



## Maya Butterfield, Ph.D

*Senior Regulatory Assurance and Quality Assurance Consultant*

### EXPERIENCE:

- Senior Regulatory Assurance and Quality Assurance Consultant, Emergo Group - Present
- Quality Assurance & Regulatory Affairs Manager, P yng Medical Corp. – 2006 to 2010
- Research and Development Manager, Sorin Group Canada Inc. – 2001 to 2006
- Senior Research Fellow, The University of Leeds, School of Mechanical Engineering – 1997 to 2001
- Research Fellow, The University of Leeds, School of Mechanical Engineering – 1996 to 1997
- Manager, Development Engineer and QA Specialist, Autogenics Europe Ltd.– 1993 to 1996
- Research Assistant, Killingbeck Hospital, Cardiac Research Unit– 1988 to 1992
- Research Assistant, St. Vincint’s Hospital, Department of Respiratory Diseases– 1986 to 1987

### AREA OF EXPERTISE:

#### *Devices:*

- Cardiovascular
- Instrumentation: Monitors, Diagnostics, Life Support
- Orthopedic
- Sleep Apnea
- Sterilization
- Anesthesia/respiratory
- Biotech
- Catheters

#### *Disciplines:*

- FDA QSR (21 CFR Part 820) Implementation
- Audits to FDA QSR (21 CFR Part 820)
- ISO 13485 Awareness Training
- 510k/513g submissions
- Clinical Evaluation Reports
- Literature Search/Review
- Due Diligence Audits
- Biocompatibility
- ISO 13485 Implementation
- ISO 13485 Internal Auditor Training
- Technical File/Design Dossier Preparation
- Auditing to ISO 13485 + CMDR
- Device Registrations for Canada
- ISO 13485 + CMDR Implementation
- Australian Device Registration/Submissions



- Brazil Technical Dossier Preparation
- Mexico COFEPRIS

**EDUCATION:**

- The University of Leeds, School of Mechanical Engineering, Ph.D. – Mechanical Engineering
- The University of Strathclyde, Bioengineering Unit, M.Sc. – Bioengineering
- University College Dublin, Department of Science, B.Sc. - Science

**AFFILIATIONS:**

- Member of ISO TC150.SC2/WG1
- International Standards Organization Technical Committee Implants for Surgery