

CAREER OBJECTIVE

5.5 years experiences in Quality Assurance with knowledge on Quality Management System, New Process set up, Handling and Conducting Audits as per QMS and Value Added Services for Pharma & Non Pharma products. I am looking for a challenging position in an organization to utilize my strengths and abilities.

EXPERIENCE SUMMARY

- Certified as Lead Auditor (**ISO 9001:2015**), from BSI.
- Internal Auditor for **ISO 9001:2015, ISO 13485 and ISO 27001**.
- Having immense knowledge in the Model of a Process Based Quality Management System, the structure and content of **ISO9001:2015, ISO13485 and ISO27001:2013**.
- Good experience in handling the external and internal audits for ISO standard.
- Knowledge on the Plan, Do, Check, Act (PDCA) cycle.
- Knowledge on 7 QC Tools.
- RCA & CAPA analysis and Experience in Risk Management.

WORK EXPERIENCE

1. DHL SUPPLY CHAIN INDIA PVT LTD

DURATION: July 2018 to till date

Role: Quality Specialist and Business Excellence.

Description: Assist in the development and maintenance of the quality systems with clients, DHL healthcare and other operations to ensure that all activities in the warehouse are carried out according to approved sops and regulatory guidelines (GMP, GDP, and ISO 13485)

Roles and Responsibilities:

- Preparation, Monitoring and Implementation of SOPs and formats.
- Investigation, Handling & timely closure of complaints, Deviations, Change control, CAPA and Non-Conformances.
- Review and up gradation of site documents/Sops as per the regulatory/customer requirements.
- Coordinate with customer or Key Account Management and plan the priorities of VAS and dispatch
- Planning the team for labeling according to labels and shipment availability
- To ensure the labels Printed onsite and issue the labels to floor with proper record.
- To perform supplier evaluation.
- Monitor and review Equipment qualifications and area qualification (Temperature Mapping).
- Ensure timely calibration of temperature monitoring instruments. Maintaining and updating yearly calibration schedule.
- Ensuring trained status of personnel involved in applicable product related activities.
- Day to day monitoring of activities applicable to process quality.
- Support operations and QA management in the preparation and review of relevant procedures, work instructions or quality documentation
- Execution of Internal Audit and Support to External Audit
- Support the follow-up and closure of audit issues in timely manner.
- Ensure DHL meets the requirements in compliance with client standards and quality

- Agreements and Regulatory Norms.
- Ensure site functions such as Pest control, preventive maintenance, cleaning are being effectively managed by site management-escalation of issue where necessary.
- Support calibration and validation schedule for all cold chain transportation, Including Transport study with gel coolants and dry ice.

2. PAREKH INTERGRATED SERVICES

DURATION: July 2016 to July 2018

Role: Quality Executive

Description: Involved in the internal auditing service for the standards ISO 13485 and ISO 9001:2015.

Roles and Responsibilities:

- Involved in Implementation and documentation work for ISO 13485 and ISO 9001:2015 standards.
- Manage implementation of Goals, Objectives, policies, procedures and systems pertaining to the quality assurance and regulatory function of the company.
- Conduct internal audit at every month at all the branches in south India.
- Act as Management Representative in external audit conducted by Client.
- Preparing SOP and Work Instruction for the QMS Processes.
- Preparing CAPA Plan for the External Audit.
- Monitoring the temperature data in all the branches in south India, in-case of temperature excursion raise an NC and report to top management.
- Responsible for documentation related to Quality System guidelines.
- Implement, communicate and maintain a quality plan to bring the company's Quality Systems and policies into compliance with quality system requirements.
- Monitor activities to ensure compliance with quality measures.
- Gather, analyze and manage quality related data.

3. INTEGRATED ASSESSMENT SERVICES (IAS)

Duration: Apr2016 to July 2016

Role: Quality Coordinator

Description: Involved in the external auditing services for the standards ISO 9001:2008 and ISO 9001:2015 and CE marking.

Roles and Responsibilities:

- Involved in the initial documentation review and initializing visit to the company, once the application is accepted
- Conduct internal audit on request basis by the organization.
- Propose corrective actions based on the standards implemented (ISO 9001:2008 and ISO 9001:2015 and CE marking) and confirm the certification audit date.
- Support in the closing of NC's and provide recommendations for the standard implementation

4. JBM AUTO SYSTEMS PVT LTD

Duration: Jul 2014 to Sep 2015

Role: Quality Control Engineer

Description: All the parts manufactured for Ford cars should pass the quality check in press shop so that it will be moved to the next level of production without any fault.

Roles & Responsibility:

- Checking the waveness, thinning and crack in the parts delivered by production department.
- Analyzing the cause for the fault, if any like tolerance, pressure and dye of the material.
- Supporting the internal and external audit by preparing the required documents
- Involved in root cause analysis discussions, if a non-confirmative Quality report is raised by client.
- Took part in the corrective and preventive measures taken with respect to the QR raised.
- Maintained all defect record in defect tracking tool and hence ensured the defect related communication to next shift employees

EDUCATIONAL QUALIFICATIONS

Examination	School/college	Board/University	Year of Passing	%
B.Tech (Automobile)	SRM Engineering College, Chennai	SRM University	2014	72%
Diploma (Automobile)	SRM Polytechnic College, Chennai	DOTe	2011	86%
S.S.L.C.	Jawahar Matriculation Hr Sec School, Neyveli	Matriculation	2008	78%

Declaration:

I hereby, declare that the above-mentioned information is correct up to my knowledge and I bear responsibility for the correctness of the above-mentioned.

Place: Chennai

Date:

(ARUNRAJ R)