Responsible Person (RP) Training Course

A 3 day intensive course for people wanting to become a Responsible Person

This 3 day intensive course is aimed at people who want to become a Responsible Person (RP). This course is presented over 3 days and is based on and includes the requirements of the **Cogent Gold Standard** for trainee RPs. The course covers the **roles and responsibilities of an RP** to help ensure that the end user receives medicinal products that have been **controlled, stored and transported correctly**. The course includes the requirements of **Good Distribution Practice** (GDP) and the legal responsibilities of an organisation holding a **Wholesale Dealers Authorisation** (WDA) to ensure that products are purchased and sold within the **legal supply chain**. During the course we cover the specific requirements for the correct **transportation**, **storage** and **distribution** of medicinal products and well as the need to have a well **designed Quality Management System** (QMS) with a focus on **compliance** and **continual improvement**. **This structured course goes into sufficient detail, with the required amount of time, to ensure that the attendees leave the course with a thorough understanding of how to be an effective Responsible Person.**

Who will the course benefit?

This course is aimed at people who want to become a **Responsible Person** as well as individuals involved in the **procurement and sale of bulk medicines**, including **Wholesale Dealers Authorisation holders**. The course is also of value as part of Continuous Professional Development of existing RPs. In addition, the course will be of value to **Qualified Persons** (QP) who need a detailed appreciation of GDP and the role of an RP. The course is also of value to 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.

Course overview:

This is a lively and highly interactive course with practical workshops and exercises throughout the programme. **The course does not just cover the theory – we also focus on practical solutions for how the working RP can deal with the many challenges that they face**. During the course delegates will create a **personal training plan and gap analysis for themselves** to ensure that, on completion of the course, they go on to gain the required **knowledge and experience** to satisfy the requirements of an RP. In addition delegates will have the opportunity to **network with the course tutors and other delegates** during events on the evenings of days 1 and 2. **This course is designed to give new RPs the confidence to perform the challenging role of a Responsible Person in an effective and efficient manner**.

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Course contents:

DAY 1: The roles and responsibilities of the Responsible Person (RP)

What is the RP?

- The legal responsibilities of the RP
- The availability of the RP and delegation rules and guidelines
- Interactions with Senior Management and the WDA holder

How do you become an RP?

- Skills and experience necessary to become an RP in the UK
- The Cogent Gold Standard
- Creating a Job Description and Objectives for an RP
- Creating individual training plans for RP personnel development

Law and Administration

- The European Medicines Agency (EMA) and EUDRAGMDP
- European Union (EU) Directives
- The MHRA and UK Regulations and Guidelines
- Wholesale Dealers Authorisations (WDA)
- The Good Distribution Practice (GDP) guidelines
- The legal status of medicines and their sale
- The Falsified Medicines Directive (FMD)
- Import and export of medicines
- Home Office licences and Control Drugs (CDs)

Evening drinks reception

- Networking event with tutors and fellow delegates (optional)

DAY 2: Transportation, storage and distribution of medicinal products

Transportation

- Transport options (road, rail, sea and air)
- Selection of suppliers
- Supply chain mapping/ route profile
- Specific requirements for road, sea and air
- Risk management during transportation
- Operations and activities at ports and airports
- Customs, export documentation and tariffs
- Control and monitoring of transport conditions

Storage

- Facility design and operation
- Different storage conditions for products
- Temperature and environmental control
- Dealing with temperature excursions
- Thermal mapping of facilities
- Equipment selection
- Validation, Qualification and Calibration of premises and equipment

(continued)

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DAY 2: Transportation, storage and distribution of medicinal products

Storage *(continued)*

- Control of goods-in and goods-out
- Goods-in and receipt of materials
- Inspection of incoming materials
- Pest control and cleaning
- Use of computer based stock control systems

Distribution

- Picking and packing of materials
- Issue and despatch of materials
- Control of returns, rejected and quarantined materials
- Supply chain integrity
- The Falsified Medicines Directive (FMD)
- Use of brokers and freight-forwarders

Evening 1-to-1 tutor meetings

- Speak to tutors in private regarding any specific concerns or queries (optional)

DAY 3: Ensuring compliance and continual improvement

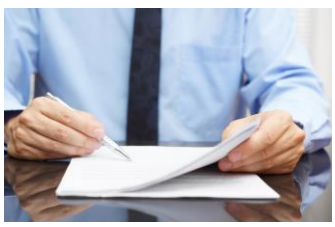
Quality Management Systems (QMS) design

- Monitoring and managing a QMS
- Documentation and records
- Dealing with Complaints and Recalls
- Correction, Corrective Action and Preventive Actions (CAPAs)

- Problem solving and root-cause analysis
- Change control
- Management Review
- Quality objectives and key performance indicators
- The self-inspection/ internal audit mechanism
- The importance of having clearly defined roles and responsibilities
- The importance of training and evaluation
- Improvement of a QMS

Supply Chain Management

- Supplier selection
- The definition of a “supplier”
- Qualification of suppliers (bona fides)
- Customer selection



- The definition of a “customer”
- Supply chain mapping and risk evaluation
- Business continuity plans

Outsourcing of activities

- Subcontractor selection and monitoring
- Auditing of suppliers

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Tutors:

Christine Morris

Christine has worked in the pharmaceutical industry for over 20 years and has extensive manufacturing and distribution experience. She currently advices organisations working to the requirements of both GMP and GDP. She is both a Responsible Person (RP) as well as a Qualified Person (QP).

Pelleren Hodges

Pelleren has over 30 years' experience of UK and international logistics and supply chain management within many industries, in particular pharmaceutical (both human and veterinary). He brings common sense and pragmatic solutions to all aspects of the distribution of medicines.

Dominic Parry

Dominic has worked in the pharmaceutical industry since 1992, and is a leading pharmaceutical quality management specialist. He is generally recognised as one of the leading GMP trainers in the UK and brings an enormous amount of interest, enthusiasm and fun into the training he presents.

Course dates, venues and times:

Please **visit our website** for full details of the course venues. If required you should book accommodation yourself directly with the hotel. It is recommended that delegates stay at or close to the course venue. Please note that the cost of accommodation is not included in the course cost.

Tuesday 26th – Thursday 28th March 2019
Reading, Berkshire UK
Tuesday 11th – Thursday 13th June 2019
Reading, Berkshire UK
Tuesday 15th – Thursday 17th October 2019
Reading, Berkshire UK

Please book via our website www.inspiredpharma.com

The timings are as follows:

Day 1:	**09.00 – 16.45**	Optional drinks reception with the tutors (17.30 – 19.00)
Day 2:	**09.00 – 16.45**	Optional 1-to-1 meetings with the tutors (17.30 – 19.00)
Day 3:	**09.00 – 16.00**	

The evening events are optional and are at no extra charge. They allow you to discuss more personnel queries in an informal setting with the tutors.

Costs:

The cost of attending is **£1950** per delegate for the 3-day course. **For group booking discounts of up to 50% for more than one delegate please visit our website for further information**. Please visit our website for further details of what is included in the course costs.

The course will be charged in GB pounds. VAT (tax) will not be charged for courses held outside the UK. VAT will be charged for the courses held in the UK, however delegates from outside the UK but within the European Union (EU) will not be charged VAT if they supply their own company's national VAT number when booking. VAT will not be charged for any delegates coming from outside the EU.

Payment and cancellations:

Full payment must be made before the course start date in order to secure a place. Payments will only be refunded in full if cancelled in writing 4 weeks before the start of the course. Delegate substitution is acceptable but please inform us.

Contact us:

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