Dr. Tarun Chugh

(Male, 53Yrs, Indian)
(Ph.D, Microbiology)
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PROFESSIONAL SYNOPSIS

Dr. Tarun Chugh is a Pharmaceutical professional with around **30+ years** of rich experience in Microbiology 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 Microbiology techniques, Clean Room Validation, Aseptic Validations, Process validation, Water system Validation, HVAC Validation, QMS Handling, ALCOA+, Data integrity and troubleshooting with Risk Assessment.

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 (Sterile and Non-Sterile) 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. ○ To perform QMS, Risk Assessment and Risk mitigation ○ Providing Trainings to the client as per requirement or need of the day
Designation: **VP Quality** / **Immacule Lifesciences, Nalagarh**	
	○ Responsible to monitor overall Quality System timely for initiation & completion all respective tasks ensuring Audit preparedness and to support stakeholders during audit. Providing timely audit observation responses in coordination with team mates. Review the QMS for correctness and completeness ○ Prepare Plant readiness for MHRA and USFDA audits
Designation: **VP Quality** / **Square Pharmaceuticals, Bangladesh**	
	○ 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. ○ To ensure readiness of units for Regulatory and Customer Audits
Designation: **Asst. VP Quality** / **Claris Lifesciences Ahamedabad, Gujrat**	
	○ 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. ○ Preparation of unit for FDA warning letter clearing
Designation: **Quality Manager** / **Baxter, Aurangabad**	
	○ 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 equipment as per preapproved calendar. ○ Prepare unit for Global Standards as per Baxter CQA policies
Designation: **QA Manager**/ **Ranbaxy Lab., Dewas**	
	○ Setup green field Sterile Powder filling Penem facility with all regulatory approvals in Dewas unit (MHRA / ANVISA / Canada). ○ Submitted more than 10 ANDA from Ponta sahib for OSD (Anti-AIDS molecules) to US PEFAR project. ○ Responsible to set Quality Assurance Cell in OSD F&D for better and fast ANDA submission. ○ Maintained Quality parameters Engg. Cell for PV / Exhibit batches in OSD at Ponta.
Designation: **Manager Quality Control** / **Oman Pharmaceuticals, Salalah, Oman**	
	○ To establish Quality system in green field pharmaceutical plant for OSD and Steroid dosage form

	○ Planning of Finish Products & Raw Materials analysis and release of the same in line with predefined time lines. Calibration of all lab equipment 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.A. Executive / Tabuk Pharmaceuticals Mfg. Co., Tabuk, KSA**	
	○ Responsible for setting Micro Lab and involved in Quality Assurance part for OSD /sterile facility (Beta lactam and non-Beta lactam) ○ Responsible for: Environmental monitoring, sterility testing and performing biological tests. Analysis and reporting of RM and Finish Products to meet the organizational commitments ○ Responsible for Process validation of exhibit batches
Designation: **Q.A. Executive / IPCA Lab Ltd., Ratlam**	
	○ Responsible for setting Micro Lab and involved in Quality Assurance part for OSD /sterile facility (Beta lactam and non-Beta lactam). Involved in USFDA inspection done for one API unit in Ratlam.
Designation: **Q.A. Office / Lupin Labs. Ltd., Mandideep, Bhopal**	
	○ Responsible for setting Micro Lab and involved in Quality Assurance part for OSD /sterile facility (Beta lactam and non-Beta lactam). Involved in USFDA inspection done for one API unit in Ratlam.

AUDIT EXPERIENCE

Sr. No.	Type of Facility	No. of Audits
1.	Formulation Facilities	**50+**
2.	API Facilities	**25+**
3.	Excipients Facilities	**10+**
4.	Packaging Material	**15+**

PERSONAL TRAITS

- QMS Knowledge (Deviation / Incidence / CAPA management with investigations and risk assessment / Good trainer
- Root Cause analysis (Sterile / Non-Sterile Dosage form)
- Upgrading facility and people as per latest guidelines and regulatory requirement
- Metamorphosis of unit from non-compliance to global regulatory requirement fit (ATR policy)
- Good understanding of Aseptic / Terminal Sterilization tech. and microbiology requirements for clean area with non-viable / viable controls, Media fill / Smoke test (for DP and air flow patterns).
- Trouble shooting for OSD products (Tablet / Capsule / Liq. / Ointment)
- Team building and up-gradation for current regulatory requirements and non-compliance occurring in industry.