MICHAEL FERNANDES

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SCIENTIST / RESEARCH & DEVELOPMENT PROFESSIONAL – PHARMACEUTICAL INDUSTRY

14+ years' rich experience in delivering optimal results & business value in high-growth environments in the areas of **Analytical Development, R&D in Pharma Industry of repute**

SYNOPSIS

Technically Competent, diligent and result oriented Analytical Scientist, offering **over 14 years** of analytical experience in analytical method development, validation and stability studies in various dosage formulations, currently spearheading functions as **Supervisor (Group Leader) with Bilim Pharmaceuticals Research Center, Istanbul, Turkey , possess all-round competencies in quality assurance domain including all fine aspects covering - Documentation, Analytical Method Development, In-Process and Chemical & Instrumental Analysis for both Generics and Branded Formulations.**

Seasoned professional with a comprehensive scholastic background in Masters of Science, Environmental Science & Graduation in Chemistry, seeking to provide top quality service in the field of Research & Development across the Pharmaceutical Industries, Exhibits an honest work ethic with the ability to excel in fast-paced, time-sensitive environments. With quick learning ability, is able to grasp and apply new concepts efficiently and effectively to get the desired outcome.

High-performing professional with a reputation of unwavering accuracy & consistently delivering results towards designing, coordinating and analyzing various compounds and their outcomes. Proficient in preparation of research reports and manuscripts for publications (USP and BP etc.), acquaintance with most of the experimental techniques. Proactive and industrious, with a comprehensive exposure of both collaborative and independent research, Excellent communication and inter-personal skills and possess contagious enthusiasm towards the achievement of organizational objectives.

CAREER GLIMPSE

BILIM PHARMACEUTICALS RESEARCH CENTER, ISTANBUL, TURKEY — **since Apr'11**

Supervisor (Group leader), Generic Division, *Reporting to Analytical Head of Department / R&D Head*

AUROBINDO PHARMA LTD., GENERIC DIVISION, HYDERABAD, INDIA — **Mar'06 – Mar'11**

Scientist (Group leader)

ELIE PHARMACEUTICALS - KHARTOUM, SUDAN, AFRICA — **May'02 – Dec'05**

Analytical Supervisor

AUROBINDO PHARMA RESEARCH CENTER (GLOBAL R&D), HYDERABAD, INDIA — **Jan'00 – Apr'02**

Research Associate

NATCO PHARMA LTD, KOTTURU, HYDERABAD, INDIA — **Oct'95 – Jan'00**

Quality Control Chemist

Key Accountabilities

- Development of analytical methods for the different pharmaceutical dosage forms. (Assay, Dissolution, Related Substance; for both compendial and non-compendial products (tablets, capsules and liquid orals). using HPLC, GC etc.
- Validation of analytical test procedure for related substances by HPLC, assay, dissolution analytical test procedure and in process analytical test by HPLC, GC etc. Accountable for preparing SOP's and STP's for development of analytical methods.
- Conducting Analysis of dissolution of solid oral dosage forms (tablets, capsule) in multimedia during the product development for selection of batch for bioequivalence studies.
- Method transfer/ Demonstration of validated analytical methods to the manufacturing plant locations.
- Characterization of In house reference standards and qualification of Working Standards against the compendia reference standards. Accountable for archiving the study documentation and correspondence and preparing final reports Accountable for creating documents that comply with regulatory guidelines in terms of content, format and structure.
- Identifying product related impurities and elucidating degradation pathways in accordance with the time lines drawn for product development, ensuring timely progress and completion of tasks.
- Responsible for conducting saturation solubility, dissolution profiles which includes multimedia with multi time points.
- Responsible for validation planning and validating methods as per the methodology and ensuring that the compliance of ICH / USFDA guidelines.
- Responsible for new method development & validation for following ICH guidelines and method development for Assay, RS & Dissolution for finished dosage forms, Solid orals.
- Full accountability in regular analysis of raw materials, finished dosage forms through Instrumental techniques and analysis of stability samples of finished dosage forms like Solid orals etc.
- Driving efforts for formal and Informal stability studies followed by ICH Guidelines.
- Preparation of validation protocols and reports as per the regulatory requirements. Preparing and checking final validation data and documentation as per the FDA requirements.