# 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 |
| 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 |
| 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 |
| 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 |
| 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 |
| 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 |
| 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. |
| 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 – Date Senior Regulatory Affairs Specialist January 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 2016 Senior 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* Education The University of Leeds, Leeds, UK, PhD Mechanical Engineering 1993  University of Strathclyde, Glasgow, Scotland, MSc Bioengineering 1988  University College Dublin, Dublin, Ireland, BSc (Hons) Science 1986  References available on request |