



Elizabeth Pugh

Consultant, Regulatory Affairs

EXPERIENCE:

- Regulatory Consultant, Emergo Group – 2011
- Regulatory Affairs Specialist, DJO Surgical – 2008 to 2011
- Regulatory Affairs Specialist, EV3 (FoxHollow Technologies) – 2007 to 2008
- Regulatory Affairs Coordinator, Stryker Endoscopy – 2004 to 2007
- Regulatory Affairs Staff Assistant, Stryker Instruments – 2003 to 2004

AREAS OF EXPERTISE:

Devices:

- Orthopedic devices
- Endoscopic devices
- Implants, non-active
- Reusable Instruments
- General and Plastic Surgery

Disciplines:

- FDA Quality System Regulations – 21 CFR Part 820
- US FDA 510(k) submissions
- CE Marking - Technical Files and Design Dossiers
- Medical Writing
- Vigilance and Post-Market Surveillance in multiple markets

EDUCATION:

- B.S. Business Administration, Walden University

PROFESSIONAL AFFILIATIONS:

- Member, Regulatory Affairs Professional Society (RAPS)