**KIRAN KUMAR AALAPATI**

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**QUALITY ASSURANCE AND REGULATORY AFFAIRS PROFESSIONAL**

*Aspire to take up targeting challenging assignments in Quality Assurance and Regulatory Affairs domain across Clinical Research and Pharmaceutical Industry.*



**PROFILE**

* Diligent & result-oriented **Quality Assurance and Regulatory Affairs Professional** with over 10 **years of experience** **, 7+ years** in Clinical, Bioanalytical Quality Assurance, Regulatory Affairs (audited more than 500 Clinical Studies) and 1+ year in Diagnostics.
* Proficient in **Regulatory affairs, DCGI and CBN (Controlled substances) filings, ICH E3/eCTD Report Review and Compilation, Implementation of QMS, Instrument Qualifications/Validations, Software validations, imparting training to team on regulatory requirements and critical review of documents for regulatory compliance.**
* All-round competencies in quality assurance domain including all fine aspects covering - **GCP, GLP,** **Instrument** **Qualifications & Validations, Software Validations, ISO9001:2008, ISO15189, QMS internal Audits, Documentation, In-Process Quality Assurance and Retrospective Quality Audits.**
* Well versed with **Change Management, CAPA, Laboratory Investigations and Deviation Management procedures.**
* Well versed with USFDA, EMEA, CDSCO (DCGI), ANVISA, Turkey MoH, BPFK Malaysia and other applicable **BA/BE, Clinical Trial regulatory** requirements.
* Extensive experience and **proficiency in conducting quality audits**, customer feedback analysis and continual implementation of new quality systems, quality planning for enhancing regulatory compliance and client satisfaction.
* Excellent **Team player** with the ability to handle cross functional teams spreading across multiple assignments.

**Core Competencies:**

*Quality Assurance  Regulatory affairs  DCGI Filings  CBN Filings  eCTD/ICH E3 Report submissions  Dossier submissions  Qualifications/Validations  CAPA  Quality Management System  Document Management  Change Control Management  Deviation Management  Training Project Management  BA/BE Operations* 

**PROFESSIONAL EXPERIENCE**

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **S No** | **Organization** | **Experience** | **Tenure** | | **Designation** | **Work Profile** | |
| 1. | RA Chem Pharma Ltd, Clinical Research & Biosciences Division | 30th May, 2013 – Till date | 8+ Months | | Head Quality Assurance and Regulatory Affairs | In-Charge for overall Quality Assurance and Regulatory Affairs activities | |
| 2. | Sapthagiri Clintrac  Private Limited (GD Group of Companies) | Nov 2012-10th May,2013 | 6 Months | | Senior Manager Quality Assurance and Regulatory Affairs | In-charge for overall Quality Assurance and regulatory affairs activities and Implementation of QMS | |
| 3. | Actimus Biosciences Private Limited | Sep 2011- Oct 2012 | 1 Year 2 Months | | Assistant General  Manager | In-charge for overall technical operations and study director for BA/BE Studies executed | |
| 4. | Actimus Biosciences Private Limited | Aug 2009-Aug 2011 | 2 Years 1 Month | | Assistant Manager - QA(Head QA directly reporting to CEO/CMD) | In-charge for overall Quality Assurance and regulatory affairs activities and Implementation of QMS | |
| 5. | Actimus Biosciences Private Limited | Jun 2007- Jul 2009 | 2 Years 2 Months | | Senior Executive - QA | Group leader for BA/BE QA Auditors and conducting | |
|  |  |  |  | |  | Quality Audits | |
| 6. | Actimus Biosciences Private Limited | July 2006 - May 2007 | 11 Months | | Quality Auditor | Study Documents review and Clinical Study audits | |
| 7. | Sri Sai Diagnostics | Nov 2004 - Jun 2006 | 1 Year 8 Months | Diagnostics In charge | | | In charge for overall diagnostics activities |
| 8. | Agriculture Department  State Govt of Andhra Pradesh | Jul 2003 - Oct 2004 | 1 Year 4 Months | Multipurpose Extension Officer | | | Implementation of State Govt. Policies related to agriculture in the rural areas |
| Total Experience | | | **10 Years 7+ Months** | | | | |

