

# TRIBUNE

Issue 03

The newsletter from Triveritas

Summer 2007

## EUROPEAN EXPERT JOINS TRIVERITAS

**Dr Rhona Banks takes up a new position as Director of Regulatory Affairs.**

**Rhona will be taking an active part in new business development as well as regulatory affairs and she will offer Triveritas clients the benefit of her specialist advice in both biologicals and pharmaceuticals.**



Dr. Rhona Banks

CBiol MIBiol PhD

"We're delighted that Rhona has joined us," says Managing Director **Julian Braidwood**, "Rhona's experience and expertise bring an added dimension to the services that we are able to offer clients."

Having worked both as an assessor at the UK Veterinary Medicines Directorate and in the Animal Health Industry, Rhona understands both sides of the submission and approvals process and can offer clients the benefits of this inside knowledge. Previously employed by Beecham Pharmaceuticals Research Division, SmithKline Beecham Animal Health, Pfizer Animal Health, Janssen-Cilag and, most recently, Fort Dodge Animal Health, Rhona has brought with her an extensive knowledge and industry perspective of the regulatory regimes in both the EU and North America.

As Director of Regulatory Affairs, Rhona is working with an established Triveritas team of Regulatory Affairs consultants, who already offer a full range of services. "We've recently completed a pan-EU submission for a client by the new Decentralised Procedure (DCP)," explains **Dr Mel Ford**; "with Rhona's experience of the DCP, CP, MRP and National procedures, the Team continues to grow from strength to strength."

Mel continues, "With particular expertise in Part II Biologicals, Rhona is a valuable addition to our panel of pharmaceutical and biological experts who cover all aspects of quality, safety and efficacy."

You can contact Rhona directly +44 845 123 28 87 or email [rhona.banks@triveritas.com](mailto:rhona.banks@triveritas.com)



t: +44 (0) 845 123 28 88

f: +44 (0) 845 123 28 89

e: [info@triveritas.com](mailto:info@triveritas.com)



# PHARMACOVIGILANCE - ARE YOU PREPARED?

**Directives 2004/28/EC (amending 2001/82/EC) and EC 726/2004 have established enhanced pharmacovigilance requirements that have transformed the old Marketing Authorisation (MA) renewal procedure, shifting the emphasis towards product safety. Dr Manju Bushi from our regulatory team discusses the implications of these changes and some of the solutions available from Triveritas.**

"Periodic Safety Update Reports (PSUR) need to be submitted with greater frequency during a product's life cycle and the pharmacovigilance requirements for MA application have also changed substantially. Companies now need to have detailed documented systems in place to deal with all aspects of pharmacovigilance: from handling and classifying SARs to database management, PSUR scheduling and reporting, system audits, training and appointment of responsible personnel and archiving. The MA holder needs to be prepared to demonstrate the robustness of their systems at impending Regulatory Authority inspections" explains Manju.

Setting up such a system is often complex and time consuming but Triveritas offers both expertise and proven experience in developing and producing documented systems that are tailor made to the client's requirements and in compliance with the new pharmacovigilance legislation.

## EXPANDING EASTWARDS

**Triveritas clients can make the most of the expanding EU community.**

**When Bulgaria and Romania joined the EU in 2007 new markets opened up for animal health products. Triveritas is well-placed to help our clients make the most of EU expansion as our German Director, Roland Ludwig, explained to delegates at a recent animal health industry conference in Barcelona.**

"Eastern Europe offers a wealth of opportunities for our clients and the animal health industry." says Roland, "For example, Poland boasts four veterinary faculties, several vet institutes, about 6000 vet practices and the fifth largest pig population in the EU! With the added benefit of fees for vets, labs and owners' compensations being lower than many other EU countries, we have the potential to conduct competitively-priced clinical trials in Eastern Europe."

Triveritas already has experience of working in Eastern Europe, including the Czech Republic and Hungary; and now our German office has strengthened its links with Poland by securing the services of a native Polish speaker. This relationship has already made working in Eastern Europe and dealing with the local authorities much more effective.

# EXPERTISE IN CLINICAL STUDIES

Triveritas can deliver whatever the scale or species.

