HANOVER SEARCH PARTNERS

RECRUITING RESULTS

VICE PRESIDENT, REGULATORY AFFAIRS

Hanover Search Partners, a global Executive Search firm has been retained by Integra LifeSciences to support a key executive search for a Vice President of Regulatory Affairs.

Integra LifeSciences, a world leader in medical technology with headquarters in Princeton, New Jersey, was founded in 1989 with the acquisition of an engineered collagen technology platform used to repair and regenerate tissue.

Since then, Integra has expanded its base regenerative technology product portfolio to include surgical instruments, neurosurgical products, and advanced wound care products, through global acquisitions and development of new and innovative products and technologies to address unmet patient needs and improve outcomes.

Integra is a global leader in neurosurgery and offers a broad portfolio of products and solutions for dural access and repair, cerebral spinal fluid management and neuro-critical care. Our regenerative tissue technologies include products that address soft tissue, nerve and tendon repairs and for the treatment of acute and chronic wounds, burns, as well as for plastic and reconstructive surgery. The company has approximately 4,000 employees and have offices, manufacturing and research facilities in Asia, Australia, Europe, Middle East, and the Americas.

Integra products are ubiquitous in many hospital intensive care units and operating rooms around the world. Some of our high-quality leading brands include AmnioExcel®, Bactiseal®, Cerebroflo®, Certas® Plus, Codman®, CUSA®, DuraGen®, DuraSeal®, ICP Express®, Integra®, MatriStem UBM™, MediHoney®, MicroFrance®, PriMatrix®, SurgiMend®, TCC-EZ®, and VersaTru™

Integra LifeSciences, a world leader in medical technology, is dedicated to limiting uncertainty for surgeons, so they can concentrate on providing the best patient care. Integra offers innovative solutions in orthopedic extremity surgery, neurosurgery, spine surgery, and reconstructive and general surgery.

Integra's orthopedic products include devices and implants for spine, foot and ankle, hand and wrist, shoulder and elbow, tendon and peripheral nerve protection and repair, and wound repair. Integra is a leader in neurosurgery, offering a broad portfolio of implants, devices, instruments and systems used in neurosurgery, neuromonitoring, neurotrauma, and related critical care. Founded in 1989 Integra is headquartered in Princeton, New Jersey and has over 4000 employees worldwide.

Integra's common stock is listed on The NASDAQ Stock Market under the symbol "IART."

Description:

Identify, Review, and anticipate emerging regulatory issues impacting the Orthopedics & Tissue Technologies ("OTT") Division.

Develop and implement regulatory strategies and guidance based on U.S. and International requirements as defined in FDA Regulations, ISO 13485: 2003 Standard, European Medical Device Directives, Canadian Medical Device Regulations, Japanese QMS Ordinance (Ministerial Ordinance No. 169), Australian Therapeutic Goods (Medical Devices) Regulations 2002 (No. 236) and other International Regulations.

Establish effective dialogue with U.S. and International regulatory authorities.

Direct the planning and preparation of regulatory submissions for the company's products.

Facilitate timely product registrations and regulatory approvals.

Detailed Description:

Responsible for providing regulatory strategy to Integra Orthopedic and Tissue Technologies Division for new product development and continuous product improvement.

Provide oversight in taking innovative ideas from proof of concept through regulatory strategy, including product development, manufacturing, filing and FDA clearance/approval, international submissions, and commercial operations.

Responsible for regulatory functions including planning and filing of documentation with domestic and international regulatory agencies.

Obtain/generate information to be submitted to regulatory authorities and prepares required regulatory submissions.

Act as liaison with appropriate local, national, and international regulatory authorities.

Collaborate with Quality in driving compliance activities related to FDA and ISO regulations, and quality system standards activities at Integra facilities, including acting as interim deputy management representative as requested.

Lead relevant project planning and review meetings; conduct the final company document review and corrections.

Identify and ensure the establishment and monitoring schedules for submission documentation, review of documentation, protocols and reports received; prepare additional written materials needed.

Coordinate the preparation of 510(k) Premarket Notifications, IDEs, PMAs, Design Dossiers, Technical Files and other International Registrations.

Coordinate and manage meetings with FDA regarding product submissions.

Prepare responses to FDA letters, supplements, and amendments; participate in FDA inspections and presentations as required.

Generally:
Exceedingly Sound "EQ" Characteristics

Demonstrate cross-functional expertise and thrive in a highly matrix environment.

Effectively communicates with team, peers, executive management, and/or Executive Leadership Team

Encourage RA team to deliver tactful and actional feedback across all levels.

Work with diverse stakeholders and build strong, collaborative relationships; manage competing agendas and priorities across different functional departments.

Set direction and focus by leveraging organizational abilities and proactive planning and oversee staff development and performance plans.

Demonstrate strong analytical thinking, organizational and communication skills.

Perform other related duties as assigned by supervisor.

10-15 Years of Regulatory Affairs Experience

Deep experience with FDA Authorities

Advanced Degree from a well-respected academic institution