ROBERT SMITH

Regulatory Affairs Associate/Supervisor

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During working on a research project, able to develop a migration assay platform for which applied for intellectual property. Installed them to make a functioning final product giving experience with design, fabrication, and installation.

MAY 2007 – MAY 2010

REGULATORY AFFAIRS ASSOCIATE/SUPERVISOR - ABC CORPORATION

- Identify and interpret regulations, guidelines, and other pertinent other regulatory organizations.
- Review protocols, consent forms, reports, scientific documents, research projects to ensure compliance with regulations.
- Ensure the compilation and maintenance of pertinent documentation required for regulatory compliance for assigned clinical research projects.
- Serve as a member of groups, teams, or committees related to regulatory affairs.
- Prepare or maintain technical files as necessary to obtain and sustain product approval.
- Recommend changes to company procedures in response to changes in regulations or standards.
- Review clinical protocols to ensure the collection of data needed for regulatory submissions.

2003 – 2007

REGULATORY AFFAIRS ASSOCIATE/SUPERVISOR - ABC CORPORATION

- 1990-1996 I worked in Drug Safety Evaluation division of Pfizer as an Exploratory Toxicology Technician.
- Performed studies following protocol and SOPs.
- Was frequently inspected by quality insurance and performed at 98-100% accuracy consistently.
- 1996-2003 I worked in the Animal Health division of Pfizer Inc.
- as an Associate Regulatory Affairs Associate.
- Was responsible for the registration of companion animal drug products in Latin America, South East Asia , Australia and Japan..
- This is Dummy Description data, Replace with job description relevant to your current role.

EDUCATION

BS

SKILLS

Microsoft Office, Ms. Word, MS Office, Outlook, Office: Word, Powerpoint, Photoshop.