CURRICULUM VITAE

VIKASH KUMAR
M No.: +91- 9980511540
E-mail: jha.vikash281@gmail.com

CAREER OBJECTIVE:

Intend to structure my growth in place with the ever-changing corporate environment. Make my learning curve to move in a linear fashion along with the growth of my technical skills coupled with overall personality development in order to face the challenging items ahead.

CARRIER HIGHLIGHTS:

- ✓ Performance driven professional with over 17+ years of diverse experience in various pharmaceutical Facilities and dosage form in Quality function with more than 10+ years of rich exposure of a leadership position. Handled the team size of more than 70+ peoples with direct reporting of 8+ managers, driven the companies to various regulatory approvals like USFDA, MHRA, TGA, WHO, ANVISA, EU GMP, etc.
- ✓ Leading Project Team Member, has designed, executed the **whole Greenfield state of the art** soft gelatin capsule manufacturing facility of Olive Healthcare Unit II along with the commissioning, validation and all required documentation.
- ✓ Equipped the New Plant of Olive Healthcare UNIT II and get it Approved by USFDA within limited period of time and resources followed by almost all major regulatory approvals across the globe.
- ✓ **Brown field project** at Olive Healthcare Unit-II, by design and execution of the expansion of the existing manufacturing/packing capacity by double the its current capacity.
- ✓ Key contact for the regulatory support and product registration for the dossier compilation, timely compliance to the registration queries and successfully got product approvals in the regulated markets viz. EU, UK, Australia, Jordan and many more.

EDUCATIONAL QUALIFICATION:

- ✓ Bachelor of Pharmacy (Graduate) from Karnataka college of Pharmacy under Rajeev Gandhi University of Health & Science, Bangalore by the year 2001-2005.
- ✓ Intermediate from J.N. College Madhubani under Bihar Intermediate Examination Council, Patna by the year 1999-2001
- ✓ Matriculation Under Bihar Secondary Examination Board, Patna by 1999.

EXPERIENCE:

- ✓ Presently working with **Olive** Healthcare, Daman as **Head QA & Microbiology (GM) and support project team and regulatory affairs** from August 2017 to till date.
- ✓ Worked with **Medreich Ltd.,** Bangalore (100% subsidiary of **Meiji Seika Pharma**, Japan) as **Head-QA** (Sr. Manager) from July 2015 to August 2017.
- ✓ Worked with **Rusan** Pharma Ltd., Dehradun as Head – QA for Aug 2013 to Jun 2015
- ✓ Worked with **Olive** Healthcare, Daman as Manager QA & Projects for Sep 2010 to July 2013.
- ✓ Worked with **J.B.** Chemicals and Pharmaceuticals Ltd, Mumbai as Corporate Quality Assurance for Aug 2009 to Sep 2010.
- ✓ Worked with **Matrix** Laboratories Ltd. Nashik (A subsidiary of **Mylan** Inc. USA), for Feb 2008 to August 2009 as a Quality Assurance Officer.
- ✓ Started carrier with **USV** Ltd. Daman as Quality Assurance Officer from Nov 2005 to Feb 2008.

JOB CAPABILITIES AND EXPOSURE: -

- ✓ Have successfully handled and received Health authority inspection approval from regulatory authorities (e.g. USFDA, EU GMP, MHRA, TGA, ANVISA, WHO Geneva) and ISO 9001, ISO 14001, BS OHSAS 18001, and national and international customer audits.
- ✓ Exposure of the complete set up of the new manufacturing facility including Designing of facility for process flow, Equipment designing and Selection, HVAC and Water systems designing, Qualification and validations, Quality Risk Management, Design and implementation of different QMS system.
- ✓ Leading the management review meetings and interface among all cross functional departments to drive and meet the quality objectives with business goals of the company.
- ✓ Monitoring and governance of various QMS system viz. Change control, Deviations, CAPA, Out of trend, Out of specification, Market complaints, Risk Management, Technical Agreements etc.
- ✓ To ensure the conformance of systems and work practices with the Standard Operating Procedures based on Current Good Manufacturing Practices & Documentation.
- ✓ Risk assessment for elemental impurities, Nitrosamine, excipients risk assessment and their levels in the drug product is controlled within acceptable limits.
- ✓ Assist customer/regulator liaison, demonstrating our quality systems as required, and leading customers and regulatory audit at site.
- ✓ Review and approval of SOP's, Validation master plan, Annual product reviews, trend analysis, validation protocols of process, equipment qualification, cleaning validation, analytical method validation, site master file etc.
- ✓ Guidance on the implementation of Data Integrity and Compliance with CGMP across the organization as per the guidance specified by the FDA US and European authority.
- ✓ Review and approval of the documentation for Technology Transfer, Specifications and STP for Finished products as per Regulatory Requirements.
- ✓ Exposure of internal auditing of different - different formulation and API manufacturing sites for preparation and support for various regulatory as well as customer audits
- ✓ Certified Trainer for GMP regulations of 21 CFR and EUGMP. Training and development of teammates to drive them towards company's goal and objective.
- ✓ Certified Auditor for Internal audit, vendor audit and periodic vendor evaluation. Responsible for API vendor audit as per ICH Q7 and EudraLex volume 4, Part II.
- ✓ Handled complete microbiology laboratory including laboratory design, set up, development of SOPs and procedure, monitoring of day to day activity in lab.

