

Dir. Global Quality – Specialized Training

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Company: SUN PHARMA

Location: vadodara

Category: other-general

Job Description

POSITION SUMMARY

Direct the Global Quality Specialized Training program, ensuring a new portfolio of training offerings are offered to the Sun Global network. (i.e. Investigator Qualifications, APQR/CPV, statistical product evaluation, 6S inspection readiness, QP forums, etc.).

The incumbent will assure individual compliance with all applicable regulatory requirements, GxP's, including Sun Pharma's Global policies, standards, standard operating procedures, Learning Management Systems, Document Management Systems, etc.

Key responsibilities:

Create specialized training and qualification programs, and then maintain those training offerings are periodically updated to align with industry standards, and comply with regulatory requirements.

Collaborate with cross-functional teams to identify and address training needs based on site audits, investigations and quality incidents within the Sun Pharma network.

Develop, implement and monitor a comprehensive investigation/CAPA qualification training program for employees involved in quality and compliance activities.

Develop new Quality specialized training. (Statistical product evaluation training programs, APQR/CPV, 6S Inspection Readiness, Qualified professional (QP) / Batch certification continuous education forums, etc.)

Training delivery, project management and Global roll-out schedule for all new Quality specialized training programs.

Liaison with both Human Resources and Quality Informational Technology departments for implementation and institutionalization of Specialized Training programs.

Author, communicate and deliver executive presentations on all specialized training and qualification programs.

MINIMUM EDUCATION/EXPERIENCE REQUIREMENTS

Health Science, Pharmacy or Industrial Engineer Graduate or Equivalent

15 years Pharmacy industry experience

REQUIRED SUCCESS ATTRIBUTE

Knowledge of GxP's, cGMP and other regulatory requirements.

ICH, and health authority regulations governing Quality investigations, CAPA, APQR & CPV

Technical report writing

Adult education learning models

Training Development

Training Delivery (class room & virtual)

Project management

Time management

Customer/Site service orientation

Secondary Success Attributes

Information Technology Learning Management Systems (LMS)

People Connect

Attention to detail

Business traveler

Effective Communication from operator to executive levels

Roles

Additional responsibilities can be assigned as required.

WORKING ENVIRONMENT/PHYSICAL REQUIREMENTS

Incumbent performs work assignments in both normal office and non-aseptic manufacturing/packaging environments. Moderate to loud noise level is common in production rooms. The incumbent must be able to comply with the gowning requirements for entry into controlled non-aseptic manufacturing areas, and wear personal protective equipment as required.

DELEGATION OF RESPONSIBILITY

In the absence of job holder, delegation of responsibility will be as follows:

Upward Delegation – Strategic corporate responsibilities to higher level

Downward Delegation – Site Operational responsibilities to indirect project reports or similar peer job roles

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