# Regulatory Affairs Project Management Experience

Experienced management of the following projects, including leading regulatory strategy meetings, performing, and leading the revision of quality management systems to meet new regulations, leading and authoring regulatory submissions, and responding to requests for additional information:

| **Device Experience** | **Position** | **Classification** |
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| **Canada** | **EU MDD / MDR** | **US FDA** |
| Neurovascular implants | RA Director – Evasc Medical Systems – [eCLIPs - Medical Devices for Cerebral Aneurysm (evasc.com)](https://www.evasc.com/) | IV | III / III | II |
| Cardiovascular implants, including implants derived from animal tissues | Senior Regulatory Affairs Specialist – Biointegral Medical Systems – [INTERNATIONAL NEWS | biointegral-surgical](https://www.biointegral-surgical.com/) | IV | III / III | II |
| Spinal Implants | Senior Regulatory Affairs Specialist – Medyssey Headquarters, Korea – [Home (medyssey.co.kr)](https://www.medyssey.co.kr/)  | IV | III / III | II |
| Hip implants | Senior Regulatory Affairs Specialist – Depuy Synthes – [DePuy Synthes Orthopaedics EMEA | J&J MedTech EMEA (jnjmedtech.com)](https://www.jnjmedtech.com/en-EMEA/companies/depuy-synthes)  | III | IIb / III | II |
| Knee implants | Senior Regulatory Affairs Specialist – Depuy Synthes – [DePuy Synthes Orthopaedics EMEA | J&J MedTech EMEA (jnjmedtech.com)](https://www.jnjmedtech.com/en-EMEA/companies/depuy-synthes)  | III | IIb / III | II |
| Barbed and non-barbed absorbable sutures | Senior Regulatory Affairs Specialist – Corza Medical Corredor Tijuana – [Home - Corza Medical Global](https://corza.com/global/)  | III | IIb / III | II |
| Orthodontic appliances | Senior Regulatory Affairs Specialist – Henry Schein – [Dental Supplies and Medical Supplies - Henry Schein](https://www.henryschein.com/)  | II | IIa / IIa & IIb | I |
| LEEP (Loop Electrosurgical Excision Procedure) electrodes and systems | Senior Regulatory Affairs Specialist – CooperSurgical Inc. – [CooperSurgical: Leading Women's Health & Fertility Solutions](https://www.coopersurgical.com/) | III | IIa / IIa | II |
| Skeletal Traction Device | Senior Regulatory Affairs Specialist – part-time contract – Arbutus Medical – [Arbutus Medical | Orthopedic Power Tools & Sterile Kits](https://arbutusmedical.com/) | III | IIa / IIa | II |

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| Competence Summary* 15+ years of excellent leadership skills
* 15+ years of excellent project planning skills
* 15+ years of technical experience with implants, active devices, SaMD, and dental appliances
* 15+ years as director who interfaces effectively with internal and external stakeholders including R&D, clinical affairs, engineering, production, suppliers, and top management.
* Author and remediator of submissions, including responding to regulatory authority requests
* 15+ years’ experience in performing gap analyses
* 20+ years’ experience performing risk management in conformance with ISO 14971 and ISO 12100
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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.***Products/Services Provided:**** Project Manager
* Technical writer
* Delivering documentation for product remediation
* Delivering risk management throughout the product lifecycle and beyond to ISO 14971
* Implementation and accreditation for ISO quality management systems, including MDSAP
* Certified Lead Auditor

***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 Regulatory Affairs Consultant
* Technical writer, including EU MDR clinical evaluations
* Delivered documentation for product remediation and submissions for Class II, III, and IV devices for Canada (MDL), the EU (CE Marking), and the US (510(k)
* Delivered risk management throughout the product lifecycle.
* Implemented and obtained accreditation for ISO quality management systems.
* Completed internal and supplier audits and reports to ISO (13485/9001) standards.

***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 |
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