



Nicole Simone

Consultant

Nicole Simone is a confident and hard-working professional with experience in regulatory affairs. She brings strong communication and negotiation skills to each and every project. She is able to manage multiple projects, prioritize and meet tight timelines. Past employers include GlaxoSmithKline Inc. and AECOM Canada.

SKILLS AND HIGHLIGHTS



Regulatory

- Helped plan and prepare numerous regulatory submissions (e.g., CTA, CTA-A, NDS, SNDS, NC, L3, and L4)
- Assisted in preparation of DIN applications and responding to Clarifaxes
- Extensive knowledge of regulatory submission requirements and international regulations
- Familiar with Food and Drug Regulations and relevant guidance documents
- Assisted in the preparation and assembly of provincial drug submissions
- Created and implemented an improved submission tracking system which allowed for better client product compliance and record keeping
- Negotiated changes to current processes between Clinical and Regulatory groups to improve the performance and functionality of both teams



Quality Assurance

- Extensive knowledge of healthcare product development and post-marketing compliance
- Understanding of the importance of product lifecycle management including clinical and post-market drug safety reporting
- Knowledge on ICH, GMPs, GLPs and SOPs



Technical Writing

- Formatting, cross-referencing, and timely completion of regulatory documents including Product Monographs and CS-BE

Computer Skills

- Microsoft Office – Microsoft Outlook, Word, Excel and PowerPoint
- Lotus Notes
- Documentum
- Adobe Acrobat

EDUCATION

- Regulatory Affairs Post Graduate Certificate, Humber College
- Bachelor of Science, University of Guelph

CONTINUING EDUCATION, CAREER DEVELOPMENT

- Canadian Association of Professional Regulatory Affairs (CAPRA) member
- Regulatory Affairs Post Graduate Certificate, Humber College:
 - Regulatory submissions (CTA, NDS, SNDS, NC)
 - NHP regulations
 - International regulations
 - Healthcare product development
 - Post-marketing surveillance
 - Medical device regulations
 - Agrichemical regulations
 - Scientific and technical Writing