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# Example of QA Specialist / Senior Specialist Job Description

Our company is growing rapidly and is hiring for a QA specialist / senior specialist. If you are looking for an exciting place to work, please take a look at the list of qualifications below.

## Responsibilities for QA specialist / senior specialist

* Provide QA support to initiate, engage and escalate major and critical compliance issues through the site QMS processes deviations and CAPAs
* Liaise with the Quality Manager/Qualified Person, as necessary, on technical issues including deviations, CAPA
* Reviews, assesses and approves deviations and change controls
* Reviewing and releasing of all records associated with external manufactured product
* Conducting record review of executed batch records from CMO operations
* Performing review of records (e.g CoA, CoC, ) and testing results
* Initiating and/or reviewing non-conformances, CAPA's and Change Management
* Conducting record review of executed batch records for finish drug products to support CMO packaging & labeling record review
* Performing review of bulk drug product executed records, if needed
* May own CAPAs associated within the QA unit

## Qualifications for QA specialist / senior specialist

* Experience with a breadth of medical devices (class I, II, III, or spanning range from kits to diagnostics to implantable devices) preferred
* Experience with supplier quality and post-market operational activities
* Experience conducting audits independently as lead auditor
* Experience with mobile device management tools like XenMobile, MobileIron, or similar tools a plus
* Living the values at Shire is a basic expectation for all Shire employees/contractors
* BS in Engineering and or Science and a minimum of 3 years of project management, process excellence, and/or project support experience with increasing responsibility in the areas of Quality Assurance