**AMIT KUMAR GURU**

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**Seeking challenging career where I can use my professional exposure, hone up and acquire new skills and work with top-notch professionals.**

**PROFESSIONAL SUMMARY**

* Current Employer Ranbaxy Lab Limited, working as **Head** DF India/Asia Regional Quality reporting to

Director QA.

* Having hands on exposure to core IT elements, quality assurance activities and data integrity aspects
* Having approx. **14** **years** of experience in **Pharmaceutical Industry –** Approx.8 years in **CQA (IT)**

5 years in **QA**,1 Year in **Production.**

* Exposure of facing regulatory audits (US FDA, MHRA - UK, WHO-Geneva, MCC-South Africa, TGA –

Australia, ANVISA - Brazil, HPFBI – Canada, IMB, PMDA etc.).

* Project Management and large scale implementations – TrackWise etc.
* Practical knowledge of **Software solution implementation (TrackWise etc.),** **Computer System**

**Validation, Quality Risk Management, Quality Management System, CAPA Management,**

**Failure investigation management, Validation and Qualification, Regulatory & Customer**

**Audits, Self Inspection, Training Management System etc.**

* Capability for handling of IT & Quality Assurance Activities as per cGMP for **high-regulated markets**.

Ability to work in fast paced environments with large team size, Flexibility in changing priorities &

Logic driven approach.

**WORK EXPERIENCE**

* Worked in US FDA, MHRA - UK, WHO-Geneva, MCC-South Africa, TGA - Australia, ANVISA - Brazil, MHLW - Japan, HPFBI - Canada approved factory of India’s Largest Pharmaceutical MNC **Ranbaxy Lab** Ltd, India from Jul 2001 to Jul 2006.
* Worked as Management Staff - Quality Assurance in US FDA, MHRA - UK, WHO – Geneva, MCC-South Africa and TGA - Australia approved plants of India’s fastest growing pharmaceutical company, **Cipla Ltd.**, Goa, India from Aug 2006 to Jul 2007.
* Worked as Executive Quality Assurance in **Merck Serono,** Goa, India from Jul 2007 to Aug 2008.
* Worked as Group Leader CQA in US FDA, MHRA - UK, WHO-Geneva, MCC-South Africa, TGA - Australia, ANVISA - Brazil, MHLW - Japan, HPFBI - Canada approved factory of India’s Largest Pharmaceutical MNC **Strides Arcolab Ltd**, India from Aug 2008 to Dec 2012.

**ACADEMIA**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name of Exam** | **University/ Board** | **Year of Passing** | **Special Subject** | **%** |
| Higher Secondary School Certificate | M.P.Board | 1997 | Mathematics & Biology | 82.89% \* |
| Bachelor of Pharmacy | S.G.S.I.T.S. College, Indore | 2001 | Chemistry | 67.6% \*\* |

\*Secured **38th rank in the State Level Merit List** in Higher Secondary School Certificate Examination (12th)

\*Got **92%** in Physics (87/100), Chemistry (96/100) and Mathematics (95/100) in Higher Secondary School Certificate Examination (12th)

\*\* Appeared in **GRE** (Graduate Record Examination) and got **1180/1600** score

\*\* Appeared in **TOEFL** (Test of English as a foreign Language) and got **257/300**

**TECHNICAL PROFICIENCY**

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SAP Skill Set : Working Knowledge of SAP.

EDMS/TrackWise : Hands on Exposure (Implementation and validation of various modules)

Reports : Crystal reports

Packages : MS-Office, Microsoft Visio

**HANDS ON EXPERIENCE**

* Effective management of Data Integrity observations, investigations, trouble shooting, CAPA etc
* Building culture of quality compliance
* Effective management of QMS elements as per quality policy
* Regulatory/customer Audit & compliance
* Implements and maintains the quality program, promotes and facilitates continuous quality improvement
* Identifies and resolves internal quality issues
* Effective management of risks to quality, patient safety and data integrity
* Participate in writing/review of SOPs to ensure appropriate compliance wrt practices and procedure
* Ensure training on SOPs, regulatory requirements and quality initiatives
* Administration and Co-ordination for implementation of EDMS - Track Wise project (More than 7 years’ experience)
  + Project Planning
  + Interact effectively with customers, developers and peers to ensure the successful delivery and implementation of the project
  + Process analysis
  + Requirement mapping
  + Development of workflows/ finalization of data fields/Integration requirement analysis etc.
  + Testing and qualification
  + Crystal Report Requirement Mapping
  + Crystal report(single and multi) development
  + Preparation and review of documents (SOP/WI/Qualification etc.)
  + Training
  + End User Support
  + Trouble shooting
  + Monitoring of enhancement requests
  + Change management for Track Wise
  + Periodic review
  + Facing regulatory/customer audit
* Computer Software Validation
  + CSV Planning
  + Workshop Facilitation
  + Preparation of CSV master plan, Policy and procedures
  + Preparation and execution of protocols/reports (Vendor Assessment/URS/FRS/IRA/FRA/IQ/OQ

/PQ/Traceability Matrix/Validation summary report etc.)

