



# Example of Staff Specialist Job Description

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Our company is looking for a staff specialist. We appreciate you taking the time to review the list of qualifications and to apply for the position. If you don't fill all of the qualifications, you may still be considered depending on your level of experience.

## Responsibilities for staff specialist

- Accountable for establishing, maintaining, adjusting and communicating regulatory submission deadlines to ensure that all product-launch related functional area activities can be planned accordingly
- Manages and executes the regulatory review of labels, labeling, advertising and promotional materials
- Develops policies and procedures which provide direction to the business on regulatory processes and requirements in support of product development
- Interprets statutes, regulations, policies and guidance documents for business teams and product development/support teams
- Remains current on regulatory issues/trends affecting business unit products, assessing and communicating their impact to RA colleagues, product development/support teams, and to others in the business
- Provides training or presentations in multiple disciplines to cross-functional groups across the business on a variety of regulatory topics
- Acts as a mentor to other Regulatory Affairs associates, participating in development discussions and assisting other associates with developmental tasks or projects
- Maintains proactive and positive working relationships with internal and external customers, both US and ex-US, to ensure the business is positioned to meet strategic corporate goals
- Independently manages and monitors multiple complex, novel, and/or diverse projects simultaneously, including projects that involve several

- Performs tasks such as assisting in the completion of Requests for Capital Expenditures (RCEs), EHS checklists, project scope documents, risk assessments

### **Qualifications for staff specialist**

- Occasionally work flexible hours because of 12-13 hour time difference with Singapore
- Combination Product regulation understanding a plus
- Drug submission
- Current knowledge of U.S. medical device regulatory requirements and Quality System Regulations (QSR)
- Be able to multi-task under pressure with minimal supervision
- Advanced degree and/or RAC certification preferred