**RA CHEM PHARMA LIMITED, Clinical Research & BioSciences Division**

**Head Quality Assurance & Regulatory Affairs 30th May2013 - Till date**

* Heading the Quality Assurance & Regulatory Affairs department at CRBio.
* Develop and successfully implement strategic objectives for quality systems and regulatory submissions.
* Lead and guide the team of quality assurance and regulatory affairs personnel.
* Responsible for ensuring compliance with Good Clinical Practices, Good Laboratory Practices, SOPs/STPs and applicable national and international regulatory guidelines for the entire BA/BE Studies, executed in the organization.
* Responsible for coordination of all Regulatory Inspections and Customer Audits.
* Responsible for the conduct of periodic system, study specific, in process, retrospective audits and vendor evaluation audits.
* Responsible for review and approval of SOPs, Testing Procedures, IQ, OQ and PQ Documents and software validations.
* Review and Approve Study Protocols and Bioanalytical method validation reports
* Clinical study Report Compilation (ICH E3/eCTD module 5) including source data and other applicable study documents.
* Handling of Change Controls and investigation of deviations, customer complaints and implementing CAPA.
* Manage and control all Master documents (SOPs, Formats, STPs, Protocols, Study Reports, Qualification Documents etc.)
* Archival Management of the study documents and ensuring periodical data back up at the organization.
* Responsible for maintenance of master study schedules and master database of quality documents and audits/regulatory inspections.
* Responsible for conducting Internal QMS audits, organizing Quality review meetings and ensuring compliance with the ISO9001:2008 guidelines as applicable.
* Responsible to interpret and implement current regulatory requirements
* Ensuring Training of Employees on Standard Operating Procedures, GCP, GLP and applicable regulatory requirements.
* Coordinating with cross functional departments for smooth functioning of study activities.
* Responsible for reporting the Management time to time on the audit findings and quality aspects.

**SAPTHAGIRI CLINTRAC PRIVATE LIMITED**

**Senior Manager Quality Assurance & Regulatory Affairs Nov 2012 to10th May2013**

* Headed the Quality Assurance & Regulatory Affairs department at SCPL.
* Developed and implemented successfully strategic objectives for quality systems and regulatory submissions.
* Leaded and guided the team of quality assurance and regulatory affairs personnel.
* Responsible for ensuring compliance with Good Clinical Practices, Good Laboratory Practices, SOPs/STPs and applicable national and international regulatory guidelines for the entire BA/BE Studies, POC, Phase Trials executed in the organization.
* Responsible for coordination of all Regulatory Inspections and Customer Audits.
* Responsible for the conduct of periodic system, study specific, in process, retrospective audits and vendor evaluation audits.
* Responsible for review and approval of SOPs, Testing Procedures, IQ, OQ and PQ Documents and software validations.
* Developed and reviewed more than 200 CT, Clinical and QA/RA SOPs
* Clinical study Report Compilation (ICH E3/eCTD module 5) including source data and other applicable study documents.
* Responsible for preparation/review/screening/compilation/submission of all Regulatory filings to DCGI & Central Bureau of Narcotics for conduct of clinical studies (BE NOC, Import/Test license & Narcotics license).
* Responsible for maintenance of master study schedules and master database of quality documents and audits/regulatory inspections.
* Responsible to interpret and implement current regulatory requirements
* Ensuring Training of Employees on Standard Operating Procedures, GCP, GLP and applicable regulatory requirements.
* Coordinated with cross functional departments for smooth functioning of study activities.
* Responsible for reporting the Management time to time on the audit findings and quality aspects.

