



Veunita Saxena

Consultant

Veunita Saxena is an enthusiastic, hard-working and responsible professional with experience in regulatory affairs, quality assurance and pharmacovigilance. She has regulatory and scientific knowledge and strong analytical skills. She is able to manage multiple projects, prioritize and meet tight timelines. Past employers include Pharmaceutical Partners of Canada Inc. and Sanofi Pasteur Ltd.

SKILLS AND HIGHLIGHTS



Regulatory

- Monitored product monograph and literature for pharmaceutical company.
 - Submitted Adverse Drug Reaction reports to Health Canada
 - Compliance with domestic reporting requirements
- Developed label standard for drug and natural health products and prepared label database
- Reviewed and drafted product labeling (carton, tray & vial labels; package insert; product monograph)
- Prepared the following reports and forms for submission:
 - Drug Application forms
 - Drug Notification forms
 - Category IV Certification forms
 - Labelling Standard Certification forms
 - Product License Application forms
 - Efficacy Summary reports
 - Safety Summary reports
 - Quality Summary reports
- Reviewed and coordinated submissions for quality, maintaining product lifecycle
- Prepared and coordinated review of ANDSs in CTD format and Notifiable Changes (PM revisions, Site Changes)



- Completed Quebec Formulary submissions
- Assisted in responding to Clarifaxes and addressed US FDA Registration Listing enquiries
- Prepare Certificate of a Pharmaceutical Product applications and obtain embassy legalizations as required



Quality Assurance

- Performed gap analysis using EP and BP for pharmaceutical company
- Ensured GMP compliance with SOPs
- Experience initiating change controls
- Reviewed deviations and non-conformance reports for compliance

Computer Skills

- Microsoft Office – Microsoft Word, Excel, PowerPoint
- Documentum
- ARISg (Adverse Drug Event & Reaction Reporting Software)

EDUCATION

- Bachelor of Science, Honours Biological Sciences, University of Guelph
- Pharmaceutical Regulatory Affairs and Quality Operations (Co-op), Seneca College



CONTINUING EDUCATION, CAREER DEVELOPMENT

- Pharmacovigilance (CanReg)
- Completed the course Industrial Drug Legislation (Seneca College)
- Pharmaceutical Regulatory Affairs and Quality Operations (Co-op), Seneca College:
 - Pharmaceutical Regulatory Affairs (FDA, DIN, NDS, ANDS, CTA, CTD, NHPs)
 - Quality Assurance (GMPs, SOPs, ISO, Validation)
 - Biotechnology & Biopharmaceuticals (Clinical Trials, Biotech Techniques)
 - Clinical Research (Ethics, Declaration of Helsinki, GCP, Clinical Study Reports)
 - International Regulatory Affairs (ICH, WHO, Electronic Submissions)