

Position Description

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| <i>Job Title:</i> | Regulatory Affairs Associate, Level II – 1 year contract |
| <i>Department:</i> | Regulatory Affairs |
| <i>Reports To:</i> | Supervisor, Regulatory Affairs |
| <i>Direct Reports:</i> | None |
| <i>Overall Function:</i> | |
| Compilation of drug submissions in the CTD format to Health Canada to achieve marketing authorization. | |
| <i>Duties and Responsibilities:</i> | |
| <ul style="list-style-type: none"> • Prepare and/or review submissions to Health Canada (NDS, ANDS, S/ANDS, CTA, NC, Annual Report, and/or Cross-Licenses) • Prepare and/or review responses to deficiency letters (Notice of Non-Compliance, Notice of Deficiency, and Clarifaxes) • Arrange for the servicing of Notices of Allegations for patents • Review Product Monographs, Package Inserts and Label text • Coordinate French translations of Product Monographs and Package Inserts • Assist in negotiations with Health Canada to ensure a prompt regulatory approval • Liaise with groups internally and externally to collect documents and information • Arrange for laboratory analysis as necessary • Review Change Controls and determine filing requirements • Provide regulatory support to internal/external customers • Maintain current awareness regulatory guidelines (Health Canada, ICH, EMEA, FDA, etc.) • Other duties as required by the Director or Supervisor | |

THE WATSON GROUP

Qualifications/Requirements:

Competencies

- University Degree, B.Sc. or higher in Chemistry or Health Sciences
- Minimum 5 years of relevant experience in Canadian Regulatory Affairs
- Strong working knowledge of regulatory guidelines
- Excellent organizational and communication skills (oral and written)
- Ability to prioritize many projects and work with deadlines
- Computer Literacy – Microsoft Package including Word, Excel, and Outlook; WordPerfect; Adobe Acrobat; Access Database

Attributes

- Detail Oriented
- The Ability to Work in a Team and Individually
- High Energy / Results Oriented

Special Considerations:

- Work with minimum supervision
- Minimal travel

Application Deadline: August 27, 2010

Human Resources

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Email: gillian@cobaltpharma.com with “Regulatory Affairs Associate, Level II” in the Subject Line