# PRADNYA B. TARKAR

**Focused professional targeting challenging assignments in Quality Management in Pharmaceutical & Healthcare industry with an organization of high repute**

(+91) 8451953277, 9821284217

pradnyatarkar@gmail.com

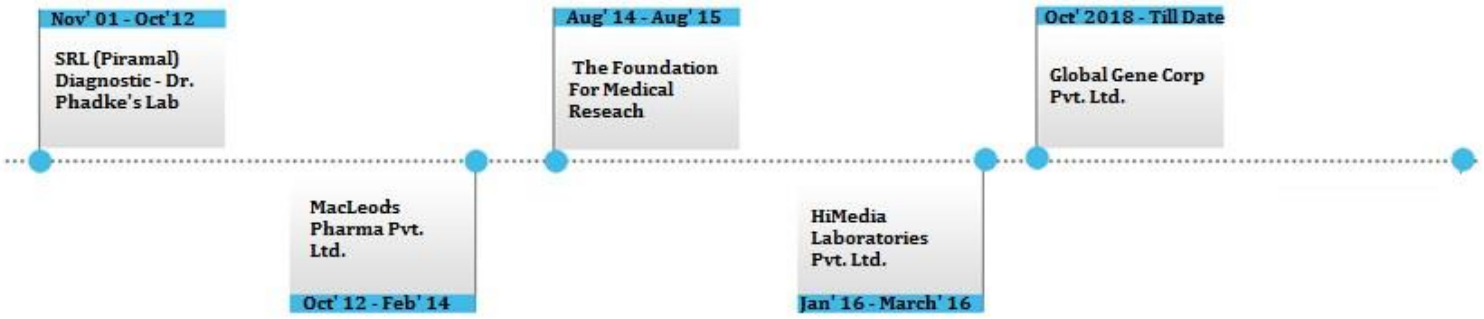
## Core Competencies

- Microbiological, Mol. Bio Analysis
- Diagnostic & Pharmaceutical Lab Set-up
- Internal Auditor : ISO 17025, ISO 15189, ISO 9001 (QMS), ISO 13485
- Audits & Statutory Compliance
- Process Improvements / Systems Implementation
- Quality Control & Management
- Reporting & Documenting

## Profile Summary

- A goal-oriented professional with 13 years of rich experience
- Effective in preparing & maintaining various documents necessary of the regulatory requirements; issuing raw data forms and logbooks of the facility; maintaining QC standards as per norms of ISO 17025:2017 (NABL), ISO 15189:2012 (NABL) and ISO 9001:2008 (QMS), CAP, ISO 13485:2016
- Proficient in microbiological analysis of formulation, raw products & finished products of the pharmaceutical company
- Skilled in managing the entire Microbiology Dept.; managing automated machines and maintaining quality control for them
- Excellent communication, training & interpersonal skills with strong analytical, team building, problem-solving and organizational capabilities

## Career Timeline




## Soft Skills

## Work Experience

## Highlights

- Conducting audits & maintaining own audit plan
- Preparation & review of Quality Manual for NABL norms ISO 17025, ISO 15189, ISO, CAP, ISO 13485
- Preparation, review & implementation of SOPs.
- Completed quality projects within time by taking initiatives
- Regulatory Compliance – GLP, ICH-GCP, GMP, ISO, NABL.
- Set up of Microbiology Laboratory for Diagnostic purpose.
- Set up of Microbiology Laboratory –Probiotic Analysis for pharmaceutical purpose.
- Certified Internal Auditor-NABL norms ISO17025, ISO15189, ISO9001 (QMS), ISO 13485
- Documentation necessary for Regulatory Requirements.

