Regulatory Compliance Specialist Resume

Job Objective

Seeking a position as Regulatory Compliance Specialist in which my abilities and experience can aid in the growth of the company.

Highlights of Qualifications:

- Huge experience with laboratory equipment and testing procedures
- Profound knowledge of FDA regulations, pharmaceutical GMPs
- Wide knowledge of Validation concepts, procedures, protocols and requirements
- Familiarity with pharmaceutical manufacturing process, facilities and equipments
- Ability to develop, organize and manage multiple tasks
- Ability to make and act upon sound, independent judgment
- Ability to identify problems and provide solutions
- Excellent organizational, record retention and time management skills
- Strong decision making and creative problem solving skills
- Excellent interpersonal and communication skills

Professional Experience:

Regulatory Compliance Specialist
Stryker, Faith, SD
May 2006 – Present

- Initiated Health Hazard Evaluation documents in document control system.
- Communicated potential actions to internal stakeholders.
- Collected partially completed Health Hazard Evaluation documents from manufacturing location.
- Analyzed complaints to determine MDR / MDV report ability to FDA / Competent Authorities.
- Oversaw reporting of recall affectivity to corporate entities.
- Took part in process improvement and automation.

Regulatory Compliance Specialist
Owens & Minor Distribution, Inc, Faith, SD
March 2003 – April 2006

- Provided validation support of all process and system validations.
- Prepared, implemented and monitored Quality System policies and procedures.
- Directed investigations and resolution of non-conformances and CAPA
- Assuredall relevant regulatory, safety and special handling training and information are delivered.
- Assisted in the timely and proper filing of required forms for DEA, FDA, State.

Education:

Bachelor's Degree in Manufacturing Engineering
Kentucky State University, Frankfort, KY

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