

Curriculum Vitae

Dhanendra Tembhare (M.Sc. Biotechnology)

E-mail: ghanendratembhare@gmail.com

Mobile: 09179172850 & 06262049375



Organizations:-

- Sun Pharma
- Wockhardt Ltd
- Ranbaxy Lab.
- Lupin Limited

Major Roles:-

- Qualified Inspector for internal and external Audits.
- Quality Management system
- Aseptic process management
- Validation Review
- Facility Qualification
- IPQA activities

Major Audit:-

- USFDA- 03
- TGA- 05
- MHRA- 01
- ANVISA- 02
- Health Canada-02
- EU-Netherlands-01

Profile Summary:

I bring over 15years 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, Inspection system, 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. I 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 Limited, Dewas (M.P.)

Manager-QA

Key Responsibilities:

(Oct-2016 to Present)

Audit and compliance:

- Internal inspection of all departments like Manufacturing, Quality Control, Microbiology Laboratory, engineering, etc.
- External inspection of vendor for API, packaging material and critical consumables.
- Preparation of Audit report for observed discrepancy with reference of GMP guidelines and examples.
- Assessment and Implementation of global action assign to site.\
- Managing the consultant during site visit and ensuring the compliance.
- Verification of compliance against other site observation and other companies.
- Project: Management of regional project (8 India sites) for enhancement of compliance and closure of regulatory inspection successfully.

Quality Management system:

- Management of Quality management system (QMS).
- Review and approval of change control, CAPA, deviation and market complaints.
- Investigation of deviation, market complaints and OOS results.
- Management of QA activities of aseptic manufacturing section.
- Review and approval of qualification documents of sterile product manufacturing section like Steam sterilizer, DHS, HVAC and medial fill.
- Project: Implementation of EU annex-1 revised 2022 & CCS, Isolator qualification and facility qualification.

Wockhardt Ltd, Waluj, Aurangabad

Executive- QA

(Oct-2014 to Oct-2016)

Key Responsibilities:-

- Preparation of response to the discrepancy reported by regulatory and corporate inspections.
- Assessment and Implementation of global action assign to site.
- Market complaint coordinator and investigation of market complaints.
- Recall coordinator – Initiation of recall, reconciliation of recall and coordinate with country representative for progress. Submission of recall update to regulatory.
- 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.

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 media fill.
- Investigation of environment excursions.
- Preparation of Product Review report for injectable products.

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 Faced:

- 2023 **Ukraine Inspection** (3rd to 7th Oct 2023)
- 2022 **TGA inspection** (08th to 18th Feb 2022)
- 2021 **Belarus virtual inspection** (29th Mar to 06th Apr 2021).
- 2020 **TGA Inspection** from 17th to 28th Feb 2020.
- 2019 **Russia Regulatory** from 10th to 12th Jul 2019.
- 2019 **ANVISA- Brazil** from 10th Jun to 14th Jun 2019.
- 2019 **EU-Netherlands** from 28th to 31st Jan 2019.
- 2018 **TGA Inspection** from 11th Mar to 22nd Jun 2018.
- 2018 **Health Canada** Audit from 22nd Feb to 01st Mar 2018.
- 2017 **CFDI China** from 06th Nov to 10th Nov 2017
- 2016 **TGA Inspection** from 10th Oct to 21st Oct 2016.
- 2015 **USFDA inspection** from 18th May to 26th May 2015.
- 2014 **ANVISA inspection** from 18th to 22nd Feb 2014.
- 2012 **MHRA inspection** from 5th to 10th Sep 2012.
- 2011 **USFDA inspection** from 19th to 24th Sep 2011.
- 2011 **TGA inspection** from 6th to 11th of February 2011.
- 2009 **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 Ahilyabai 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 and in Mar-2024 at Hyderabad.
- 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.

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.
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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, MP, 452010.

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
