TO
The Hiring Manager,

Subject**: Requisition for the placement in your Quality Assurance and CSV Regulatory Compliance department -in your esteemed organization.**

Qualifications & Experience: **IRCA- ISO Trained & Certified Lead Auditor ISO 9001:2015 ,27001:2013**

Master degree in Organic Chemistry and Post-Graduation in Quality Assurance and International Regulatory affairs (Certification Course) and having ~ 11 Years Experience in ITCSV QA , Audits and Compliance, documentation, GxP, 21 CFR Part -11, Agile Methodologies, GAMP-5, Annex-11, Data Management, Internal ,External audits, Vendor assessment audits, SDLC knowledge IT & Pharmaceutical Quality systems Compliance and leading the team as a QA Manager - Compliance have experience in dealing with FDA (Food & Drug Administration), Knowledge of local (State FDA, CDSCO, DCGI, ICH, USFDA, EMA) regulatory guidelines, WHO, ISO, NPCB National pharmaceutical Control Bureau Ministry of Health Malaysia (NPCB /NPRA) at Malaysia. &Several Customers Audits (Internal & External).

Dear Sir/ madam,

As a QA documentation, conscious personality from June 2010 to till now, good experience in pharmaceutical Bulk Drug Companies like Navitas, Dr. Reddys Laboratories, Apotex Inc, Pfizer , Symbiotica Specialty Ingredients as Asst.Manager Audits and Compliance at Malaysia and **Head QA & Compliance** at Lake Bangalore Location India and currently working in Navitas as **Quality Manager** . I can contribute effectively to your organization.

Currently Iam leading the team as a Quality Manager working in key areas like Quality Management Systems, CSV-QA , Audits and Compliance, documentation, GxP, 21 CFR Part -11 assesments ,Data Management, Internal ,External audits, Vendor assessment audits, SDLC , Handled projects from various clients from diverse industry domains viz., Pharmaceuticals, CROs, Life Sciences, Clinical Research, pharmacovigilance domain and drug safety applications – Argus & other regulatory service providers, etc. & Monitoring the Compliance activities and responsible for the effective and efficient selection, qualification and quality management of IT suppliers, indirect management of the supplier quality managers and communication and escalation of major issues to the management and Responsible for Internal and External Compliance Requirements (e.g. ISO 9K ,27K, GAMP5, US FDA, 21CFR PART -11) and PICs Guidelines .

I have experience in handling GxP documents, reviewing of VMP, Risk Matrix by handling FMEA tool, Validation Protocols (DQ,IQ,OQ,PQ), URS, SRS,DS,CS, Release audits, Project closure audits effective and efficient selection, qualification and quality management of CSV, GAMP-5, IT Compliance, GMP suppliers, Audits & Compliance, Manufacturing, documentation activities and handling tools like DMS,TMS, Compliance Management tool, ERP, SAP etc. Product Validations, Continued Process Verification , Quality Risk Analysis, Deviations Change control activities, reviewing and approving of Validation and Qualification protocols and leading the Audits and also handling of regulatory audits, Worked at Green field Project having knowledge in loan licensing activities, exposure with DCGI for submission of new molecules and good exposures in implementing QMS , Manufacturing and CSV Audits and its Compliance activities.

I have adequate knowledge about cGMP, Agile Methodologies,Scrum Master activities ,GAMP-5, GxP, Standard like ISO9001 &IS0 27001 :Compliance activities and basic computer skills.

I would like to take up the responsibilities with sheer excellence and utmost dedication as well as ready to face the new challenges involved with in the job

I request you to view my particular profile go to the next pages to view my complete CV.

Hope I can get the opportunity to meet you during the interview.

Achievements in Previous Organisations:

1. Received a Award & Special reward from Managing Dirrector for implementing the QMS systems in various departments of lake enabling the company to face EU Regualtory Audit successfully(Inspection date : 18/09/2108-21/09/2018) @ Lake Chemicals Pvt.Ltd Bangalore.
2. Actively Performed Internal Audits Vigilance and Surveillance and faced USFDA without any major observations (USFDA- Inspected i.e.(11-09-2017-15-09-2017)@Malaysia.
3. Have done successfully Internal and External Audits (Visited China, Malaysia for Supplier and Contract Laboratories Audits and Make reports and CAPA)
4. Individually Monitored successfully responded Compliance Activities for customer Audits report in time and Compliance.

