CURRICULUM VITAE

VISHAL RAMESHRAO SURKAR
Contact No. - +91 9960435044,
+91 7588140335
Email- vishal.surkar@gmail.com

- **OVERVIEW:**
  Provide technical leadership to the Respiratory and Injectable Product Development groups including Formulation Development and Analytical Development. Development of stable products across all markets, with a focus on regulated markets. Responsible for complete technical oversight of Respiratory and Injectable Product Development on a global scale from inception through Marketing Authorization submission.

- **PROFESSIONAL EXPERIENCE:**

  (Overall experience ≈ 15 Years)

  - **PAR Formulation Pvt Ltd (Endo Pharmaceuticals)**, Airoli, Navi Mumbai from August 2019 to till date as a Sr. Manager in Product Development Department.
    (Total Exp. 4 Year 5 Months)

  - **Glenmark Pharmaceuticals Ltd**, Taloja, Navi Mumbai from March 2016 to August 2019 date as a Research Scientist in Formulation Development Department.
    (Total Exp. 3 Year 5 Months)

  - **Macleods Pharmaceuticals Ltd**, Andheri (E), Mumbai from October 2013 to March 2016 as a Dy. Manager in Formulation Development Department.
    (Total Exp. 2 Year 5 Months)

  - **Cipla Ltd,** Vikhroli (W), Mumbai from January 2010 to October 2013 as a Management Staff in Formulation Development Department.
    (Total Exp. 3 Year 9 Months)

  - **Meyer Organics Pvt Ltd,** Thane from December 2008 to January 2010 in Formulation Development Department.
    (Total Exp. 1 Year 2 Months)

- **PRODUCT DEVELOPMENT – KEY OBJECTIVES:**
  - Steer the product development process as per timelines and manage project as per various regulatory requirements.
  - Coordinate with other departments to execute the assigned projects.
  - Ensure regulatory requirements are met for achieving successful product approvals.

- Write/review technical reports for submissions.
- Review of technical sections for submission documents.
- Support and guide the team to decide on the development strategies and activities for product development.
- Develop new techniques & manufacturing process for the formulation development.
- Identify new systems and techniques to improve the delivery quality and timeline.
- External Interfaces - Vendors, CMOs, Device Manufacturers.
- Internal Interfaces - IPM, Commercial Teams, Project Management, Plant QC/QA, Production and Supply Chain Group, Regulatory Affairs, Packaging Development, Sourcing/Procurement, Business Development team.

- **KEY MILESTONES ACHIEVED:**
  - Formulation and process development of 2 Inhalation Solution product and 1 Suspension products resulting into the successful commercialization in USA market.
  - Formulation and process development of Nasal Spray product resulting into the commercialization of 1 NDA product in USA market and 1 generic product in EU market.
  - Formulation and process development of Metered Dose Inhalers product resulting in the successful execution of exhibit batches of 1 product for USA market, completed the R&D development activities of 1 generic product and successful commercialization of several MDI product for domestic and ROW market.
  - Actively participated in facility design, equipment setup, installation and qualification of all equipments and instruments of MDI facility to conduct formulation development batches and analyse the same at all phases of generic development at R&D centre.
  - Worked with Regulatory, QA and Engineer Team to develop manufacturing processes to support US ANDA filing, for a range of MDI, Nasal Spray and Inhalation Solutions / Suspension products.
  - Evaluated ANDA development opportunities for commercial Nasal Spray, Inhalation Solutions / Suspension and MDIs including technical challenges, suppliers for API/ excipients/devices, intellectual property and clinical study requirements to support continual success of the organization.
  - Coordination with cross-functional teams including Project Management, Analytical R&D, Manufacturing, Clinical, Legal and Regulatory Departments to ensure delivery of project within timeline and allotted budget.
  - Workflow establishment and optimization to maximize operational efficiency.
  - Personnel recruitment, establishment of training and leadership.
  - Managed drug product development program from concept to commercialization.

