



Kashyap Nagariya Ph. D.

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Seeking senior level assignments in product development/Strategic planning with a leading organization of repute in health care industry. Evolved strategies that reached out to global markets: repeatedly produced, improved, sustained growth in dynamic and rapidly changing global market.

Professional skills: Possessing a M. Pharm., Ph. D. with 14 years of experience in sterile formulation & development. An in depth of all aspects of formulation and ability to work in team-based environment.

- Experienced in end-to-end product development/ process development of Injectable, Parenteral dosage forms
- Have enough exposure of infusion (ready to use solution, emulsion & suspension, sterile dry powder, lyophilized); Ophthalmic (solution, suspension, emulsion, ointment) product development, exhibit to commercial scale batch manufacturing.
- Sound experience on Extractable Leachable of Sterile dosage forms.
- Experienced in Elemental Impurities; Nitrosamine Impurities; Cytotoxicity studies; Toxicological assessment.
- Have good understanding about Reverse Engineering of Innovators /Reference product.
- Have good experience on pre-formulation trials & development batches during development of parenteral products.
- Have good understanding about preparation of development strategy report, QbD Based PDR, protocols, reports, SOPs, and tech transfer documents i.e., MFR, BOM, sampling protocols, stability protocols etc. of formulation Development dept.
- Can address the problems and queries related to the development of the formulation

- Analyze the formulation strategy, efficiency, working relations and cross-functional issues in R&D.
- Co-ordination with analytical team and providing product development and sample submission planning support as per the project requirement. Review and analysis of results and discussion with the analytical team during the product development.
- Vast experience of Injectable generic product development and troubleshooting for regulated market is preferred.
- Good communication and Coordination skills and ability to work with a diverse cross-functional teams.
- Good analytical data interpretation skills and report writing skill with creative thinking ability.
- Shouldering team of scientists for the development / Scale up / exhibit of sterile formulations for Regulated & emerging Market.
- Complete Responsibility as project lead for assigned projects from initiation to commercial launch. Carry out project management activities for research projects in conjunction with the project team: Project milestones and tasks, Timeline for project completion, Resources required for the project, Cost schedule associated with the project
- Proper planning of strategies for appreciable development and successful execution of projects within the defined timeframe.
- Play a pivotal role to crack complex technical challenges and support the PDTs meet due date performance and achieve desired value of filings
- Well familiar formulation development skills with available/suitable manufacturing facilities. Expertise in quality improvements, reformulations of existing products.
- Design and implement experiments with QbD approach regarding Pre-formulation, selection of excipients, development and optimization of composition to render stable, reverse engineering and patent non-infringing formulation.
- To support team in designing and developing products, from ideation, to prototyping and proof of concept evaluation.
- Involved in trouble shooting of various existing and commercial products.

- Managing skills of formulation development with available resources.
- Support the Strategy team in designing for development of Sterile Formulations by defining target, product profile (from cost, quality, manufacturing standards)
- Assist in troubleshooting at commercial stage along with the launch preparation team by helping resolve the formulation related technical issues during commercialization phase.
- Well acquainted about various methods for sterilization to develop a unique formulation for FDA standards.
- Contribute to new IP for current and next generation technology platforms
- Expertise in novel inventive formulations like Nanoemulsion, Nanospray.
- Strong in technical writing, interpersonal, and communication skills
- Intra and inter department co-ordination with various CFTs viz. PM, IPR, RA, Packaging, Production, Purchase, QA, QC and BD for intermediate activity linked with timely completion of projects.
- Assist RA in addressing deficiencies or regulatory queries by providing support w.r.t. receiving, analyzing & resolving the formulations related queries / deficiencies
- Bring in new technologies & advances in Sterile formulations by attending seminars, conferences & external networking with leading academicians.
- Knowledge transfer to the domain members and contributing towards continuous learning of self & team members.
- Work according to appropriate SOPs, [GMPs](#), ICH and regulatory guidelines in the R&D center. Conversant with the documentation aspects of the research lab and maintenance of records.
- Contribute as an R&D member on cross functional project teams; interact with Operations, and Quality personnel to support product development activities
- Perform duties as assigned; supervision, counseling and disciplining team; planning, monitoring, and appraising job results; conducting training; implementing enforcing systems, policies and procedures.

