Responsible Person and GDP Cogent approved

Cogent Gold Standard Approved

Delivery: Classroom, Online, Inhouse **Duration:** 3 days Cost: £1900 (+VAT)

Course overview

RSSL has been providing Responsible Person training since 2012. Our latest Cogent Gold Standard Approved online and classroom courses incorporate the very latest regulatory aspects, best practice, customer and industry input.

About the Cogent Gold Standard Approved status, "Cogent Skills alongside the MHRA have developed a new Gold Standard role profile for Responsible Person in Medicinal Products which in turn has led to the agreement of a training standard which is recognised by the MHRA."

If your organisation already has or is applying for a Wholesale Dealers Authorisation (WDA) they must a have a Responsible Person (RP) named on the license. The RP must ensure compliance with Good Distribution Practice (GDP) and fully understand the legal responsibilities of an organisation holding a Wholesale Dealers Authorisation (WDA) license. Thereby, ensuring all medicinal products are purchased and sold within the legal supply chain and receive the correct handling, transportation, storage and distribution of medicinal products.

Another core requirement of Good Distribution Practice is to have a well-designed Quality Management System (QMS) with a focus on compliance and continual improvement. The Responsible Person is legally required to ensure the QMS is implemented by maintaining oversite of its routine operation. This area will be covered in detail as it has been highlighted by the Medicines and Healthcare Products Regulatory Agency as the number 1 area deficiencies are found during inspections for several years.

Who should attend?

This course has been designed for people who are seeking to be named as a Responsible Person on a Wholesale Dealers Licence (WDA). However, the content is also relevant in the education of those who are involved in the procurement and sale of medicinal products, including Wholesale Dealers Authorisation holders. Similarly people who are involved in the selection of organisations involved in the storage and transport of finished products, as well as supplier auditors who audit such organisations will find this course beneficial to enhance their knowledge of what to expect during site visits.

Existing RP's may also find the course is a valuable part of their Continuous Professional Development particularly those who have performed the role for a number of years. If you are a Qualified Persons (QP) who needs a detailed appreciation of GDP and the role of an RP or maybe looking to be named as an RP, but concerned that you don't have the depth of knowledge required then you will be most welcome and may find the interactive nature of the course of significant benefit.

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Course programme

The course includes the following topics and is reinforced using group exercises:

Day 1	Day 2	Day 3
• Expectations to become a RP • About the RP, history of GDP • Regulatory background • MHRA and it's role • What does GDP cover and the license types • The WDA(H) and how to apply • License checks EudraGMDP & MHRA GMDP • Key personnel in the supply chain and GDP • The RPi, Brexit	• Quality Management and it's tools • Personnel and the role of the RP • Premises and Equipment • Documentation • Operations • Complaints, returns, suspected falsified medicines & recalls	• Outsourced activities • Self-inspection and regulatory inspections • Transportation, Containers, Packing & Labelling products requiring special conditions, Import & Export • Specific provisions for brokers • Controlled drugs • Specific provisions for the RP • RP in the organisation • responsibilities for the WDA holder • Parallel distribution • Assessment/Test

Learning outcomes

Attending this course will ensure that you :

- Understand the role of the Responsible Person (RP) with respect to personal responsibilities and to that of the employing company or agent and of the importance of patient and the product user safety
- Understand the legislation and licensing requirements applicable to the wholesale distribution of medicinal products and the role of the RP, with a particular focus on the primary responsibilities and accountabilities of the RP and their role as quality management representative within the Supply Chain
- Have a clear understanding of the role of the Competent Authority for medicinal products in the licensing of the wholesale dealing of medicines and as the competent authority in the enforcement of Good Distribution Practice (GDP) guidelines
- Have an understanding of the relevant role of National Organisations that also regulate the Supply Chain of medicinal product control
- Understand all aspects of the European Pharmaceutical directives and guidelines related to GDP for Medicinal Products and be aware of Good Manufacturing Practices (GMP) within the Supply Chain
- Understand and recognise best practice in Good Distribution Practice (GDP) and why this is essential in maintaining the quality and the integrity of medicinal products throughout the supply chain
- Appreciate how to apply and maintain the knowledge of how an effective quality compliance system that meets the requirements can be implemented maintained and improve.
- Be able to identify a medicinal product, the different legal categories, storage conditions and Marketing Authorisation (MA) types such that they can be appropriately handled, stored, managed and supplied. Understand the importance of applying due diligence in the discharge of his/her duties and of reporting to senior management, the competent authority and the MA holder any suspicious events of which he/she becomes aware, such as non-compliant products or the receipt or offer of medicinal products which are suspected of or identified as being falsified
- Understand how to review the effectiveness of an organisation’s quality management system and implement effective corrective and preventive actions (CAPA) to address any deficiencies or non-conformance issue identified. These may include product recalls, disposal and physical segregation etc.

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Tel: +44 (0)118 918 4000 Email: trainingsales@rssl.com www.rssl.com
RSSL Training, Reading Science Centre, Whiteknights, Reading, Berkshire RG6 6LA