



## Course Mapping and Certification

### *Medicinal Products - Responsible Persons*

**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.**

The Responsible Person Gold Standard sets out an industry agreed framework that identifies the skills required by a Responsible Person in four skills areas. This spread of skills ensures that the role includes not only the traditional qualifications and technical requirements but also the behavioural skills required to do the job to a high standard. These include business improvement, leadership and communication. The training standard shows what good training entails to meet the Gold Standard competencies.

Cogent Skills can now offer official recognition that your training meets these standards, as well as provide certificates which will feature the MHRA logo to individuals who have undertaken the assured Gold Standard training.

#### What is it?

The Cogent Skills Gold Standard is a Competency Framework for individuals in the science based industries. The Cogent Gold Standards set an aspirational industry standard for expected levels of on-the-job performance. Training standards that are derived from the Gold Standards set out the learning objectives needed to achieve those levels.

It supports individual Continuing Professional Development (CPD), setting out the skills required for world class performance in key job roles.

When companies invest in upskilling, one of the key factors to consider is the ability to demonstrate that delegates receive consistent quality training, and that learning outcomes are meaningful and measurable. This is particularly important in regulated industries such as the science industries.

One of the ways that companies can gain reassurance that delegates are being trained to a national level is to procure training that has been mapped to the learning objectives detailed in the training standards.

Cogent Skills is now able to map your Responsible Person course against the Medicinal Products training standard which will provide you with the ability to give your delegates certificates.

#### How does it work?

As the custodian of Gold Standards and National Training Standards for the Responsible Person, we are expertly positioned to map your training. We can provide:

**Analysis:** We will provide you with the structure to review your current training and demonstrate how it meets the learning objectives and competencies identified in the standard.

**Mapping:** We will verify that your course maps to the standard.

**Recognition:** Once we confirm your course meets the standard, you will receive a Cogent Skills certificate stating that your training content has met the standard.

**Certificates:** Once you have demonstrated that your delegates have met the learning objectives, we will organise certificates for your delegates showing that they have had training that meets the training standard. This certificate will be validated with the Cogent Skills and MHRA logo.

*The MHRA\* also recognise the standards in the Orange Guide (Rules and Guidance for Pharmaceutical Manufacturers and Distributors).*



#### How do I get involved?

If you would like to find out further information please contact us on 01325 740 900 email [industry@cogentskills.com](mailto:industry@cogentskills.com)

[www.cogentskills.com](http://www.cogentskills.com)

## The Benefits?

There are lots of benefits to mapping your training to standards:

- Assurance and recognition that your training is being delivered to an industry approved standard
- Receive Gold Standard certification for your employees / delegates
- A route to ensure investment in training meets the specified needs of the industry
- Recognition that your training is being mapped to Gold Standards / National Training Standards that are regarded as exemplar by regulatory authorities
- You can be assisted in identifying what is required for a course to meet the standard criteria

## How much does it cost?

- Mapping Service**  
£500 Per day
- Certification Fee**  
£250 Annual fee  
£20 per delegate

### The Medicines & Healthcare products Regulatory Agency UK

The MHRA is the UK Government agency that regulates medicines and medical devices to ensure their quality, safety and efficiency can place the UK at the forefront of a global drive to improve public health.



"Responsible Persons play a vital part in ensuring the quality and the integrity of medicinal products are maintained throughout the distribution chain. It's essential that they have the right knowledge, demonstrate competence and deploy the right skills so that patients and healthcare professionals have the confidence and trust to use medicines.

We completely support the decision by industry to adopt the Gold Standard framework to standardise the requirements for the Responsible Person as it will generate a template for excellence in this role for the future."

Mark Birse, Group Manager GMDP Inspections at MHRA

*"It is a fantastic step for the pharmaceutical industry in developing a clear standard for the Responsible Person role to meet their requirements. The Gold Standard framework provides a solid foundation on which the industry can build a workforce, which is not only a technically skilled but also competent in the wider demands of the role that are not taught as part of a qualification or course"*

John Holton, Operations Director at Cogent Skills

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for science industries