

Update

RSSL PHARMA

Why RSSL has the chemical X-factor

One of the great joys of working in RSSL is finding out about those times (and there are lots of them) when we really make a difference to you. It's good to know that you trust us for the quality of our science, thoroughness of method development, and accuracy of results, but as scientists that is the least we would hope for. What really counts is that you notice we go the extra mile. Every scientist in the RSSL family knows what role they play in maximising value to you and delivering excellence. We've gone to enormous lengths to work out the 'how' and 'why' of product contamination incidents. We understand that 'chemical x' represents the key active that must be there in your product, or the serious contaminant that must not. So when we have to give you a result you don't want to hear, we'll work closely with you to find out what happened and provide you with a comprehensive solution. This expertise often spares the massive expense of an unnecessary recall or an acrimonious court case. That's why it is very gratifying to hear your feedback "You can trust RSSL", and that "If we had used RSSL in the first place, we'd not have had to do a product recall".



Jacinta George
Commercial Director

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PartnERS, HelpERS and Problem SolvERS

It is impossible to estimate how much money our Emergency Response Service (ERS) has saved our clients over the years. In the past few months alone we know of several recalls that have been avoided because of the speed and accuracy of analysis provided by the ERS.

Our ERS provides rapid answers to questions of immediate concern. This may mean identifying the contaminants in ingredients or products, or addressing other concerns about product quality. We have also helped clients in cases where contamination has not actually occurred, but has been feared or threatened.

Whatever the incident, the ERS can be relied on to provide the answers at the earliest opportunity, even if that means working over the weekend or starting at two o'clock in the morning. We can also be relied on to back up results with advice and further investigation to get to the root cause of a problem. It is no wonder then that more companies from the pharmaceutical sector are signing up with the ERS so that our service can be on call whenever it is needed.



Who is responsible?

Pharmaceutical wholesalers have to employ the services of a Responsible Person, whose primary role is to safeguard the end users of pharmaceutical products. It is their role to ensure that supplies have been stored and handled in an acceptable and appropriate fashion.

Perhaps surprisingly, the Responsible Person currently needs no special qualifications. Experience counts for a lot, of course, but everyone agrees that experience allied with expert training is a better option than experience alone.

That is why we have launched a new course for Responsible Persons in the UK, which follows the pattern of a course that has already run successfully in Ireland. Following a thorough consultation process the MHRA recently signalled its intention to demand such training in the future, so our intervention is both timely and significant. Courses can run in-house but the first open course is scheduled for November 2009.

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



Doing our best to be in-solvent

We have built our business on scientific excellence and brilliant customer service, but we also know we have to exercise sound and careful management of our resources in order to be successful.

That includes making sure we do not waste any of the chemicals or equipment we use. Wherever possible methods are developed and optimised to use the minimum of resources. We also use new technologies that are energy efficient and sparing in their use of solvents which is good for the environment and limits waste production.

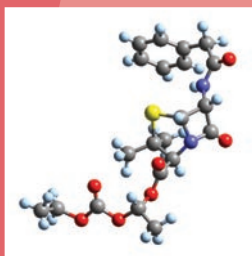


And by chance, this policy meant that the recent shortage of acetonitrile did not prevent us from carrying out our normal duties. We were able to continue offering analyses using acetonitrile because we had ample reserves.

More significantly, we were able to bring our method development expertise in to play. In some cases, we were able to develop methods using different solvents, removing acetonitrile entirely. In other cases, we were able to adapt existing methods so that the amount of acetonitrile we use was greatly reduced. We also make sure that we use solvent retrieval procedures at the end of every analysis so that we can limit our waste and perhaps re-use a solvent if appropriate.

Competition

Identify the chemical structure below:



- A. Ibuprofen
- B. Penicillin
- C. Insulin

Email your answer to pharmacompetition@rssl.com by 30 November 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
Clinical Services
Consultancy
Emergency Response Service
Investigative Analysis
Microbiology
Natural Products
Pharmacopoeial Testing
Physical Properties
Stability Management
Training

Supply chain integrity

There are always lessons that can be learned from other industries, and it seems the FDA has taken note of problems in the pet food and human food sectors in recently issuing guidance of the potential risk of melamine contamination in pharmaceutical components.

Melamine is a nitrogen rich chemical that was added to dairy ingredients in China to boost the apparent protein content of products. Now the FDA is proposing that a host of ingredients used in certain pharmaceuticals, including but not limited to lactose, copovidone and povidone, and albumin, should also be tested for melamine contamination. Some analytical methods have been suggested, mainly using LC-MS and GC-MS but none of these methods have been validated for these products.

Of course, melamine is not the only contaminant that has caused problems across different sectors, and we have experience in developing methods to look for trace levels of the same contaminant in many different matrices. Indeed, our investigative work in food products often assists our investigative work on pharmaceuticals and vice versa.

Key dates for your diary – forthcoming training courses

QP Analysis & Testing	26 – 27 Oct 2009
QMS Auditor/ Lead Auditor training course, designed for Auditors in the Pharmaceutical Industry	9 – 13 Nov 2009
QP Quality Management Systems	17 – 19 Nov 2009
QP Investigational Medicinal Products	8 Dec 2009
Responsible Person	9 – 10 Dec 2009

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