## **Crown Pharmacovigilance**

## Training Programmes in Pharmacovigilance for holders of a science degree (BSc or MSc or PhD), medical degree, pharmacy degree, nursing degree

Crown Pharmacovigilance is a specialist drug safety company providing pharmacovigilance, drug safety, risk management and medical communication services to pharmaceutical and biotech companies. Our introductory training programmes are designed to equip attendees with practical hands-on skills to enable them gain entry into the field of pharmacovigilance or do their jobs effectively and efficiently.

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems. Pharmacovigilance involves evaluating information provided by healthcare professionals, pharmaceutical companies and patients in order to understand the risks involved with a particular drug. By law pharmaceutical companies are required to conduct pharmacovigilance activities on all drugs on the market and those in clinical trials. Due to the ever increasing regulatory requirements, the increasing number of clinical trials on new drugs and the increasing number of drugs introduced to the market, the need for skilled staff in the field of pharmacovigilance continues to grow.

Pharmacovigilance is part of the discipline of Pharmaceutical Medicine which in turn is a recognised specialty/faculty of the Royal College of Physicians.

Course title: Introductory Intensive and Practical Course in Pharmacovigilance and Drug Safety Content:

Overview of drug development process	Narrative writing
History of Pharmacovigilance	MedDRA coding
Regulatory guidelines	Medical review of cases
Terminology/Definitions	Causality assessment
ICH/CIOMS	Investigator's Brochure/Core Data Sheet/SmPC
Pre-marketing pharmacovigilance	Reference documents/Labelling /expectedness assessment
Post-marketing pharmacovigilance	E-reporting of cases
Case processing activities	Signal detection
Safety Databases	Periodic reporting
Data entry	

Who should attend?

- Those who are interested in research medicine, looking to gain entry into jobs in Pharmaceutical or Biotech companies and have
  - $\circ\,$  a medical degree or a pharmacy degree or a science degree or a nursing qualification
- Those who have recently started a job in pharmacovigilance and want a quality introductory programme to get up to speed quickly

Course Leader: Dr Joy Chukwujindu MBBS, DTM&H, MPH, DipPharmMed, FFPM, MBA

Dr Joy has spent over 20 years in the pharmaceutical industry in a variety of pharmacoepidemiology, pharmacovigilance and safety risk management roles in both clinical and post-marketing pharmacovigilance within pharmaceutical companies and contract research organisations (CROs). She has extensive practical and hands-on experience in all aspects of pharmacovigilance and safety risk management.

Dates: Available on request (usually weekend lectures followed by practical exercises over weeks) Fees: £500.00 excl VAT (self funding); £1000.00 excl VAT (Industry)

Venue: Crown Pharmacovigilance, Hainault Business Park, 51-55 Fowler Road, Hainault, Essex, IG6 3XE

To book contact info@crown-consultants.com