**ABBAREDDY SRIRAM REDDY**

H.No:15-204, Tirumala Nagar Colony

Near: MRO Building

Almas Guda Email: abbireddy2005@yahoo.co.in

Hyderabad. Mobile-+91-9603680854,7095197288 , 8500252997

**Career objective:**

Seeking senior position in the area of Quality assurance, where my managerial experience matches the organizational growth and strength.

**Career:**

17 Years of experience in, R&D, Production, Quality assurance and Regulatory affairs in different organizations.

**Academic back ground:**

* M.Sc chemistry through distance education.
* Bachelor of Science from Osmania University from 1988-1991
* Intermediate (Maths, Physics, and Chemistry) from Board of Intermediate education, Hyderabad in 1988.
* S.S.C from Board of Secondary Education, Hyderabad in 1986.

**Technical Skills:**

* + Post Graduate Diploma in computer applications.

**Exposure to Regulatory AUDITS:**

* Recently completed FDA audit in 2012(July 16-19, 2012) without any 483. Directly involved with the FDA auditor. (Mr. Khampommachanh).
* Completed TGA audit (May 21-23, 2012) during 2012 with two minor observations. Directly involved with the TGA auditor. (Mr. David Row bury)
* Completed KFDA audit (January 05-06, 2012) with three minor observations. Directly involved with the KFDA auditor. (Mr. Choi & Ms.Park).
* Total so far 3 TGA audits and 7 FDA audits are faced. Nearly 15 MNC customer audits are faced i.e. Ranbaxy, Wockhardt, Mylan, Pfizer, Poll Pharma, Sunpharma, Dr.Reddys, Arafarma, Teva etc………..
* Completed the CDSCO (Central Drug state control organization) EU “Written confirmation certificate” audit in January 2014
* Completed the COPP certification (WHO GMP) audit January 2014

**Professional Experience:**

***Current:***

**Organization :** M/s Srini Pharmaceuticals Limited

***[A joint venture company of Apotex pharmachem.Inc, Canada and USFDA, TGA, WHO & ISO certified Company]***

**Designation :** Head

**Department :** QA

**Duration :** From April: 2003 to Till Date

**Location :** Choutuppal, Nalgonda (DT)

***Previous:***

**Organization :** Dr.Reddys Laboratories Limited

***[USFDA, TGA, WHO & ISO Certified Company]***

**Designation :** Sr.Executive

**Department :** QA

**Duration :** From April: 1996 to 2003

**Location :** Unit-IV-Jeedimetla-Hyderabad

**Organization :** M/s SOL Pharmaceuticals Limited

**Designation :** Chemist

**Department :** Production

**Duration :** From April: 1995 to 1996

**Location :** Patancheru (Dist: Medak)

**Seminars/workshops attended:**

* Global challenges in Regulatory Affairs during 2011 in Hyderabad.
* Data integrity management by FDA Auditor Mr.Peterbacker.
* Seminor on lackhmen consultants.
* Several seminors conducted by various consultants.

**Job responsibilities:**

* Achieves quality assurance operational objectives by contributing information and analysis to strategic plans and reviews; preparing and completing action plans; implementing production, productivity, quality, and customer-service standards; identifying and resolving problems; completing audits; determining system improvements; implementing change.
* Investigate and record customer complaints regarding product performance, specifications, and reliability.
* Prepare for monthly summaries of quality issues for the technical support for the presentation to the senior management team.
* Monitor emerging trends regarding industry regulations to determine potential impacts on organizational processes.
* Review all regulatory agency submission materials to ensure timeliness, accuracy, comprehensiveness, or compliance with regulatory standards.
* Prepares quality documentation and reports by collecting, analyzing and summarizing information and trends including failed processes, stability studies, recalls, corrective actions and re-validations.
* Validates quality processes by establishing product specifications and quality attributes, measuring production; documenting evidence; determining operational and performance qualification; writing and updating quality assurance procedures.
* Approving changes that potentially impact intermediate or API quality. Providing supplier driven changes to the customer with supporting documentation before implementing the changes.
* Reviewing and approving validation and qualification protocols and reports. (Site master file, Process validation, cleaning validation, analytical method validation, equipment qualification, Facility qualification, validation of utility systems, DM water / purified water systems and HVAC. Handling commissioning and qualification of new projects.)
* Review and approval of stability study protocols, shelf life extension reports, deviation reports, annual product review reports and quality agreements.
* Making sure that quality related complaints, OOS/OOT and Returned goods are investigated and resolved. Also ensure implementing CAPA and follow-up of effectiveness of CAPA.
* Establishing a system to release or reject raw materials, intermediates, APIs, packaging materials.
* Audit and approval of intermediate and API contract manufacturers, contract testing laboratories and supplier/vendor qualification activities.