Due Diligence & Regulatory Information Management – Online Workshop

03 & 04 December 2020

Introduction

Regulatory information management is a critical component of the value of a company – it underpins the legitimate operations, safeguards the Intellectual Property, supports supply chain and facilitates compliance activities. The importance of managing regulatory information correctly (over lifecycle, mergers, acquisitions, computer system migrations, etc.) cannot be overemphasised.

This online workshop aims to provide those in Regulatory Affairs and Compliance Departments an overview of the data and GxP requirements related to Health Products.

The workshop is split over 2 days – in half-day sessions (10:00 – 14:00) and is hosted via Zoom.

Who should attend?

- ☑ Responsible Pharmacists
- ☑ Regulatory/Compliance System Information Managers
- ☑ Regulatory Pharmacists
- ☑ QA Managers
- ☑ Product Development Managers
- ☑ GxP Compliance Managers
- ☑ Regulatory Operations Managers
- ☑ Regulatory Specialists

Course Outcomes

At the end of the course, the delegate will have insight and knowledge of the following:

- Legislation related to Health Products
- Classification methodology for Health Products
- Data requirements for submission purposes
- Cohesive compliance information management – Business, RA, QA & PV
- Regulatory Information Management requirements over Product and Facility Lifecycles.

Presenter

Henriette Vienings – MRA Regulatory Consultants (Pty) Ltd
henriette@mra-regulatory.com | 083 435-4453