United Kingdom Jobs Expertini®

Responsible Person (RP) / Responsible Person Import (RPi)

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Company: BeiGene

Location: United Kingdom

Category: other-general

BeiGene continues to grow at a rapid pace with challenging and exciting opportunities for experienced professionals. When considering candidates, we look for scientific and business professionals who are highly motivated, collaborative, and most importantly, share our passionate interest in fighting cancer.

General Description:

To perform the services and duties of a Responsible Person (RP) under the Regulations and the provisions of the Wholesale Distribution Authorisation. Ensure that compliance is maintained as per Human Medicines Regulations 2012 and EU Directive 2013/c343/01 with Good Distribution Practice (GDP).

To fulfil the duties of the Responsible Person (import) (RPi) for BeiGene UK as described in regulations 45AA and 45AB of the Human Medicines Regulations 2012 (as amended).

Essential Functions of the job:

To be named as Responsible Person (RP) & Responsible Person Import (RPi) on BeiGene's UK Wholesale Distribution Authorisation (WDA).

Acting as the RP –

ensuring that the provisions of the WDA and Home Office Licences are observed

ensuring that the guidelines on Good Distribution Practice (GDP) are complied with

ensuring that the operations do not compromise the quality of medicines

ensuring that a quality management system is implemented and maintained

focussing on the management of authorised activities and the accuracy and quality of records

ensuring that initial and continuous training programs for all personnel involved in GDP/distribution activities are implemented and maintained

co-ordinating with the Regulatory Authorities and perform promptly any recall operations of medicinal products

ensuring that relevant customer complaints are dealt with effectively

ensuring that suppliers and customers are qualified

deciding on the final disposition returned, rejected, recalled or falsified products

approving any subcontracted activities which may impact on GDP

ensuring that self-inspections are performed at appropriate regular intervals following a prearranged program of monthly visits at the administration site and necessary corrective measures are put in place

delegating duties (but not accountability) when absent and keeping appropriate records relating to any delegation

advising BeiGene should additional regulations, introduced by the MHRA, Home Office or the EU, require changes or additions to the existing GDP processes

find reviewing and approving any changes to existing GDP SOPs, or new GDP SOPs, of BeiGene.

Acting as the RPi –
To be named as Responsible Person for Import on the MHRA Wholesale Distribution Authorisation (WDA) and ensure the provisions of the license are observed.

To take responsibility for implementing a quality management system for the WDA(H) as a whole including all sites listed.

To maintain current personal training and an understanding of the industry in order to qualify for the role.

To be responsible for implementing a system to confirm that the required QP certification has taken place for products that have been imported into the UK from countries on a list for onward supply or export ensure that written evidence is available to demonstrate that each batch of product has been EU QP certified as required in Article 51 of Directive 2001/83/EC.

Acting as the RP -
Pharma QA experience

Knowledge and experience of Responsible Person Training (Gold Standard)

Personnel knowledge of the Human Medicines Regulations 2012 and amendments

The relevant legislation in the intended market the organisation is supplying to

Guidelines on Good Distribution Practices

Knowledge of the products traded under the license and the conditions necessary for safe storage and distribution

Qualifications:
A diploma, certificate or other evidence of formal qualifications awarded on completion of a university or other higher education course of study in: Pharmacy, Chemistry, Medicine, Biology, or a related life science

Equivalent qualifications include: o Level 5 qualifications from Chartered Institute of Logistics and Transport (); A Quality Management System Lead Auditor or Pharmaceutical GMP Lead Auditor qualification awarded by Chartered Quality Institute ()

Other qualifications may be acceptable. Suitability of qualifications can be checked by email to: k.

Experience:
The RP should have a at least 1 years experience in maintaining a quality management system appropriate to the license for which nominated.

A minimum of 8 years' experience in performing the functions of a responsible person on a WDA(H).

Evidence of performing other functions, for example a quality assurance role for a pharmaceutical manufacturer, may also be considered equivalent.

Professional Body Membership

Acceptable professional body memberships are: Royal Society of Biology, Royal Pharmaceutical Society, Pharmaceutical Society of Northern Ireland, Royal Society of Chemistry

Additional bodies that the licensing authority considered to be equivalent for RPi candidates include: The Chartered Institute of Logistics and Transport, The Chartered Quality Institute

Other professional associations may be acceptable. Suitability of qualifications can be checked by email to: k.

BeiGene Global Competencies

When we exhibit our values of Patients First, Collaborative Spirit, Bold Ingenuity and Driving Excellence, through our twelve global competencies below, we help get more affordable medicines to more patients around the world.

Fosters Teamwork

Provides and Solicits Honest and Actionable Feedback

Self-Awareness

Acts Inclusively

Demonstrates Initiative

Entrepreneurial Mindset

Continuous Learning

Embraces Change

Results-Oriented

Analytical Thinking/Data Analysis

Financial Excellence

Communicates with Clarity

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