# OBJECTIVE:

# Seeking senior management position in Corporate Quality Assurance.

# *PERSONAL INFORMATION*

|  |  |
| --- | --- |
| Name | :A.V. Jayakumar |
| Date of birth | :15/05/1972 |
| Address for correspondence | :T-4, Disha Square, Sutgurni Chawk, Garkheda, Aurangabad, Maharashtra.  Cell: +91 9545511337 |
| E-mail | : jayakumarav1972@gmail.com |
| Religion | : Hindu(Nair) |
| Marital status | : Married |

### Experience

|  |  |  |
| --- | --- | --- |
| **Organization** | **Post Held** | **Duration** |
| Ajanta Pharma Limited | Sr. Vice President -Corporate Quality | Since May 2013 |
| Glenmark Pharmaceutical Limited | Cluster Head Quality | Oct 2012-May 2013 |
| Ajanta Pharma Limited | Associate Vice President –Corporate Quality | Dec 2006-Oct 2012 |
| USV LTD. | Manager QA/QC | May 2005 – Dec 2006 |
| Aurobindo Pharma Limited | Manager QC | Aug 2004- May 2005 |
| Cipla Ltd., Bangalore | Functional Head QC | Aug 1999- Aug 2004 |
| Torrent Ltd. | Executive QC | May 1994- Aug 1999 |

* Presently responsible for complete quality operations of Ajanta Pharma. Ajanta has five (5) formulation manufacturing sites and one (1) Active Pharmaceutical Ingredient manufacturing site. Besides this, responsible for all contract manufacturing quality operations for 35 manufacturing sites. These sites include sterile and non sterile manufacturing operations. Ajanta’s manufacturing sites have been approved by all stringent regulatory authorities such as USFDA, MHRA, ANVISA, WHO Pre-Q etc. Ajanta is coming up with two more manufacturing sites in Gujarat exclusively for the regulated markets. The sites will produce both sterile and non sterile pharmaceutical preparations.
* At Ajanta heading Corporate Quality function. Both QA and QC functions reports to Sr Vice President Corporate Quality. Implemented all required quality systems at Ajanta and the facilities undergone successful inspections from WHO Geneva, USFDA, ANVISA and UK MHRA. Implemented Laboratory Information Management System (LIMS), which is compliant to 21 CFR Part 11. Lot of automation introduced in the laboratory to avoid manual errors and to improve the quality standards. Approximately 800 staff directly or indirectly reports to the current position.
* My current senior team includes one Associate Vice President, one Sr General Manager, five General Managers, two Dy Genral Managers and four Asst. General Managers.
* Recently company rolled out SAP with integration to e-LIMS. This has minimized the concerns of data integrity in the entire operations as the equipment are connected directly to LIMS system to avoid manual intervention on data handling.

**Current Job responsibilities are as below:**

|  |
| --- |
| 1. To participate in designing, developing, approving and implementation of the quality systems at all Ajanta manufacturing sites in India. |
| 1. To oversee that quality system, procedures, validation master plan, site master file, quality manual and such documents are maintained in current state and implemented effectively. |
| 1. Monitor vendor audit schedule for starting material and packaging material vendors; and external testing laboratories. |
| 1. Perform vendor audits for starting material and packaging material vendors; external testing laboratories; contract manufacturing sites and other service providers. |
| 1. Participate in self inspection and implementation of its observations. |
| 1. Provide training on cGMP and Quality Systems. 2. Responsible for all remediation and compliance requirements. |
| 1. Participate in the investigation of complaint, deviation, change control, non conformance, incidence, returned goods, product recall, vendor audit, external testing laboratories audit, contract manufacturing sites audit; its impact assessments; approval of its reports and monitor the implementation of Corrective and Preventive Action (CAPA) |
| 1. To oversee the stability program at manufacturing sites. |
| 1. To participate in formulation technology transfer to manufacturing sites. |
| 1. Approval of Site Master Files. |
| 1. Participate in the external inspections of the manufacturing sites, prepare corrective and preventive action (CAPA) plan for observations and monitor its implementation. |

**Organization Chart at Ajanta**

Managing Director  Sr. Vice President Corporate Quality  QA Heads of site  QC Heads of site  Quality staff

* At Glenmark, responsible for quality operations of their three manufacturing sites located at North India (i.e Baddi, Nalagarh and Sikkim). Baddi site is catering products to all regulated markets and Nalagarh site was for rest of the world markets. Sikkim site was exclusively for domestic market.

**Organization Chart at Glenmark**

President Global Quality  Cluster Head Quality  QA Heads of site  QC Heads of site  Quality staff

* At USV, responsible for both Quality Assurance and Quality Control Functions. Responsible for all strategic decisions, execution. Under my leader ship the Organization cleared the European Union Audit (Ministry Of Health Finland). The facility approved by USFDA without any 483. Leader for USV to select and implement Laboratory Information Management System to meet the 21 CFR Part 11 requirements. I was heading a group of 46 staff
* Organization Chart at USV

COO  Vice-President QA & RA  Manager QA/QC  Staff QA/QC

* At Aurobindo I was responsible for total functioning of quality control department and quality assurance department that engaged in the formulation activities of Aurobindo. About 60 qualified chemists were working in various sections, including 5 Asst.Manager and several executives. The plant was approved by all regulatory agencies (USFDA, MHRA, WHO, ANVISA Brazil, Health Canada). During this tenure involved in the execution of exhibit batches of products for US market. Executed the implementation of LIMS for documentation in laboratory.
* At CIPLA taken care of the activities in the quality control department (both API and formulations). Quality control consists of various sections like raw material, formulations, bulk drugs, validations and stability studies.
* The plant at Bangalore is approved by all major regulatory agencies like USFDA, MHRA, MCC South Africa, TGA Australia, and WHO Geneva
* During the tenure with Torrent ltd., I was managing the day-to-day functioning of the department which includes work distribution, maintenance of GLP, maintenance of instruments, internal communications, product registrations, validation of analytical methods, stability studies etc.

**Educational Qualifications**

|  |  |  |  |
| --- | --- | --- | --- |
| **Qualification** | **Board/University** | **Year of passing** | **% Marks** |
| PG, Analytical Chemistry | Sardar Patel University | 1994 | 59.00 |
| BSc (Chemistry) | Mahatma Gandhi University | 1992 | 64.00 |
| Pre-Degree | Mahatma Gandhi University | 1989 | 45.00 |
| SSC | Board of Public Examinations, Kerala. | 1987 | 55.00 |

**Additional Information.**

* For compliance to 21 CFR part 11, scientific data management system installed (Nugenesis) at CIPLA and I was the administrator for the same.
* Attended a training program on “FDA inspections” at Amsterdam, The Netherlands organized by institute of validation technologies. There were about 120 participants from various parts of the globe.
* Attended various seminars organized by ISPE on “PAT” (Process analytical technology)
* Attended “Technical briefing seminar” at WHO Geneva in the year 2010. Participated various stake holder meetings at WHO Geneva.
* At Ajanta I have been awarded as the ***“Man of the Year”*** (Best performance award) for the year 2007-2008
* Delivered training on QbD, Data integrity at various seminars organized by IDMA, ISPE etc.
* Audits faced
* USFDA (12) with direct involvement
* MHRA (5)
* TGA (2)
* WHO Geneva (10)
* MCC (3)
* Vendor Audits carried out (Many to count with international audits)
* EU GMP (2)
* Health Canada(1)

***REFERENCES: Upon request.***