Pharma iQ
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10 Top Tips for Effective Pharmacovigilance



In association with the 5th Annual Pharmacovigilance Asia Summit
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5th Annual Pharmacovigilance Asia 2014



Introduction

The Asia Pacific region has seen the introduction of stringent local and global regulations which have forced the concept of pharmacovigilance to expand beyond just identifying adverse events to incorporating risk management plans. Today pharmacovigilance is on the minds of every pharma and bio executive, and starts earlier in the drug development process. And rightly so, considering the startling fact that 200,000 patients die each year from Adverse Drug Reactions.

There are several challenges around pharmacovigilance in Asia and perspectives are different for industry, regulatory authorities, academia and healthcare professionals. Ahead of the *5th Annual Pharmacovigilance Asia Summit*, Dr Deepa Arora MD, Global Head, Drug Safety & Risk Management at Lupin Limited, reveals her top 10 tips for pharmacovigilance.

We hope you enjoy reading!

The Pharma IQ Team

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1. Inspection Readiness



While ensuring **Inspection Readiness** is the key to success during unannounced inspections-like that of US FDA, inspection readiness also helps to smoothly sail through planned inspections like that of MHRA. Regular Internal audits are one of the best means to achieve this objective.

2. Reconciliation



Ensure that appropriate procedures are in place for **Reconciliation** to confirm that all cases received have been processed. Absence of reconciliation between key departments for example medical information and case processing is considered a critical finding.

3. Corrective and Preventive Actions (CAPA)



Errors are bound to happen. Make sure that all adequate processes are in place to identify and document errors, assess their implications on the safety of patients. Implement appropriate **Corrective and Preventive Actions (CAPA)** to avoid repetition of the errors.

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4. Reading



As the field of pharmacovigilance is developing rapidly, it's important to be aware of the changes to deliver effectively. **Reading** is the best way to learn about the changes and new developments. Make sure that you read at least two documents every week, which can include guidance documents and good relevant articles.

5. E-mail Alerts



Several Regulatory authorities send alerts regarding new or changed guidance documents. Subscribe to the **e-mail alerts** of key regulatory authorities relevant for your operations.

6. Organisational Awareness



Managers should spend a considerable amount of time to increase **organisational awareness** regarding pharmacovigilance regulations and processes. This will help in generating adequate cross functional support to support compliance.

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7. Organisational Alignment



For appropriate functioning, pharmacovigilance staff require a lot of information from other departments, like regulatory, quality, business development, sales and marketing. Therefore, pharmacovigilance managers should spend adequate time for **organisational alignment** to ensure smooth flow of information to pharmacovigilance department for meeting their compliance requirements.

8. Initial Receipt Date (IRD)



The concept of **Initial Receipt Date (IRD)** is one of the most basic and preliminary learning for pharmacovigilance staff. This is usually well covered during all staff as well as cross functional training. However, it's well known that lack of understanding about IRD is one of the most common causes of delays in submission of expedited reports. Make sure that your staff really understands the concept of IRD for all types of reports, as well as information received from business partners, vendors and third parties.

9. Job Profiles and Training Documentation



Job profiles and training documentation- Regularly review job profiles to ensure that they adequately reflect the current activities of the staff and training documentation is in line with the current or expanded job profile.

10. Change Control



Change Control- While making any changes, fully assess the impact of those changes on all downstream and upstream processes so that change in one area does not adversely impact other parts of the process and other functions.



Complying with Regulations, Reviewing RMPs for Asia, and Improving Audits and ADR Reporting

Join us in November 2014 and be part of our growing pharmacovigilance community to discuss the latest challenges and solutions in the PV field for ensuring drug safety in Asia.

25 - 27 November, 2014 - Grand Copthorne Waterfront Hotel, Singapore

www.pharmacovigilanceasia.com

Questions? Contact us on +65 6722 9388 or email enquiry@iqpc.com.sg now!

