LIVE ON-LINE TRAINING COURSE: QUALITY RISK MANAGEMENT

THIS COURSE INCLUDES THE FOLLOWING:

- ON-LINE SESSION – FULL DAY, INCLUDES 4 SESSIONS, WITH LIVE TRAINER

- PRIOR TO THE COURSE - Delegates to register and pay on-line, download course material through a link, and prepare an example for the workshop session

- TRAINING TO BE CONDUCTED USING MICROSOFT TEAMS PROGRAM –
  Delegates will join each session at least 10 minutes prior to the start of each, in order to facilitate appropriate timekeeping

- DURING THE COURSE – Delegates will complete a questionnaire in session 4 on the day and submit to SAAPI for marking, in order to obtain a certificate of attendance and competency

- COURSE OUTLINE –

  - ✓ Regulatory Guidelines and references
  - ✓ How does QRM fit into the cGMP requirements?
  - ✓ QRM models – HACCP principles and FMECA
  - ✓ How to conduct a QRM Process –
    - ➢ Team members
    - ➢ QA documentation used as references
    - ➢ Use of Process flow diagrams
    - ➢ Risk assessment tools – Ishikawa; 5 Whys
    - ➢ Practical compilation of an Excel QRM register
    - ➢ Calculation of the RPN
  - ✓ Workshop on examples of QRM entries across the pharmaceutical departments (Delegate participation)
    - ➢ Integration of QRM in QMS and Regulatory processes
  - ✓ How to perform a periodic review of the QRM
    - ➢ Additional Excel QRM register entries
  - ✓ Linking QRM results to CI
  - ✓ Linking QRM results to Senior Management communication
  - ✓ Linking QRM results to Departmental / Company budget preparation

- TARGET GROUP –

  Teams from Pharmaceutical Manufacturing, Applicant only and

  Wholesale & Distribution sites – Human and Veterinary Medicines:

  - ✓ Quality Assurance
  - ✓ Production
  - ✓ Operations
  - ✓ Batch release Pharmacists
  - ✓ Regulatory Pharmacists
  - ✓ Senior Management
  - ✓ Engineering
  - ✓ IT

- PRESENTER – Rosemary Kietzmann