Sincerely,
Ayyappa. Vengalthuri

RESUME

Ayyappa Vengalthuri,
Door No : 5A, Sampangi Street,
New Perengalthur, Old GST Road,
Chennai, India -600063.

Email: ayyappa.chemistry@gmail.com,
Mobile No: +917893185972.

Career Objective:

Looking forward to pursue an environment which provides me opportunity to enhance my knowledge, experience in Audits and Compliance, documentation, having experience in GxP, 21 CFR Part -11, GAPM-5, Annex-11, Data Management, Internal ,External audits, Vendor assessment audits, SDLC knowledge and serve best to the company.

Professional Experience

- Presently working in Navitas Lifesciences as **Quality Manager,** Navitas is a dedicated life sciences company of TAKE Solutions, harnesses the combined knowledge and experience of three legacy companies-Ecron Acunova, Navitas, and Internet -to provide end-to-end services and solutions.
- **Previous Organization: -**
- Worked as **QA-Manager Compliance** at **Lake Chemicals Pvt.Ltd**. Lake Chemicals is an EU GMP Certified; API Manufacturing Facility located in Bangalore and is in manufacturing operation since 1992.
- Worked as **QA-Assistant Manager Audits & Compliance** at **SYMBIOTICA SPECIALITY INGREDIENTS SDN Bhd is the first USFDA inspected manufacturing company in Malaysia.** The company holding several CEPs from Europe and other countries in all over the world.
- Worked as a Quality Assurance Executive at **Pfizer India Ltd.** (Maharashtra). One of the World's premier biopharmaceuticals & **U.S.-based global pharmaceutical MNC Company).**
- Worked as a **Quality Assurance Executive at Alivira** (Joint Venture B/W Strides and Shasun)
- Worked as Assistant -II in **Apotex Pharma Chem. India Pvt. Ltd** Bangalore. (An advanced generic Canadian MNC company).
- Worked as Senior Executive in **Dr. Reddys Laboratories Ltd., A company which is one of the largest manufacturers of API and intermediates.**

Job Responsibilities: Working as a Quality Manager @ Navitas Lifesciences (June 2019 to till date)

- Manage site quality council meeting preparation and collate site quality metrics for reporting to site and corporate management.
- Ensuring all company policies, procedures, and work instructions are in compliance with GAMP5, 21CFR Part11 Assessment, ISO 9001:2015 & 27001:2013 requirements and ensure certifications/accreditations are maintained..
- Handling tools like QMS Management-Sharepoint, Compliance Management, DMS, TMS, Etc.
- Determining, negotiating and agreeing on in-house quality procedures, standards and specifications..
- Maintaining and improving quality by completing process, company, system, compliance, and surveillance audits; investigating customer complaints; collaborating with other members of management to develop continual improvement methods.
- Ensuring the personnel have received appropriate training and are assessed as competent to perform tasks.
- Preparing and implementing audit plans, monitoring quality objectives, delivery, productivity and customer-service standards; identifying and resolving problems (Quality issues).
- Collaborate with and train all teams to ensure client processes and validation goals are understood and followed/met.
- Review of validation lifecycle documentation including URS, FRS, DS, TM,VP, VSR, protocols (e.g. DQ,IQ, OQ, PQ), and test scripts (e.g. UAT, Regression Testing) ,RTM and support execution of validation testing and reviewing of Risk Assessments documents.
- Conducting quality and ISMS system compliance audits, Internal audits, Release Audits, Project closure audits.
- As a ISG member performing periodic IT systems reviews and assessments. Analyze IT and system related deviations/ incidents, propose corrective actions or issue resolutions.
- **Achievements in Current Organization :** As a Quality professional make sure the operational objectives by contributing information and analysis to strategic plans and reviews; preparing and completing action plans; implementing quality, delivery, productivity and customer-service standards; identifying and resolving problems; completing audits; determining system improvements; implementing changes as per the requirements.

