

Jitendra Vasant Pund

Total Experience: 15+

PROFESSIONAL SUMMARY

Email ID: jitupund@yahoo.com	Objective: To be potential resource to the organization where, I can utilize my skill and knowledge which would help the organization to grow and future enhance my growth profile. It would be my never- ending dedication to maintain the spectrum of integrity, honesty and character.
Mobile Number: 9879065082	Achievement: <ul style="list-style-type: none">➤ Recently successfully face and completed the regulatory audit of US-FDA, EU-GMP, TGA, CANADA, Ukraine and Brazil.➤ Member of European compliance academy.➤ Total 25 Training attendance certificate received from US-Food and Drug Administration, USP education, and European Pharmacopeia with different training topic.➤ EU training certificate received from Turning quality management into leadership.➤ US-FDA Certificate for Regulatory Do and Don'ts.➤ USP Certificate for DPSV prednisone reference standard.➤ USP certificate for pharmaceutical continuous manufacturing for drug substances.➤ Training on Investigation for the Pharmaceutical Industry (Trainer – Jose Hernandez and Kathryn Hernandez former FDA inspector).➤ Training on OOS/OOT investigation attended – Third Party consultant -Eliquent.➤ Vendor audit performed for different Laboratories such as Hetro drugs, Optimus drug, Neuland Laboratories etc.➤ Audit Trail procedure implemented successfully and accepted by US-FDA, EU-GMP, TGA, Canada, Brazil.
Date of Birth 01 June 1976	Work Experience
Education Master of Science (Analytical Chemistry) From Pune University 2000	<ol style="list-style-type: none">1. Shilpa Medicare Ltd, Hyderabad Telangana Working in AQA compliance 03/2022 to till date2. Vapi Care Pharma Pvt. Ltd, Vapi Working in QC Compliance 02/2020 – 02/2022
	<ol style="list-style-type: none">3. Macleods Pharmaceutical Ltd. Daman Position: QC-Compliance 05/2017 - 2/2020

<u>Permanent Address</u> Jitendra Vasant Pund Shri Guru Krupa, Janardhan Swami Nagar, New Adgaon Naka, Panchavati, Nashik- 422003, Maharashtra	4. Ajanta Pharmaceutical Ltd, Dahaj Asst. Manager Q.C. in Compliance section 11/2015 – 04/2017
	5. Unique Pharmaceutical Laboratories Ltd (A division of J.B. chemicals and Pharmaceutical Ltd) Asst. Manager QC in GLP section 09/2012 – 11/2015
<u>COMPUTER KNOWLEDGE</u> Computer software: MS office, troubleshooting in computer- course done in NIIT.	6. Alkem Laboratories Ltd, Amaliya, Daman Position: Sr. Executive QC in stability section 10/2007 – 08/2012
	7. Ipca Laboratories Ltd, Piparia (Silvassa) Position: Sr. Officer in stability section 03/2006 – 02/2007
<u>Audits Faced</u> CDSO, USFDA, CANADA, MHRA, MCC, TGA, AN-VISA WHO, UKARINE KENYA	8. Nicholas Piramal India Ltd, Pithampur, Indore Madhya Pradesh Position: officer in Raw Material section 08/2004 – 03/2006
	9. Cipla Ltd. At Kurkumbh Tal. Daund Dist. Pune Position: Analyst in stability section 12/2000 – 08/2004

