

## GMP Training Officer – Pharmaceutical – Durban

### Description

#### WE ARE HIRING:

### GMP TRAINING OFFICER – PHARMACEUTICAL – DURBAN

#### About the role

- The GMP Training Officer is responsible for the effective development, implementation, management and execution of a competency-based Good Manufacturing Practice (GMP) training program, in support of our clients mission, vision, core values and the quality management system, thereby ensuring organisational compliance with cGMP and regulatory requirements.

Partner and conduct training needs analysis with key stakeholders to identify training needs appropriate to the individual departmental functions, to initiate and implement a competency-based GMP training program supported by appropriate and effective post training assessments.

#### Minimum Requirements

Relevant qualification in Quality/cGMP

Relevant Training Qualification

Must possess knowledge of adult learning theory, instructional design and effective training methodologies Computer literacy (MS Office, Visio, SAP, Internet).

Minimum of 5 years' experience in a pharmaceutical manufacturing or quality assurance environment, with working knowledge of cGMP, pharmaceutical facilities, processes, equipment and systems.

At least 2 years' experience in a Training role

Post Basic PMA preferred

#### Key Performance Areas

#### Hiring organization

MJM Recruitment

#### Employment Type

Full-time

#### Beginning of employment

30 June 2023

#### Duration of employment

Full Time

#### Job Location

Durban

#### Date posted

June 14, 2023

#### Valid through

30.06.2023

## **Implementation and maintenance of competency-based cGMP training system that meets business and regulatory requirements**

Design a framework for implementation and maintenance of a competency-based cGMP training program at our client.

Identify cGMP training needs in Manufacturing (Operational departments) and other areas through detailed task analysis, appraisals and consultations.

Collaborate with the CAPA Officer, Internal Auditor and compliance team to identify cGMP gaps and design training accordingly.

Collaborate with subject matter experts to prepare and update training modules and materials for cGMP competencies.

Ensure that the cGMP training matrix for each department is appropriate and adequate and in line with the departmental functions.

Develop an appropriate cGMP module for induction of new staff

Provide guidance and inputs to managers and document compilers when drafting cGMP competency assessment questionnaires.

Keep up to date with developments and methodologies in workplace learning and training by reading relevant journals, standards and guidelines, going to meetings and attending relevant courses.

Understand and apply e-learning techniques, and where relevant, be involved in the creation and/or delivery of e-learning packages.

## **Execution of Training related Administrative requirements independently and in conjunction with relevant stakeholders where required.**

Amend and revise programmes and training content as necessary, in order to adapt to changes occurring in the work and regulatory environment.

Consult and collaborate with department supervisors and managers to devise an appropriate training schedule that meets the training requirement with minimal impact to routine operations.

Collaborate with the Learning, Development and Performance Management Division to schedule training events and to ensure personnel training records are up to date.

Collaborate with the qualified trainers to execute cGMP training in line with the set schedule. Provide or facilitate training in conjunction with the qualified trainers.

Monitor and review the progress of trainees using assessment tools relevant to each of the competencies.

Follow up with personnel in case assessments were not successfully completed.

Manage the competency assessment program, using tools such as Skillogical.

Manage the training records, in line with current NBI practice and in collaboration

with the Learning and Development Team.

Maintain Training Curricula and training records in an inspection ready state.

Evaluate effectiveness of GMP training

Provide statistics and frequent reports on cGMP training and the levels of competency, as inputs to quarterly and annual quality management review meetings.

Maintain applicable administration procedures, policies and reports to ensure compliance with process and regulatory requirements.

### **Quality Assurance General Support**

Promote and execute the Quality Policy throughout our client.

Promote cGMP Training throughout our client.

Attend and participate in routine meetings as required.

Participate in Quality and GMP initiatives.

Training of QA systems

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