Vivek Saxena

(Male, 49Yrs, Indian)
(M.Sc. Chemistry)
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PROFESSIONAL SYNOPSIS

Vivek is a Pharmaceutical professional with around **28 years** of rich experience in Quality Control and Quality assurance Department. Presently associated with M/S GXPZONE Pharma Solutions Pvt. Ltd. as GMP Auditor. Expertise in performing the gap analysis of Formulation, API, Excipients & Packaging Material manufacturing units with respect to the various regulatory standards like USFDA, MHRA, EU, PICS, TGA, ANVISA, WHO etc. He is expert in various analytical techniques, analytical method transfer, analytical method validation, process validation, Water system Validation, HVAC Validation and QMS Handling.

CORE COMPETENCIES

Quality Assurance	○ Performing Risk assessment of various aspects of the facilities. ○ Preparation & review of audit compliances ○ Handling of Warning Letters or other GMP Non-conformance situations. ○ Review of the Quality Management System to suffice GXP requirements ○ Expertise in Validation Master Plan, Quality Manual, Risk Analysis Documents, User Requirement Specifications, Standard operating procedures, Qualification / Validation protocols, Training Modules, Batch Manufacturing and Packing Record. ○ He has audited many formulations, API and Packing Material manufacturing facilities nationally and internationally.
Other Project Activities	○ Evaluation of projects with respect to requirements as intended against FDS to ensure smooth execution of activities. ○ Conduct the training sessions to enhance awareness of various groups resulted in to reduce review observations and thus failure rate.
Audit Compliances	○ Ensuring ATR of organization by evaluating Quality System of various departments by monitoring implementation status of applicable procedures and GAP assessment and bridging the same subsequently.

Work Experience	
Designation: **GMP Auditor M/S GXPZONE Pharma Solutions Pvt. Ltd.**- **March** '19- Till date	
Job Profile	○ To Audit the facilities in line with Various Regulatory norms as intended by Sponsor
	○ To perform GAP assessment as per Guidelines for which Client company seeking the certification. ○ To guide plant team for up gradation/build up the system in order to bridging the GAP/Remediated the identified discrepancies.
Designation: **Manager QA Compliance** / **Sun Pharmaceuticals Industries Ltd. Dewas** (Erstwhile Ranbaxy Laboratories Limited)	
	○ Ensuring Audit preparedness and to support stakeholders during audit. Providing timely audit observation responses in coordination with teammates. Review the investigations for correctness and completeness
Designation: **Manager QA/ Anglo French Drugs & Industries Ltd. Pithampur**	
	○ Responsible to monitor Overall Q.A. Activities Timely for initiation & completion all respective tasks i.e. Review of BMR and Release of Finish Products, Responsible for all Validation activities like Autoclave/ DHS tunnel qualification, HVAC Validation, water system validation etc. To ensure the completeness calibration activities. To ensure the execution environmental monitoring program.
Designation: **Asst. Manager Q.A/Rusan Pharma Ltd. (Gandhidham-Guj.)**	
	○ Review of Process validation documents and respective analytical data review Review of Change Control documents to ensure the correctness and completeness of the same. Review of BMR and BPR.
Designation: **Senior Executive Q.C.** / **ZYG Pharma Limited, Pithampur** **[An associate of Fulford India Ltd. (Schering Plaugh U.S.A.)]**	
	○ Review of Finish Products & Raw Materials analysis data and to release of the same in line with predefined time lines. To ensure the calibration of lab equipments as per preapproved calendar. Core team member of analytical method transfer activities.
Designation: **Senior Executive Q.C.** / **Choksi laboratories Ltd. Indore**	
	○ Work planning of Finish Products & Raw Materials analysis and to submit the data for release of the same in line with predefined time lines. To involve in trouble shooting activities and discuss with respective clients for way outs as per need.
Designation: **Q.C. In charge/ Makin Laboratories Pithampur**	
	○ Planning of Finish Products & Raw Materials analysis and release of the same in line with predefined time lines. Calibration of all lab equipments as per predefined schedule. To investigate the failures in concurrence with team mates for trouble shooting and to ensure the successful implementation of corrective measures.
Designation: **Q.C. Chemist./ Prem Pharmaceuticals Indore (Large Volume Parenteral Company)**	

	○ Responsible for: Environmental monitoring, sterility testing and performing biological tests. Analysis and reporting of RM and Finish Products to meet the organizational commitments.

AUDIT EXPERIENCE

Sr. No.	Type of Facility	No. of Audits
1.	Formulation Facilities	**28**
2.	API Facilities	**20**
3.	Excipients Facilities	**12**
4.	Packaging Material	**30**

PERSONAL TRAITS

- A keen communicator with hone problem solving, analytical abilities and team management skills.
- Ready to accept changes and challenges
- Excellent knack of solving day to day project issues
- Honest, Punctual and a man of strong integrity
- Inner Drive and Tenacity for excellence