

WORK EXPERIENCE LETTER



To whomsoever concerned

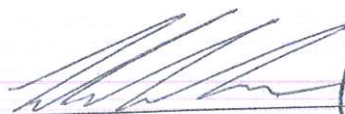
1st December 2012

This is to certify that Dr. Vandana Jolad Shivangi, was a full-time employee of Dune Medicare Pvt. Ltd as Head of Global Regulatory from Feb 2012 to Dec'2012. Dr. Vandana has been reporting to myself, the undersigned.

I verify the job responsibilities, duties and achievements while employed with us, as in below:

1. All intra- and inter-related Regulatory and related development work.
2. Follow up with regulatory authorities on submissions and regulatory issues and maintenance of licenses.
3. Writing of expert clinical, nonclinical, quality reports and standard operating procedures. Writing, reviewing and advising on SmPCs, usertested leaflets and packaging.
4. Direct negotiations and liasion with third party companies, globally and other departments of the company concerning quality and submission applications. Involved actively in cGMP audits ,factory visits and key interface for regulatory related QA and Technical Activities, related Agreements and contracts.
5. Keep up to date with the latest guidelines and legislation, attending conferences, workshops and seminars
6. Business development activities to company by actively searching partners for contract manufacturing , analytical services, API vendors, outlicensing and inlicensing.
7. Advise best alternatives and Regulatory strategies to ensure business flow and cost efficient quality emphasised routes
8. Preparation of CTD dossiers from old format, or anew and also building eCTD and relevant submissions with followon validation procedures for MRP/ national submissions in EU, semiregulatory.
9. Responsible for training and career development of the team through setting objectives and performance review processes.
10. Involved directly in API audits and reporting for ICH-Q7A cGMP guidelines. Liasing between Indian and European authorities to suffice inflow information and solutions for submissions and related. by co-partnering and development activities with R and D, QA, Production and commercial.

For Dune Medicare Pvt. Ltd.:


Jacob Sporon-Fiedler
Managing Director