- **EXPOSURE:**

  A. Referencing:
  - Literature survey and compilation of the same for product development.
  - Evaluation and interpreting patented information pertaining to the product, pharmaceutical compositions and looking for non-infringing composition if required.

  B. Formulation and Process Development:
  - Pre-formulation Studies: Evaluation of raw material for development.

- Market Products Evaluation: Evaluation of local and international competitor, Reverse Engineering of innovator formulation and development of ideal parameters to suit our formulation and process specification.
- Conduction of lab scale trials: Carrying out various formulation and process trials by applying QbD approach & DOE strategies and evaluating product for physico-chemical parameters so as to achieve preset/equivalent specifications.
- Optimization of formula and process parameters so as to achieve reproducibility of predetermined and finalized product specification.

C. Stability Studies:

- Preparation of stability protocols of various dosage forms as per international guidelines.
- Stability monitoring of the finalized R&D batch in proposed packing materials under accelerated conditions and generate real time data.

D. Scale Up & Registration Batches:

- Finalize product formula in co-ordination with production department.
- Observing various activities during scale up trial at production plant and trouble-shooting the problems.
- Finalizing the Raw Material and Finished Product Specification after successful evaluation and process optimization of Scale up batch at shop floor.

E. Packaging Development:

- To carry out the drug product and packaging materials compatibility and monitoring the stability of the same.
- Finalizing the Primary Packing Specification after successful evaluation of the same.
- Reviewing of DHF documents for device combination products.

F. Documentation:

To prepare documents such as Product Development by QbD Strategy , Formulation and Process Development Report, In Vitro Study Protocol and Reports, Drug Product Characterization Studies Protocol and Report, Stability Study Protocols, Formulation and Process Optimization Study Protocol and Reports, Test License Application, Manufacturing License Application, Packaging Development Checklist, Finished Product Specification, Manufacturing Guidelines for Production Unit.

G. Equipments Handled:

Crimping and Filling Machine, Leak Test Apparatus, pH Meter, DO Meter, Osmometer, Digital Microscope, Vibromixer, Zetasizer, Rheometer, Surface Tensiometer, Brookfield Viscometer, Ultrasonicator, Ink Jet Printer during product development.

- **EDUCATIONAL ACHIEVEMENTS:**
  - **Master of Pharmacy (Pharmaceutics)**

    From: Vinayaka Mission's College of Pharmacy, under Vinayaka Missions University, Salem (T.N.) with 70.23%.
  - **Bachelor of Pharmacy**

    From: Agnihotri College of Pharmacy, Wardha under Rashtrasant Tukadoji Maharaj University, Nagpur with 65%.

- **CO-CURICULAR ACTIVITIES:**

  2021 – Lean six sigma yellow belt

2013 - Participate in the training program of 'Six Thinking Hats' and 'Lateral Thinking' based on New innovative ways of Thinking.
2011 - Participate and won the best participant in training program based on Aseptic Filter Validation conducted by Merck Millipore India Pvt. Ltd.
2011 - Participate in the training program based on Basics of Rheology conducted by Anton Paar.
2009 - Attend seminar on Operational Excellence & Quality by Design organized by FMC Biopolymer & Signet Chemicals Pvt. Ltd.

- **PERSONAL DETAILS:**

Name	:	Vishal Rameshrao Surkar
s	:	C-402, Mangeshi Srushti II, Vasant Valley Road, Gandhare Village, Khadakpada, Kalyan (W), Thane, Maharashtra. Pin Code: 421301.
Date of Birth	:	11-12-1984
Nationality	:	Indian
Language Known	:	English, Hindi & Marathi.
Marital Status	:	Married
Strength	:	Hardworking, Innovative, Good communication skills.
Hobbies	:	Listening music, Reading books, Watching Movies etc.

- **DECLARATION**

I hereby declare that the above details furnished are true to the best of my knowledge and belief.

Date:
Place: Mumbai

(Vishal Rameshrao Surkar)