Lake Chemicals Pvt.Ltd:- (From November 2017 to June 2019)-Head QA and Compliance)

- Manage site Quality council meeting preparation and collate site quality metrics for reporting to site and corporate management.
- Responsible to qualify, monitor and communicate with the existing and new suppliers to ensure that they are approved, certified and qualified in the approved vendor list of suppliers based on the plan.
- Responsible for Quality Risk Assessments for Process Validations, Qualifications and for new Equipments.
- Support the QC-team on computerized system audits to ensure compliant vendor/supplier management program and services.
- Review and QA approve various types of system validation and infrastructure qualification documentation, including but not limited to, Master Plans, User Requirements and Functional Requirements Specifications, Design Specifications, IQ, OQ, PQ, Traceability Matrix, Validation protocols and reports as per GAMP5 requirements.
- Prepare, co-ordinate, conduct walkthrough, Internal and Supplier Audits. As a Lead Auditor which assumes the responsibility of coordinating the efforts of a team of auditors and leading the audit process
- Participate in biannual or quarterly supplier meetings, provide expert support for continuous improvement and lead major investigations and resolution of issues with GMP suppliers.
- Participated on cross functional teams as the SME for CSV projects; including inquiries pertaining to the interpretation of FDA and other regulatory requirements for computer system validation.
- Participate and coordinate regulatory agency inspections and corporate audits. Assist to follow up all action plans and ensure effective regulatory commitment tracking to assure no overdue CAPA.
- Responsible to Monitor QMS systems (Deviations, Change Control, OOS, OOT & Risk Analysis).
- Responsible Compile and collate all information about the medicines marketed by the company in US and the EU markets.
- Responsible for the regulatory submissions & issues and provide solutions to keep assigned CAPA on time, while maintaining the highest quality agreement.
- Responsible for MDF review, Raw Material Specification, Packing Material Specification & Method of Analysis of products and with Executed records on daily basis.
- Communicate with Regulatory Affairs & Cross Functional departments to resolve query raised by Local authorities, customers and Regulatory authorities.
- Handling of Product Quality complaints from Customers. Coordinate with the cross functional units for investigation and preparing the complaint feedback report within stipulated timelines.

Worked as QA-Assistant Manager Audits & Compliance at SYMBIOTICA SPECIALITY INGREDIENTS SDN Bhd is the first USFDA inspected API manufacturing company in Malaysia (From April 2016-2017 November)

- Assist to General Manger- Higher management with Product Compliance & disposition activities as required & improvement plan to top management related to the product quality and process
- Responsible for Supplier Qualification as per the Audit Schedule and make sure the compliance status
- Perform gap analysis of validation documentation, systems and practices. Communicate identified gaps including recommending and implementing corrective actions and improvements.
- Actively Performed Internal Audits Vigilance and Surveillance and faced USFDA without any Major Observations (USFDA- Inspected i.e.(11-09-2017-15-09-2017) @Malaysia.
- Responsible for Internal Audits and Compliance activities as per GAMP5 requirements..
- Maintaining the Validated state of the system, post GO-Live
- Regulatory audit compliance, implementation of QMS systems, Complaint Handling, Validations, Training and cGMP compliance.
- Develops and evaluates quality processes and system standards to ensure compliance with company standards and regulatory requirements
- Participates on cross functional teams as the SME for CSV projects; including inquiries pertaining to the interpretation of FDA and other regulatory requirements for computer system validation.
- Review of validation lifecycle documentation including URS, FRS, DS, TM,VP, VSR, protocols (e.g. DQ,IQ, OQ, PQ), and test scripts (e.g. UAT, Regression Testing) ,RTM and support execution of validation testing and reviewing of Risk Assessments documents as per GAMP5 requirements..
- Responsible Compile and collate all information about the medicines marketed by the company in US and the EU.
- Responsible for Handling of Risk assesments by using FMEA Tools and taking proper recommendation and trainings

Worked as a Quality Assurance Executive at Pfizer India Ltd. (Maharashtra). One of the World's premier biopharmaceuticals & U.S.-based global pharmaceutical MNC Company (From April 2015-April 2016)

- End user in SCADA/PLC/HMI operation in shop floors as per GAMP5 requirements at Sterile operations.
- Participates on cross functional teams as the SME for CSV projects; including inquiries pertaining to the interpretation of FDA and other regulatory requirements for computer system validation as per 21CFR part requirements..
- Responsible for preparation and review of Quality Assurance SOPs.
- Responsible for handling of Deviation, Incidents and Investigations.
- Responsible for handling of change controls.
- Responsible for handling of CAPA.
- Management of Regulatory inspections and customer audits. Review and response of CAPAs for the observations.
- Responsible for Vendor Qualification and Vendor Evaluations.
- Responsible for conducting of Internal Audits (conducting of internal audit, updation of corrective and preventive actions etc.)
- Responsible for external audits preparation and compliance.
- Responsible for handling of Market Complaints & related investigations.
- Responsible to attend the training programs & conducting SOP and GMP trainings.
- Handling of Quality Risk management risk assessments and impact assessments.
- Handling of Returned products.

