

ALTER PHARMA GROUP NV

GENERIC BUSINESS UNIT

QUALITY ASSURANCE OFFICER GENERICS

ABOUT OUR COMPANY

Alter Pharma is a Belgian group of pharmaceutical companies with headquarters in Anderlecht (Belgium) and offices in Ireland and the United States. Employing in total over 140 employees, the Group distributes a wide range of pharmaceutical products to pharmacies, wholesalers, hospitals and retirement homes. At the same time, Alter Pharma is a global player on the generics market, with around 15 molecules on the European and US market and a fully stocked pipeline of niche, complex and added value products.

Our values

Our talented staff daily work in accordance with our company values:

- We are proud of our entrepreneurial culture and foster open communication, mutual respect, professionalism and efficient decision-making and we believe that our multicultural organisation is one of our most important competitive advantages.
- We believe that timely and well considered decisions as a response to emerging opportunities and ideas is the key to our success.
- We believe that the success of the company lies in the competence, dedication and motivation of each of our employees.
- We believe that freedom returns flexibility and empowerment returns commitment.

We are currently looking for a talented Quality Assurance Officer Generics to help us proactively managing our quality and compliance of our medicinal products. The successful candidate must have proven skills in Quality Assurance and Manufacturing and has at least 2 years relevant experience in QA in the pharmaceutical industry with good knowledge of the relevant European regulations for manufacturing of pharmaceutical products.

You will report directly to the Team Leader QA Generics and will be based in Anderlecht, Belgium or Balbriggan, Ireland.

Travel activities is a natural part of the job, so the candidate must be willing to travel in average once a month with an average duration of 2-3 days.

The job description

The Quality Assurance Officer Generics will be responsible for the following quality aspects within the business:

- Help with due diligence and integration during new product developments / new product introductions
- Agree Quality Agreements with external partners (contract manufacturers, logistic service providers, clients and distributors).

- Support technical product transfers, qualification and validation work
- Investigate quality incidents, OOS, deviations and complaints, identify and follow-up CAPA's and supplier improvement plans together with contract manufacturers.
- Evaluate and follow-up Change Controls as per company procedure
- Write Product Quality Reviews.
- Agree annual stability programs and review stability results.
- Be part of Supplier Qualification and Regular Supplier Auditing.
- Identify gaps and areas for improvement in QA processes and handling and lead remedial actions and initiatives.
- Keep a going awareness of new and developing regulations related to GDPs and GMPs.
- Support in ensuring ongoing inspection readiness

The Quality Assurance Officer Generics will act according to the companies' mission, vision and strategy.

Your professional profile

The successful candidate has a master degree in pharmaceutical sciences, industrial pharmacy, engineering, biochemistry, chemistry ... or equivalent through experience and have at least 2 years of relevant experience in QA in the pharmaceutical industry. Qualified Person certification is an asset.

You have good knowledge of the relevant European regulations for manufacturing of pharmaceutical products as well as good knowledge of the manufacturing process for injectables and tablets. Knowledge of and experience in FDA regulations is an asset.

Your abilities

- You have a positive "can-do" spirit. You have strong project management skills and the capacity to work effectively in a multicultural environment.
- You are an enthusiastic teamworker who gets the job done.
- You are a self-starter and capable of working autonomously.
- You will be travelling internationally on a regular basis (once a month).
- You speak and write fluently English; any other language is an asset.

For more information about our company, please visit www.neogen.be and www.alterpharmagroup.be. Motivation letter and CV can be sent to recruitment@alterpharma.be.