

Mana Shirazi-Kia

SUMMARY

- Ten+ years' experience in Quality Assurance and process improvement in the biotech industry
- Knowledge of regulatory requirements (e.g., ISO 13485:2003, CE mark, FDA CFRs)
- Familiarity with Continuous Improvement concepts
- Advance knowledge of MS Office tools, i.e. Access, SharePoint, etc.
- Trained Lead Auditor
- B.A.Sc. Graduate

PROFESSIONAL EXPERIENCE

Management System Analyst

Alpha Technologies (Burnaby, BC)

2011 –current

- Supporting Quality systems and procedures such as Nonconformance's and Corrective and Preventative Actions
- Maintaining the Electronic Document Control System and Record Control
- Leading the internal audit team
- Developing Quality Training Modules and conducting training sessions on related quality assurance systems
- Providing technical support to all staff as related to quality practices
- Participating in cross departmental project teams related to Quality

QA Specialist

Angiotech Pharmaceuticals (Vancouver, BC)

2005 - 2011

- Developed Standard Operating Procedures for all quality system processes
- Participated in internal and supplier audits, prepared audit reports and followed up on non-conformances
- Reviewed and approved internal and external change control documents
- Provided input on decisions to approve/reject CRs (Change Requests)
- Managed the CAPA system
- Provided data for preparation of periodic Quality Assurance reports and management review meeting, including quality issues by product, metrics and summary of any quality problems
- Participated in Design Reviews as required
- Development and executed Quality Plans during product development and transfer to production
- Provided staff training on QMS procedures

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- Reviewed and approved verification and validation documentation
- Assisted with document and record control tasks

QA Engineer

Sorin Group Canada-Mitroflow Division (Burnaby, BC)

2002 to 2005

- Led the root-cause analysis processes;
- Developed sampling plans for processes and implemented statistical process controls
- Decided on inspection requirements for incoming material and manufactured products
- Supported processes and yield improvements
- Analyzed production and quality trend data to identify and solve problems
- Assisted in the review of processes to provide solutions for improving productivity
- Tracked, documented, investigated and analyzed rejects and failures in production
- Provided support for engineering by testing and validating new procedures
- Gathered and analyzed quality data for system improvement projects
- Designed and implemented quality processes used for quality management system
- Reported on safety incidents and attended Safety committee meetings

Manufacturing and Development Engineer

MDMI Technologies (Richmond, BC)

2000 to 2001

- Improved manufacturing operations strategies

Validation Engineer

Stanley Pharmaceuticals (North Vancouver, BC)

1999 to 2000

- Improved a full range of manufacturing and laboratory equipment through writing and implementing validation plans and protocols

EDUCATION

Bachelor of Applied Sciences in Mechanical Engineering

University of British Columbia: Vancouver, BC

2001