

TRIBUNE

Issue 04

The newsletter from Triveritas

Autumn 2008

YOUR PARTNER FOR CLINICAL STUDIES



Nick Gibson

Product Development Manager

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Another new face and a renewed focus on one of our core services.

Triveritas has extensive experience of designing and implementing clinical studies across the EU and, with the appointment of our new Product Development Manager, Nick Gibson, we can now offer you even more expertise in this crucial area.

Clinical studies are a key area of expertise at Triveritas. Our experience ranges from small single site trials to the largest multi-national studies and covers both companion and food animals. Our work in this area supports biological and pharmaceutical product development in a variety of ways - confirming clinical efficacy, field safety and dosage - as well as supporting existing products with post-marketing studies.

Part of Nick's new role will be to develop this part of the business. "Our local offices in France, Germany and the UK offer the full package - initial study design, an extensive study site database, document preparation, full monitoring capabilities and comprehensive data and documentation handling, including statistical analysis and reporting," says Nick. "I'll be working with our VICH GCP trained monitors and network of experienced veterinary investigators across the EU, using their local contacts and knowledge to ensure that Triveritas continues to offer clients exactly what they need."

Experience: Over 23 years in veterinary medicine product development in industry and most recently at Charles River Laboratories.

Expertise: Nick is a parasitology expert, with broad knowledge across the vaccine and mass medication markets as well as significant practical experience of running safety, residue, dose determination and efficacy studies.

"I feel at home already as many things at Triveritas are important to me too - a quality-driven environment, working as part of an expert team and the focus on client relationships. I am enjoying getting to grips with the studies already in progress and with the priorities for future development."



your expert partner in Animal Health

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EXPANSION IN THE EU

Triveritas is seeing continued development across Europe with the recruitment of new team members and 30% growth in the scale of our operations to meet customer demand.



Roland-G Ludwig

Veterinarian

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Booming in Berlin

Triveritas Germany is also continuing to expand and Director **Roland Ludwig** is building his team. **Thomas Krüger** (Dipl. Ing.) joined to support Roland back in 2007 and **Olaf Fialkowski** (Dr. med. vet.), who has a background in toxicology, joined in August 2008.

The clinical team located at the Berlin office are currently conducting several VICH GCP companion animal and large animal studies at sites across Germany, and are planning to add another expert clinician in the New Year.

"Germany is a good place for our clients to run clinical studies," says Roland. "It typically takes just three weeks to get trial clearances for food producing animals and around two weeks for companion animal field studies. Triveritas has excellent local contacts and a large database of possible sites to make things happen efficiently and effectively."

Soon to be Strasbourg

Our French operation is due to move into new offices near Strasbourg before the end of the year. The team, led by DVM **Pascale Sierra**, have completed a wide variety of clinical studies this year in France and Spain for a range of clients.

"We recruited DVM **Pascal Cahen** to the team at the end of 2007," says Pascale, "and **Marie** joined the team soon after that. Business has continued to grow and, in order to maintain our level of quality and service, we are preparing for the arrival of two more vets later this year to support this clinical programme and further increase our capacity."

The Triveritas team based in France offer clients both clinical studies and regulatory affairs and the project management capability in the office has already proved invaluable to a number of clients.



Pascale Sierra

Dr. Vét.

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TRIVERITAS HELPING YOU TO SUCCEED



As many of you already know, Triveritas has expertise in all aspects of animal health product development so we thought it about time that a few more of our key functions had some Tribune limelight.

Training to suit you

For the past 6 years, Triveritas has been designing training courses for clients, often running these on the client's site and always tailoring the content to match client processes and priorities.

"Product development and registration processes have been the key areas for in-house training," explains Managing Director **Julian Braidwood**. "Bringing together a client's own team for bespoke training can have all sorts of practical benefits – clear objectives, direct relevance, flexibility, cost and travel and time savings – as well as the added bonus of team development and internal networking."

Regulatory Affairs - forward planning for regulatory systems

Dr Rhona Banks, Director of Regulatory Affairs for just over 18 months, has seen a rapid rise in the number of projects that the regulatory team now handles.

"Regulatory considerations can be seen to be shaping the new product priorities in our industry and that makes Triveritas, with its expert knowledge, an invaluable partner in the development process," says Rhona. "We have worked on all types of veterinary medicinal products - including novel genetically modified and conventional vaccines as well as many pharmaceuticals and MUMS products."

Pharmacovigilance - helping you to stay in compliance

Triveritas has already worked with a number of clients on their pharmacovigilance systems. Director **Sue Lester** explains how Triveritas is helping clients meet the obligations of recently evolved EU Directives that put the emphasis firmly on product safety.

"Our team are involved in most aspects of pharmacovigilance – revision of written procedures, conducting audits and training. Our veterinary team located at offices in the UK, France and Germany can handle receipt, review, evaluation and dissemination of suspected ADR's, including completing databases, compiling PSURs and even reporting to the authorities."



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COMING UP...

31 October - Edinburgh

BARQA - Keeping it together, Global AH GCP studies.

Speaker - Sue Lester

26 to 28 November - Prague

*Planning a study timeline.
Licensing for recombinant vector vaccines.
Development & registration of vet. vaccines.*
Speaker - Rhona Banks

11 & 12 December - London

Veterinary Clinical Trials.
Speaker - Julian Braidwood

13 & 14 January - London

Regulatory Affairs for Veterinary Medicines.
Speaker - Pascale Sierra

21 & 22 January - London

GCP for Veterinary Clinical Trials.
Speakers - Julian Braidwood & Sue Lester

03 & 04 February - London

Veterinary Clinical Trials.
Speaker - Julian Braidwood

06 February - London

Clinical Development of Medicines for Companion Animals.
Speaker - Julian Braidwood

**For further details 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

Julian Braidwood

BVSc (Hons) MRCVS

Sue Lester

BSc (Hons) FRQA

Roland-G Ludwig

Veterinarian

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