Introduction to Pharmacovigilance

Presenter
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Introduction
Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems. Pharmacovigilance is needed to address the limitations of clinical trials and the burden of adverse drug reactions on patients and health systems. Those working in pharmacovigilance must have a good working knowledge of the principles of drug safety, its regulations and proactive strategies for risk management.

The Course:
The Introduction to Pharmacovigilance course is designed to provide solid practical foundations for those working in drug safety. This course will benefit staff working in pharmacovigilance departments and will be of interest to a broad range of staff in the pharmaceutical industry who require a basic understanding of pharmacovigilance concepts.

Aims of course

- To describe the history and importance of pharmacovigilance
- To ensure an understanding of basic terminology and provide definitions of key concepts
- To describe the roles and responsibilities of the South African Health Products Regulatory Agency (SAHPRA) from a pharmacovigilance perspective
- To introduce delegates to current key South African regulatory requirements for reporting of adverse events related to human medicines and medical devices
- To introduce delegates to the basic concept and structure of periodic safety update reports (PSURs)
- To introduce delegates to the basic concept and structure of Risk Management Plans (RMPs)

Key Topics

- Historical aspects and evolution of drug safety

- South African Pharmacovigilance regulatory requirements, including the requirements for medical devices
- Periodic Safety Update reports
- Risk Management Plans

Who should take this course?

Pharmacovigilance Officers who have recently been employed in industry and other industry colleagues (i.e., Medical Affairs, Regulatory Affairs, Medical Information, Responsible Pharmacist, auditors) who require a basic understanding of pharmacovigilance.

Course Content:

This course will be presented on the Microsoft Teams Platform.

DAY 1: 30 June 2021 (9:00 to 13:00)

Time	Session title	Topics
9:00 to 10:00	History and importance of pharmacovigilance	1. Definition of PV 2. Disasters affecting PV legislation 3. Medicines withdrawals due to drug safety concerns 4. Limitations of Clinical Trials 5. Effects of ADRs
10 minute break		
10:10 to 10:45	South Africa Context	1. SAHPRA 2. Studies
10:45 to 11:15	Standard Definitions	Essential PV definitions
15 minute break		
11:30 to 12:45	SAHPRA Guideline 2.33	South African pharmacovigilance requirements for human medicines post marketing

DAY 2: 01 July 2021 (9:00 to 12:30)

Time	Session title	Topics
9:00 to 10:15	SAHPRA Guideline 8.04	South African pharmacovigilance requirements for medical devices
10 minute break		
10:25 to 11:15	PSURs	1. Benefit-risk balance 2. Objective of a PSUR 3. PSUR principals 4. Content of PSUR (PSUR template provided)
15 minute break		
11:30 to 12:45	Risk Management Plans	1. Aim of an RMP 2. RMP terminology 3. Principals of an RMP 4. RMP parts and modules 5. Points to consider (EMA RMP template will be shared)

Course Outcomes:

- Knowledge on the founding principles of pharmacovigilance and landmark cases that affected changes to drug safety regulations
- Explain key operational drug safety definitions
- Demonstrate good pharmacovigilance practice and locate key sources of information and documentation
- Understanding of the SAHPRA regulatory requirements for human medicine and medical devices
- Understanding of PSUR objectives, content and structure
- Understanding of RMP aims, terminology, parts and modules