

**Senior Regulatory Affairs Executive****Price £0****AD**Ad URL: <https://loot.com/15663466>

Ad reference number #15663466

**DEALER**

Johnson &amp; Johnson

[info@adview.online](mailto:info@adview.online)**DESCRIPTION**

Ad Type: Offered  
Posted on: 11/09/2020, 02:57

**DESCRIPTION**

J&J Family of Companies Senior Regulatory Affairs Executive Maidenhead , United Kingdom  
Apply Now

UK REGULATORY AFFAIRS - SENIORREGULATORY AFFAIRS EXECUTIVE NORTHERN CLUSTER

Location : High Wycombe, UK

Main Responsibility :

Management of a product or specified products within a therapy area for Cosmetics, OTC and/or Medical Devices

Responsible for a large number of products across the J&J portfolio range in the UK, Ireland and Malta.

Development of regulatory strategies, preparation of regulatory applications and support maintenance activities within relevant therapy area

Support regulatory activities for National and/or European procedures (Decentralised, Mutual Recognition) as appropriate.

Develop and support regulatory strategies (local and regional) in line with business plan.

Complete regulatory activities for a defined number of products to ensure all regulatory obligations and business objectives are met.

Prepares and compiles regulatory submissions (Marketing Authorisations, Reclassifications etc.), responses to Regulatory Agency (RA) questions and other correspondence in accordance with EU regulations and guidelines.

Sign off of packaging material, leaflets, SmPCs and advertising material to ensure regulatory compliance for submissions via Zinc, COCOON, Starfish systems etc.

Ensure Marketing Authorisations are maintained and renewed.

## Senior Regulatory Affairs Executive

Price £0

Inform the Regulatory Agency/Department of Health (as appropriate) of product discontinuations and licence cancellations.

Ensures compliance within the department by ensuring

Global, EAME and local databases are fully maintained.

Processes, SOPs and working instructions are adhered to.

Update relevant local and global databases (e.g. Documentum, Aris, GLR, Connect etc.) to track current product information.

Provide regulatory advice and perform due diligence for product acquisitions and distributor agreements with third parties.

Good Regulatory Practice

Maintain awareness/knowledge of current regulatory legislation.

Ensures regulatory best practice at all times.

Monitor changes in the regulatory environment and highlight any potential impact on McNeil Products Ltd / J&J products.

Customer Service

Act as an ambassador for the Regulatory Affairs department and continue to raise profile of team both internally and externally.

Represent Regulatory Affairs on cross-functional product/project teams and provide regulatory advice (as appropriate).

Interact with Regulatory Agency

Seek advice when appropriate.

Respond to requests for further information and queries.

Resolve any regulatory matters and expedite approval of pending applications.

Provide regulatory guidance to internal stakeholders, to allow them make key decisions on business critical activities and project feasibility.

Represent J&J and provide regulatory advice at e.g. joint Company/Trade Association initiatives, Regulatory Agency meetings etc (as appropriate).

Personal Development

Identify own training and development needs in discussion with Manager, to ensure a broadening skill and knowledge base and to maximise/optimize career development and opportunities.

Develop product and therapeutic area knowledge as needed, according to product responsibilities list.

Qualifications

Skills, Knowledge, Qualifications and Experience :

Life sciences or chemistry graduate to honours level or equivalent.

Works independently to plan, conduct, and manage regulatory submissions and multiple projects to meet department and company objectives.

Work with minimal supervision to determine and develop approaches to solutions with technical guidance on a variety of problems of moderate scope and complexity.

May mentor Regulatory Executives and provide day to day support.

Project management, understanding of regulatory environment, interaction with the Regulatory Authorities, commercial/ strategic awareness, implement regulatory strategy, managing and maintaining Marketing Authorisations.

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.