Dear Joint Program students and recent graduates,

The following position will be posted on <https://www.careers.jnj.com/> and will be searchable with 2105941831W as the keyword. This position is a starting point for a challenging and rewarding career that uses the knowledge gained from studying physics, chemistry, biology, and/or engineering amongst other talented Johnson & Johnson colleagues. This position plays a critical role in bringing products that benefit patients to the market by navigating global medical device regulations.

Please feel free to email me to set up a time to discuss further before deciding to apply.

Thank you,

Mitch Ohiwa (MS, Physical Oceanography, 2002)

**Mitch Ohiwa, MS, MBA, JD**

Associate Director, Regulatory Affairs

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Description automatically generated

DePuy Spine, Inc.

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**Job Description**

DePuy Synthes Companies of Johnson & Johnson is recruiting for a **Regulatory Affairs Specialist I – Spine,** located in **Raynham, MA**.

DePuy Synthes Companies of Johnson & Johnson is the largest, most innovative and comprehensive orthopaedic and neurological business in the world. DePuy Synthes Companies offer an unparalleled breadth and depth of products, services and programs in the areas of joint reconstruction, trauma, spine, sports medicine, neurological, craniomaxillofacial, power tools and biomaterials. With a focus on activating insights to develop innovative, comprehensive solutions, we are inspired to advance patient care in greater ways than either company could accomplish on its own. To learn more, visit www.depuysynthes.com

**Key Responsibilities**:

* Provides independent regulatory guidance to product development teams in defining regulatory strategies, pre-marketing, and related submissions to support optimal timelines for new/modified product launches in the global market
* Leads the submission of licenses and authorizations for the maintenance of existing products, international registrations, and dossiers, including, but not limited to 510(k) submissions, IDE/IDE Supplements, PMA/PMA Supplements, Annual Reports, HDEs, IND/NDA Supplements, Design Dossiers/Change Notifications, and Technical Files.
* Guides conformance with applicable regulations in product development, support of claims, content labeling, and promotional materials.
* Defines data and information needed for regulatory approvals.
* Develops labeling specifications and approves proposed labeling, packaging, advertising and promotional materials after evaluating conformance to regulations.
* Provide Regulatory Affairs support during internal and external audits.
* Plans schedules for delivery of supporting documentations required for regulatory submissions on a project and monitors project through completion.
* Assists in the development of improved and efficient processes practices for Regulatory Affairs processes.
* Represents Regulatory Affairs on cross-functional project teams, guiding and supporting product development teams on both US and international issues.
* Partners with other functions to define and generate data to assist with regulatory submissions.
* Review and provide regulatory authorization for Engineering Change Orders (ECOs).
* Respond to requests from foreign governments and/or distributors to prepare and submit documentation for marketing approvals in other countries, as well as provide routine regulatory information to associates and affiliates.

**QUALIFICATIONS**

**Education:**

* A minimum of a bachelor’s degree required, advanced degree(s) preferred.
* Educational background in scientific, engineering, business, or legal subject areas preferred.

**Experience and Skills:**

* Motivation and intellectual capacity to identify, read, understand, and address global medical device regulations are required.
* Practical knowledge of medical device or another regulated industry is preferred.
* Knowledge of US and European regulatory processes is preferred.
* Experience in the preparation and submission of US Regulatory files (510(k)s, PMAs) as well as European technical files and design dossiers is preferred.
* Must have excellent written, verbal communication, and presentation skills.

**Other:**

This position will be located in Raynham, MA, and may require up to 10% domestic/international travel.

**BE VITAL in your career, be seen for the talent you bring to your work. Explore opportunities within the Johnson & Johnson Family of Companies.**

Johnson & Johnson is an Affirmative Action and Equal Opportunity Employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, age, national origin, or protected veteran status and will not be discriminated against on the basis of disability.