

SHASHANK SINGH

QA-Executive

PROFESSIONAL SUMMARY

To ensure a quality management system enforces the required standards of Safety, Legality, Quality, Compliances and Accreditation. I have a proven record of accomplishment of hiring and developing individual to become high performance team members. As a superb communicator, I have the vision and insight needed to be able to influence and provide strategic and capital decisions to senior management. Being a true professional, I can optimize internal processes for maximum efficiency.

WORK EXPERIENCE

TORRENT PHARMACEUTICAL LTD. Ahmedabad, Gujarat

Approved by: USFDA, MHRA, ANVISA, MCC, WHO

Position: Executive in the Department Quality Compliance (Laboratory Quality Assurance), From Oct.2016 to till date.

Cipla LTD. Indore SEZ-I

Approved by: USFDA, MHRA, ANVISA, MCC, WHO

Position: Management staff in Department Quality Compliance (Laboratory Quality Assurance), From Dec.2014 to Sep.2016.

USV Limited. Dabhel, DAMAN

Approved by: USFDA, MHRA, ANVISA, WHO

Position: Officer in QC, June-2014 to Dec.2014.

SUN PHARMACEUTICAL IND. LTD. Halol, Vadodara (Gujarat)

Approved by: USFDA, MHRA, MCC, ANVISA, WHO

Position: Technical Assistant in QC: May-2012 to June 2014.

MEDICEF PHARMA Baddi, Distt. Solan (HP)

Approved by: WHO, GMP.

Position: Tr. QC. Officer from: Apr -2010 to May-2012.

KEY SKILLS AND COMPETENCIES

- Competent professional with about 11+ years of experience in pharmaceutical Quality & Compliance (**Quality Assurance**).

QUALITY ASSUARANCE:

- Responsible to all activity related to OOS/OOT investigation, Approval of Hypothesis analysis, expanded hypothesis or new experiments. Review of OOS report, OOS synopsis and preparation of QA evaluation report.
- Prepare investigations (OOS/OOT) disposition report.
- Ensured appropriate corrective actions and preventive actions (CAPA) are proposed and implemented based on the outcome of the investigation.

AREA OF EXPERTISE

Quality Management System

- OOS/OOT investigation
- CAPA
- Initiation of FAR
- Product recall
- Change Control
- Deviation
- Audit compliance
- Handling of customer queries
- Trainer

Quality Control Analysis

- Method validation
- Analytical approach for FG & Stability samples

CONTACT

Shashank Singh

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WhatsApp Camera
to contact me
directly on
WhatsApp



TECHNICAL APTITUDES

SAP EHP 6.0/ Hana software

QMS-Trackwise Software

Lab Desires- QCMS, TMS &
LIMS

Chromatography-Empower &

Chromeleon 6.8 software etc.

CipDox software

PERSONAL DOSSIER

DOB : 15th Apr,1988

Father's Name: Satyadev singh

Sex : Male

Status : Married

Nationality : Indian

Languages known: English, Hindi

STRENGTH

➤ Punctual ➤ Honest

➤ Adaptability ➤ Flexibility

➤ Attracting Power ➤ Dedication towards Goal

- Initiation of initial Field Alert Reports (FAR)/Notification and preparation of follow up and final FAR report for submission to FDA/Customer.
- Coordination with RA for medical risk assessment report, remaining stock in market, evaluation of impacted batch and initiation of recall.
- Issuance of extension of OOS, monitoring the status of open and closing activities within timeline.
- Preparation of trend data of OOS/OOT, PPT presentation for awareness of errors and product failure.
- Reviewing departmental SOPs to upgrade and conduct the training sessions
- Preparation of Retrospective review report of OOS.

ANALYTICAL ABILITY:

- Electronic Data review of Analytical Equipment and Prepare Audit trail reports.
- Review of Finished Goods, Stability & method validation reports.
- To ensure that procedural deviation or any failures, Aberrant Results, out-of-specification (OOS/OOT) and complaints had properly investigated with risk assessment and documented.

QUALITY CONTROL:

- Responsible to do review analytical documents of QC department with respective protocols.
- Communicate adhere to best testing practices to ensure that non-confirming batch leaves company premise.
- Having Experience in review and approval of Calibration reports, Method Validation documents, Analytical Method transfer Reports etc.

MANAGEMENT SKILLS:

- Preparation of Audit Observation report and Co-ordinate with cross functional departments.
- Authenticating implementation of CAPA and ensuring the effectiveness of CAPA in periodic review.
- Representing from QA department, while explaining concern departmental activities.
- Identifying and developing the quality team structure and involve in timely Audit the Quality facilities and prepares inspection report.

REPORTING ORANOGRAM

- Directly reporting to Quality Assurance -> Manager ->Assistant General Manager -> General Manger of Quality Assurance Department.

"I would perceive myself with strong learning attitude by strong determination to succeed and achieve my level and I would prove myself as a most eligible candidate"

PARTICIPATED IN AUDITS

- **USFDA** (United States Food and Drug Administration - **US.**)
- **MHRA** (Medicines and Healthcare Products Regulatory Agency - **UK.**)
- **ANVISA** (Agencia Nacional de Vigilancia Sanitaria - **Brazil**)
- **WHO** (World Health Organization)
- **MCC** (Medicines Control Council – **South Africa**)
- **TGA** (Therapeutics Goods Administration – **Australia**)

SOFTWARES HANDLED:

Software name	Activities
TrackWise	: Investigations, Deviation, Change control
LIMS (Lab. information management system)	: Approval of QC reports, issuance of qc documents, investigations.
CipDox	: Change control, SOP
Smartsole, Trackwise	: Deviation
QCMS (Quality control management system)	: Log entries, Issuance of qc format and annexure
SAP (Systems Applications and Products in data Processing)	: Retrieval and collection of data.

INFORMATION TECHNOLOGY SKILLS

Operating system : MS-Office, Windows 2007,2008 & 2010.
Excel, Word, Powerpoint,

ACADEMIC QUALIFICATION

- Post-Graduation in General Chemistry from MKU (2013-2015)
- Graduation in (Biotechnology with CBZ) (2007-2010) Passed from Alpine Institute of Management & Technology affiliated from H.N.B Garhwal University, Srinagar (Uttarakhand).
- Intermediate (12th 2005) passed with 2nd division from C.I.C Allahabad (U.P. Board).
- High School (10th 2003) passed with 2nd division High School Ramgarh (Bihar Board).

DECLARATION:

I Shashank singh hereby declared that all above information about my profile hold true.

Date:

Place:

SHASHANK SINGH