Competency Areas for Pharmacovigilance Professionals

Information management skills

- Knowledge of relevant Pharmacovigilance information sources including: printed publications, unpublished sources, databases, websites, social media sites, market research, patients and healthcare professionals, investigator sponsored research and external bodies.
- Effective understanding and use of the principles of information capture, storage, searching and retrieval.
- Effective use of appropriate IT systems and programs.

Scientific knowledge

- Ability to understand in detail clinical, biomedical and scientific reports about pharmaceutical products at a level to allow appropriate capture, review and processing of safety data.

Analytical skills

- Ability to analyse and appraise safety data as part of the ongoing benefit-risk assessment of the company’s products.
- Ability to make informed decisions after finding the relevant facts.

Communication skills

- Ability to communicate information effectively and clearly in written form to allow sharing of safety data within the company and to regulatory bodies as required.
- Understanding the wider context
- Knowledge of the business and of the pharmaceutical industry.
- Understanding of the external environment: the NHS, Government policy, regulatory requirements.

Understanding of relevant legal and related issues

- European and Global PV Regulations
- Medicines Act and Statutory Instruments.
- Data Protection legislation.
- Copyright.
Ethics

- Understanding of, and compliance with, company policies, legal requirements, the European Good Vigilance Practice Modules, ABPI Pharmacovigilance Expert Network guidance and other industry guidelines that are relevant to pharmacovigilance.
- Application of sound professional judgement to ethical issues.

Workload Management

- Ability to prioritise, plan and organise work with the appropriate sense of urgency based on regulatory requirements and business needs.

Personal skills

- Team management and leadership skills (for team leaders and managers).
- Strategic planning (especially for managers).
- Interpersonal skills.
- Understanding of the needs and priorities of regulatory bodies.
- Use of effective questioning to accurately record safety data.
- Ability to actively listen.
- Teamwork.
- Courteous manner and consideration of others' views.

Proactivity

- Informing management of important issues as they arise which require their attention.
- Ensuring all company employees and contractors are appropriately trained to capture safety data.
- Actively increasing awareness of Pharmacovigilance requirements to colleagues and third parties in appropriate ways.

Accountability

- Compliance with regulatory requirements.
- Compliance with standard operating procedures and company policies.

Continuous development

- Developing and improving knowledge and skills.
- Keeping abreast of developments in regulatory requirements.
- Developing the role in line with regulatory requirements and the company's needs.
- Identifying and implementing improvements in ways of working - for self and for team/department.