

# ROBERT SMITH

## Regulatory Affairs Associate

Phone: (0123)-456-789 | Email: info@qwikresume.com | Website: Qwikresume.com

### SUMMARY

Management professional with experience in the Life Sciences industry. Strong understanding of Clinical Research, Regulations of Drugs and Medical Devices. Experienced in managing the Regulatory documents, facing Inspections by appropriate Regulatory authorities, analyzing the complaints and reporting accordingly.

### CORE COMPETENCIES

MS word, Excel, PowerPoint, Outlook, GCP, ICH, FDA, HIPAA, IND, NDA.

### PROFESSIONAL EXPERIENCE

#### Regulatory Affairs Associate

ABC Corporation - December 2012 – January 2014

##### Key Deliverables:

- Provide support for Regulatory processes of the various meat and other food products clearance.
- Oversee quality control of Regulatory documents and submissions.
- Organize meetings with Regulatory agency staff.
- Assist in the preparation of routine reports and Regulatory agency communications.
- Update and maintain paper/electronic document archival systems.
- Prepare legal documents for import/export, registrations, tenders/bids or other purposes.
- Coordinate internal audits and inspections and reported all initial and supplemental for complaint files.

#### Regulatory Affairs Associate

ABC Corporation - 2011 – 2012

##### Key Deliverables:

- Raritan, NJ 1976 - 1979 Manufacturer of diagnostics for blood typing and manufacturer of intravenous catheters, syringes and blood collection tubes.
- Regulatory Affairs Associate Revised labeling for reagent red blood cells and blood typing serum due to change in regulations.
- Applied new device law as regulations developed including creation of QA procedures.
- Prepared 510(k)s.
- Supervised analysis of complaints and competitive products.
- Participated in promulgation process through interactions with other Johnson and Johnson subsidiaries..
- This is Dummy Description data, Replace with job description relevant to your current role.

### EDUCATION

2259 Oak Street, Old Forge, New York, 13420

© This [Free Resume Template](#) is the copyright of Qwikresume.com. [Usage Guidelines](#)

# ROBERT SMITH

## Regulatory Affairs Associate

Phone: (0123)-456-789 | Email: info@qwikresume.com | Website: Qwikresume.com

---

- MS