Brian O'Connell

Principal Regulatory Affairs Specialist

brian.oconnell@email.com
(858) 555-0197
San Diego, CA
linkedin.com/in/brianoconnell

SKILLS

- EU MDR
- Technical Writing
- PMA Supplements
- IDE Applications
- Regulatory Strategy
- Clinical Evaluation
- Notified Body Negotiations
- Health Canada
- ISO 13485
- FDA

EDUCATION

Master of Science 05/2016

University of Southern California

Los Angeles, CA

Biomedical Engineering

CERTIFICATES

Regulatory Affairs Certification (RAC-Devices)

03/2019

Regulatory Affairs Professionals Society (RAPS)

SUMMARY

Principal regulatory affairs specialist with 10 years in medical device regulatory affairs, the last 4 owning global strategy for Class III neurostimulation implants. Leads PMA supplements, EU MDR technical writing and notified body negotiations, and sets submission standards for a 9-person regulatory team.

EXPERIENCE

Principal Regulatory Affairs Specialist

01/2022 - Present

Torrey Pines Neuromodulation — San Diego, CA

Developer of implantable spinal cord and sacral nerve stimulators with 900 employees.

- Own global regulatory strategy for **3** Class III implant platforms sold in the US, EU, Canada and Australia.
- Lead 18 PMA supplements, including 2 panel-track supplements, all approved without a major deficiency letter.
- Direct EU MDR certification of 6 implant families, writing the clinical evaluation and SSCP sections.
- Set technical writing standards and templates for 9 specialists, cutting internal review rounds by 30%.

Senior Regulatory Affairs Specialist

05/2018 - 12/2021

La Jolla Cardiac Systems — San Diego, CA

Cardiac rhythm management device company.

- Authored 2 IDE applications and 12 PMA annual reports for cardiac rhythm devices.
- Negotiated labeling and post-approval study terms with FDA reviewers in 5 pre-submission meetings.
- Built Health Canada and TGA submissions for 4 products, all licensed within 10 months.

Regulatory Affairs Specialist

06/2016 - 04/2018

Sorrento Valley Orthopedics — San Diego, CA

Spinal implant and instrument maker.

- Wrote 6 510(k) submissions for spinal implants, all cleared on first review.
- Revised ISO 13485 regulatory procedures and closed 8 audit findings.
- Tracked 50 international registrations and renewals in Excel.