- **Global Gene Corp Pvt.Ltd., Andheri** **Oct'2018 – Dec'2019**
  **as Quality Manager**
- **Himedia Laboratories Pvt. Ltd., Ghatkopar** **Jan-16-Apr'16**
  **as Senior Officer (Regulatory Affairs & QA)**
- **The Foundation for Medical Research, Worli** **Aug'14-Aug'15**
  **as Researcher/QA Executive**
- **Macleods Pharmaceuticals Ltd., Andheri** **Oct'12-Feb'14**
  **as Manager (Microbiologist)**
- **SRL (Piramal) Diagnostics - Dr. Avinash Phadke's Pathology Lab, Mahim** **Nov'01-Oct'12**
  **as Senior Scientific Officer**

## Key Result Areas :

- Conducting audits & maintaining own audit plan; evaluating internal as well as external quality data.
- Ensuring that processes needed for the quality management system are established, implemented and maintained.
- Preparation & review of Quality Manual, Quality System Procedures, Quality Management Plan, Safety Manual, Sample Collection Manual (As per NABL, ISO, CAP regulatory)
- Preparation, review & implementation of SOPs.
- Regulatory Compliance (GLP, ICH- GCP, GMP, NABL, ISO, CAP etc.)
- Conducting management review meeting & preparing minutes for same; assisting & providing training and monitor its evaluation
- Ensuring the quality system is implemented and followed; reviewing raw data and compiling reports.
- Checking the daily QC of the department, completing all the tasks of audits.
- Reporting to management at the level at which decisions are made on laboratory policy, objectives, and resources, on the performance of the quality management system and any need for improvement.
- Maintaining record of all major and minor instruments; maintaining IQ, OQ, PQ for same.
- Reviewing & generating of raw data and final data capturing in ERP; preparing monthly indent preforming & maintaining the stock
- Prepare & maintain various documents necessary of the regulatory requirements.
- Review of raw data and compiled reports; QC check of raw data and data updated in LIMS.
- To issue raw data forms and logbooks of the facility.
- Maintain QC standards as per norms of ISO 17025:2017 (NABL), ISO 15189:2012 (NABL) and ISO 9001:2008, CAP (College of American Pathologist), ISO 13485:2016 (medical devices)
- Follow up with national and international regulatory bodies for scheduling of audits; completion of audits by taking corrective action on the non-conformities raised; closure of non-conformities.
- Maintaining Quality Control Program by participating in Proficiency Testing (PT, CAP-PT), External Quality Assurance Program (EQAS); selection of PT/ EQAS program, processing of PT/EQAS samples, reporting of PT/ EQAS results, evaluation of PT/ EQAS performance.
- Daily and monthly QC check, reporting the same.
- Developing specification SOPs and relevant documents as well as undertaking analytical method validation and related documents
- Supervising the analytical work & documentation as per the biotechnological regulations and various regulatory authorities
- Arranging documentation of the in-house developing analytical methods developing and standard testing procedures and specifications for routine use by QC personnel
- Directing the training sessions for employees and maintaining the documents.
- Reviewing the operational practices, identifying the areas of obstruction / quality failures and advising on system and process changes for qualitative improvement and energy conservation
- Imparting training to supervisory staff and workmen to ensure safe work practices
- Conducting field, site surveys and tests and managing various experiments for method development

## Skills : Microbiology, Molecular Biology, Genetics

- Solely responsible and accountable; Maintaining quality control techniques.
- Preparing media and validating, microbial limit test, growth promotion test, sampling and analyzing water samples
- Monitoring microbiological analysis of water, environmental (air, surface, personal) & air sampling, cleaning validation and microbial swab sampling for process
- Interpreting & trending of environmental monitoring results, identification Assessment of environmental isolates (microbial profiling), microbial pathogenicity & risk assessment
- Performing DNA as well as RNA isolation for sequencing; preserving & reviving of stock microbiological cultures
- Executing DNA extraction, DNA amplification, hybridization from all types of samples for processing & reporting of mycobacterial identification, susceptibility by HAIN method and GeneXpert test.
- Administering all types of cultures like aerobic, anaerobic, fungal, mycobacterial & reporting susceptibility for the same.
- Processing of mycobacterial cultures by digestion-decontamination procedure for rapid BacT/Alert, MGIT system as well as L.J. Method and reporting the same.
- DNA and RNA extraction using automated techniques – Qiagen QiaSymphony, Roche Magnapure 96.
- Performing Real Time PCR using automated ABI Real Time PCR and reporting the same.
- Performing Gel Analysis for extracted DNA.
- Managing operation theatre surveillance for different hospitals, blood banks using air sampler & reporting for the same
- Analysis and reporting of food & water samples for different airlines through Air India, Indian Airlines, Go Air .

