Position: Manager of Toxicology & Biocompatibility
Location: Raynham, Massachusetts; Warsaw, Indiana
Function: R&D

Job Description
DePuy Synthes (Part of Johnson and Johnson Family of Companies) is recruiting for a Manager of Toxicology & Biocompatibility, located in Raynham, Massachusetts or Warsaw, Indiana.

DePuy Synthes, part of the Johnson & Johnson Medical Devices Companies, provides one of the most comprehensive orthopedics portfolios in the world. DePuy Synthes solutions, in specialties including joint reconstruction, trauma, craniomaxillofacial, spinal surgery and sports medicine, are designed to advance patient care while delivering clinical and economic value to health care systems worldwide. For more information, visit www.depuysynthes.com.

The Manager, Toxicology & Biocompatibility, is responsible for leading a group of scientists and toxicologists in the safety evaluation of DePuy Synthes Medical Device products per internal, global standards and regulations. This person manages timely execution of safety evaluations and product chemical characterizations supporting new product introductions, risk assessments, regulatory submissions, health authority audits, and on-going base business activities throughout a product lifecycle. He/she applies technical expertise to solve complex biocompatibility problems, utilizing ingenuity, business experience and independent judgment. Furthermore, this person interacts closely with cross functional team leaders and provides consultation and technical expertise necessary to achieve a high-quality product.

The candidate should excel in an environment that embraces change, risk-based decision-making and flexibility. Interpersonal skills that foster conflict resolution as it relates to technical situations will be required.

Key Responsibilities:

Work with management across DePuy Synthes to oversee, manage and prioritize resources conducting toxicological and biocompatibility assessments for projects across multiple global business platforms.

Ensure effective execution of studies and provide scientific input and rationale for high potential projects to effectively direct and utilize resources.

Establish team effectiveness and lead the team to develop and achieve its goals by utilizing the diverse group of individuals on the team in the spirit of J&J Credo values.

Provide strategic guidance and interpretation of regulatory requirements related to medical device submissions for the global organization and assigned business platforms.

Qualifications

Required:

A minimum Bachelor's degree in Engineering, Chemistry, or Biological Sciences.

Minimum of 2 years of experience managing senior scientific staff or cross functional projects

Experienced professional with a complete understanding and wide application of principle, theories, and concepts in the biocompatibility of medical devices, including demonstrated expertise with the suite of ISO 10993 standards.

Demonstrated leadership skills to serve as a change agent to identify needs and solutions, and to implement and support the transformation of a function

Demonstrated knowledge of working within a highly regulated industry and strong knowledge of quality systems management (e. g. ISO 13485, EU MDD/MDR and 21 CFR 820) to avoid and resolve issues with CAPA, product recalls and external audits is required.

Working knowledge and understanding of medical device product development as guided by ISO 13485 and ISO 14971.

Excellent problem solving, decision-making, and root cause analysis skills

Previous technical writing experience

Excellent organizational, project and time management skills

Ability to work with and communicate well across all levels of the organization

Strong written and oral communication with an ability to interact with multi-lingual associates

Interpersonal skills that foster conflict resolution as it relates to technical issues

Must be self-driven, able to work independently, and prioritize multiple projects

Preferred:

A Master's or Doctoral degree in Engineering or Sciences or Business

Experience with Risk Analysis, Internal Audits, and third-party inspections

Knowledge of process and design excellence tools and Green or Black Belt training

Previous experience in the medical device industry

Experience with change management

Other:

Full proficiency in written English language and can communicate issues and concepts in a clear, concise manner

This position requires up to 25% travel (international and domestic).

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.

Primary Location
United States-Massachusetts-Raynham-
Other Locations
North America-United States-Indiana-Warsaw
Organization
Medical Device Business Services, Inc (6029)
Job Function
R&D
Requisition ID
5919200610

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