ **Prepare a master SOP document which clearly states how the documents are numbered/coded and linked as reference documents along with the duration for revision/expiry.**
- ✓ **The document should contain information about author, review and approval process.**
- ✓ **A well defined "Change management" workflow process should be in place so as to track changes in the SOPs and versions.**

# SOLUTION - 2

**Training: is the back bone for performance!**

- ✓ **Prepare a SOP document which provides information on how the training is performed and should include the detailed process of induction and orientation for new hires and experienced employees along with how frequently the trainings are conducted.**
- ✓ **The document should also contain about training assessment and procedure where pass/minimum criteria is established to measure the training effectiveness.**
- ✓ **The lack of "train the trainer" process, storing and maintaining of training records is one of most ignored procedure by many organisations. It is better to implement certain processes to improve the training effectiveness.**

# SOLUTION - 3

- ✓ **All communication gaps existing between teams needs to be addressed and this is very important**
- ✓ **a monthly review meetings must be conducted to oversee if there were any "Deviations" which requires immediate attention to be made aware to the QA team and file the deviations on time**
- ✓ **A detailed annual audit plan/audit schedule must be prepared ahead mentioning the types of audits (Affiliates, Service providers/vendors, licensed partners, Importers/distributors) as the documents, processes and procedures varies.**

# SOLUTION - 3

- ✓ **Proper training on internal monitoring tools for tracking of SLA and KPI, KRAs to have thorough knowledge of deviations and CAPA.**
- ✓ **Good workflow process for filing deviations and measuring the effectiveness of CAPAs after implementation and closure.**

SMART SOLUTIONS

# Preparedness in advance with well written documents, procedures and processes will eliminate most findings!

# Handling PV activities?

- ICSR monitoring and reporting
- Literature surveillance
- Periodic/Aggregate reporting – DSUR/PSUR/PBRER
- Signal detection & management
- Risk management plan (RMP)
- PSMF

# Need help?

## Yes, we know that most companies does, but why us?

- **We will help you with set-up and establish a good QMS**
- **a detailed audit plan/schedule along with audit readiness and preparedness**
- **Draft, review and approve documents with right and proper content with no scope for errors for all PV activities**
- **Guaranteed elimination of critical and major findings**
- **Impress your clients by showcasing highly efficient QMS**
- **Approach us for a professional PV audits**

**Contact us:**

www.Globalplacosolutions.com