## Clinical Trials

- Isolation of fungal species from the blood cultures of HIV positive patients & studying susceptibility pattern for the same. Trial for Quintiles

- Study of susceptibility pattern of Ceftazidime, Ceftazidime/Tazobactum, Cefperazone/Sulbactum, Cefperazone/Tazobactum on different clinical isolates – TRIAL FOR LUPIN PHARMA.

- Study of susceptibility pattern of Cefepime, Cefepime/Tazobactum, Piperacillin /Tazobactum, Cefperazone/Sulbactum, Cefperazone/Tazobactum on different clinical isolates & checking the MIC values of Cefepime/Tazobactum using E tests- TRIAL FOR LUPIN PHARMA.

- Study of susceptibility pattern of Nadifloxacin,Mupirocin & Fusidic Acid on different clinical isolates. TRIAL FOR MAXTER – A DIVISION OF LUPIN PHARMA.

- Study of susceptibility pattern of fungal isolates from specimens received to Voriconizole, Fluconazole, Itraconazole & Amphotericin -B. TRIAL FOR MAXTER – A DIVISION OF LUPIN PHARMA.

- Study of susceptibility pattern of Ceftazidime, Ceftazidime/Tazobactum, Cefperazone/Sulbactum, Cefperazone/Tazobactum on different clinical isolates& checking the
MIC values of Ceftazidime /Tazobactum using E tests- TRIAL FOR LUPIN PHARMA.

## Knowledge Purview

- BacT/ALERT 3 D: Aerobic, anaerobic, fungal blood cultures as well as for Mycobacterial cultures from any specimens as well as Mycobacterial susceptibility.
  MGIT system : Mycobacterial cultures from any specimens as well as Mycobacterial susceptibility.
  VITEK – 2 SYSTEM - Identification & susceptibility of aerobic, fungal isolates
- HAIN Test: Identification & susceptibility of Mycobacterium species using Mini Centrifuge, Sonicator, Dry Bath, Thermal Cycler, Twincubator
- GeneXpert – For identification & susceptibility of Mycobacterium species.
- ABI Real Time PCR – For performing Real Time PCR from extracted DNA.
- Magnapure 96, QiaSymphony – For automated DNA, RNA extraction.

## Academic Projects

- Isolation of Amylase Producer and studies on its Kinetics
- Isolation and screening of Antifungal Antibiotic Producer
- Isolation of Phenol Degrader and study of Phenol Degradation with respect to time

## Professional Qualifications

**YEAR –** 2021 "Post Graduate Diploma in Clinical Trials Quality Assurance, GCP Audits & Inspections" from Cliniminds Institute of Health Science Training and Management

"Diploma in Clinical Research" from Cliniminds Institute of Health Science Training and Management

ISO 17025:2017 Trained Internal Auditor from SGS

ISO 13485:2016 Trained Internal Auditor from SGS

**YEAR**- 2015 ISO 15189:2012 Trained Internal Auditor from QCI

**YEAR**- 2014 ISO/ IEC 17025:2005 Trained Internal Auditor from SGS

**YEAR**- 2013 ISO QMS 9001:2008 Lead Auditor Training from ISC (International Standard Certifications)

**YEAR** - 2000 MS Office 2000 from NIIT

## Academic Details

| Year | Degree |
|---|---|
| **1999** | M.Sc.(Microbiology)from Mumbai University,Mumbai |
| **1997** | B.Sc.(Microbiology)from Mumbai University, Mumbai |
| **1994** | H.S.C. from Sathaye College ,Mumbai |
| **1992** | S.S.C. from IES New English School,Mumbai |

## Seminars/Presentations

Successfully completed the fifth certificate course in "Good Clinical Laboratory Practices", conducted by Dept. of Biochemistry & Clinical Nutrition at Seth G.S. Medical College & K.E.M. Hospital

## Personal Details

**Date of Birth:** 12th February 1977
**Language Known:** English, Hindi & Marathi
**Address**: 29, Teachers' Colony, Building No.1, Bandra (East), 400051, Mumbai