ATUL CHATURVEDI

SENIOR MANAGER – QC

Experienced with US-FDA, MHRA, TGA, ANVISA & WHO-GMP Approved Plant

CAREER HIGHLIGHTS

Leading Quality Control functions to ensure implementation of quality control systems, manage the operational performance of section, ensuring the successful delivery of business strategy, key performance indicators (KPIs) and organisational objectives.

Contact

Nashik

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Key skills

- **Second line role to deliver Head Stability (QC) funtions.**
- **QMS, OOS, OOT , Atypical and LIRs investigaion.**
- **Implemention ALCOA+**
- **Implemention 5-S and Kaizen.**
- **TrackWise,**
- **Plan systematic CAPA and effectiveness.**
- **Innovative and Service-focused.**

EDUCATION

Master of Science (M.Sc.) — I I- Div
Chemistry
Sridhar University, Pilani, RJ

WORK EXPERIENCE

Mylan Pharmaceuticals Limited — Feb. 2009 to till date.
Sr. Manager QC
Nashik, Maharashtra

IPCA Laboratories Limited — Jul 1997 Feb. 2009
Executive, QC
Ratlam, M.P.
(US-FDA, MHRA, ANVISA, WHO-GMP Approved Plant)

JOB PROFILE AND RESPONSIBILITIES

Leading and overall responsibility of Stability section in QC department, ensure time base analysis and release of stability samples activity.

Strengthen Organizational Objectives:

- Key member of Quality excellence group to ensure productivity enhancement, system simplification, adherence of quality tool to achieve the sustainable performance of department.

Major Audit Faced

USFDA
United State Food and Drug Administration, USA

MHRA
Medicine and Healthcare Products Regulatory Agency

WHO -GENEVA
World Health Organization

ANVISA – BRAZIL
Agência Nacional de Vigilância Sanitária

TGA-AUSTRALIA
Therapeutic Goods Administration

Operating computer software's

Trackwise

Caliber LIMS

Laboratory information management system

Document management system

Learning Management System (LMS)

SAP

- Timely completion of stability sample analysis and summary report preparation.
- Review and approval of Change control / Deviation/ CAPA/Laboratory investigation.
- Calibration / Validation of Analytical Instruments schedule monitoring, review and Approval.
- To investigate and review investigation report.
- Preparation and Execution of SOPs in line with current regulatory requirements and pharmacopeia.
- Review of equipment qualification, IQ, OQ, PQ and requalification protocol and reports.
- AMC preventive maintenance schedule preparation, monitoring, review and Approval.
- Overall Management of Stability department (Analysis plan, Troubleshooting, Review of stability study protocol, batch wise stability schedule, batch wise sampling log, monthly stability schedule and stability summary report).

Operation Excellence:

- To investigate the OOS/OOT/Incidents through TrackWise of investigation report.
- Responsible for stability samples management and GLP activity. Leading a team of 3 supervisor levels (Manger, Deputy Manager and Asst. Manager) and 20 doer level (Executives, officer & analyst) team.
- To ensure Change Control, Planned / Unplanned Deviation, OOS / OOT and CAPAs are initiated as per the timelines by the SOP's, appropriately addressed / concluded and closed.
- Preparation, review and approval of Risk assessment.
- Training and skill development of Laboratory personnel in adherence with current Regulatory requirements. Ensuring right first time (RFT) approach is adhered appropriately.
- To ensure effectiveness of 5-S approach and continuous improvement in Laboratory.
- Review of calibration data of analytical instruments as per current effective SOP's.

Instrument's/Software hand on Experience

HPLC

UV visible spectrophotometer

FTIR

Particle Size Analyzer

XRD

Dissolution apparatus

Karl fisher apparatus

Disintegration Apparatus

Friability Apparatus

Polarimeter

Others
Operation of chamber

Stability Chambers
(Mack and Thermolab)

- Prevention of lab errors and repeat testing through analytical data review process, ensuring 100% GMP compliance in line with SOP, STP and Specifications.
- Review of Laboratory documents for audit compliance to the requirements.
- Coordination with the Regularity Affair department regarding registration of new products, day one launches and other technical queries.
- Direct interactions with USFDA auditor in quality control laboratory.
- Internal audit of laboratories for compliance of current GMP. Response preparation for regulatory queries.

Organizational achievement

- Saved analyst cost of the organisation through reduce charging of multiple batches of different market as annual addition batch of every Year
- Full time three-month HPLC chromatograms review with Quintiles USA team against USFDA Observation for Unexplained peak (for Assay/DR/CU) and inhibit integration for related substance Test
- Successful completion of Migration of Empower-2 software to Empower-3 software for 171 Waters HPLC System.
- Major improvement (online documentation, strong planning, education to team, elimination of Data Integrity concern etc. in stability department having a team of about 16 team Members.
- Achieved many awards by management for improvement in quality system, Regulatory submission and successfully completion of external audits.

Scholastics

Master of Science (M.Sc. chemistry)
From Sridhar University, Pilani, RJ

Bachelor of Science
From Bhagat Singh College, Jaora,
Vikram University Ujjain, M.P.

Personal Details

DOB	:	**22.09.1972**
Sex	:	**Male**
Nationality	:	**Indian**
Marital status	:	**Married**
Linguistic Abilities	:	**English and Hindi**

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Nashik, M.H., India. 422101

I hereby declare that the information given above is true to the best of my knowledge and belief.

Atul Chaturvedi
Nashik