

Update

RSSL PHARMA



Coping with counterfeits

At a recent conference, the MHRA stated that keeping counterfeits out of the UK was top of its agenda. One speaker highlighted the specific concern of internet sales, claiming that the vast majority of a random sample contained no more than 80% of any active ingredient.

Clearly everyone involved from government to manufacturers, from legitimate pharmacists through to law enforcement, must play their part in combating counterfeits. For our part, when counterfeit products are suspected, we can offer immediate analytical support to customers through our Emergency Response Service (ERS). We are able to investigate suspect product and packaging, and sometimes suggest potential sources for rogue products.

Of course, prevention is always better than cure, and our scientists are always available to advise on technical solutions for dealing with counterfeits. If your security committee would appreciate a briefing from one of the ERS experts, this can be arranged.

Training for the wider workforce is also available. Our courses in Good Manufacturing Practice and Good Distribution Practice both have a strong focus on how best practice can help to eliminate procedures that leave a company vulnerable to counterfeiting. Similarly, auditor training equips delegates to spot the gaps, for example, in traceability and documentation, which might be exploited by the counterfeiters.

Dealing with a shortage

Method development and validation has always been a key service offered by us. When drugs and formulations are developed, new methods are also required to check their purity, impurity, safety and stability. However, the impetus for new method development does not always come from innovative products. Recently, the limited availability of analytical reagents has also been a driver.

There has been a worldwide shortage of acetonitrile, a reagent frequently used in chromatography systems as a mobile phase component. This has meant we have had to be proactive in finding new sources, and also in finding new ways to carry out analyses that normally would have used this chemical. One solution has been to use less in certain extractions, and to recover acetonitrile wherever



possible. In other cases, we have developed new methods, replacing acetonitrile with an appropriate alternative, or even developing an entirely new method that is equally sensitive and accurate but relies on some other technique.



Antibiotic identification

We are using a new accurate mass liquid chromatography - mass spectrometer (Q-TOF LC-MS) to provide an antibiotic identification service.

The GMP verified instrument can differentiate between the mass of ions to five decimal places, and will provide a much greater degree of certainty when analysing samples for the presence or absence of antibiotics in APIs, waste water and cleaning swabs.

In addition to screening for antibiotics the LC-MS can also be used to investigate and identify other contaminants.



Email: enquiries@rssl.com Freephone: 0800 243 482

Not just for QPs

The knowledge required by a Qualified Person is detailed and broad ranging. But much of what the QP has to know is equally valuable to many other pharmaceutical professionals. It is no surprise therefore that our QP courses regularly train many delegates who are not intending to gain QP status.

The modular nature of this course means that it is easy for delegates to pick and choose the topics where extra knowledge is required. So whilst one person might elect to be trained in 'Maths and Statistics' someone else might choose to undergo extra training in 'Medical Chemistry'.

It is not just employees from the manufacturing environment that are benefiting from the practical, interactive and intensive training on offer from us. Several of the QP modules are just as valuable for people working in wholesaling or distribution, or in a variety of other roles within the pharmaceutical sector.



Competition

Guess the foreign body.



- A. Plastic ampoule chewed by ants
- B. Cross section of a soldered joint
- C. Dried soapsuds on glassware
- D. Ice frosting on a plastic sample on a cryo stage

Email your answer to pharmacompetition@rssl.com by 30 June 2009.

All correct entries will be placed in a prize draw for a bottle of champagne. The winner will be notified and the correct answer will be sent to all entrants by email.



RSSL's Services

- Biopharma Testing
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- Training

On your metal

Attempts by the US, EU and Japanese Pharmacopoeia to reach agreement over testing for heavy metals appears to have reached something of an impasse.

From a practical standpoint, it is no surprise that it has been difficult to agree a standard method that is suitable for every situation. So for the time being, we continue to offer a range of methods for heavy metals analysis that include atomic absorption spectroscopy and ICP-MS (inductively coupled mass spectrometry). Our laboratories can work to existing pharmacopoeia methods, or devise and validate new methods if required.



Key dates for your diary – forthcoming training courses

Good Distribution Practice	3 June
Internal Auditing	16 – 17 June
QP Biotechnology Issues	20 July
QP Packaging	15 – 16 Sept
Pharmaceutical Lead Auditor	14 – 18 Sept

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