

# TRIBUNE

Issue 06

The newsletter from Triveritas

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## EXPANDING TO MEET YOUR NEEDS



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Triveritas - UK - France - Germany


**Facing a complex clinical study? Triveritas can offer continuity, contingency and capacity as new recruits join the clinical team.**


**Clinical studies in the animal health sector are becoming more and more complex – changing legislation and different animal husbandry models all add to the challenge. Triveritas has expanded its team in recent months to meet the increasing demands.**

**Nick Gibson** leads our Clinical Team: "We have recruited four new members of staff in the past six months and they each bring their own expertise and experience to our projects," he said. "Sometimes a project just needs extra resources and the increased size and capability of our team means that we are in a good position to take on a wider variety of both clinical and marketing studies."

### Strengthening across Europe

"Our expansion and recruitment of specialists in the area of clinical studies covers all three Triveritas offices," explained Managing Director, **Julian Braidwood**.

 In Germany, veterinarian **Sonja Haase** has joined with several years of clinical study experience and was previously head of a field trial unit with IDT Biologika GmbH.

 In France, **Marie Laure Mainsant** is a Masters graduate with animal health and statistics experience. She has joined us from Ceva France where she has been working in clinical development.

 Finally, **Debbie Johnston** and **Lindsey Edwards** bring 16 years of experience between them to the UK team. Both join us with monitoring and project management experience from Charles River Laboratories.

"As well as adding to the range of services that we can offer, the growth of the team at Triveritas also means that we can provide valuable security and continuity to our clients," concluded Director, **Sue Lester**, "and we have the capacity to cope with complexity in terms of study design too."



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# EMBRACING REGULATORY CHANGES

**In times of extensive legislation changes, Triveritas can help you to prepare.**

**It's an exciting time in the area of regulatory affairs, with many key European regulatory changes in the pipeline that need to be implemented. Triveritas has been preparing for these changes and has already been working with clients and providing training in these areas.**



## **New Dossier Structure – Annex 1 (2009/9/EC)**

The long-awaited Directive 2009/9/EC amending 2001/82 (the 'New Annex 1'), which revises the Regulatory Dossier format, came into force in September. "The new Directive needs to be implemented now for all Centralised, DCP and MRP applications," explained **Dr Mel Munro** of our Regulatory team, "even though the updated Guideline (Notice to Applicants) is not yet available. The animal health industry hasn't been given long to prepare for the new requirements but we've already been anticipating the changes and preparing dossiers in the new format."

## **Variations Improved**

The new Variations Regulation (EC/1234/2008) will apply from 1st January 2010 for European MAs; it revises the submission categories and describes new work-sharing arrangements which will allow the MAH to group Variations.

Under the new structure, applicants will be able to inform the authorities of minor variations in 'annual reports', the so-called **"Do and Tell"** Type IA variations; and a new subgroup has been defined for those that will require immediate notification (Type IA<sub>IN</sub>). Type II or **"Tell and Do"** will cover major variations as before, although these will now be pre-defined; the default category has been reassigned as Type IB or **"Tell, Wait and Do"**.

"We're looking forward to working with the new procedures," observed **Dr Rhona Banks**, Director of Regulatory Affairs. "There should be great opportunities for our clients to make the most of the reduced administrative burden and cost saving from the grouping potential."

## MUMS/LM (Minor Use Minor Species/Limited Markets)

In July, EMEA issued new guidance (EMEA/CVMP/370663/2009) on data packages for MUMS and Limited Market products with the aim of stimulating the development of products for use in MUMS/LM. **Dr Rhona Banks** explained: "We've already been through the process of requesting the CVMP to classify VMPs as intended for use in MUMS/LM and we have also successfully had an item added to the immunologicals list so we are in a good position to share that early experience with our clients. We've also been working with MUMS products in the USA, and have up to date experience with the FDA requirements."

## Other Key Changes Coming Up...

### Electronic dossier submissions:

All National Competent Authorities have a commitment to be "e-submission ready" from January 2010. From this date, MAH will have the option to submit electronic regulatory documents; both industry and the environment should see the benefits quickly.

### Pharmacovigilance Guideline Update:

Following changes to the regulatory framework for PhV in 2004, the European Commission has drawn up a new Veterinary Pharmacovigilance Guidance document (Volume 9B of Notice to Applicants-in consultation).

"These regulatory changes will have a large impact on our industry," said **Dr Rhona Banks**, our head of Regulatory Affairs. "We've been anticipating the changes and adapting to meet the new demands for over a year and we can now pass on this practical experience to our clients."

### Managing change through training

*Investing in training for your team can have tremendous returns.*

*Triveritas has run in-house training courses for client companies on all aspects of veterinary product development, specifically tailored to your needs to address particular issues associated with your projects.*

*Training takes place at your chosen location.*

*You can include as many staff as you like covering confidential or sensitive aspects in a secure environment.*

*More on training to come next time.*

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# EVENTS DIARY

## Recent presentations...

### 01 October – Boston USA

*Developing and Registering Veterinary Products for the USA & EU*

Speaker: - Julian Braidwood

### 06 & 07 October – London

*Regulatory Affairs for Veterinary Medicines*

Speaker: - Mel Munro

## Coming up...

### 03 & 04 December - London

*Veterinary Clinical Trials*

Speaker: Julian Braidwood

### 03 & 04 December - London

*An Introduction to Potency Testing for Veterinary Vaccines*

Speaker: Rhona Banks

### 26 & 27 January - London

*Practical Implementation of GCPv*

Speakers: Sue Lester & Julian Braidwood

**For further details on these conferences or our bespoke in-house training services please contact the Business Development Team on +44 (0) 845 123 2888.**

## 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 STUDIES



In-depth veterinary clinical study expertise, specialist in-house and EU Veterinary Investigators committed to delivering quality clinical trials.

### IN-HOUSE TRAINING



Our tailor-made courses are a cost effective way to train your staff using real examples from your own product portfolio.

### REGULATORY AFFAIRS



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

### SPECIALIST 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.

### SCIENTIFIC WRITING



Our scientific and clinical experts offer a specialist document writing service for expert technical reports or articles for scientific publication.

## Directors

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