KEY WORK ATTITUDE:

- ✓ Involves in team based activities and self-initiative in achieving company's objectives.
- ✓ Initiates creative changes in terms of ideas, methodology, work practices in improving efficiency and effectiveness of the work system, processes and practices.
- ✓ Conduct day – to day work with high level of honesty, ethical and fair in achieving required work results.
- ✓ Understand and support continuous development of employee to improve their effectiveness.
- ✓ Inter – departmental co-ordination and provide personal support to all.

TRAINING: -

- ➢ Certified Internal auditors for Quality Management System according to ISO 9001 & ISO 19011.
- ➢ Certified Trainer for GMP regulations of 21CFR and EU GMP.
- ➢ Data Integrity, Reliability and Data governance workshop by Novartis
- ➢ Supply chain securities and challenges by Expedetors and Air-India Stats and Cathy Pacific.

COMPANY PROFILES: -

Olive Healthcare is one of the largest soft gelatin capsule manufacturing companies in India. Olive healthcare has two state of art soft gelatin capsule manufacturing facility and for Unit II, I was the leading team member for complete commissioning of project. Facility is approved by USFDA, EU GMP, JFDA, TGA, SFDA, etc.

Medreich Ltd. (subsidiary of **Meiji Seika Pharma**, Japan) is a fully integrated pharmaceutical company with an established presence across the globe. With a client base spread across 54 countries, the company is involved in manufacturing of formulations for multinationals like GSK, Pfizer, Sanofi Aventis, Wyeth, Adcock Ingram, Mylan, Actavis and many other customers.

J.B. Chemicals and Pharmaceuticals Ltd. group of companies, involved in manufacturing various dosage forms like Tablets, capsules, SVP, LVP, Liquid orals as well as Active Pharmaceutical Ingredients.

Matrix Laboratories Ltd (A subsidiary of Mylan Inc. USA), A USFDA, MHRA, MCC, WHO Geneva &India approved Company. The New Mylan (Mylan + Matrix + Generic business of Merck) is the world's third largest pharmaceutical organization in Generics business.

USV Ltd, **Daman** a USFDA, NDA Uganda, and various other regulatory agency approved company having more than 800 corers turnover, manufacturing various dosage form like Tablets, capsules and SVP.

PERSONAL PROFILE: -

Name	**:**	**Vikash Kumar**
Father's Name	:	Sri Baidyanath Jha
Date of Birth	:	5th July 1984.
Nationality	:	Indian
Marital Status	:	Married.
Hobbies	:	Playing Volleyball, cricket, and football & reading books
Motto	:	Do the work right, first time, every time.
Strength	:	Hard work, Commitment, Confidence, and Grace of my elders
Computer Knowledge	:	M.S.-office, SAP& Internet application.
Other achievements	:	Various certificates in Volleyball, athletics, etc.
Language Known	:	Hindi, English, Maithili (reg. language)

COMMUNICATION :

Present Address	:	Dunes Residency, I/402, Dunetha Nani Daman. 396210.
Permanent address	:	At & PO: -Nahar Bhagwatipur PS: Pandaul Dist: - Madhubani (Bihar) 847236

DECLARATION :

All the information's provided in this resume is authentic as per my knowledge and belief.

Date: -

Place: -

VIKASH KUMAR