



Rashmi Sharma – Consultant

Rashmi is a congenial, hard-working, adaptable professional with excellent organizational and problem-solving skills and experience in regulatory affairs, quality assurance and pharmacovigilance. She has regulatory and scientific knowledge, strong analytical skills and excellent communication, presentation and team work abilities. She is able to manage multiple projects, prioritize and meet tight timelines.

SKILLS AND HIGHLIGHTS



Regulatory

- Provided guidance regarding Canadian regulatory requirements (e.g., protocol development, drug supply issues, timing of submissions)
- Liaised with various departments within a company to obtain information on a study, to assess its impact in Canada
- Performed protocol and CMC assessments to determine how submissions were to be filed, and prepared Notifiable Changes
- For both Therapeutics and Biologics: Prepared Clinical Trial Applications, Clinical Trial Application Amendments, and Notifications
- Completed Supplemental New Drug Submissions, Establishment Licences, and DIN applications (e.g., Category IV Monograph Submissions)
- Coordinated responses to Health Canada clarifaxes and liaised with appropriate groups to ensure Health Canada deadlines were met
- Provided regulatory guidance on all aspects of clinical research in Canada as requested from global team members
- Maintained Clinical Trial Site Information Forms for sites, site closures, and completed end of trial notification to Health Canada
- Participated in meetings with Health Canada
- Responded to questions from regulatory authorities and distributors
- Reviewed advertisement dockets from the Marketing department
- Prepared various post-marketing requirements (i.e. annual updates, monthly product commitments, yearly biologic product reports, licence amendments)
- Updated Product Licence Commitments (PLCs) for international countries
- Prepared and submitted Product Licence Applications and Amendments

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Regulatory (*continued*)

- Completed Product Renewal Submissions and post-approval commitments to CBER
- Performed label reviews for drugs, NHPs and cosmetics
- Submitted Therapeutic Adverse Drug Reports and Medical Devices Problem Reports (Safety Reports) to Health Canada
- Prepared and submitted design dossiers, screening deficiencies and Request for Additional Information from Health Canada for medical device applications (Class II-IV Applications, Amendment Applications)
- Classified medical devices



Quality Assurance

- Ensured compliance with Canadian Medical Device regulations and interpretations
- Prepared Change Assessments for Medical Device products
- Managed tracking and reconciliation of physician samples for Sales Representatives
- Compiled specific manufacturing and release data to support the preparation of reports such as annual product reviews, validation summaries, investigations and trend evaluations
- Conducted timely release of Canadian clinical drug supplies, ensuring compliance of supplies through the assessment of certificates of analysis against product specifications filed to the authorities



Technical Writing

- Reviewed technical documentation for product release, development of procedures and maintenance files in compliance with Canadian GMPs
- Assisted in the development of new SOPs and revision of existing SOPs to ensure continued GMP and corporate compliance

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Computer Skills

- Microsoft Office – Microsoft Word, Excel, PowerPoint

EDUCATION

- Bachelor of Science, Life Sciences, McMaster University, Hamilton, Ontario
- Pharmaceutical Regulatory Affairs & Quality Operations (RAQC) Post-Diploma, Seneca College, Toronto, Ontario

CONTINUING EDUCATION, CAREER DEVELOPMENT

- GMP training certification (sanofi)
- ISO certification training (sanofi)
- eCTD training (sanofi)
- Technical Writing course (Q&C)

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