* + Change Management wrt Software Validation
  + Software Risk Assessment and Managements
  + Regression Qualification
  + Periodic Monitoring of Applications and impact Analysis on CSV
  + Training on CSV
  + Knowledge Management for CSV
  + Coordination with CFT/Vendor to ensure timely completion of CSV
  + To conduct periodic audits to ensure ongoing state of control of CSV
* Drive risk management initiatives as defined in risk prioritization index
  + Coordinate execution of risk-management for identified areas
  + Coordinate closure activities of the mitigation recommendation in consultation with relevant owners
  + Coordinate with plant representatives for monitoring of risk index
* Effective management of IT practices as per GxP requirements
* Project management and provide support to various quality initiatives
* Completed LONZA MODA (Mobile Data Acquisition –Paperless Microbiology) Project
* Completed Goose STOM (Dashboard for Key data from various QMS software application) Project
* Completed Newgen DMS (Document Management System) Project for MFR/MPR/DL/BMR/BPR/Validation & QMS event tracking sheet
* Completed AERS (Adverse Event Reporting System) project
* Completed SAP ECC 6.0 project
* Coordinating LIMS project validation
* Completed Material Tracking project (Take Solusions)
* Completed OAMS (Online Artwork Management System) project
* Completed Minitab Project for Statistical Process Analysis and Product Quality Review
* Completed Procon Tracker project
* Computerized System Validation – EDMS/SAP/AERS/LIMS/LMS/OAMS/Procon Tracker etc
* Training of employees on cGMP/QMS elements – Preparation of training modules and delivery
* Harmonization of procedures (e.g. Change management, deviation management, RCI, CAPA, Complaint Management etc.) across all locations
* Define procedures for Regulatory Compliance and put in place systems for implementation.
* Regulatory/Technical knowledge management – Gap analysis based upon changes in regulatory & industrial guidelines/norms (i.e. USFDA/MHRA/Health Canada/TGA/WHO/MCC/EMEA/PIC/S/PDA/ISPE/ISO/BS etc), proposal to senior management and tracking of recommendations
* Preparation of key policy documents viz. Risk management policy, Validation master plan, SIF, Quality Manual etc.
* Audit preparation & compliance as per GxP - USFDA, MHRA, MCC, TGA, MHLW, HPFBI, WHO- Geneva
* To conduct internal audits as per Quality System Inspection Techniques to monitor compliance with SOPs and regulatory and industrial norms
* To prepare and maintain QMS documents - SOPs Self-Inspection reports, Training Manual and associated records, Change Control, Deviation, Market Complaints, Product Recall etc.
* Failure investigation -market complaints/OOS/OOT etc.
* Liaison with internal and external clients
* Preparation of Annual Budgets and staffing requirements
* Audit of off-site supplier and contractor facilities.
* To assist in the development of an integrated, team based culture within the manufacturing and QC/QA areas
* To develop and promote continuous improvement behavior and programmes to comply with regulations and customer expectations in an effective and efficient manner.
* To implement and ensure proactive approach within the framework of integrated quality system based upon cGMP environment and risk management to avoid discrepancies and mishaps.
* Facilitate the identification and implementation of Continuous Improvements initiatives and Corrective / Preventative projects within the product / process areas
* To implement Quality Policy and to ensure that quality objectives are met.

**KEY AREAS**

* Audit (Regulatory/Customer) and compliance –As auditee and auditor
* Plant Quality Assurance activities, Handling QMS elements, Batch Release etc.
* Hands on exposure to shop floor production/Lab/QMS as well as GxP Software implementation which provides holistic approach towards QMS and data integrity
* Quality Risk Management
* Validation and Qualification
* Training
* Harmonization of procedures and practices across organization
* Regulatory/Technical knowledge management
* TrackWise project implementation
* SAP Validation
* GxP Software implementations (Lonza MODA/Minitab/Newgen DMS/AERS/LIMS/LMS/STOM/SAP ECC 6.0 etc.)
* Computerized system validation
* LIMS Validation
* Software Lifecycle Management
* Preparation and review of QMS documents
* Liaison with internal and external clients
* Cleaning Validation
* CQA Activities including CQA IT

**TECHNICAL/OTHER PROJECTS**

**Title : Track Wise –EDMS (QMS/DMS/Audit Management along with AEP/ Vendor**

**Qualification/Knowledge Management)**

**Vendor**  : **Sparta System**

Role : Administration and Co-ordination for implementation (Project planning/development of work flows/ finalization of data fields/configuration/Testing/Qualification/Training/Crystal Report Requirement Mapping/ Crystal report(single and multi) development/User Support/Trouble shooting etc.)

