HANDS-ON-TRAINING: VIGILANCE IN THE SOUTH AFRICAN ENVIRONMENT.

The dynamic pharmaceutical industry sees a rapid turnover in staff members and the day-to-day tasks require a multitude of fields of expertise. This course will provide real and hands-on focused training and mentorship for **newer regulatory personnel**. The goal of the training is to empower the junior staff member and give him/her confidence in the task he/she was trained on.

Date: Thursday 11 July 2019
Venue: Venue: Glenhove Events Hub, 52 Glenhove Rd, Melrose
Time: 09:00 – 16:00
Cost: Members R2900.00, Non-Members R3400

Who should attend:

- Newly appointed responsible pharmacists
- Newly appointed vigilance officers/ pharmacists

Presenter and facilitator:
Leneri du Toit and Esthi Beukes

Topics:

1. **Introduction to vigilance**
   - What is vigilance and why is it needed?
2. **Vigilance requirements in South Africa**
   - What information should a local company provide to the regulatory authority to comply with local requirements.
   - Vigilance requirements for CAMS and medical devices.
   - Compliance with your principal's requirements.
   - How should the submission be made to the SAHPRA.
   - Representative training
3. **Reporting of ADR's experienced during clinical trials and Section 21 use**
   - When to report.
   - How to report.
   - What to report.
   - Who to report to.
4. **Preparing for a vigilance audit.**
5. **Trouble shooting and questions**
   - Sharing of experiences between delegates.