**Curriculum vitae**

**Mukesh P Shewalkar, Ph.D.**

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**Profile Summary**

* High performing pharmaceuticals R&D professional with over twenty years of industrial experience.
* Thrives in environment that demands cost effective and time-bound product development through industry-oriented research.
* Expertise in development non-infringing process and transfer of APIs and advanced intermediates to commercial scale.
* Adept at managing end-to-end CRAMS/CMO projects leading cross-functional teams.
* Expert in Scifinder, Reaxys, and other online chemistry resources.
* A complete document support to enable DMF filing and other regulatory requirements like Product development report, justification for Specifications, Impurity management (Process impurities, GTI and Nitrosamine impurities),   
  Characterization reports, Risk assessment, KSM justification report, Vendor qualifications etc.
* Dealing with clients through teleconferences and regular updates.

**Qualification details**

Holds Ph. D. degree in Chemical technology. The thesis entitled as “Process development of some bioactive molecules”. It’s my immense pleasure to mention here that a renowned scientist, **Dr. A V Ramarao** is my research guide. I gave my total devotion to learn from him. It is also my pleasure to start my professional career also under his guidance.

**Professional Profile**

Had proportionate career growth with Avra laboratories Pvt ltd since July 2000. Started professional career with Avra laboratories in 2000 as a trainee chemist. After joining as a Trainee chemist, I have successfully handled various position in the organization. **Presently working as a DGM, R&D, API development and Tech transfer.**

Along with growth of carrier, acquired experience in different levels and areas.

* Worked with a team which was responsible for CRO work.
* Expertise to handle critical reagents on commercial scale.
* Developed economically viable synthesis processes for development substance and its intermediates.
* Trouble-shoots problems in existing processes at manufacturing facilities.
* Owns and delivers on-time, high quality performance within tight deadlines for end-to-end R&D operations of active pharmaceutical ingredients and intermediates with or without regulatory complains as per requirement.
* Managed all contract research and manufacturing services (CRAMS), early stages of API and APIs.
* Undertook project feasibility studies, costing and timeline projection for the projects.
* Designed and developed non-patent-infringing, commercially viable manufacturing processes and synthetic routes for APIs.
* Experienced in developing polymorphic study as well as development of new polymorphs.
* Leads cross-functional teams in design and development of new and existing processes and process validation activity.
* Drives technology transfers, process hazard evaluation, and HAZOP throughout project lifecycles.
* Delivered timely and actionable insights to senior management based on in-depth literature surveys.
* Supported senior management in technology transfer projects.
* Prepared and implemented departmental SOP and training.
* Liaised with senior management and clients for progress monitoring.
* Manages all activities related to DMF filing and cGMP compliance of manufacturing site.
* A thorough knowledge of all the requirements for regulatory like scouting of route, vender selection process, impurity profile, carry over study, characterization, lab validation, lab development and report preparation, technology transfer document etc.
* Leads technical team for regulatory and QA department to complete all the technical needs required for DMF and other regulatory.
* Sound knowledge to prepare and review of all the documents and training program as per regulatory requirement.
* Revives and answers all type of customer / regulatory queries.
* Presentation / reporting of the development stage to the clients.
* Responsible in regular updates, continuous monitoring the progress of the API in all stages.
* Responsible for making and follow ups micro planes on daily basis to meet the specified time line.
* Leads a team of 25-30 chemists.
* Commercially developed API includes from Oncology, Alzheimer, Cardiovascular diseases, Psoriatic arthritis and even Antiviral categories.

**Academic Profile**

I. Ph. D. (Chemical Technology), May 2015

Dr. B. A. Marathwada University, Aurangabad

II. B.Sc. Chem Tech (Chemicals and Pharmaceuticals), July 2000 with 1st division.

Dr. B. A. Marathwada University, Aurangabad

III. B. Sc. (MPC), July 1997 with 1st division.

Dr. B. A. Marathwada University, Aurangabad.

**Awards**

**Best Technology award by Avra Laboratories Pvt. Ltd in 2006-2007.**

**Publication includes four papers and nine patents**

**Personal Profile**

Date of Birth: January 02, 1977

Marital status: Married

Address for correspondence: Fl. No. D-105,

May Flower grande apartment,

Mallapur,

Hyderabad-76

**References will be given if needed.**