



## Pharmacovigilance /Medical Device officer Job Description

Pharmacovigilance/Medical device officer is responsible for instituting and maintaining the key aspects of medical device regulation. Additionally, the role involves collecting, monitoring, processing, and documenting of adverse reactions reported to all medical products.

The incumbent will provide guidance to health care providers to take responsibility for medication error detection, reporting, evaluation, and prevention and provide guidance to medical device suppliers in Abu Dhabi to comply with regulatory requirements. Additional responsibilities include drafting regulatory policies, development of protocols, SOPs and all related duties to enable PV workflow and activities.

### Medical device Responsibilities:

- Develop and implement appropriate controls for medical devices that are aligned to the Health Authority Abu Dhabi's objectives and policies.
- Provide scientific expertise and services to satisfy the expectations of the public, device users and hospital institutions and the medical device industry.
- Evaluate and regulate medical devices intended for use in Abu Dhabi, with the objective of ensuring all medical devices sold in Abu Dhabi meet the required safety, efficacy and quality standards, as devices and their performance according to their intended purpose within the scope of accepted regulatory practices.
- Review and approve devices for reimbursement by the relevant insurance companies.
- Routinely review, identify, investigate, alert, and where necessary, resolve safety issues for medical devices that could potentially affect the health and safety of patients.
- Assist with the development and creation of tools and programs to improve regulatory efficiencies.

### PV Responsibilities:

- Process and evaluate adverse event and medication error reports from health care providers and public in timely manner.
- Assessment of case reports in respect of: Quality of documentation, Casualty Assessment, Clinical Relevance and Quality control, in particular to identification of duplicate reports.
- Communication of relevant safety information to national and regional regulatory authorities, health professionals, pharmaceutical companies and other players as appropriate.
- Information sharing at regional and global levels.
- Timely advice to health professionals and consumers on drug safety.
- Regular follow up with designated focal points at each health care facility for clarification, reconciliation and management when necessary.
- Continuous monitoring and regular audit of Health care facilities for their Adverse Reaction (AR) and Medication Error (ME) incidences.
- Ensure accuracy and quality of all reports handled by PV center.
- Prepare a periodic (weekly/monthly/biannual/annual) consolidated report in regard to AR and ME handled by PV center.
- Develop and organize regular sensitization programmes targeting HCP's and public
- Coordinate with all concerned internal and external stake holders in implementing AR and ME prevention and management plan
- Other PV duties as defined within scope and mission of PV.

### **Knowledge and experience:**

- Degree in health sciences with 3-5 years of regulatory work experience in medical devices, drugs and/or biologics.
- Strong understanding of current global regulations related to Medical Devices and IVDs and a knowledge of ISO 13485.
- Possess good analytical skills and a keen interest in and an understanding of policy issues, especially in the area of public health
- Experience in pharmacovigilance/medical device vigilance
- Must be detail oriented and possess good communication skills (written and verbal).
- Highly motivated with a strong desire to protect public health and safety.
- Good communication and interpersonal skills as well as the ability to work well in a multicultural team is essential.
- Proficient in Microsoft Office Applications