



NICHE GENERICS LTD.

Job Description

Regulatory Affairs Officers – Permanent, Full-Time and Part-Time options

Location: Clonmel, Co. Tipperary

Niche Generics Limited is a company dedicated to the successful registration and launch of generic pharmaceutical products throughout the EU, South Africa, Australia, New Zealand and MENA territories. We now invite applications to join the regulatory team, based in Clonmel, Co. Tipperary.

The ideal candidate will have at least 2 years regulatory experience in the pharmaceutical industry, a life science or pharmacy background and a sound knowledge of European submission procedures and electronic applications (both NeeS and eCTD).

Role & Responsibilities:

- Management of a specific portfolio of products
- Co-ordination, preparation and submission of new MAAs (abridged) in the EU via national, MRP and DCP routes
- Authoring and co-ordinating responses to questions from competent authorities
- Co-ordination, preparation and submission of variations, renewals and transfers
- Providing regulatory support for out-licensing activities in EU and non-EU territories including the provision of responses to queries arising from dossier audits
- Planning and tracking of regulatory procedures through to completion in a timely manner
- Liaising with other internal departments and external parties to generate supporting data for submissions
- Reviewing documentation to ensure compliance with MA details and relevant guidelines and Directives

Skills & Competences:

- Practical experience of registration and variation procedures in the EU (national/MRP/DCP)
- Good understanding of the content and format of MA registration files (CTD)
- Knowledge and understanding of the requirements for product information (QRD template, user testing, Braille, etc.)
- Understanding of the application of change control to regulatory procedures
- Knowledge and understanding of the EU regulatory framework
- Accuracy and attention to detail
- Strong verbal and written communication skills
- Excellent organisational, prioritisation and time management skills
- Good interpersonal skills
- IT literacy in word processing, spread-sheets, document management
- 'Soft' skills – team working, negotiation and influencing skills

We offer a competitive salary, 23 days annual leave, private healthcare cover and a non-contributory pension scheme to suitable candidates.