

Amjad Rana

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OBJECTIVE

Aspiring for a senior **quality management** opportunity with emphasis on regulatory and health and safety aspects in a regulated industry to utilize my education in **engineering** combined with **quality management** and **regulatory affairs experience** to help your organization meet customer requirements.

PROFESSIONAL EXPERIENCE

Vivosonic Inc., Toronto, Ontario

2004 to 2010

DIRECTOR QUALITY ASSURANCE AND REGULATORY AFFAIRS

- Developed, implemented and maintained quality management system ISO 13485:2003 including implementation of quality strategy by developing policies, procedures and systems to ensure minimum nonconformances
- Prepared and submitted regulatory submissions (US FDA (QSR), FCC, Industry Canada, EU Tech File (MDD), Canadian Medical device License (CMDR) and other countries) for class II medical devices.
- Acted as lead on scheduled and unscheduled quality audits from notified bodies
- Worked with all departments to continually improve quality processes and chairing management review meetings
- Tracked of nonconformances through Corrective and preventive actions to prevent recurrence by performing root cause analysis

Obus Forme Ltd., Toronto, Ontario

2000 to 2003

QUALITY ASSURANCE MANAGER

- Developed and implemented ISO 9001-2000 and ISO 13485 as Management Representative for medical device industry
 - Supervised all inspection and quality assurance activities of bodycare products
 - Established Q.A. department, trained all personnel and established inspection specifications and reports
 - Worked with a wide variety of calibrated equipment and gages to inspect quality
 - Trained entire workforce on quality systems that has continuous improvement as the guiding policy
 - Established and documented systems, standard operating procedures, work instructions and various forms at all levels in the organization that are cost effective with relevant corrective and preventive actions
 - Worked closely with production, marketing, design, sales and shipping to ensure the right quality of products being shipped out
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EDUCATION

Diplom-Ingenieur (FH) (Bachelor of Engineering) Technical Chemistry from Germany
Course in Business Administration from Erlangen University, Germany
Course on Quality Management Systems Installation and Auditing from ICQMS, Rotterdam,
IRCA and RAB approved Lead auditor Course for ISO 9001-2000 from Deloitte and Touche at
Mississauga