



Shawn Blankier

Consultant

Shawn Blankier is a resourceful regulatory professional with excellent time-management skills. He has comprehensive knowledge of both the drug discovery process (preclinical, clinical and post-marketing studies) and the Food and Drug Regulations and guideline documents. Shawn's excellent written and verbal communication skills make him an asset to each project and team. Past employers include GlaxoSmithKline Inc. and the Hospital for Sick Children Research Institute.

SKILLS AND HIGHLIGHTS



Regulatory

- Completed and submitted Site Licence Application amendments
- Planned and prepared BGTD/TPD regulatory submissions with aggressive targets (NDS, S/NDS, YBPR)
- Managed imperative regulatory submissions including CTAs, CTA-As, N/Cs, and Annual Notifications
- Prepared detailed submission plans and ensured that Canadian regulatory requirements were fulfilled
- Prepared and finalized specific CTD modules 1-5 documents with cooperation from operations, clinical and CMC departments
- Reviewed submission data to ensure compliance, while identifying submission issues and resolving them
- Reviewed product labels
- Extensive knowledge of regulatory submissions (CTA, NDS, SNDS, NC), NHP regulations, international regulations, medical device regulations, and agrichemical regulations
- Assisted in responding to Clarifaxes



Technical Writing

- Prepared protocol addendums for animal laboratory services
- Prepared, revised and submitted scientific abstracts and manuscripts

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Computer Skills

- Microsoft Office – Microsoft Word, Excel, PowerPoint, Outlook
- Corel WordPerfect, Lotus Notes, Documentum
- Adobe Photoshop, Illustrator & Acrobat

EDUCATION

- Regulatory Affairs Post Graduate Certificate, Humber College
- Master of Science, Pharmaceutical Sciences, University of Toronto
- Bachelor of Medical Science, University of Western Ontario

CONTINUING EDUCATION, CAREER DEVELOPMENT

- 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
- Technical Writing Course, Q&C