# 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 – Date Senior Regulatory Affairs Specialist January 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 2016 Senior 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*  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 |