# Medical Device Subject Matter Expert [SME]

Expert in obtaining medical device accreditation for the following regulatory jurisdictions and device classifications:

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| **SME Device Experience** | **Position** | **Classification** |
| **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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| Professional Experience  |
| Ailsa Biomedical Consulting Corp., North Vancouver, BC ([www.ailsabiomedical.com](http://www.ailsabiomedical.com))***Senior Director***June 2021 – DateSenior Regulatory Affairs SpecialistJanuary 2017 to June 2021 – when Ailsa Biomedical Consulting Corp. was founded |
| ***Emergo Group (now a UL Company), Surrey, BC* (**[***www.emergobyUL.com***](http://www.emergobyUL.com)**)**February 2011 to December 2016Senior Regulatory Affairs Specialist***Py***n***g Medical Corp., Richmond, BC***March 2006 to January 2011*Director of Quality Assurance & Regulatory Affairs****Mechanical Engineering Department, The University of Leeds, Leeds, UK***September 1996 to July 2001***Senior Research Fellow/Research Fellow******Autogenics, Glasgow, Scotland, UK***September 1993 to August 1996*Operations Manager, Development Engineer, and Senior QA Specialist* ***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 |