Joint DIA/EFGCP Pharmacovigilance Audit and Inspection Workshop – Opportunities for Patient Safety

1 October 2010

DE VERE Venues Canary Wharf | London, UK

Programme Committee

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Objectives

- To provide a neutral platform for regulators and industry to jointly review experience from pharmacovigilance audits and inspections across national boundaries
- To increase the common understanding of the role of pharmacovigilance inspections and improve future collaboration

Key Topics

Audit and inspection findings related to:

- Management of individual case safety reports such as assessment of case validity, lack of efficacy, information derived from the Internet
- Record retention and storage, paper versus electronic records
- Pharmacovigilance quality system, structure, documentation, Detailed Description of Pharmacovigilance Systems (DDPS) updates, role of European Qualified Person for Pharmacovigilance (QPPV)
- Reporting of inspection findings, assessment against internal/external references, interpretation of regulatory requirements, consistency across inspections, options for dialogue and escalation

Other aspects:

- Targeted versus routine inspections
- Feedback from assessments relevant to pharmacovigilance quality system
- Affiliates inspections in the EU and rest of the world
- Inspections of licensing partner, distributors and vendors
- Best practices on how to prepare, conduct, report a pharmacovigilance inspection – mutual experience and recommendations
- Role of performance metrics in pharmacovigilance quality systems

Who Will Attend

Professionals from regulatory agencies, industry, non-profit organisations involved in clinical research, drug safety monitoring and related quality management activities

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