# QMS Competence Summary

List of recent ISO 13485 / 9001 QMS and US FDA QSR implementation, maintenance, and lead auditor performances:

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| **Position** | **QMS Experience** |
| Senior Quality / Regulatory Affairs Specialist – Corza Medical Corredor Tijuana – [Home - Corza Medical Global](https://corza.com/global/) | * Gap analysis of QMS with respect to EU MDR requirements
* Gap analysis of existing SOPs with respect to EU MDR requirements
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| Senior Quality / Regulatory Affairs Specialist – Sonic Incytes Medical Corp.– [VELACUR™ | Office Based Fatty Liver Disease Assessment](https://www.sonicincytes.com/) | * Internal auditor of ISO 13485 to MDSAP Requirements
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| Senior Quality / Regulatory Affairs Specialist – Henry Schein – [Dental Supplies and Medical Supplies - Henry Schein](https://www.henryschein.com/)  | * Gap analysis with respect to EU MDR requirements
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| Senior Quality / Regulatory Affairs Specialist – Sparrow Acoustics Inc. – [About Us - Sparrow BioAcoustics](https://stethophone.com/us/en/about/) | * Internal auditor of ISO 13485 to MDSAP Requirements
* Team leader involved in implementation of ISO 13485 MDSAP QMS
* Obtained ISO 13485 MDSAP Accreditation
* Trained all applicable staff in QMS, design controls and risk management
* Mentor to QA staff
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| Senior Quality / Regulatory Affairs Specialist – Biointegral Medical Systems – [INTERNATIONAL NEWS | biointegral-surgical](https://www.biointegral-surgical.com/) | * Internal auditor of ISO 13485 QMS to EU Requirements
* Gap analysis of QMS with respect to EU MDR requirements
* Gap analysis of existing SOPs with respect to EU MDR requirements and clinical testing
* Mentor to junior QA staff
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| Senior Quality / Regulatory Affairs Specialist – PrecisionOS Technology Inc. – [About PrecisionOS - Revolutionizing Surgical Training with VR](https://www.precisionostech.com/about/) | * Full implementation of ISO 13485 MDSAP QMS, including design controls and manufacturing controls
* Obtained ISO 13485 MDSAP Accreditation
* Trained all applicable staff
* Mentor to QA staff
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| Senior Quality / Regulatory Affairs Specialist – Tryten Technologies, Inc. – [Tryten – Mobility Platforms by Capsa Healthcare](https://tryten.com/) | * Internal auditor of ISO 9001
* Implementation of ISO 9001 QMS, including design controls and manufacturing controls
* Obtained ISO 9001 Accreditation
* Trained all applicable staff
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| Overall Competence Summary* Strong customer focus and cross-functional collaboration experience with an ability to interface effectively with internal and external stakeholders, including R&D, clinical affairs, engineering, production, suppliers, regulatory authorities, and management.
* Experience in performing audits and gap analyses of ISO QMS and responding to accreditation authority’s CAR and PAR.
* Experience with full implementation of QMS to ISO 13485 and ISO 9001 standards.
* Experience with obtaining accreditation for ISO 13485 and ISO QMS.
* Certified Lead Auditor for ISO 13485:2016, including MDSAP, ISO 9001, and US FDA QSR.
* Strong and work very effectively with internal and external stakeholders including R&D, operations, suppliers, QA, RA, and legal teams.
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| Professional Experience  |
| 1. Ailsa Biomedical Consulting Corp., North Vancouver, BC ([www.ailsabiomedical.com](http://www.ailsabiomedical.com))***Senior Director – Regulatory Affairs & Technical Writer***June 2021 – DateSenior Regulatory Affairs SpecialistJanuary 2017 to June 2021 – when Ailsa Biomedical Consulting Corp. was founded.***QA Products/Services Provided:**** Implementation and accreditation for ISO quality management systems
* Certified Lead Auditor
* Risk management throughout the product lifecycle and beyond to ISO 14971 & 12100

***2. Emergo Group (now a UL Company), Surrey, BC* (**[***www.emergobyUL.com***](http://www.emergobyUL.com)**)**February 2011 to December 2016Senior Regulatory Affairs Specialist***Products/Services Provided:**** Experienced QA-RA Consultant
* Implemented and obtained accreditation for ISO quality management systems
* Completed internal and supplier audits and reports to ISO (13485/9001) standards
* Completed risk management throughout the product lifecycle

***3. Py***n***g Medical Corp., Richmond, BC***March 2006 to January 2011*Director of Quality Assurance & Regulatory Affairs* |
| ***4. Mitroflow Inc., Burnaby, BC (***now ***Corcym Canada Corp***) (***[Corcym](https://corcym.com/contact-us)***)July 2001 to March 2006*Director of Quality Assurance & Regulatory Affairs****5. Mechanical Engineering Department, The University of Leeds, Leeds, UK***September 1996 to July 2001***Senior Research Fellow/Research Fellow******6. Autogenics, Glasgow, Scotland, UK***September 1993 to August 1996*Operations Manager, Development Engineer, and Senior QA Specialist* ***7. Cardiac Research Unit, Killingbeck Hospital, Leeds, UK***September 1988 to August 1992*Research Assistant & Medical Writer*EducationThe University of Leeds, Leeds, UK, PhD Mechanical Engineering 1993University of Strathclyde, Glasgow, Scotland, MSc Bioengineering 1988University College Dublin, Dublin, Ireland, BSc (Hons) Science 1986References available on request |