With six vets on board we have the capability to perform large clinical studies across the EU. Our clinical group are conversant with VICH GCP, and are able to support new product development as well as existing products requiring post marketing studies.

Triveritas delivers clinical studies efficiently and cost-effectively within a quality assured environment to consistently high regulatory standards.

"In the past three years alone, we have conducted studies in cows, chickens, horses, pigs, dogs, cats, even fish, on a diverse range of pharmaceutical and biological products" explains veterinarian **Lynne Braidwood**. "We've recently completed a large multi-centred field study in a food producing species in Northern Europe. The trial involved over 15,000 animals located at over one hundred study sites across three European countries. Few, if any, of our competitors would have the number of veterinary experts required to handle a clinical study on this scale and complexity."



## FRENCH BASE OFFERS DIVERSITY

With offices across the EU and local know-how, Triveritas can implement your clinical trials and manage your development projects at the heart of the key European markets.

Dr. Vét. **Pascale Sierra** has many years of experience in project management and clinical trials in the animal health industry, enabling Triveritas France to grow in this important market.

"We're already managing complex contracts in France," explains Pascale, "and are continuing to expand our client base even further. Due to our regional differences in climate there's a great diversity in the range of diseases observed so it's a good place to conduct clinical studies."

In addition to considerable experience of running field trials in France for both companion animals and livestock, the French office is also monitoring a substantial clinical study in food-producing species in Spain as well as project planning for a novel pan-European development.

### COMING UP SOON

#### June 2007

London

Julian

Veterinary Drug Development in the EU and USA

#### July 2007

Amsterdam

Rhona





Target Animal Safety Guideline Update

For further details of attendance, please contact the Business Development Team on: **+44 (0) 845 123 28 88**

www.triveritas.com

# TWO CENTURIES OF EXPERIENCE

You may already be familiar with a few aspects of the Triveritas service, but do you realise how much more we have to offer?

-  200 years of combined experience in the animal health industry, gained from working in more than 10 animal health companies including Merial, Pfizer, Fort Dodge Animal Health and Virbac; regulatory authorities and contract research organisations.
-  A team of 19 (including 6 vets and 3 PhD's) offer a broad range of experience and depth of animal health knowledge, as well as a network of offices across Europe.
-  Experts in Part II, III and IV for pharmaceuticals and biologicals.
-  Trained clinical investigators, monitors, project managers, strategic project developers; regulatory experts; statisticians and QA auditors.

## RANGE OF SERVICES

### START-TO-FINISH SERVICE



With our breadth of knowledge we can help you take projects from proof of concept to international approval swiftly and efficiently.

### VETERINARY CLINICAL TRIALS



We have access to experienced EU investigators and provide fully compliant support and monitoring at all stages.

### MANAGED TRIALS



A specialist team of dedicated Triveritas veterinary investigators are committed to delivering clinical trials to VICH GCP.

### REGULATORY AFFAIRS



From strategic advice to MA maintenance, with our up-to-date knowledge of legislation we can help you through the regulatory maze.

### CONTRACT PRODUCT DEVELOPMENT



Unrivalled experience in veterinary pharmaceutical and biological product development. We offer a full range of project management services.

### CONTRACT QUALITY ASSURANCE



With excellence in QA, we provide contract QA to current quality standards to the principles of GCP, GLP and GMP.

### STATISTICAL ANALYSIS



Expertise in study design and data analysis from R&D trials that evaluate safety, efficacy and quality.

## Directors

### Julian Braidwood

BVSc (Hons) MRCVS

### Sue Lester

BSc (Hons) FRQA

### Roland-G Ludwig

Veterinarian

### Pascale Sierra

Dr. Vét.

### Rhona Banks

CBiol MIBiol PhD

## German Office

Triveritas Germany Limited  
Kantstrasse 52  
10627 Berlin  
Germany

roland.ludwig@triveritas.com

## French Office

Triveritas France Limited  
BP 30004  
01151 LAGNIEU Cedex  
France

pascale.sierra@triveritas.com

## Head Office

Triveritas Limited  
Bank Barn  
How Mill  
Brampton  
Cumbria  
CA8 9JY  
United Kingdom

