



Milan Frohlich

Consultant

Milan is a detail-oriented and proactive regulatory professional with over 14 years of experience ensuring manufacturing processes comply with regulatory standards. He brings a wealth of knowledge about quality and regulatory requirements in Canada, USA & Europe combined with a proven successes designing, implementing and managing corporate quality systems and strategies. Milan offers strong critical thinking, investigative and research skills to manage complex projects, ensuring that all deadlines and standards are met. Previous employers include Akuna Health Products and Agrokarpaty.

SKILLS AND HIGHLIGHTS



Regulatory

- Built an internal submission process and prepared full-cycle submissions for FDA and NHPD
- Consulted for cross-departmental managers and technical staff to provide guidance on the interpretation and application of regulatory guidelines and policies
- Reviewed, customized and updated product labels and marketing materials
- Liaised with Health Canada throughout the submission cycle. Prepared responses to information requests, identified issues and responded to questions from regulatory authorities
- Evaluated scientific data against regulatory guidelines and advised clients of potential problems
- Provided clients with insights, data and solutions from a regulatory affairs perspective to drive business decisions

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Quality Assurance

- Established internal quality control system and SOPs, resulting in enhanced compliance and improved communication with branches
- Served as a subject matter expert on compliance with governmental regulations and internal policies and procedures including GMP, ICH, and GCP standards
- Directed overall quality specifications and standards for raw materials, processed and finished products
- Ensured departmental compliance with governmental regulations and internal policies and procedures including GMP and SOPs
- Performed sampling and testing of raw material. Conducted inspections of products and reviews of manufacturing documentation for product release
- Ensured documentation, files and records were properly filled and adequately maintained
- Performed investigations for quality deviations and customer complaints
- Reviewed research on product defects and recommended modifications to products and quality standards
- Collaborated and communicated with various departments to develop and refine strategies to manage quality issues



Auditing

- Implemented the internal and external quality audit program and led the complete cycle of departmental and vendor audits
- Conducted internal control audits and provided continuous training to assist manufacturers and other departments with improving their systems after audits

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Laboratory

- Conceptualized, designed and led the formulation of 7 herbal products with strengthening effect
- Introduced a drying process energy saving device that reduced cost for drying products
- Collaborated on the manufacturing of 23 herbal products
- Oversaw a 15-member department in the harvesting, drying and processing of medicinal herbs for formulation design
- Developed and implemented process documentation and supporting reports
- Liaised with Ministry of Health to finalize certification process of products

Computer Skills

- Proficient in use of MS Office – Word, Excel, PowerPoint and Outlook

EDUCATION

- Clinical Research Associate Professional Development Program, Kriger Research Center Inc., Toronto, ON
- Postgraduate Diploma in Pharmaceutical Research and Development, Toronto Institute of Pharmaceutical Technology, Toronto, ON
- Postgraduate Diploma in Biology, University of P. J. Safarik, Slovakia
- Master of Science, Biology and Mathematics, University of P. J. Safarik, Slovakia

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