Status : Completed

**Title : Risk Based Self Inspection (RBSI)**

Role : Conceptualization, Training to the Auditors & Co-ordination

Status : Completed

**Title : Unified Monitoring Center**

**Vendor**  : **In-house**

Role : Co-ordination for QMS elements

Status : Completed

**Title : Learning Management System**

**Vendor**  : **Wizdom –G-Cube**

Role : Execution and Co-ordination

Status : Completed

**Title : Empower Automated Calculation**

**Vendor**  : **Waters**

Role : Project Lead

Status : Started

**Title : AERS**

**Vendor**  : **HCL**

Role : Execution and Co-ordination

Status : Completed

**Title : SAP ECC 6.0**

**Vendor**  : **IBM (PwC as consultant)**

Role : Execution, Validation and Co-ordination

Status : Completed

**Title : DMS (Document Management System)**

**Vendor**  : **Newgen**

Role : Execution and Co-ordination

Status : Completed

**Title : LIMS**

**Vendor**  : Labware

Role : Validation Co-ordinator

Status : Completed

**Title : Procon OAMS –Online Artwork Management System**

**Vendor**  : Goose Technologies Pvt. Ltd

Role : Execution and Co-ordination

Status : Completed

**Title : Procon Tracker**

**Vendor**  : Goose Technologies Pvt. Ltd

Role : Validation/Implementation Co-ordinator

Status : Completed

**Title : Paperless Microbiology -MODA**

**Vendor**  : Lonza

Role : Validation/Implementation Co-ordinator

Status : Completed

**Title : Statistical Quality/Process Assurance - Minitab**

**Vendor**  : Cubic Quality

Role : Validation/Implementation Co-ordinator

Status : Completed

**Title : PLC/SCADA/BMS Validation**

Role : Validation in Strides’ Poland Site

Status : Completed

**Title : Risk Based prioritization of Quality Risk Management Activity**

Role : Execution and Co-ordination

Status : Completed

**Title : Reduced Sampling and Testing of APIs for WHO Market**

Role : Preparation of documentation package for WHO with Cross functional participation

Status : Completed – Got Approval from WHO

**Title : Training on QMS elements across the organization**

Role : Training, preparation of PPTs

Status : On- Going

**Title : Harmonization of procedures across the organization based on process**

**flow approach**

Role : Execution and Co-ordination

Status : Completed

**Title : Training on CSV across the organization**

Role : Training, preparation of PPTs

Status : Completed

**OTHER EXPOSURE**

* To manage all Quality Assurance activities at each stage of the production cycle from Incoming Inspections to Final Product Release
* To identify and implement Continuous Improvement and Problem Solving initiatives within the Manufacturing and Quality Assurance areas (including cycle time reduction, use of Information Technology, complaints investigation and failure analysis)
* Review of batch records prior to final batch release for dispatch
* Trending of Key Quality Indicators and preparation of management report
* Established a system for Review of the cGMP related documents such as MFR, BMR, BPR, qualifications and validation protocols and reports, specifications for the Raw and packing materials, Bulk and finished products, Stability protocols
* To coordinate Self-Inspection as per Six System Inspection model of USFDA as tool for improvement and evaluate the quality system
* To monitor cleaning validation activity at plant level
* To manage preparation of Product Quality Review
* Corrective and preventive action Management
* To ensure that a site validation strategy and plan is developed and implemented
* To monitor equipment qualification at plant level
* To check and release daily dispatches documents
* In system development, controlling and auditing in the observance of GMP in the plant
* To provide recommendations for regulatory market issues
* Handling trouble shooting of commercial products at Shop-floor
* Implementation and achievement of the set targets and laid down Quality Policy in co-ordination with other departments
* Management of training activity, preparation of gross training plan and Individual training plan and maintaining the records
* Documentation control in issue and retrieval like SOP, Batch Records, Formats and Protocols.
* Handling of Change control, Process Deviation, Self Inspection, Market Complaint, Failure Investigation and preparation of respective report
* Initiation of vendor assessment procedure, OOS reports, Change Control Proposals, Failure investigation reports, CAPA and approval of the same
* Process Capability Study of different products
* To guide and direct shop floor in process quality assurance activities and handling GMP incidences.
* Risk Management

**PROFESSIONAL MEMBERSHIP OF INTERNATIONAL ORGANIZATION**

* Active member of International Society for Pharmaceutical Engineering (**ISPE**)
* Active member of Parenteral Drug Association (**PDA**)

**TRAINING ACTIVITIES**

* Given presentation on Electronic Management of Quality System during Networking event sponsored by Sparta Systems as Guest Speaker in Singapore in year 2012 and 2013
* Delivered Webinar on Managing effective QMS

**OTHER INFORMATION**

* Actively contributed as team leader in **OPERATIONAL EXCELLANCE** programme and imparted some highly recognized suggestions
* Participated in **CAPACITY ENHANCEMENT** programme actively
* Participated in **SIX SIGMA** project actively
* Structured and completed **CSV in Warsaw, Poland** Site
* Participated in **Track Wise Connection – Carlsbad, California, USA**

**VISA Details**

* **US business VISA** valid upto 2021

**HOBBIES**

* Reading literature of Leo Tolstoy, Playing chess and Playing Cricket