Sanjay Sharma

(Male, 54 yrs, Indian)
(M.Sc Chemistry, MSc TQM)
Email: sanjaysharma@gxpzone.com

PROFESSIONAL SYNOPSIS

A dynamic professional with around **31 years** of rich experience in **Quality Control and Quality assurance** Department. I am **presently** associated with **M/S GXPZONE Pharma Solutions Pvt. Ltd.** as a **founder** and **Lead GMP Auditor**. A project planner with expertise in planning, executing and spearheading Pharmaceutical projects and ensuring on time deliverables with GXP compliances. Excellent communication & interpersonal skills with strong analytical, team building, problem solving and organizational abilities.

I have successfully handled more than 60 inspections by reputed customer and Regulatory agencies like USFDA, MHRA, TGA, MCC, WHO, ANVISA, UKRAINE and regulatory inspections of AFRICAN countries successfully. I have a rich experience in conducting Global GMP, GDP audits and across other GXPs including 'For Cause Audits' for various clients.

I have conducted more than 100 API, EXCEPIENTS, Primary Packaging material, Warehousing and Formulations facilities across the Globe.

CORE COMPETENCIES

Quality Assurance	❖ Analyse audit results in accordance with client requirements and Relevant guidelines, diagnose quality critical issues, assess Corrective and preventive actions before successful closure of audits. ❖ Risk assessment and approval of suppliers and processes from quality perspective and to ensure delivery of a regulatory compliant audit program to fulfil requirements of business and continuity. ❖ Provide Executive summary and key critical areas that could impact Quality, Safety and Efficacy of the Products in scope of audits. ❖ Identifying to impart/arrange training on various GMP topics like Cleaning Validation, Impurity profile, Method validation, Audit & compliance, Quality Risk assessment etc. and arrange external training whenever required. ❖ Designing /Commissioning and monitoring the internal quality audits, escalating it to Senior management as part of periodic Quality Review and identify the risks associated with the facility and products. ❖ GMP / GDP Auditing and Pharmaceutical Quality management System. ❖ Conducting Due diligence Audits.

	❖ Investigation, Root cause Analysis and CAPA ❖ Expertise in Good Laboratory Practices Audits and implementation of Lean Lab management. ❖ Computer System Validation and Compliance to 21CFR part 11 & Annex 11 (EU). ❖ Expertise in implementation of ALCOA principle for Data Integrity. ❖ Reduction of QMS elements related to Human Error. ❖ Handling of Warning Letters and providing response to the USFDA.
Other Project Activities	o Monitoring of projects with respect to budgeted cost, time over-runs to ensure timely execution of projects. o Review of cost estimates for change orders, review & analyze change order proposals & submittals
Audit Compliances	o Ensuring that non-conformances are duly complied with the audit
Work Experience	
Designation: **Director / GMP Auditor** **M/S GXPZONE Pharma Solutions Pvt. Ltd. since Jan 2019**	
Job Profile	o ***Performing Gap Assessment of Formulation & API facilities to evaluate the compliance as per Regulatory requirements of USFDA, MHRA, EU etc.*** o Performing GXP Audits of the Formulation, API, Excipients & Packaging Material manufacturing sites. o Preparation and implementation of **Quality management System** at various manufacturing facilities o Preparation of all the master documents like **Site Master File, Validation Master Plan, Quality Manual, Risk Analysis Documents, User Requirement Specifications, Standard operating procedures, Qualification / Validation protocols, Training Modules, Batch Manufacturing and Packing Record** etc. o Execution of Project Validation Master Plan o **Establishment** of laboratory in respect of installation and qualification of all the high end and sophisticated instruments like **HPLC, GC, AAS, UV, IR, Stability Chambers, Incubators** etc along with their operation and calibration procedure documents o To impart **training** to employees on basic GMP, Data Integrity, and Quality systems & maintain the records.
Designation: **Sr. General Manager Quality Zydus Healthcare Ltd.** **Dec. 18 to Dec 19**	
	❖ Responsible for the Quality functions of two plants. ❖ Implementation of Lean Lab practices at site. ❖ Change control reviews and implementation ❖ Leading in regulatory and CQA Audits and ensure timely compliance. ❖ Ensure Zero tolerance for Data Integrity at site ❖ Responsible for Implementation of Quality culture at site. ❖ Responsible for compliance to the accepted KPA / KPI at site. ❖ Monthly QRM presentation to the higher management

