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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:-** A pharmaceutical professional having 14+ years experience in quality Assurance department and well versed with Aseptic manufacturing process, facility and equipment qualification, QMS & Investigation of events.  Block QA lead for injectable facility at Sunpharma Dewas.  Team reporting – 10 persons **Professional Synopsis:-** **Sun Pharmaceuticals, Dewas (M.P.)**  **Manager-QA**  **(Oct-2016 to Present)**  **Key Responsibilities: -**  **Aseptic Process & Validation review :**   * 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.   **Wockhardt Ltd, Waluj, Aurangabad**  **Executive- QA**  **(Oct-2014 to Oct-2016)**  **Key Responsibilities:-**   * Review of facility and equipment 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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