**ACTIMUS BIO**

**Assistant General Manager Sep 2011-Oct 2012**

* Served as In-charge of Technical operations for the entire BA/BE studies executed at the organization.
* Acted as Study Director for the entire BA/BE studies executed at Actimus.
* Ensured compliance of BA/BE Studies executed at Actimus Bio with GCP, GLP, USFDA, EMEA, ANVISA etc.
* Was accountable for Clinical, bio analytical, pharmacokinetic and statistical Operations as per laid down Standard operating procedures.
* Managed Regulatory filings to DCGI & Central Bureau of Narcotics for conducting the clinical studies (BE NOC, Test license & Narcotics license).
* Handled Project Management and was responsible for all Client and regulatory communications.
* Coordinated with all the Departments like Quality Assurance, Clinical Research, Bioanalytical, Diagnostics,

Pharmacokinetics and Biostatistics, Technical Support, Human Resources, Business Development and Finance for smooth functioning of the activities.

* Handled of client and regulatory audits.
* Acted as Deputy Management Representative for Quality Management System implementation
* Supervised scanning, compilation and submission of Study Reports to clients in eCTD and ICH E3 formats.
* Trained and updated the team members on regulatory updates and guidelines.
* Successfully planned all the projects executed and ensured the quality deliverables to clients as per the committed timelines and project plan.
* Organized manpower planning and ensured the availability of resources for BA/BE operations.

**ACTIMUS BIO**

**Career Growth in QA**

**Assistant Manager-QA (Head QA directly reporting to CEO/CMD) Aug 2009-Aug 2011**

**Senior Executive-QA Jun 2007-Jul 2009**

**Quality Auditor Jul 2006-May 2007**

* Led Quality Assurance operations at the organization.
* Designed and implemented QA Standard Operating procedures, quality management standards and applicable regulatory requirements.
* Supervised, managed and supported the quality assurance personnel.
* Deftly managed complete quality assurance operations in line with the requirements of Good Clinical Practices, Good Laboratory Practices, Actimus Bio SOPs/STPs and applicable regulatory guidelines.
* Handled Regulatory/customer audits and compliance.
* Coordinated with DCGI office/CBN Office/Customs and other regulatory authorities
* Prepared/reviewed/compiled/submitted all Regulatory filings to DCGI & Central Bureau of Narcotics for conduct of clinical studies (BE NOC, Import/Test license & Narcotics license).
* Maintained Records and Tracking Status of regulatory applications and Query Responses.
* Ensured QA Standard Operating procedures are up to date, was responsible for coordination and implementation of quality standards and applicable standard operating procedures through periodic system specific audits.
* Reviewed and Approved IQ, OQ and PQ Documents, Monitored Instrument/Equipment Qualifications and Validations.
* Ensured CFR Part 11 Compliance for all computer systems.
* Reviewed, monitored and approved Software validations.
* Was accountable for ensuring the Preventive Maintenance and Calibration of Instruments as per laid down procedure, availability of Calibration Schedules, Annual maintenance schedules, Instrument History cards etc. in place.
* Organized and ensured Quality Checks are in place for all the critical process
* Reviewed and approved Standard Operating Procedures and Standard Testing Procedures.
* Reviewed and Approved Study Protocols, Bioanalytical method validations, Clinical study Reports including source data and other applicable study documents.
* Ensured investigation is conducted and root cause is eliminated to meet specification, including quality attributes.
* Reviewed and Approved Change Controls.
* Conducted and supervised investigation of deviations, customer complaints and implemented CAPA.
* Conducted and organized Audits for ensuring compliance to policies and procedures: on paper vs. practice.
* Reviewed Quality Agreements and conducted periodical vendor audits.
* Managed and controlled all Master documents (SOPs, Formats, STPs, Protocols, Reports, Qualification Documents etc.)
* Maintained and managed master study schedules and master data base of quality documents and audits/regulatory inspections.
* Ensured timely backup of electronic data and document archival as per regulatory requirements.
* Supervised Document Archival Management
* Conducted Internal QMS audits, organized management review meetings and ensured compliance with the ISO9001:2008 and ISO15189 guidelines.
* Promoted Internal and External Training of Employees on Standard Operating Procedures, GCP, GLP and applicable regulatory requirements.
* Coordinated with cross functional departments for smooth functioning of the activities.
* Reported and updated Management time to time on the quality aspects.

