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| **Curriculum Vitae** | | |
| **Dhanendra Tembhare**  **(M.Sc. Biotechnology)**  **E-mail:** [**dhanendratembhare@gmail.com**](mailto:dhanendratembhare@gmail.com)  **Call:+91- 9179172850** | |  |
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| **Organizations:-**   * **Sun Pharma** * **Wockhardt Ltd** * **Ranbaxy Lab.** * **Lupin Limited**   **Major Roles:-**   * Management of overall QA activities * Aseptic process management * Validation Review * Facility Qualification * QMS Management   **Major Audit**:-   * USFDA- 03 * TGA- 05 * MHRA- 01 * ANVISA- 02 * Health Canada-02 * EU-Netherlands-01 | **Profile Summary:-** I bring over 14 years of experience and expertise in quality and compliance functions for the pharmaceutical industry on diverse portfolio including QMS system, Audit & compliance and Injectable.  In my current role, I lead and manage the quality management system and compliance activities for Sunpharma (injectables). I have successfully handled numerous regulatory inspections by agencies such as USFDA, TGA, Health Canada, ANVISA, and others, ensuring the highest standards of quality and compliance across the organization.  My mission is to deliver quality excellence and ensure customer satisfaction by developing and executing comprehensive quality strategies, quality oversight and control, resolving quality issues, and facilitating successful regulatory audits. **Professional Synopsis:-** **Sun Pharmaceuticals, Dewas (M.P.)**  **Manager-QA**  **(Oct-2016 to Present)**  **Key Responsibilities: -**  **Quality Management system:**  **Audit and compliance:**   * Management of overall QA activities of Injectable block. * Management of QA activities like QMS, investigation, APQR, Batch release, control sample, etc. * ~~Evaluation and implementation of CCS strategy as per the Annex-1 Revised 2022.~~ * ~~Reviews of media fill protocol and report.~~ * Equipment qualification like Isolator, steam sterilization, depyrogenation tunnel, DHS, smoke study etc. * Management of Environment monitoring program. * Ensuring the compliance of regulatory requirement and guidelines. * Investigation of events like deviation, environment excursion and OOS results. * Review, approval and closure of change control proposals. * Review& approval of deviation, market complaints and CAPA records.   Managing Team – 10 persons  **Wockhardt Ltd, Waluj, Aurangabad**  **Executive- QA**  **(Oct-2014 to Oct-2016)**  **Key Responsibilities:-**   * ent qualification like HVAC, steam sterilization, depyrogenation tunnel, DHS , smoke study etc. * Worked with facility modification and establishment of new microbiology laboratory. * Data analysis and preparation of presentation for monthly meeting. Coordinated with US consultant for QMS section. * Preparation of remediation protocol and report for USFDA compliance. * Market complaint coordinator- Login, acknowledgement, investigation, response to complainant and trending. | |
| **Ranbaxy Laboratories, Dewas (M.P.)**  **Executive- QA**  **(Nov-2013 to Oct-2014)**  **Key Responsibilities:-**   * Management of IPQA activity and review of batch production records. * Review of water and environment monitoring reports and trends. * Review of validation documents like Steam sterilizer, DHS, HVAC, water system, depyrogenation tunnel and medial fill. * Investigation of environment excursions. * Preparation of Product Review report for injectable products. * Review of change controls, deviation and investigation.   **Lupin Limited Mandideep (M.P.)**  **Executive- QA**  **(Aug-2009 to Nov-2013)**  **Key Responsibilities:-**   * IPQA activities during manufacturing and packaging stages. * Line clearance and inprocess checks. * Withdrawn of finished product sample and control sample. * Environment monitoring and water sampling. * Review of Environment monitoring and water reports * Preparation of EMP trends. * Calibration of IPQA instruments. * Review of batch production records and analytical records. * Login and review of QMS documents and preparation of investigation report for inprocess failure and IPQA deviation. * Review of validation documents like media fill protocol and report, HVAC, Steam sterilizer, DHS, vial washing machine, depyrogenation tunnel.  **Major Regulatory Inspection Exposure** Th   * 2023 Exposure of **Ukraine Inspection** (3rd to 7th Oct 2023) * 2022 Exposure of **TGA inspection** (08th to 18th Feb 2022) * 2021 Exposure of **Belarus virtual inspection** (29th Mar to 06th Apr 2021). * 2021 Exposure of **Ukraine Virtual inspection** from 22nd to 26th Feb 2021. * 2020 Exposure of **TGA Inspection** from 17th to 28th Feb 2020. * 2019 Exposure of **Russia Regulatory** from 10th to 12th Jul 2019. * 2019 Exposure of **ANVISA- Brazi**l from 10th Jun to 14th Jun 2019. * 2019 Exposure of **EU-Netherlands** from 28th to 31st Jan 2019. * 2018 Exposure of **TGA Inspection** from 11th Mar to 22nd Jun 2018. * 2018 Exposure of **Health Canada** Audit from 22nd Feb to 01st Mar 2018. * 2017 Exposure of **CFDI China** from 06th Nov to 10th Nov 2017 * 2016 Exposure of **TGA Inspection** from 10th Oct to 21st Oct 2016. * 2015 Exposure of **USFDA inspection** from 18th May to 26th May 2015. * 2014 Exposure of **ANVISA inspection** from 18th to 22nd Feb 2014. * 2012 Exposure of **MHRA inspection** from 5th to 10th Sep 2012. * 2011 Exposure of **USFDA inspection** from 19th to 24th Sep 2011. * 2011 Exposure of **TGA inspection** from 6th to 11th of February 2011. * 2009 Exposure of **USFDA inspection** from 24th to 29th November 2009.  **IT skills**  * Trackwise, EDMS, LMS system, SAP system, MS word, MS excel and power point.  **Academic Qualification**  * 2008 Master in Sciences (Biotechnology) from Dr. Hari Singh Gour University Sagar M.P. with first division (60%). * 2006 Bachelor in Sciences (Biotechnology) from Devi Ahiliyabai University Indore with first division (73%).  **Achievements & Rewards**  * Attended PDA session on EU Annex-1 revised in Aug-2023 at Ahmedabad. * Attended PDA annual meet in Feb-2023 at Bangalore. * Received best idea award in Sep-2023 from the hands of Honorable MD of Sunpharma Mr. Dilip Shanghvi. * Received best performer award in 2015 from the hands of Honorable Managing Director of Wockhardt Ltd ‘Dr. Murtuza Khorakiwala’ for contribution towards the organization. * Training attained for How to face USFDA inspection conducted by Sunpharma in 2017. * Certified investigator. * Certified Auditor and Trainer.  **Strength**  * Good interpersonal communication skills and enthusiasm to constitute friendly and supportive work place. * An out of box thinker with demonstrated abilities to meet the deliverables in available circumstances.  **Personnel Details**  * Father’s Name: Shri. B. L. Tembhare * Date of Birth: 26th Sep 1986 * Languages Known: English & Hindi. * Address: 692 MR-3, Mahalaxmi Nagar, Indore.   I hereby declare that the mentioned information is correct up to my knowledge and I will solely be responsible for any discrepancy found in them. Dhanendra Tembhare | | |
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