Job Title:	**Regulatory Affairs Officer - UK**
Name:	
Reporting to:	RA Manager
Location:	UK Office, Crawley – Full-Time

Job Purpose:

To maintain all UK Product licenses, import licenses and wholesaler dealer licences in accordance with the UK regulatory guidelines (MHRA), ensure all UK license applications are submitted in accordance with Torrent Pharma UK company expectations and be responsible for the full process of European Marketing Authorisations including preparation, submissions and maintenance.

Key Duties and Responsibilities:

[Please note; this list is not exhaustive and responsibilities may include any other reasonable requests in line with your skill set]

- To ensure that the company's products comply with the regulations of the Medicines and Healthcare Regulatory Agency (MHRA)
- To submit applications for addition of products to TPUK manufacturer importer's authorisation (MIA) and wholesale dealer (WDL) licenses to ensure that they are up to date to allow importation and distribution of all company's products
- To support Torrent Pharma UK and the Torrent Group's regulatory department with eCTD and NeeS submissions by either National, DCP or MRP procedures
- To prepare submissions of license variations and renewals to strict deadlines, respond to questions from regulatory authorities raised during technical review of submissions, variations and renewals
- To liaise with assessors at regulatory agencies
- Maintain filing and databases relating to regulatory activities
- To co-ordinate with EU QPPV for PV activities relating to Torrent – UK responding to medical information queries from patients
- To write and review SOP's within the regulatory department
- To keep abreast of all European regulatory legislation, guidelines and customer practices
- To keep up to date with the company's current and future product range
- To interface all regulatory affairs with the in QA function of the company
- Monitoring and setting timelines for license variations and renewal approvals by reporting to the General Manager on an agreed format and frequency
- To write clear, accessible product labels and patient information leaflets
- To manage the user testing of patient information leaflets when required
- To specify storage, labelling and packaging requirements in accordance with the product licences
- To undertake and manage all regulatory inspections
- To support regulatory affairs aspects for project management of new product development and launches
- To manage electronic interface (RAMA portal) with the MHRA for license maintenance.
- To manage payments and accounts with the MHRA for all UK company regulatory activity
- To undertake ad hoc duties on behalf of the General Manager as and when required
- To comply with the office policies and guidelines

Knowledge & Experience Required:	Personal Skills Required:
• Experience with communicating with the MHRA at an administrative and strategic level • Understanding of European regulatory guidelines, regulations and procedures • Knowledge of other European Market Authorisation bodies eg IMB • Knowledge of GMP and GDP • Knowledge of MHRA fees • Understanding of the timescales of the approval processes within the MHRA • Understanding the company Regulatory Affairs SOP's • Understanding of pharmacovigilance practices and procedures • Understanding of the drug development process	• Ability to manage conflicting priorities • Excellent communication skills • Strong interpersonal skills • Accurate • Methodical • Attention to detail • Proactive

Torrent Pharma Values and Behaviours:

All employees at Torrent Pharma are expected to demonstrate and embrace our Values, Behaviours and Ways of Working.

Our Values:

- Integrity
- Passion for Excellence
- Participative Decision Making
- Concern for Society & Environment
- Fairness for Care
- Transparency