Murtuza Bohari

Rolleston, Canterbury, New Zealand

murtuzabohari@yahoo.com www.linkedin.com/in/profile-of-murtuza-bohari

+64 21 756 098 https://murtuzabohari.com/

Summary

Dynamic Quality Assurance and Regulatory Affairs professional with over 13 years of experience in the Medical Device, Nutraceutical, Food, Dairy, and Cosmetic industries. Proven track record in developing, implementing, and managing quality systems, achieving ISO certifications, and ensuring compliance with global regulations. Recognized for my proactive approach, meticulous attention to detail, and ability to lead successful teams and projects.

Experience

Supplier Quality Engineer at Zimmer Biomet ANZ

Sep 2023 - Present

- Manage supplier quality and performance in the orthopedic industry, ensuring top-tier product quality and safety.
- Plan and select suppliers for 3D printing, antimicrobial coating, cleanroom packaging, and gamma sterilization of orthopedic implants and instruments.
- Conduct supplier qualifications, including site audits and process approvals.
- Oversee supplier product process approvals, including material validations and raw material declarations.
- Handle suppliers change notifications and negotiate NDAs and quality agreements.
- Prepare supplier corrective action reports and foster strategic partnerships.
- Monitor supplier performance against set objectives and refine supplier development processes.

Consultant at Klaston Management

Sep 2023

- Contract auditing to quality management system standards including ISO 9001 and Brazilian INMETRO Ordinances.

Senior Quality Associate at SQA Services, Inc.

Oct 2021 - Sep 2023

- In this role, I performed contract assignments to conduct audits and assessments, ensuring clients' compliance with industry standards and regulatory requirements.

Quality and Regulatory Manager at Canterbury Scientific Ltd

Apr 2019 - Sep 2023

- Ensured conformance with ISO 13485:2016 and ISO 14971:2019.
- Maintained compliance with 21 CFR Parts 820 and 11, and the EU IVDD for CE Marking.
- Oversaw all internal and external audits, both regulatory and customer based.
- Communicated regularly with Notified Bodies, Authorized Representatives, Registrars, Consultants, and Customers.
- Managed customer complaints and feedback.
- Handled supplier quality management.

- Coordinated product registrations in the US, EU, UK, and NZ, supporting over 30 countries.
- Led and mentored a motivated team, including recruitment efforts.

Key Projects:

- Implemented an electronic QMS (Greenlight Guru) and electronic regulatory suite (RAMS) to streamline processes and enhance compliance.
- Led regulatory approval projects for product registrations in the EU, UK, US, and NZ, including CE Marking to EU IVDR 2017/746.

Quality Assurance Manager at Xtendlife Group Limited

Jun 2018 - Apr 2019

- Managed the day-to-day operations of the Risk Management Programme (RMP) and the Food Control Plan (FCP).
- Demonstrated expertise in regulatory standards such as 21 CFR Part 111 and the Dietary Supplements Regulation 1985.
- Oversaw Supplier Quality Management, including qualification and approval processes.
- Handled all external and internal audits effectively.
- Ensured compliance with packaging and labeling regulations.
- Managed customer complaints and resolutions.
- Oversaw the calibration and maintenance of laboratory equipment.
- Drove continuous improvement projects to enhance quality processes.
- Led and motivated a small team to achieve organizational objectives.
- Notably, achieved premises EU listing for seafood, highlighting a commitment to regulatory compliance and quality standards.

Quality Systems and Compliance Coordinator at Danone

Jan 2016 - Jun 2018

- I led vital compliance efforts and spearheaded key projects for a company specializing in spray-dried dairy-based nutritional powders. I ensured top-tier audit performance, managed internal and subcontractor audits, and facilitated management reviews.
- Notable achievements included achieving organic certification, securing registrations, and implementing robust internal audit protocols. My role involved driving quality system development and fostering a culture of continuous improvement.
- Each year, I championed impactful projects, such as validating bag seals, registering the site in China, and achieving FSSC 22000 certification.

