



## Charlette Tam

### Consultant

Charlette is a highly motivated, punctual and hard-working individual with strong communication and interpersonal skills, and excellent time management and organizational skills. With her work experience in quality control, particularly related to product release and its associated activities, and quality assurance, she is a valuable addition to our team and an asset on any project.

### SKILLS AND HIGHLIGHTS



#### Regulatory

- Compiled and submitted Drug Establishment Licence Renewal, Annual Drug Notifications, Site Licence Amendment, Notifications and Renewal, Product Licence Amendment and Notification
- Performed product label review for regulatory compliance (drug, cosmetic, NHP)



#### Quality Control Officer (QCO) Services

- Performed product release activities
- Performed annual product reviews and prepared reports
- Reviewed finished product, raw material and stability specifications against compendial monographs
- Reviewed stability protocols against ICH and Health Canada's guidelines
- Reviewed certificate of manufacture and analysis against finished product specifications
- Reviewed stability summaries against pre-established stability specifications and protocols
- Initiated, executed, and monitored change controls
- Initiated, investigated and determined corrective and preventative actions for deviations and non-conformances

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- Investigated and communicated with clients regarding various deviations, including:
  - out-of-specification results
  - sample label deviations
- Created Finished Product Specifications and Quality records



### Quality Assurance/Quality Control

- Participated in internal audits:
  - Reviewed and updated company policies and manuals
  - Interviewed employees in various departments
  - Participated in meetings regarding the progress of current audits and the follow-ups from past audits
- Initiated, determined actions and managed closure of actions for change controls related to all aspects of Quality Assurance
- Conducted quality investigations and prepared reports
- Initiated and finalized field alert reports
- Compiled and submitted recall packages to the FDA
- As a member of a consumer complaints team:
  - Composed monthly complaints report and prioritized problems of statistical importance
  - Determined the source of the problems and established solutions accordingly
- Performed physical and functional tests on all packaging components in compliance to GMP, SOP, and GLP
- Documented coherent records in accordance to SOP and GMP
- Worked with various analytical instruments
- Maintained and updated computer system SAP on a regular basis



### Technical Writing

- Applied GMP knowledge to write SOPs

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## Computer Skills

- Microsoft Office – Microsoft Word, Excel, PowerPoint, Access
- SAP,
- Trackwise
- LIMS

## EDUCATION

- Bachelor of Science, Honours Biochemistry / Biotechnology Specialization (Co-op), University of Waterloo
- Pharmaceutical Regulatory Affairs and Quality Operations (Co-op), Seneca College

## CONTINUING EDUCATION, CAREER DEVELOPMENT

- Pharmaceutical Regulatory Affairs and Quality Operations (Seneca College)
- Product Disposition, Q&C
- Technical Writing Course, Q&C

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