**Curriculum Vitae -AJAY PATHANIA**

Manager- Regional Quality Operation Management- Mylan, Hyderabad.

**OBJECTIVE**

To guide work operations through the establishment of objectives, policies, rules, practices, methods and standards so as to make GMP an integral part of our actions and quality culture.

To develop leadership with ownership that results in progress toward organizational objectives so that to become a high performing team asset.

**Experience**

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| Experience | 11 years’ experience in Quality Control, R&D and Corporate Quality Operation Management.  Presently associated with (Since June-2015) with Mylan laboratories Limited as Manager- Corporate quality assurance.  Previous employers: - Cipla API (abt. 1 Years), Panacea Biotech R&D (abt. 2.5 Years), Ranbaxy labs Ltd (abt. 6.5 Years) and Indswift Labs Ltd. (abt. 1.1 Years). |

**Position Summary**:

**Reports to** : Sr. G.M- Corporate Quality Assurance.

Responsibilities (Quality Control Operations):

**Responsible for continuous improvement in Quality Control Operations w.r.t Testing, Review Procedures, Standard test procedures, Standard operating procedures, Training procedure, Handling of Laboratory Deviations/OOS/OOT, Handling of AMT/AMV , Handling of Internal/External audits etc.**

Currently Heading 90 member QC team for FDF Jadcherla since SEP-2015 (In absence of Head QC)

*Responsible for timely release of In-process, raw material, finished product and Packaging material. Handling of Site method transfers. Responsible for timely execution of stability studies Installation and qualification of laboratory instruments.*

1. To ensure minimization of human errors and to improve investigation quality.

* Review of LIRs (OOS, OOT), identification of the gaps to improve quality of investigation and to make certain that investigations are performed in-line with SOP.
* Support/suggestions for effective failure mode experiments to identify and substantiate root cause for Laboratory failures.
* Suggesting QC personnel to improve technical & scientifically sound justifications.
* Monitoring for effective corrective and preventive actions implementations to minimize recurrence of repeated laboratory errors.Improving Lab Investigation quality by 25% - (Through effective root cause analysis through failure mode experimentation).

1. All time readiness for Regulatory audits.

* To ensure completeness and authenticity of QC documents for its completeness and authenticity and data integrity.
* To ensure compliance of electronic data w.r.t 21CFR Part-11.
* To ensure laboratory practices w.r.t current/approved procedures.
* To ensure online documentation w.r.t the testing /activities performed at quality control laboratory.

1. Regulatory Audit preparation, Implementation and compliance at all the sites.

* Review of audit response to meet regulatory expectations.
* Ensuring implementation of proposed CAPA across all FDF sites.
* Extending support during audit, review of documents pertaining to audit products and QC documents for its completeness.

1. Review and implementation of harmonized practices at Mylan FDF sites.

* To support all FDF sites for implementation of harmonized practices of core Quality SOPs.
* Ensuring site procedures are inline to Global directive/policies.

5.0 Monitoring of resource utilization at Quality control laboratory.

* Monitoring of Instrument utilization at quality control laboratory to identify scope for improving efficiency.
* Review of batch release time to identify scope for improving efficiency.
* To ensure effective and timely preventive maintenance of laboratory instruments to reduce the down time.

6.0 Audit of FDF sites.

* Audit of FDF sites as per the schedule
* Preparation of audit report, discussion with site quality head w.r.t to critical findings and its corrective and preventive action.
* Review of audit response and ensuring effective implementation of the corrective and preventive action taken against the audit findings.

7.0 Training session at FDF sites.

* Conducting training on Global SOP’s, Developmental trainings and awareness trainings w.r.t ensure cGMP compliance at all the four FDF sites.

**Previous eMPLoyers:-**

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| **Company** | **Responsibilities** |
| **Indswift Labs Ltd. /Derabassi- Mohali** / Deputy Manager- Q.C.  (May-2014 to Jun-2015) | * *Responsible for* handling laboratory audits. Responsible for replying the queries / observations / audit response w.r.t. quality control laboratory. * *Responsible to ensure* that Standard Operating Procedures are adequately written and are being practiced with respect to those regulatory guidelines. * *Responsible to ensure* that all laboratory investigations related to OOS/OOT/Deviations are being performed timely, with compliance to standard operating procedures and have scientific rational. * *Responsible for conducting* internal audit of Q.C. , Warehouse, PDC etc. and execution of required CAPA as a resultant of audit observations outcome. Responsible for revision in procedures required to be changed as part of internal finding, customer requirement, regulatory compliance or any audit observation. * *Responsible for conducting audits of* APIs, key packaging materials and Contract Formulation unit’s vendors as per established schedule to assess and ensure that facility and Quality systems meet GMP requirements and established Indswift policies and standards. * *Responsible to ensure* that all calibrations, working standards preparations and instrument installations are being done as per the requirement .Monitoring and planning of monthly/yearly calibration and working standard preparation plan. Monitoring and procurement of impurities/reference standards. AMC management, vendor’s service scheduling. Monitoring of consumption of standards, utilization of systems etc. * *Responsible to ensure* that all electronic data has been installed, validated and managed as per the requirement of *21 CFR guidelines*/ *Annexure IV, Chapter 6* of *EU GMP* guidelines. Responsible for implementing user/system policies on application software, audit trail verification policies and data backup policies. |
| **Ranbaxy Labs Ltd.** /Paonta sahib / Executive- Q.C.  (DEC-2009 to MAY-2014 & Feb-2006 to Aug-2007) | * *Responsible* for handling of Change controls, Revision of SOP’s and Laboratory investigations related to OOS/Deviations/OOT. * *Responsible* for preparation of audit response and ensuring QC compliance against the external audit observations. * *Responsible* for conducting training activities for QC personals. * *Responsible* for installation, operational and performance qualification of laboratory instruments. * *Responsible* for preparation of protocol and report for analytical method transfer being done at Q.C. lab as receiving laboratory as well as sending laboratory. |
| **Panacea biotech Ltd. ,** Lalru, Chd., Sr. Officer  (Sep-2007 to Dec-2009) | * *Responsible* for Analytical method validation and analytical method transfer to the manufacturing site. * *Responsible* for preparation of protocols and SOP’s related to instruments operation/calibrations. * *Responsible* for calibration and qualification of laboratory instruments. |
| **Cipla API,** Bangalore Officer. (Feb-2005 to Feb-2006) | *Responsible* for testing of Raw material/ in-process and finished product. Responsible for calibration of analytical instruments. |

**Behavioral Competencies:**

1. Strong interpersonal and communication skills.
2. Ability to work cross-functionally.
3. Ability to work in good coordination with the peers.
4. Excellent track record of sound decision making and good judgment skills.
5. Ability to mentor, motivate, educate and interact with people at all levels within the organization.
6. Results oriented.

**Personnel details**

Qualification : M.Sc. :- Analytical Chemistry from B.U. (2002-2004)

B.Sc. :- Physics/Math/Chemistry from H.P.U. (1999-2002)

High School :- Kendriya Vidyalaya (1997-1999)

Permanent Add : S/O Sh. O.P. Pathania, Paonta Sahib, Distt. Sirmour Himachal Pradesh.

Marital Status : Married.

Current Add : Hyderabad.

Contact number/ID: 9459702063/[Pathaniaajay.81@gmail.com](mailto:Pathaniaajay.81@gmail.com)

I hereby declare that the above information is true in best of my Knowledge.

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| Ajay Pathania. |