Regulatory Affairs Associate/Consultant

ROBERT SMITH

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Objective

Dedicated and focused professional that has experience working with equipment maintenance and team supervision that have management and manufacturing experience. Strong customer service skills and satisfaction to deliver a great customer experience.

Skills

Physiology, drug delivery, modeling, orthopedics, Ms. Word, MS Office, Outlook, Office: Word, Powerpoint, Photoshop.

Work Experience

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ABC Corporation - May 2007 – May 2010

- Maintain and manage complaint records, and other complaint handling documents.
- Coordinate and maintain the Corrective Action Preventive Action Process as required and tracked verification of effectiveness.
- Perform gap analysis on Vigilance and Medical Device Reporting Standard procedures.
- Maintained Medical Device registration and license renewal.
- Participated in annual quality system audits, both internal and external, third-party representatives and consultants.
- Prepared technical documentation for regulatory submissions.
- Assist in Regulatory and submissions Compile and complete the within the regulatory guidelines and timelines.

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ABC Corporation - 2006 – 2007

- Involved in compilation of eCTD dossiers for various clients for filing in Europe and US through DCP, MRP, National and Centralized procedure, and for NDA/ANDA applications.
- Extensively involve in review of quality documents manufacturing batch record, analytical method, validation report, packaging, validation protocol and specifications (excipients, API and finished product).
- Prepared and reviewed labelling documents including, package inserts, SmPC and Labels considering regional labeling requirements.
- Handled queries received from various health authorities and assisted in preparing deficiency response letter.
- Assisted in variation filing for post-approval changes and reviewed change control documents considering regulatory requirements.
- Supported regulatory, formulation development and analytical department by providing the literature, references for dossier preparation, interpretation of regulatory guidelines and preparation of regulatory strategy for new products..
- This is Dummy Description data, Replace with job description relevant to your current role.

Education

BS