

Update

RSSL PHARMA

Welcome to our first newsletter of 2010

Despite the economic climate I'm delighted to say that 2009 continued to be a year of investment for RSSL. We added several new services to our portfolio including melamine and HF analysis.

We're also the first UK provider of a 'Responsible Person' training course in response to the rising issues associated with counterfeit drugs.

RSSL has a vibrant development plan in place for 2010 with new skills, knowledge and expertise continuing to enhance our capabilities to stay at the forefront of science. Already, we have a new LC-MS, NMR and further enhancements to our Results Online system in place. If you have a specific development need please do contact us.

We have always prided ourselves on the relationships we have with you, our customers, and we are looking to increasing our partnerships further in 2010. Our problem solving abilities have assisted many of you in resolving business critical issues, and to enhance this we have appointed Philip Payne as our new Investigative Providing hands-on support with GMP/GDP, quality, manufacturing and supply chain issues.

I wish you continued success in the coming year and look forward to working with you and meeting you at our roadshows.

With kindest regards



Jacinta George
Commercial Director

Problem solvERS

During the past year our Emergency Response Service (ERS) investigated a staggering 768 incidents involving food and pharmaceuticals. That meant an average of more than two priority investigations per day, on top of our routine work.

"This volume of work represents an increase in customers registering for the ERS, particularly from companies manufacturing drugs or supplying APIs and excipients," says Karen Masters, who heads the ERS. "Many customers appreciate the priority service that membership provides, and whenever there's an urgent need for test results, they know they can rely on the ERS for the quickest answers."

As always, the range of problems investigated by the ERS was incredibly varied, but our foreign body identification service was especially busy in 2009. There was also plenty of work for our chemistry labs, investigating rogue peaks, and identifying residual solvents, degradation products, heavy metals and other forms of chemical contaminant.

For many customers, it is not enough just to know that their product or ingredient is somehow compromised. They also need help in understanding how the problem occurred and what needs to be done to put things right. That is why we have created a new role for Philip Payne, who is already known to many of you. Philip has been appointed as Investigative Partner, with a remit to assist you in implementing the necessary changes highlighted by both routine and ERS investigations. It is a role that comes naturally to Philip, having held quality, production management and supplier audit roles with a well-known API manufacturer.



Matching up to melamine

After thousands of food products were withdrawn from sale because of contamination with melamine, the US Food and Drug Administration warned the pharmaceutical industry to be on the look out for similar problems with their own supplies. In fact, the FDA issued a list of more than 20 'at-risk' components in a guidance note published in August 2009.

Many of these compounds were derived from milk – no surprise given that the melamine scandal arose because it had been added to milk supplies in China to boost their apparent protein content.

In response to this issue, our laboratories set about developing a reliable test for melamine, which can be used, subject to validation, on a wide range of pharmaceutical matrices. The method developed uses highly sensitive liquid chromatography-mass spectrometry (LC-MS) to detect melamine at levels of as low as 2.5 ppm.

The method will fit into a regime of testing, certification and supplier audit to provide assurances that melamine is not entering the pharmaceutical supply chain.

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science with service

Rave reviews

There were rave reviews for our first Responsible Persons (RPs) course, held in November 2009. Delegates consistently gave us top marks of 'outstanding' for both content and delivery.

It is not at all unusual for our training events to get high praise, but since this was the first course of its kind to be held in the UK, it was especially pleasing to receive such positive feedback.



The RP role is seen as crucial in preventing counterfeit products from entering the legitimate supply chain, and under Article 79(b) of Directive 2001/83/EC licence holders for wholesale distribution of pharmaceuticals must have a RP available to safeguard users against poor distribution practices. Whilst formal training for RPs is not yet a legal requirement, it is something that the MHRA is currently consulting on, and will be coming into force in the not-too-distant future; the MHRA have shown their support of such training by providing key speakers on our recent courses.

Our course ensures that all RPs will have the necessary knowledge and theory to implement and oversee EU Guidelines on Good Distribution of Medicinal Products for Human Use 94/C 63/03, and the requirements included in the MHRA 2007 Orange Guide.

Lyndsey Wright, Training Manager, notes, "We are confident that our course is giving RPs the information they need to exercise their responsibilities back in the workplace. Take up of places for the next courses in February and June has already been strong so we are looking to add further dates in 2010."

Under the microscope

Our expertise and experience in investigating and identifying foreign bodies is unrivalled, and our status was reinforced last year by several hundred ERS investigations carried out by our microscopy laboratory. This was in addition, of course, to the routine work of the lab, such as carrying out structural investigations of powders, the analysis of surfaces, and measurements of sub-visible particle.

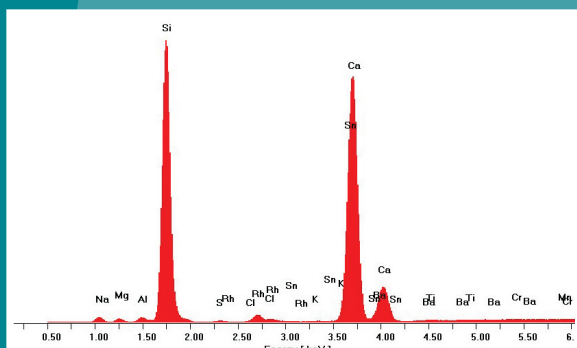
There is a lot of sophisticated equipment that goes into a foreign body investigation. We have a powerful scanning electron microscope linked to equipment that can identify the elemental composition of materials. We have technology that can analyse the surface of packaging, especially useful in investigating suspect counterfeits, and various instruments that help us to differentiate between different fragments of plastic, glass and metal. We also identify animal body parts, secretions, precipitates, fibres and a whole range of weird and not-so-wonderful foreign bodies that crop up from time to time.

It is a feature of many foreign body investigations that first appearances can be deceptive. What looks like one thing to the human eye is often shown to be something else by more thorough investigation. So the scientists in our microscopy lab take pride in giving our customers the most thorough and detailed reports to explain exactly what they've found in their products.



Competition

Which of the following has this elemental composition?



A. Silicone Grease B. Rubber C. Glass D. Starch

Email your answer to pharmacompetition@rssl.com by 30 March 2010.

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.

Key dates for your diary – forthcoming training courses

External Auditing	16 – 17 March 2010
GMP (3 day)	19 – 21 April 2010
Introduction to Microbiology	22 April 2010
Biotech for the Non Biotechnologist	25 – 26 May 2010
QMS Auditor/Lead Auditor (IRCA Ref A17129)	7 – 11 June 2010

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