	❖ Evaluation of change control, deviations and incidents related to equipment's, utility products. ❖ Preparation of Validation Master Plan. ❖ Ensuring Cleaning Validation. ❖ CQA audit team member for conducting vendor audit for Raw material and packing materials. ❖ Compliance to safety and CGMP guidelines. ❖ Equipment Qualifications, HVAC and Water system Validation. ❖ Training and system compliance on shop floor and across plant. ❖ Ensuring Self inspections as per schedule and compliance. ❖ Carrying out Annual product review to ensure process consistency. ❖ Investigation in case of market complaints, Product failure, Product recall, ❖ OOS results and failure in stability study and do the RCA and implement an effective CAPA and monitoring its effectiveness.
Designation: **Sr. General Manager Quality Intas Pharmaceuticals Ltd. JUN 09. to Dec 18**	
	❖ To involve, implement and monitor Q.A. activities on site ❖ Review and approval of SOPs, ❖ To define systems, standards & procedures to be followed ❖ Qualification of equipment and systems, review and approval ❖ To frame & issue policy, manual /guidelines regarding Quality. ❖ Ensuring cleaning validation of each API products and its review ❖ To ensure availability of authorize procedures / specifications. ❖ To approve, control & maintain all documents. ❖ To authorize Master Formula Record, Batch Manufacturing Record & Batch Packing Record ❖ To authorize Validation Protocols and Reports. ❖ To ensure compliance to local statutory requirements & to liaison with local drug authorities ❖ To verify implementation of system/procedure e. ❖ To ensure amendments in specifications and procedures to reflect current pharmacopoeial standards. ❖ To investigate product recalls & initiate corrective /preventive actions ❖ To ensure systems & specifications meet CGMP & other regulatory standards. ❖ To review & approve all SOPs. ❖ To handle customer complaints and investigate along with Corporate QA ❖ To control non-conforming products. ❖ To authorize change controls and Deviations. ❖ Stability protocol and report review ❖ Leading Internal Audit team ❖ Investigation for incidents/deviations ❖ Risk assessment ❖ Product quality review ❖ Approval of validation/preventive maintenance and calibration calendars ❖ To be prepared for regulatory audits and query response

Designation: **General Manager QC M/s Synmedic Laboratories. May 2008. to May 2009**	
	❖ Review and approval of SOPs ❖ Quality management system, actions review and closure ❖ Qualification of equipment and systems, review and approval ❖ Stability protocol and report review ❖ To ensure amendments in specifications and procedures to reflect current pharmacopoeial standards. ❖ Leading Internal Audit team ❖ Investigation for incidents/deviations ❖ Risk assessment ❖ To be prepared for regulatory audits and query response.
Designation: **Deputy General Manager QC Ochoa Laboratories Limited Feb2006. to May2008**	
	❖ Review and approval of SOPs ❖ Qualification of instruments and systems, review and approval ❖ To ensure amendments in specifications and procedures to reflect current pharmacopoeial standards. ❖ Stability protocol and report review ❖ Leading Internal Audit team ❖ Investigation for incidents/deviations ❖ Risk assessment ❖ Approval of validation/preventive maintenance and calibration calendars ❖ To be prepared for regulatory audits
Designation: **Sr. Manager QC Windlas Biotec Limited May 2004. To Feb 2006**	
	❖ Review and approval of SOPs ❖ Qualification of instruments and systems, review and approval ❖ Process validation batches monitoring and its documents. ❖ Ensuring cleaning validation of each API products and its review ❖ Stability protocol and report review ❖ Leading Internal Audit team ❖ Investigation incidents/deviations ❖ To be prepared for regulatory audits.
Designation: **Manager QC Mega International Limited Mar. 2000. to Feb. 2004**	
	❖ Site Master File and Validation Master Plan preparation and up-dation ❖ Review and approval of SOPs ❖ Quality management system, actions review and closure ❖ Qualification of equipment and systems, review and approval ❖ Process validation batches monitoring and its documents. ❖ Stability protocol and report review ❖ Leading Internal Audit team ❖ Investigation for incidents/deviations ❖ Product quality review ❖ Approval of validation/preventive maintenance and calibration calendars ❖ To be prepared for regulatory audits.
Designation: **Manager QC M/s. Oasis Pharmaceuticals Ltd. Aug 96. to Mar 2000**	
	❖ Preparation and implementation of **Quality management System** ❖ To impart **training** to employees on basic GMP and Quality systems & maintain the records.

	❖ Keeping accountability of change control report, deviation report, vendor audit reports, Self inspection reports ❖ To carry out Quality audit of all API, excipient and packing material supplier's manufacturing facility and contact laboratories ❖ Qualification of all the critical utilities like Compressed Air, Purified Water and HVAC ❖ Qualification of all the production equipments and machines ❖ Qualification of all the QC Instruments and Equipments ❖ Process validations ❖ Cleaning Validation
Designation: **Executive QC M/s. Panacea Biotec Ltd.** **July 96. to July 96**	
	❖ Responsible for Analysis of finish goods. ❖ To ensure amendments in specifications and procedures to reflect current Pharmacopoeial standards. ❖ Responsible for calibration of all instruments. ❖ Coordination with production for timely release of samples
Designation: **Incharge QC M/s. Haryana Drugs and Pharmaceutical Ltd.** **Apr 90. to June 93**	
	❖ Responsible for overall QC/ QA activities. ❖ Qualification of all the critical utilities like Compressed Air, Purified Water and HVAC ❖ Qualification of all the production equipment's and machines ❖ Qualification of all the QC Instruments and Equipment's ❖ Process validations ❖ Analytical Method Validation ❖ Cleaning Validation
Designation: **Senior Analytical Chemist. M/s Albega Biological Pvt. Ltd. .** **Jan 87. to April 90**	
	❖ Analysis of Drug and Drug products

AUDIT EXPERIENCE

Sr. No.	Type of Facility	No. of Audits
1.	Formulation Facilities	**10**
2.	API Facilities	**80**
3.	Excipients Facilities	**10**
4.	Packaging Material	**10**