Robert Smith

Regulatory Affairs Associate/Analyst

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SUMMARY

To secure a position within an agency that will benefit from a trained legal professional with excellent administrative, research, and organizational skills. Dedicated and focused professional that has experience working with equipment maintenance and team supervision that management and manufacturing experience.

SKILLS

Cubes, Microsoft Office, SAP, Label Review, Product Sign-Off, Online Databases.

WORK EXPERIENCE

Regulatory Affairs Associate/Analyst

ABC Corporation - September 2004 – October 2005

- Responsible for reviewing new and revised labeling materials along with marketing materials for accuracy and conformance to dietary supplement regulations.
- Evaluated and tracked the impact of proposed formulation, documentation and raw material changes through the Change Control process.
- Determined the impact of these requested changes on labeling materials.
- Compiled and reviewed supporting documentation for Change Control product labels in corresponding countries.
- Approved color proofs and label releases for print quality and accuracy.
- Edwards system for final proof and color proof labels.
- Researched and evaluated the regulatory status of ingredients for New Product Proposals.

Regulatory Affairs Associate/Analyst

ABC Corporation - 2002 – 2004

- Executed regulatory projects including assistance in the drafting, editing, preparing, and assembly of regulatory submissions including INDs, BLAs, NDAs, annual reports, amendments, and orphan drug applications.
- Performed final compilation and publishing of all regulatory submissions to US, Canadian, and European regulatory agencies resulting in accurate and complete documentation for all investigational new compounds across development products.
- Created and implemented all new templates used for submission in traditional IND format and, most recently, a comprehensive Common Technical Document (CTD) format used in first successful IND to FDA oncology division.
- Participated in the review of labeling, advertising and promotional material to ensure compliance with FDA Advertising and Promotional Manual.
- Evaluated software from vendors for planned future eCTD submissions which resulted in proposal for new publishing system to management committee.
- Experience.
- This is Dummy Description data, Replace with job description relevant to your current role.

EDUCATION

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