Laboratory Team Leader at Fonterra

Apr 2015 - Dec 2015

- Provided technical expertise for Microbiological, Chemical, and Physical testing of processed milk and ice cream products, ensuring compliance with quality standards and NZS/ISO/IEC17025 requirements.
- Drove Food Safety and Quality across the site through regular feedback and presentations at biweekly Food Safety Team Meetings.
- Supported IANZ audits and conducted follow-up on corrective actions.
- Maintained laboratory SOPs through regular audits and reporting processes.
- Ensured proper maintenance and calibration of laboratory equipment.

- Participated in ILCP testing and follow-up procedures.
- Maintained monthly reporting to MPI.
- Conducted Annual Laboratory Management Reviews.
- Demonstrated a strong understanding of HACCP, RMP, and FSSC 22000 standards.
- Proficient in SAP.
- Served as a health and safety representative, fire warden, and first aider, contributing to a safe work environment.

Microbiology Supervisor at AsureQuality

Nov 2013 - Apr 2015

- Led a team of 40, ensuring timely completion of duties.
- Delegated tasks, coordinated staff rosters, and handled recruitment.
- Identified and addressed training needs, managed performance, and approved time records.
- Managed staff leave and deputized for the management team as needed.
- Conducted appraisals, managed performance, and enforced disciplinary actions.
- Monitored KPIs, oversaw process flow and system changes, and ensured adherence to quality standards.
- Managed non-conformances and document control.
- Utilized and coached team members on the Laboratory Information Management System (LIMS).
- Acted as an IANZ accredited Authorized Person, signing out laboratory results.

Analyst/Senior Technician at AsureQuality

Feb 2013 - Nov 2013

- Conducted calibrations, process improvements, and troubleshooting to enhance laboratory efficiency.
- Managed workflow by coordinating with laboratory staff to ensure timely completion of tasks.
- Provided technical advice and training to laboratory staff, fostering skill development and knowledge sharing.
- Ensured strict adherence to health and safety procedures, promoting a safe and compliant working environment.

Microbiology Technician at AsureQuality

Sep 2011 - Jan 2013

- Conducted comprehensive food safety testing for pathogens including Salmonella, Listeria, E. coli O157, Campylobacter, Enterotoxins, Enterobacter sakazakii, and Clostridium perfringens.
- Performed product integrity and spoilage testing to ensure quality and compliance.
- Executed shelf-life testing in accordance with NZFSA guidelines to maintain food safety standards.

Education

Lincoln University (NZ)

Master of Business, Global Management and Marketing

Feb 2023 - Jul 2024

Auckland University of Technology

Master's degree, Applied Sciences

2013 - 2015

Auckland University of Technology

Post Graduate Diploma, Applied Sciences

2011 – 2011

Licenses & Certifications

RAPS Member - Regulatory Affairs Certification Program

Regulatory Affairs Certificate: Medical Devices

Chartered Quality Professional – Member (CQP MCQI)

Lead Auditor ISO 13485:2016 – BSI 226383

Medical Devices Risk Management ISO 14971:2019 – BSI ENR-00767756

Requirements of the In Vitro Diagnostic Regulation (IVDR) EU 2017/746 – BSI ENR-00767760

Implementation of the In Vitro Diagnostic Regulation (IVDR) EU 2017/746 – BSI ENR-00767761

Implementation of the Medical Device Regulation (MDR) for CE Marking – BSI ENR-01422648

ISO 9001:2015 QMS Execution and Auditing Techniques – Alison 4588-32535443

How to Maintain a QMS Compliant to MDR & IVDR

Introduction to Risk Management for Medical Devices and ISO 14971

Introduction to Design Control for Medical Devices

MDR 2017/745 Mini-Course

Good Documentation Practices

Skills

- Good Manufacturing Practice (GMP) • Quality Management System • Auditing
- Regulatory Affairs • Supplier Quality • Process Validation • Risk Management
- Continuous Improvement

References

- Available upon request and will be from Zimmer Biomet, Klaston, SQA Services and Canterbury Scientific.