**SRI SAI DIAGNOSTICS Nov 2004 -Jun 2006**

**Diagnostics Incharge**

* Established procedures for manual methods and trained staff on handling of instruments and also monitored Diagnostics sample analysis
* Involved in Review of diagnostic controls, Review and authorization of the results.
* Guided technicians on Instrument maintenance, calibrations & qualifications

**AGRICULTURE DEPARTMENT STATE GOVERNMENT OF ANDHRA PRADESH**

**Multi Purpose Extension Officer Jul 2003 - Oct 2004**

* Implemented agriculture policies in the villages
* Reported the data and assisted the divisional head in promoting the schemes
* Created the village development groups (Rythumitra) and trained them about the latest technologies in the field of agriculture
* Created awareness among the villagers regarding the bank subsidies and other welfare programmes

**Achievements**

* Successfully faced and cleared BPFK Malaysia Inspection.
* Successfully cleared numerous DCGI Audits
* Successfully implemented Quality Management System ISO 9001-2008 at Actimus Biosciences Private Limited.
* Successful in clearing the ISO15189 (NABL) Audit and obtaining NABL approval for Actimus Biosciences Private Limited.
* Successfully handled more than 50 customer/client, local and international third party audits
* Achieved DCGI and CBN approval for critical molecules
* Successfully obtained facility registration to Actimus from Drug Controller general of India, CDSCO
* Submitted more than 50 ANDA studies to USFDA and other regulatory bodies



**EDUCATIONAL CREDENTIALS**

**Industry Programme in Pharma Regulatory Affairs 2013** ~ Bioinformatics Institute of India, Noida, Uttar Pradesh

**Professional Diploma in Clinical Research 2013** ~ Catalyst Clinical Services Private Limited, Delhi

**MBA in Human Resources 2009 ~** Andhra University, Visakhapatnam, Andhra Pradesh

**MSc Biochemistry 2003 ~** Bharatidasan University, Tirchy, Tamilnadu

**BSc Microbiology, Genetics and Chemistry 2001 ~** Osmania University, Hyderabad Andhra Pradesh

**Computer Proficiency ~** Windows (98, 2000, XP, Vista), MS Word, MS PowerPoint, Adobe Acrobat, ESG, Web applications and LIMS

**Certifications**

* Good Clinical Practices(GCP)
* Good Laboratory Practices(GLP)
* ISO 9001:2008(QMS) & ISO15189(NABL)
* Received online certifications on various clinical research trainings from UMDNJ, OHRP, CDER (US FDA), Norton Training Institute, OHRS.
* Recipient of merit certificate for project on biodegradation of pharma effluents using microorganisms at Biology division IICT (Indian institute of chemical technology) Hyderabad

**Projects and Seminars Presented**

* Presented seminar on and submitted project report on Biodegradation of pharma effluents using microorganisms as a part of Master's degree at University
* Submitted project report on Performance Appraisal System In Actimus Biosciences Private Limited, Visakhapatnam to Andhra University as a part of Master's degree in Business Administration (MBA)



**PERSONAL DETAILS**

* Date of Birth **~ 06/12/1981**
* Languages Known **~ English, Hindi and Telugu**
* Father **~ A. Krishna Rao**
* Marital Status **~ Married**
* Nationality **~ Indian**
* Contact Address **~ Flat no. – 304 ,Sai Srinivasa Residency ,Sai Manik Nagar, Sangareddy , Medak Dist, AP 502001**



**References:** Available on Request