Regulatory Affairs Associate

ROBERT SMITH

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Objective

A pharmaceutical regulatory professional with experience extending from drug discovery to late-phase development Familiar with Strong experience, knowledge and leadership skills in Project management Regulatory strategies and filings Process optimization New product development CRO outsourcing Risk management Budget.

Skills

Microsoft Office, Ms. Word, MS Office, Outlook, Office: Word, Powerpoint, Photoshop, Photography, Sales, Typing, Windows.

Work Experience

Regulatory Affairs Associate

ABC Corporation - 2012 – 2014

- Review, publish, compile and QC all sections of aggregate reports such as global regulatory submissions.
- Manage and control all submission dossiers and related documents in accordance with and regulatory guidelines.
- Develop and maintain SOPs as required to assure consistency and compliance.
- Support regulatory affairs activities in the emerging markets, including, operation perspective.
- Evaluate systems and tools that are needed for the regulatory operation group and other related functional groups.
- Perform special tasks as assigned, such as importation of our drugs for a quality test.
- Acts as an essential communications connection for the Regulatory Affairs managing expenses and travel for Regulatory Affairs.

Regulatory Affairs Associate

Baxter Healthcare - 2007 – 2012

- Coordinate all level 2 drug change controls with impact in multiple countries.
- Collaborate and effectively communicate with global change owners and other functions.
- Run distribution data using advanced database functions.
- Design monthly metrics using Trackwise 8.
- Design monthly submission metrics.
- Extensive knowledge of SharePoint 2013.
- Develop continuous process improvements..

Education

Diploma