

REGULATORY MANAGER

We are seeking to appoint a Regulatory Manager who is of graduate level in a science subject and has a working knowledge of MHRA/HPRA regulatory requirements for Medicinal Products, including Pharmacovigilance and a working knowledge of Cosmetic and Food Supplements regulations.

Reporting to The Operations Director, your key responsibilities will include:

Regulatory:

- The liaison for Weleda UK with the MHRA/HPRA and other Regulatory bodies (if required) as well as the liaison with our International Regulatory Affairs;
- Preparation and submission of Regulatory dossiers to MHRA/HPRA;
- Maintenance of Regulatory dossiers throughout the product life-cycle, including preparation and submission of variations and licence renewals;
- Provide responses to Regulatory bodies regarding product information or issues with submissions. Preparation of product information including Summary of Product Characteristics, labels, cartons and leaflets;
- Handling of Medical Information requests for medicinal products;
- Maintenance of company manufacturing, import and wholesale dealer licences;
- Keep up to date with changes in the Regulatory Affairs area and communicate with all necessary parties;
- Preparation and submission of new applications for Natural and Organic Cosmetic products;
- Maintenance of the Product Information Files (PIF) for Weleda UK cosmetics – including preparation and submission of changes.

Pharmacovigilance:

- · Liaison with the EU QPPV;
- · Review of weekly literature searches;
- Preparation of CIOMs and reports for any adverse reaction reports to Weleda UK medicinal products;
- Input into Weleda Group requests for data for PSURs;
- Training for customer-facing staff on Pharmacovigilance responsibilities.

Your profile:

- Educated to degree level within a science discipline;
- Relevant experience within the Pharmaceutical/Cosmetic Industry:
- Good knowledge of MHRA/HPRA regulatory requirements;
- Good knowledge of European legislation for medicines and cosmetics;
- Knowledge of advertising regulations;
- Knowledge of Pharmacovigilance legislation and requirements;
- Experience of working cross functionally and with multidisciplinary teams is essential;
- Experience of managing a small team would be advantageous.

Our ethos

Weleda was established almost one hundred years ago as a place of human development through a common goal - to create natural products that support and enhance health and well-being, profitably.

Today, we operate globally across 50 countries and we are recognised as the industry leader.

We share a common culture founded upon strong sustainable principles for the environment, for the economy and for our personal well-being and development. This includes adopting a flexible approach to work; acting responsibly, honestly and ethically and placing responsibility on each and everyone of us to uphold these values.

When will we get to know you?

We look forward to receiving your application which should include your CV and covering letter, convincing us of your ability and quoting your salary expectations to:-

Irene Bent, HR Manager, Weleda (UK) Ltd, Heanor Road, Ilkeston, Derbyshire DE7 8DR <u>irene.bent@weleda.co.uk</u>

Closing date for receipt of applications: 14th February 2020