CPD planned learning form – advisory / regulatory / government

1. What are you planning to learn?

I am planning to reacquaint myself with the falsified medicines legislation as it is important to me to have a general understanding of the contents of this legislation as a regulatory consultant.

2. How are you planning to learn it?

I am planning to learn it by reading the following documents as well as finding further information on the UK MHRA website and other websites:

- Falsified medicines Directive 2001/62/EU published on 1 July 2001 and effective as of 2 January 2013.
- The delegated act (Commission delegated regulation EU 2016/161) detailing the characteristics of the safety features on medicines packs, how medicine authenticity should be verified, and by whom, was adopted on 2nd October 2015 and published on 9 February 2016.

3. Give an example of how this learning has benefited the people using your services.

Undertaking this exercise was very helpful as I to provide clarification on a specific point concerning the delegated regulation. A client required clarification of a point in the directive for pack identifiers. I was able to explain that information other than the unique identifier in the 2D barcode is voluntary, not mandatory which helped the client in their preparations to meet the requirements of the directive.

There is a description of what you want to learn

There is a description the relevance of the learning to your practice

There is a description how the learning will affect the people using your services

There is a description the options or activities you have selected to carry out

There is a description how you have applied the learning

There is a description how the learning – once you have applied it – has benefited the people using your services, illustrated with an example