



## SORIN ALB

### Consultant

Sorin comes to Q&C with 10 years of pharmaceutical experience, including 4 years of Canadian GMP in a manufacturing role and more than 6 years in progressive Regulatory Affairs roles. As a result, he has good technical knowledge of pharmaceutical manufacturing, clinical research, GMP and the regulatory process for drug development. Sorin has built a solid reputation of easily achieving superior rapport with both his colleagues and customers. Through his interactions with Health Canada he has also proven to be reliable and prompt when time-sensitive responses were expected from his employer. As part of New Product Development, Sorin has successfully filed and addressed deficiencies for new submissions that are now approved or in the final stage for approval in Canada, EU, Australia and USA. This was achieved due to his good understanding of the different regulatory requirements and guidelines for these markets, including GMP/GLP.

Sorin's solid record of achievement, skill set, education and experience, matched with his strong attention to detail and quality, well-developed analytical and problem solving skills, and his dedication to life-long learning, makes him an asset to both Q&C and our clients.

### SKILLS AND HIGHLIGHTS

#### Regulatory

- Prepared, compiled and filed regulatory submissions with minimal guidance, within a given timeline. For example:
  - For Health Canada: NDS, ANDS, DIN, Category 4 Monographs, Product Monograph updates, NC, CTA, and labelling
  - For U.S. FDA: ANDA, Amendments, CBEO and CBE30
- Responded to questions from regulatory authorities/agencies regarding submissions, within the timeframes specified
- Designed/updated, reviewed and approved artwork (labelling)
- Maintained up-to-date knowledge on regulations/guidelines

Sorin Alb, Consultant – CV, page 1 of 3

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## Regulatory (continued)

- Filed and obtained timely approval for three successive NCs to counteract the brand's strategy to prevent employer from launching upon patent expiry
- Interacted with regulatory colleagues and extra-departmental personnel, to ensure that the projects were completed within the agreed timelines



## Technical Writing

- Ensured that all documentation for regulatory submissions complied with pertinent local/global regulations, as well as, with corporate SOPs and RA Business Processes
- Collected and assumed the responsibility for various legal and regulatory reference documents



## Quality Assurance

- Acquired good technical knowledge of pharmaceutical drug development: manufacturing (dosing, tableting), clinical research, and GMP
- Performed batch record reviews, wrote stability protocols, reviewed stability data, and reviewed laboratory data

## COMPUTER SKILLS

- Expert user of Microsoft Office programs, Adobe Acrobat, eCTD submission, electronic repository and labelling software
- Designed, presented and trained RA associates in the use of Optical Character Recognition feature of Adobe - this training drastically reduced the time needed to complete a Product Monograph for Canadian submissions
- Designed a form that permitted printing the box inventory at the touch of a button - as opposed to 30 minutes of data entry in Excel
- Redesigned and handled the transition to Access 2003 of the three databases from the regulatory affairs department, without service interruption
- Designed and implemented a device to improve the control of SAP labels in the control room



## EDUCATION

- Pharmaceutical Regulatory Affairs and Quality Operations Program, post-graduate diploma (graduated with Honors), Seneca College, Toronto
- B. Sc. in Chemical Engineering, "Babes- Bolyai" University Cluj-Napoca, Chemical Technology Faculty, evaluated by University of Toronto
- Information Systems - Data Base Management Certificate, DeVry College of Technology, Mississauga

## CONTINUING EDUCATION, CAREER DEVELOPMENT

- Regulatory Affairs Certification, Canada
- Effective Communication for Pharmaceutical Professionals, English Refresher, Seneca College at Apotex
- Foundations of Project Management, University of Toronto
- Good Manufacturing Practices (GMPs) for Importers/Distributors, 2012
- Good Manufacturing Practices (GMPs) for Natural Health Products (NHPs), 2012

Sorin Alb, Consultant – CV, page 3 of 3

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