Worked as a Quality Assurance Executive at Alivira- (Joint Venture B/W Strides and Shasun) Green field Project From (July2014-April 2015)

- Responsible for obtain Technical documents like Manufacturing / Product licenses, GMP Certificates, Stability Data, Finished Product COAs, Process & Analytical Raw Data from existing manufacturing sites. -Loan Licensing Activities -Worked for Green Field Project.
- Reviewing the equipment occupancy and costing of the new products
- End user in SCADA/PLC/HMI operation in shop floors as per GAMP5 requirements.
- Review of new BMR as per the tech-Transfer & Scale up BMR and
- Responsible for preparation and review of Validation Protocol and Reports.
- Implementation of QMS systems at new Site as per the current guide lines.
- Handling ERP Quality Management systems.
- Train the team and ensure the Validations and Manufacturing activities.
- Responsible for Equipment Qualifications and Process Validations New Project

Worked as Assistant -II in Apotex Pharma Chem. India Pvt. Ltd Bangalore. (An advanced generic Canadian MNC company (From August 2012- June2014)

- Responsible for preparation Final Master BMR based on MMR, & review Finished Product Specification, Raw Material Specification, Packing Material Specification & Method of Analysis of products and Executed records on daily basis.
- Preparation of Change control and Deviations from manufacturing compliance.
- TrackWise quality management system (QMS) software tool was used to improve product quality, achieve regulatory compliance, and reduce risk
- Reviewed and approved the test protocols and all the supporting documents are according to the requirements and standards specified.
- Indexed Documents using appropriate keywords or Tags and stored Electronic Documents in the EDMS
- Provide input and decision making for quality on the shop floor with regard to manufacturing and deviations. To review Events, change control and CAPA and provide input.

Worked as Senior Executive in Dr. Reddys Laboratories Ltd., A company (From June -2010 July 2012)

- Ensured and tracked the deadlines for all the CAPAs and change management documents and made sure before the implementation.
- TrackWise quality management system (QMS) software tool was used to improve product quality, achieve regulatory compliance, and reduce risk
- Responsible for review the BMRs and Validation BMRs and cleaning records within the time line.
- Responsible for Process validations and monitoring the critical Process parameters
- Create and maintain all validation documents ensuring compliance with internal company standards and health authority regulatory requirements.
- Maintaining product performance and quality for existing products by leading and assisting with issues relating to CAPA's, non-conformities, customer complaints and manufacturing processes.

Audit Exposure:

- Exposure in the following Regulatory & IT inspections
- **VENDOR AUDITS:** Audits were performed for Key starting material and starting materials vendors in China, & Malaysia.
- **CUSTOMER AUDITS:** Faced numerous customer audits notably Pfizer, Novartis, Torrent, GSK, Teva, Sanofi Avantis, SGS Pharma, Roading pharma, Mylan, STADA, FAES, Glenmark, & Many more

Strengths:

- Knowledge in QMS, ISMS ,SDLC & 9K & 27K certified from IRCA Lead Auditor
- Having knowledge in GxP, CSV, GAMP, sterile QA- manufacturing activities -Worked in Sterile QA - Pfizer and handled tools like DMS, TRMS,Compliance Management tool as a end user.
- Supplier Audits- Participate in biannual or quarterly supplier meetings experience International exposure (China, Singapore, Malaysia & India)
- Show a strong business mindset as per the management Requirements
- Experience in leading people and multi-cultural project team.
- Faced USFDA, WHO, ISO Audits - successfully 2 Times for Sterile and API facilities
- Faced numerous Customer Audits notably Pfizer, Novartis, Torrent, GSK, Teva, Sanofi Avantis, SGS Pharma, Roading pharma, Mylan, STADA, FAES, Glenmark, & many more.

