

Robert Smith

Product Quality Manager

CONTACT DETAILS

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PERSONAL STATEMENT

Seeking a Product Quality Manager position with an outstanding career opportunity that will offer a rewarding work environment along with a winning team that will fully utilize management skills.

WORK EXPERIENCE

Product Quality Manager **ABC Corporation - 2013 - 2013**

Responsibilities:

- Recruited to PB by former manager to assist in preparation for impending consent decree with FDA to re-engineer quality system and documentation to address FDA concerns regarding critical care and portable ventilators.
- Reorganized and led incoming, in process and final product inspection group.
- Stream lined Supplier Quality Engineering group.
- Implemented audit strategies, and cost saving measures resulting in 15 % decrease in supplier audit travel costs, while completing more audits.
- Successfully addressed on-going supplier issues in support of FDA consent decree audit issues.
- Led team (internal and consultant team) to review, correct where necessary and validate over 600 mechanical/electrical component specifications.
- Oversaw the Injection Mold remediation team tasked with evaluating mold performance, developing repair/replacement strategy, developing relationships with injection mold suppliers, and contract molding process suppliers.

Product Quality Manager **Delta Corporation - 2010 - 2011**

Responsibilities:

- Managed supply chain coordinating quality engineering efforts for Sonicare flagship projects Investigated legacy product customer complaints and .
- Created, launched, and lead the Product Quality Technical Support group designed to facilitate Product Quality and regulatory filing improvements .
- Project management of priority initiatives.
- Management - Managed a team of nine local and remote Product Quality associates, specialists, and contractors Created and Launched the Product .
- Reporting to the Vice President of Operations, providing leadership to the organization through the following Created an Incoming Receiving .
- MARCONI MEDICAL SYSTEMS (Formerly Picker International), Cleveland, Ohio.
- Supervised the successful completion of Integration and Regression

SKILLS

Risk Management,
Design Control, Failure
Investigations, ISO
13485 Lead Assessor,
Blood Borne Pathogen
Training, Sterilization
Validation- All Methods,
Management Of
FDA/Notified Body
Audits.

LANGUAGES

English (Native)
French (Professional)
Spanish (Professional)

INTERESTS

Climbing
Snowboarding
Cooking
Reading

REFERENCES

Reference - 1 (Company
Name)
Reference - 2 (Company
Name)

Testing of new release of flagship enterprise legal matter management solution; .

Education

BA