**APARNA KOTHARE**

Name : Aparna Kothare Tel No.: 91 9892064523

Address : 308, Aradhana 76 Jakeria Road Res No.: 91 22 28822986

Malad (West) Mumbai: 400064

Email : [aparna.kothare@gmail.com](mailto:aparna.kothare@gmail.com)

: anukot@yahoo.com

**Career Objective**

Seeking a position to utilize my skills and abilities. To gain valuable experience in a professional organization, which offer ample of scope for growth, development & which also fosters learning.

**Sr. Quality Assurance Auditor: Quality Assurance**

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1. ISO 9001:2008 Lead Auditor
2. M.Sc in Inorganic Chemistry with about 6 years experience in Quality Assurance & a total of 10 years experience in Analytical Laboratory. Good working knowledge of the Good Laboratory Practices, relevant Regulatory requirements & also on Clinical Research processes & Good Clinical Practices. Capable of working independently but also can work effectively in a team.

# PROFESSIONAL EXPERIENCE

**Glenmark Generics Ltd Apr 2005 - Present**

## Sr. Quality Assurance Auditor

Currently overseeing all aspects of the Quality Assurance systems which include the following:

* Manage the development, organization, control and monitoring of Quality Assurance systems related to all Bioanalytical procedures including internal systems and personnel audits.
* Provide training to team members on various aspects of audit techniques
* Working as a Training coordinator for the Bio-analytical department staff.
* Induction and training of new employees and ongoing training of SOP’s and GLP for the existing staff.
* Provide Management with the evaluations of non-compliances. Recommend, implement & participate in Quality Improvement initiatives.
* To support Quality Assurance during regulatory inspection/ audit
* Develop Audit Plans and participate in audit analysis and presentation of significant findings.
* Conduct internal system audits and external vendor audits for the purpose of assessing Regulatory Compliance in the area of Good Laboratory Practice and relevant regulatory requirements
* Audits of project documentation, in-process phase, study reports and data management.
* Preparation and review of Standard Operating Procedures of Quality Assurance and Bioanalytical department.
* Worked for US FDA/EU/DCGI/ANVISA Inspections
* Manage Document Control for SOPs, forms, log-books etc.
* Inventory & Archive of Study related data.
* Audit of Bioanalytical Method Validations & review of the Method Validation reports.
* Audits of Instrument Validations, their dockets and routine Calibration verifications.
* Audits of Calibration Records of Instruments & Equipments used in the department.
* Audit of Clinical study report.
* Review of WinNonlin concentration data from Statistical department with time point deviation and randomization and treatment.
* Review of statistical output and its compliance with acceptance criteria
* Preparation & Updation of Quality Manual & of Site Master File.

**S. H. Kelkar Company Mumbai**

Senior Analyst – Analytical department

Worked in the Analytical department of the company in the following areas:

* Analysis of finished products.
* Analysis of raw materials.
* Worked on instruments such as GC/HPLC for analysis of the products.
* Worked on the validation of instruments.

**Ador Welding Ltd. Mumbai**

R &D Chemist – R & D department

* Interface with R & D & Production department.
* Worked on the ISO related documentation

**Duphar Interfran Ltd. Mumbai**

Chemist: Analytical department

Qualitative & Quantitative analysis of product using instruments & methods like:

* UV/Vis spectrophotometer
* HPLC
* Polarimeter
* Melting point apparatus
* Karl-fisher titrator
* Analysis of finished products.
* Analysis of raw materials.

**Merind India Ltd. Mumbai**

Analyst: R& D department

* Analysis of finished products.
* Analysis of raw materials
* Handled instruments like HPLC/Karl Fisher/TLC/Dissolution tester etc

**Areas of Interest:**

Quality Assurance, Auditing, Documentation Management & Monitoring

**Extracurricular Activities:**

Interested in dance & music, reading books

**Educational Qualification:**

### ISO 9001:2008 Lead Auditor (IRCA certified training course. Certificate No.: 6118)

### Masters Degree (M.Sc) in ‘Inorganic Chemistry’

### Mumbai University

* Diploma in Industrial Analytical Chemistry through Ruia college Mumbai

**IT skills:**

Diploma in Computers from NIIT

**Personal Vitae:**

Permanent Address : 308 Aradhana, 76 Jakeria Road, Malad (West) Mumbai: 400064

Date of Birth : 15th May, 1975

Sex : Female

Marital Status : Married

Email : [aparna.kothare@gmail.com](mailto:aparna.kothare@gmail.com)

: anukot@yahoo.com

#### Training:

* Training on ‘Current FDA Inspection trends for Bio-analytical Laboratory performing Bio-availability/ Bio-equivalence studies’ presented by Carl Chancey at Glenmark Research Centre.
* Attended Workshop on ‘Auditing B.A.B.E’ organized by Pinnacle Healthcare at The Orchid Hotel, Mumbai.
* Training on ‘Use of Watson LIMS in Bio-analytical Laboratory’ conducted by Joel Usansky at Glenmark Research Centre.
* Attended APA-India Seminar organized by The Boston Society USA at The Novotel Hotel Hyderabad.
* Training received on ‘Dangerous Good Awareness with concentration on preparing, handling and transporting Infectious substances by air’ conducted by World Courier Pvt. Ltd.