

V. Hariharan

Flat No.:203, C-Block,
Sai Mithra Appartments,
Kushaiguda,
Hyderabad.

Manager,
HR department,

Dear Sir/Madam,

I am writing to express my interest to join your esteemed organization with anticipation that it will be a challenging and progressive program that will assist me in achieving my immediate and long term career goals. I'm enclosing a copy of my resume for your kind consideration.

I was associated with Vimta Labs Ltd. as a Manager for Bio-analytical department wherein I was responosible for leading and managing the bioanalytical activities prioritizing the quality aspects.

My 17 years of aggressive experience has given me the opportunity to interact with multitude sponsors, building an extensive relationship by knowing their specific requirements. During my tenure I have faced many audits/inspections and successfully implemented the procedures with high quality standards. My professional creed is to take pride in the quality of my work and willingness to perform even the most menial task to remove project obstacles and get the job done. I have a very successful track record for regulatory audits from: USFDA, WHO, MCC, DCGI, NPRA & UK MHRA.

Excellent in guiding , motivating, training and mentoring the peer colleagues. With my proven ability to manage and maintain high quality standards, I feel that I would be able to make significant contribution to your company's management team. I hope you will find me competent enough as desired for the post. Should you however require any additional information, I shall be pleased to furnish the same.

I would appreciate providing any opportunity to discuss my qualification abilities and capabilities in more detail and would make myself available at your earliest convenience.

Thanking you in anticipation of an early reply.

Yours sincerely,
V. Hariharan.

Encl: Resume



Bio Analytical Manager consummate in the overall operations of a Bioanalytical lab with profound knowledge in current regulatory practices. Adept in technical writing and interpreting analysis reports. Responsible for the development and validation of analytical methods for pharmaceutical dosage forms in both clinical and non-clinical samples utilizing LCMS/MS and HPLC techniques.

CAREER AT A GLANCE

- Proficient in preparing, planning, reviewing project reports, updating existing standard operating procedures (SOPs), drafting and reviewing new laboratory SOPs.
 - Adept in team building skills with proven ability in establishing quality systems / procedures and managing resources.
 - Adept in Bio-Analytical method Development, Method Validation and Study sample analysis through operating LC-MS/MS.
 - Supervised the analysis of over 180 BA/BE studies for regulatory submissions.
 - Involved in the development and preparation of training modules for methods, equipments etc.
 - Excellent ability to meet tight deadlines under pressure.
 - Strong job allocation skills to achieve the efficiency in overall operations.
 - Possess excellent time management skills, with high degree of technical competence and commitment to quality.
 - Increased Productivity by eliminating wastage, training, planning and preparation of lead times for all the processes.
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PROFESSIONAL SUMMARY

August 2004 – Till Date:
Ltd,Hyderabad

Vimta Labs

Vimta Labs is India's leading contract research and testing organization. VIMTA currently has a team of 840 comprising 450 scientists in various disciplines such as Chemistry, Pharma, Medicine, Microbiology, Molecular biology and Informatics. The Operational segments are like; Pre-Clinical Research, Clinical Research, Clinical Reference Laboratory, Analytical testing, Advanced Molecular Biology, Environmental Assessments, Food & Agriculture products, Drugs & Pharmaceuticals. The Services comply with applicable GCP, GLP and ISO standards.

Manager (Bioanalytical Division)	: April-2014 – Till date
Deputy Manager (Bioanalytical Division)	: August. 2010 – April-2014
Group Leader (Bioanalytical Division)	: April. 2008 - August 2010
Scientist (Bioanalytical Division)	: August 2004 - April 2008

Manager (Bio Analytical Division):

Responsibilities:

- Supervising and conducting the PK (BA/BE) analysis in both clinical and non-clinical samples in accordance with the regulatory guidelines.
- Providing expertise, guidance and training to junior staff members to work in a regulated environment.
- Preparing Standard Operating and Testing Procedures for the Analytical Development.
- Involved in various regulatory audits like USFDA, WHO, MCC, DCGI, NPRA & UK MHRA.
- Involved in Method development and validation in accordance with GLP and ICH guidelines, LCMS/MS techniques, operations and trouble shooting them on time.
- Extensively working on sample extraction procedures, performing analysis for Bioequivalence/Bioavailability studies using LCMS/MS and HPLC.
- Ensuring that the tests are completed according to project timelines; and responsible for writing, reviewing validation protocols, validation reports, method transfer reports and other analytical technical reports as necessary.
- Responsible for updating existing SOPs, drafting and reviewing new laboratory SOPs.
- Involved in the preparation of method validation protocols, reports and bioequivalence reports for submission to various regulatory authorities.
- Leading, monitoring and guiding a team of 24 members.

Core Competencies:

- Interacting with the regulatory team during audits and implementing the procedures with high quality standards.
- Skilled in preparing and finalizing the responses regarding sponsor queries and also regulatory queries.
- Expertise in interacting with the sponsors to ensure complete acquaintance of the sponsor with the Bioanalytical facility and systems.
- Aggressive experience in preparation and implementation of various SOPs as per GLP and ICH guidelines in Bioanalytical department.

Quality System Experience:

- GLP
- ICH-GCP
- ISO 17025
- cGMP

ACADEMIC PROFILE

M.Sc. (Organic Chemistry) from Bharkatullah University during 2002-2004.

B.Sc. (Chemistry) from Nagarjuna University. A.P during 1999-2002

Intermediate from Board of Intermediate. A.P during 1996-1998

PERSONAL PROFILE

Name	:	V. Hariharan
Father's Name	:	V.V. Ramana
Date of Birth	:	24-10-1980
Sex	:	Male
Languages	:	English, Hindi, Telugu
Nationality	:	Indian
Address for correspondence	:	Flat – 203, C-Block, Sai Mithra Apartments, Kushaiguda, Hyderabad- 500062. India.

REFERENCE

K. Ravi Kumar, (Mobile-9963344003)
VP – TAL Pharma,
Vimta Labs Ltd,
INDIA.

M. Rambabu (Mobile-8978000331 & 9100057608)
VP- ClinSync Clinical Research Pvt Ltd
Hyderabad
INDIA.

VVV. Prasad (9849075424)
Former AVP-Clinical Research
Vimta Labs Ltd,
INDIA.