Industrial Experience

Present: Otsuka Pharmaceutical India Pvt. Ltd., Ahmedabad *for Europe and Brazil market* as Section Manager (Sr. Manager)-Formulation Development from Oct. 2020

to present

Past: Jamp Pharma Corporation, Quebec, Canada, (based in Ahmedabad) *for Canada market* as Manager-Product Development from Nov. 2018 to Oct. 2020
Cadila Pharmaceuticals Ltd., Dholka, Ahmedabad *for Europe & MENA countries* as Senior Research Scientist (Manager) – NDDS Formulations from Apr. 2017 to Nov. 2018

Zydus Cadila Healthcare Ltd. - PTC, Ahmedabad *for US Market* as Deputy Manager - F & D from Apr. 2016 to Apr. 2017; Associate Research Scientist from Apr. 2013 to Mar. 2016

Ahlcon Parenterals (I) Ltd. (R & D Division), Bhiwadi, Rajasthan (a B. Braun group company) *for Europe & CIS countries* as Senior Executive – R & D from Feb. 2011 to Mar. 2013

Kusum Healthcare Pvt. Ltd. (R & D Centre), Bhiwadi, Rajasthan (a unit of Glad Pharm, Ukraine) *for CIS countries* as Officer – R & D from Nov. 2008 to Feb. 2011

Ranbaxy Research Laboratories Ltd. (PDR-US Division), Gurgaon, Haryana *for US market* as Trainee – R & D from Oct. 2007 to Oct. 2008

Sun Institute of Pharmaceutical Education & Research, Lahar, Gwalior (M.P.) as Lecturer from Oct. 2005 to Sep. 2006

Computer Proficiency

- Well versed with Windows, MS Office, Adobe, Acrobat Professional, SAP, DoE, MiniTab.
- Scientific data retrieval from various Internet portals like FDA, EMEA, Health Canada, ANVISA, TGA, South Africa, medicinesuk, uspto, ipcom, ipindia, eponline, wipo, espacenet, Pubmed, Sciencedirect & numerous other search engines.

Academic Profile

Ph. D. (Pharmaceutical Technology) (2011 to 2014)

From Faculty of Pharm. Sci., Bhupal Noble's College of Pharmacy, Udaipur

M. Pharm (Pharmaceutics) (2006 to 2008)

From Department of Pharmaceutics, Bhupal Noble's College of Pharmacy, Udaipur with 74% marks.

B.Pharm (2001 to 2005)

From Rajiv Gandhi Technical University, Bhopal (M.P.) with 67% marks.

Certifications MBA (International Trade Management) 2010 with 68% marks (Grade 'A')

Nano-Pharmaceuticals & Its Industrial Applications 2011 with 72% marks (Grade 'A')

Six Sigma Black Belt certificate from Project Management Institute

Certified Project Management Professional from Project Management Institute

Achievements

Credited with one US Patent & two Indian Patents

Published five products monographs (05) in Indian Pharmacopoeia 2014

Awarded for Indian Pharmacopoeia member in AICTE sponsored seminar in 2014 by Bhupal Nobles' Institute of Pharmaceutical Sciences, Udaipur

Recognized twice for exemplary performance by CEO –Otsuka Pharmaceutical India in 2022

Received two times Best Performer Award (Kshitij) in 2014 & in 2015 by Zydus Cadila Healthcare Ltd.

Received honor of Outstanding Industry Professional Award in 2014 by Dharmsinh Desai University (DDU), Nadiad

Received honor of RSD Memorial Award -2014 by Association of Pharmacy Professional
Received Young Talent Award -2019 by Association of Pharmacy Professional

Published fourteen (14) International/National Research/Review Articles

Credit of Life membership of various International/National Pharmaceutical Societies

Badge with credit of Editorial board & reviewer panel in various International/National Pharmaceutical Journals

Seminars & Workshops:

1. Seminars attended on "Redundant filtration, Extractable & Leachable"; "Sterile filtration and validation"; "Filtration Forum"; "EMPROVE"; NDDS Technical seminar organized by Merck Millipore Inc.
2. Seminars attended on "Sterile filtration; Filter Validation; ICH Q3D; Extractable & Leachable" organized by Sartorius Stedim Biotech.
3. Seminar attended on "Sterile Filtration and its validation organized by Pall Inc.
4. Seminars attended on "Pharmaceutical Packaging systems" conducted by West Pharmaceuticals.
5. Seminars attended "Fiolax Academy for Pharmaceutical Glass for Sterile Packaging, delamination, Extractable & leachable"; Road Show conducted by Schott Kaisha group.
6. Seminar attended on "Pharmaceutical Glass for Sterile Packaging, delamination,

Extractable & leachable" conducted by SNG group companies.

7. Seminars attended on "Pharmaceutical Packaging systems" conducted by Aptar Stelmi Pharmaceuticals.
8. Seminar attended on "Solubility Enhancement approaches using cyclodextrin" conducted by Roquette Inc.
9. Seminars attended on "Pharmaceutical Solvents and their role in formulation" conducted by Croda Chem Inc.
10. Seminar attended on "Pharmaceutical Application of Carbopol Polymers" conducted by Lubrizol-Noveon Polymers.
11. Seminar attended on "Polymers for Pharmaceutical formulations" conducted by Ashland Inc.
12. Seminar attended on "Quality Management System" organized by SAI Global.

Personal profile

Father's Name Sh. B.P. Nagariya

Mother's Name Smt. Manjulata Nagariya

Date of Birth August 24, 1983

Blood Group O+

Marital Status Married

Spouse's Name Dr. Reshu Gupta

Language Known: English, Hindi, Gujarati, Regional

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