SPECIALIST IN PHARMACETUICAL CHEMISTRY

Make the Current GLP compliance

Investigation of OOS

Investigation of Incidence

Investigation of OOC

INSTRUMENT HANDLED	JOB DESCRIPTION
1. HPLC Make: Shimadzu, Waters, Perkin Elemer, Agilent, Dionex and TSP with 21 CFR part 11 compliance software	1. Successfully implemented Chromeleon software audit trail review procedure with administrator audit trail, this audit trail procedure reviewed and accepted by US-FDA, EU-GMP, TGA and Canada Auditor. 2. Successfully implemented Standalone instrument audit trail review procedure with administrator audit trail, this audit trail procedure accepted by TGA auditor and Canada Auditor. 3. Out of Calibration SOP implemented successfully. 4. Audit trail procedure for Stability chamber, incubator, Refrigerator and freezers. 5. SOP for Handling of Pharmacopoeia updating and its implementation successfully completed. 6. LIR investigation reviewed and approved in ampl logic software. 7. Out of Calibration documents reviewed and approved 8. Practices vs SOP gap identified and successfully completed. 9. The oversight and assessment of investigation 10. Reviewing and approving the investigation plan, report and timely resolution of all investigations.
2. GC Make: Perkin Elemer and Shimadzu with 21 CFR part 11 compliance software.	
Others	
FTIR	
UV spectrophotometer	
Dissolution Instrument	
KF Auto Titrator	
Potentiometric Auto-titrator	
IR Moisture Analyzer	
Melting Point Apparatus	

<p>Stability Chambers (Thermolab, Mac-pharma and Newtronic with 21 CFR part 11 compliance software)</p>	<p>11. Responsible for current Good Manufacturing Practice(cGMP) that focuses on the systematic investigation of root causes of unexpected incidences to prevent their recurrence (current action) or prevent their occurrence.</p>
<p>Works in LIMS 3.3 and 3.7 software Amp logic software for – QMS Amp logic software for – SOP CAMS software for Training</p>	<p>12. Responsible for team members typically comprised of heads from Quality, Manufacturing, Qualified person, regulatory, Laboratory or their qualified designs used to review and provide a disposition for the proposed deviation.</p> <p>13. Responsible for an unplanned or uncontrolled/unexpected GMP incident or deviation or an event in the form of departure from the designed systems or procedures at any stage of material receipt, manufacturing, packing, testing, holding and</p> <p>14. storage of drug substance and system failure or equipment breakdown or human interventions and observed at a later time during execution audit.</p> <p>15. Responsible for acknowledge and complete the hypothesis, investigation plan and approach and obtained required resources and required data and intended analytical techniques.</p> <p>16. Responsible for identify the cross functional investigation team comprised of individuals from affected or other sites resources external to the company, or subject matter expert in the areas relevant to the investigation.</p> <p>17. Responsible for Investigation technique such as Brain storming, 6M, Fishbone analysis, issue analysis, Trend analysis, Pattern analysis, Cause/Effect, Link analysis, Linkage analysis such as Flow charts, Force field analysis tree diagram and 5 why's.</p> <p>18. Drive the investigation to the timeline in the plan; update the plan as required and maintain the communication with functional management.</p> <p>19. Identify and obtain resources from respective functional head as needed to complete through and effective investigation.</p> <p>20. The most probable cause of the deviation/incident/nonconformance/failure/event and what was done to confirm the true cause.</p> <p>21. Responsible for the investigation shall include the caused that were specifically eliminated as the root cause and supporting rationale for that judgment shall be documented.</p> <p>22. Reviews, approves, and writes SOP, tests standards, investigations, deviations, and specifications as they relate to quality control department.</p> <p>23. To search for ways to improve the compliance status by implementing quality improvement initiatives and ensuring corrective actions are implemented.</p>

	<p>24. <u>Documentation</u></p> <ul style="list-style-type: none">• Preparation and review of STP and SOP as per quality requirement.• Review and submission of stability data to regulatory affairs.• Prepare and review of qualification document for instrument qualification and analyst qualification.• Review of dossier document related to quality control for regulatory submission.• OOS, OOT, OOC investigation and documentation.• Review of method transfer and analytical method validation document for its correctness.• Preparation and review of stability document like protocol, LIMS protocol, chamber qualification and validation• Review of all QC instrument qualification for its correctness and SOP follow up. <p><u>Skills:</u></p> <ol style="list-style-type: none">1. Leadership: An experienced team leader.2. Influencing, leading, and delegating abilities.3. Strong verbal and personal communication skills.4. Result oriented: Ability to achieve the target within given time5. Effective communicator with all levels of staff.6. Self-motivated, initiative, high level of energy.7. Good planning skills and be able to lead projects through to completion.8. Familiar with methodologies, tools and concepts in quality management.9. Masters in Computers, Quality control mall functions instrument trouble shooting with highly communication skills.
--	--

DECLARATION

I hereby declare that all the information furnished in this resume is completely true to the best of my knowledge and belief.

Jitendra Vasant Pund