



Example of Director, Quality Assurance Job Description

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Our innovative and growing company is searching for experienced candidates for the position of director, quality assurance. 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 director, quality assurance

- Establish, maintain and enforce division and group policies and procedures necessary for compliance with current FDA medical device regulations, Quality System Regulation (21 CFR Part 820)
- Participate in inspections/audits by the notified body or other regulatory agencies to include FDA by producing requested documents or answering any inquiries for information
- Prepare all correspondence to FDA
- Assist staff in the preparation and submission of all premarket notifications [510(k)] to the FDA
- Provide guidance and strategy to M- BCs and interact with FDA as necessary to develop regulatory and device strategy, including all necessary testing and documentation that may be required for device clearance
- Establish and maintain a strategy for automating test cases across multiple projects and products
- Partner with development and product teams to understand product architecture and project timelines
- Work with operations team to build system and process expertise
- Establish manual and automated testing best practices and research and recommend tools, applications and frameworks to help QA achieve its goals and objectives

Qualifications for director, quality assurance

- Manage and oversee all local GxP audits and assessments, including but not limited to PV, REMS, GMP audits at Specialty Pharmacies, inpatient pharmacies, and data/IT audits (AIM)
- Master's Degree in Science (Chemistry, Microbiology or Biology preferred)
- Solid understanding of US and international PV regulations and guidelines (CFR, ICH...) their practical implications
- Experience working collaboratively with senior level management
- Experience working with DOT, government regulatory agencies
- Strong analytical, research, and forecasting skills