PharmaConsult (Pty) Ltd
Reg. No. 2018/030383/07
Cell: 082 457 1380
Email: rkietz2@gmail.com

Workshop - Quality Auditing: Qualification of Suppliers and Conducting Contract – Acceptor Site Audits.

PRESENTER: Rosemary Kietzmann
B. Sc (Chemistry & Biochemistry)
082 4571380
rkietz2@gmail.com

Rosemary has spent more than 35 years working in the pharmaceutical industry, specifically in Quality Control, Quality Assurance, Regulatory Affairs and Technical Operations including Supply Chain, for manufacturers of medicines and for Applicants of registered medicines. The products ranged from: sterile blood plasma-derived therapeutic preparations; allopathic, generic and complementary medicines; homeopathic and herbal preparations; OTC products.

She has extensive knowledge of conducting numerous cGMP inspections nationally and internationally and is passionate about ensuring quality is built into each product by applying an effective quality management system and following cGMP requirements.

Rosemary is the owner and Director of consulting company PharmaConsult (Pty) Ltd., which provides expert project management activities, training sessions and implementation of theoretical and practical QMS processes, amongst other service offerings.

COURSE INTRODUCTION:

Holders of a Certificate of Registration (HCR) for medicinal products need to adhere to current Good Manufacturing Practice (cGMP) requirements, based on the SA Guide to GMP (4.01) and the PIC/S Guides to GMP (PE 009-15). Chapter 7: Outsourced Activities, provides guidance on the roles and responsibilities of Contract Givers and Contract Acceptors. The South African Health Products Regulatory Authority (SAHPRA) includes reviews of the HCR's contracts entered into with outsourced service providers involved in any part of the lifecycle of the registered products. The expectation is that the HCR personnel are suitably trained and possess the requisite level of knowledge to enable them to competently perform external cGxP inspections of proposed or of existing Contract Acceptor sites, from Warehouses, Manufacturers and Packers, Quality Control Laboratories – analytical chemistry and microbiology, Distributors, Printed artwork producers, API and IPI sites, Retention sample storage, Document storage, Stability Trials laboratories, Packaging suppliers, Utilities providers and such like. Any cGxP activity that is outsourced should be appropriately defined, agreed and controlled in order to avoid misunderstandings which could result in a product or operation of unsatisfactory quality. HCR cGxP Auditors are required to establish appropriate Standard Operating Procedures and an Audit Schedule that is based on the assessment of risk, to inspect these sites for compliance to ensure that all registered medicines are of the required quality, safety and efficacy.

SAHPRA requires each site to implement and perform the scheduled inspections on time and to provide evidence that the Contract Acceptor meets the predefined criteria for

qualification and acceptance by the HCR. The frequency of ongoing inspections is required to be stated in order to ensure that each product remains compliant during its life-cycle.

This one-day course held over two mornings by SAAPI via MS Teams, introduces personnel involved in managing outsourced activities, to key requirements in terms of the process to define each supplier type, to qualify suppliers, and the planning, preparation, exposure to key cGxP elements to include in the various audit programs, activities to be performed, compilation of the Inspection Report, liaison with Senior Management at both parties, review of Contract Acceptor responses to the deficiencies and closing out the process, followed by an effectiveness check. Practical tools, documentation and relevant examples will be included in order to prepare you to conduct your external audits to maximum benefit to ensure that your objective is met.

WHO SHOULD ATTEND THE COURSE:

Pharmacists (Regulatory and Quality Assurance) and Quality Assurance personnel, in Human and Veterinary Medicines (Act 101 of 1965) who are responsible for ensuring that their outsourced activities comply with the Guidelines, are implemented and beneficial in terms of reducing risk and providing evidence of continuous improvement initiatives, as well as Senior Management who wish to develop their knowledge in this area. In addition, personnel from Contract Acceptor sites involved in the supply chain will benefit in terms of awareness of the requirements to prepare for their Contract Giver's audits.

- Pharmaceutical Sites – Manufacturing, Packing, Testing
- Applicant only Sites (Importing &/or Procuring from local contract sites)
- Warehouse & Distribution sites
- QC Laboratories

COURSE CONTENT:

- ✓ Definition and Types of External cGXP audits
- ✓ Regulatory Guidelines and references
- ✓ Objectives and expectations for the audit
- ✓ Benefits of a comprehensive external audit process
- ✓ Selection criteria for the audit personnel
- ✓ Qualification process to appoint suppliers
- ✓ Technical Quality Agreements and Audit Schedule compilation on a risk-based approach
- ✓ Administrative planning and preparation internally & with contract sites
- ✓ Auditor knowledge preparation and upskilling
- ✓ Auditor planning and strategies –
  List of initial documents to review and make notes to audit on site
  Selection of products or processes to audit
  Identification of high-risk areas based on review of internal QMS Registers
- ✓ Checklists covering expectations of requirements in the areas to be inspected on site
- ✓ Audit execution – from opening to closing meetings, with practical examples of hot spots to include in the audit

PharmaConsult (Pty) Ltd
Reg. No. 2018/030383/07
Cell: 082 457 1380
Email: rkietz2@gmail.com

- ✓ Compiling the Audit Report and deficiency classification
- ✓ Post audit communication with Senior Management at both sites - agree CAPA
- ✓ Risk rating review and effectiveness check

COURSE OUTCOMES:

At the end of this course the attendees should have a clear understanding of the following:

- ✓ Knowledge of the concepts of the requirements that need to be in place in order to appoint contract acceptors and to prepare to conduct a comprehensive external cGxP audit
- ✓ Tools to equip the auditor to upskill and gain the necessary information to facilitate an audit that adds value to the both the Contract Giver and Acceptor
- ✓ Practical activities to enable a successful audit execution
- ✓ Audit Report details and the CAPA response format required with timelines
- ✓ Integrating Quality Risk Management into the external cGxP audit process
- ✓ Communication with the Senior Management regarding the audit process and highlighting continuous improvement initiatives as well as areas of concern