Professional Education: -

- Post-Graduation diploma in **Quality Assurance and International Regulatory Affairs** from Annamalai University (64%).
- **Msc.Organic Chemistry** from Sri Venkateswara University First **Class.**

Academic Qualification: -

- B.Sc. (**Biotechnology, Chemistry and Biochemistry**) from Sri Venkateswara University with **DISTINCTION-78%**
- Intermediate (**Botany, Zoology and Chemistry**) from Board of Intermediate Education with FIRST Class
- SSC. Board of Secondary Education with Ist Class.

Presentations and workshops:

- Presented a Paper on **Recent Trends in Synthetic Organic Chemistry** organized by SV. University 29 & 30 March 2010.
- Presented paper on **International Symposium on Emerging Trends in biochemical and Nano Biotechnology** organised by Nagarjuna University 19-21, 2009.
- Participated on National Work shop on Bio fertilizers organised by SV. University, 30th -31st August, 2009.
- Participated on **National Work Shop on Molecular Techniques in Microbiology and Plant Pathology**.
- Participated and awarded certificate in the **GREEN Olympiad sponsored by the Ministry of Environments** and forests, Government of India at 9th standard Higher School -(2004).

Achievements:

- **ISO9001:2015** Certified **QMS -Lead Auditor from IRCA (**International Register of Certificated Auditors)- Trained, Successfully Qualified and Implemented.
- Awarded for best **Paper Presentation in 2nd AP. SCIENCE CONGRESS** Organized by SV. University.14th -16th, 2009
- Faced and successfully completed USFDA without 483 in Sep-2011 at Dr Reddys laboratories CTO Unit-VI.
- Holds a recognized Lead Auditor (Vendor-Audits) & Internal Auditor certification from Symbiotica Malaysia.-Conducted Several Supplier Audits.

Training & Certification (s) completed on:

- ✓ ISO 9001:2015 QMS Certified Lead Auditor from IRCA(Intertek Bangalore)
- ✓ ISO 27001:2013 ISMS Certified Lead Auditor from IRCA(Intertek Bangalore)
- ✓ Trained and certified from USP - Computer System Validations and DI.
- ✓ Trained and certified from USP education- Auditing Techniques.
- ✓ Trained and certified from USP education- QRM,Quality Management Systems,RCA,Qualifications etc.
- ✓ Trained and certified on Quality and Product Management,Risk Management,World compliance,Investigaions -CDER FDA
- ✓ Trained & certified in Manufacturing Quality assurance activities by Mr. Kevin Hawes: Pfizer Director Corporate Quality operation unit from PFIZER Inc. Lake forest (USA).
- ✓ Trained and Qualified in Train the Trainers program at Pfizer.
- ✓ Successfully completed the blue book international training course & Pfizer Integrity pledge from the LRN legal compliance and ethics centre on October 10th 2015 at Pfizer.
- ✓ Handling of investigations by Mr. Ramesh Kumar pillai, Head-RA.
- ✓ ICH guide lines by A.G. Raghu, Co-chairman- Local Scientific Committee, IPC.
- ✓ First Aid training attended & awarded the certificate by Indian Red Cross Society.
- ✓ Participated on Regulatory updates & Data Integrity Trainings conducted by Waters Compliance.

Below topics by Dr. Eric Richmond, Senior Director, Lachman Consultants, NY. (From US)

- ✓ Computer System Validations and DI
- ✓ Validations & 21CFR, part 11 CGMP /DI/ GDP/ Quality Guide Lines (Q1-Q12)
- ✓ Handling of Investigations (Case studies)
- ✓ Handling of Regulatory Inspections (Case studies)
- ✓ Handling of CAPA (Case studies)

Computer skills:

- ➢ MS Office word, Excel, Power point Presentation Skills,
- ➢ Hands on experience in handling tools like Track wise QMS,SAP,ERP, LIMS, DMS,TMS,Change management tool, Compliance Management tool for Deviations, Quality issues , CAPA, Audits and compliance, Adobe Acrobat, etc.

Personal Traits :

- ➢ QMS
- ➢ Six sigma Black Belt Certification.
- ➢ Good Interpersonal Relations with teams
- ➢ Metrics Collection and usage
- ➢ Good comprehension , analytical and presentation skills
- ➢ Proactive /Takes Initiatives
- ➢ Postive Attitude.

Declaration:

I hereby declare that the information furnished above is true and correct to the best of knowledge and belief.

Place: **Chennai.** **(Ayyappa. Vengalthuri)**