

TRIBUNE

Issue 05

The newsletter from Triveritas

Spring 2009



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BREADTH OF KNOWLEDGE, DEPTH OF EXPERTISE

When your dossier needs expert input or assessment, we have the experience.

"The Triveritas team has experts covering the full range of fields relevant to veterinary product development" explains Director, [Sue Lester](#), "Biochemistry, immunology, pharmacology, toxicology, microbiology, parasitology, clinical development, manufacturing, QA – whatever your product development or registration needs."

"A well planned development project needs expert regulatory input from the start. We offer a range of regulatory services from the early stages of planning right through to the final expert review," continues Regulatory Affairs Director, Dr [Rhona Banks](#). "We routinely write Expert Reports in line with current legislation (Directive 2001/82 as amended) and already have significant experience in writing benefit-risk assessments in preparation for the new draft guideline which is expected to come into force later this year."

What makes a good Expert Report?

To demonstrate to the regulators that it is appropriate to register the product, a good Expert Report should be a detailed and critical evaluation of the data – scientific, clinical and regulatory – and it needs to explain any circumstances that may require a pragmatic decision. "Our team prepare Expert Reports for all parts of the dossier for both **biologicals** and **pharmaceuticals**," says Rhona. "We are always conscious of the scientific and commercial need to help regulators to fully understand and appreciate a product."

Balancing the Risks & Benefits

The new EMEA guideline, on the evaluation of the benefit-risk balance of veterinary medicinal products (EMEA/CVMP/248499/2007) should be finalised in 2009. Rhona adds, "Applicants are already being encouraged by the regulators to include a benefit-risk assessment for most applications. The challenge is knowing what to include, how to present potential risk mitigation measures and clearly demonstrate why a product can be considered acceptable to licence. We are already writing assessments for MA applications, variations, renewals, MUMS products, PSURs and immunologicals licensed under exceptional circumstances. Our clients benefit as we understand the task, know what to include and can rapidly assimilate an in-depth knowledge of the dossier so we can present the client's case as clearly as possible."



your expert partner in Animal Health

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NEW FACES AND RENEWED CLINICAL FOCUS IN EUROPE

Facing tough decisions on complex new studies? Our two new recruits offer increased clinical scope and expertise.

The recent arrival of DVM **Anne-Marie Viallet** in our French office and Dr. med. vet. **Sonja Haase** in Berlin strengthens the Triveritas team across Europe, in particular our ability to deliver complex clinical studies.

"Triveritas already have an excellent reputation for conducting VICH GCP studies," confirms Product Development Manager, **Nick Gibson**. "Our flexible approach enables us to routinely handle complex clinical studies, particularly in companion animals where a successful clinical study for rare target diseases require multifactorial screening, a good network of specialists and a local understanding of veterinary procedures.

"We understand that complex clinical studies are a huge commitment for any Sponsor. By offering clients the option to commission a full feasibility report before committing to roll out the clinical study our clients can make informed decisions with increased confidence, reassured about our capacity and capability to deliver the study on time and on budget."

New face in France

Anne-Marie Viallet is a qualified vet with postgraduate degrees in Pharmacovigilance and Statistics. As a member of both IFAH and SIMV she has been actively involved in working groups on ecotoxicity and safety. Anne-Marie joins us after more than ten years in Regulatory Affairs at Vetoquinol.

"Anne-Marie is a first class asset for the team." says **Pascale Sierra**, Director of Triveritas France. "She will be focusing on regulatory affairs, writing dossiers and Expert Reports and offering advice on the registration of all pharmaceutical VMPs."



Anne-Marie Viallet

Project Manager

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Sonja Haase

Veterinary Consultant

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Clinical focus in Germany

Sonja Haase is an experienced veterinarian with expertise in equine, small animals, pigs and cattle. Sonja was previously head of the field trial unit with IDT Biologika GmbH and she brings significant clinical field study and monitoring expertise with a focus on biologicals.

Director of Triveritas Germany **Roland Ludwig** says, "Sonja's main role will be leading our clinical team, conducting VICH GCP field safety and efficacy studies for our increasing number of clients in continental Europe."

MAKING THE MOST OF WHAT YOU HAVE



Triveritas offers specialist strategic advice and gap analysis to enable you to expand, extend and grow your business.

“We are increasingly aware of clients’ needs to maximise their portfolio,” recognises [Julian Braidwood](#), Triveritas M.D. “This may involve expanding into new countries or launching new products. Whatever their priorities, our strategic advice and detailed gap analysis of existing dossiers is proving invaluable.”

Strategic advice – the complete package

If you want to register a new product in the EU Triveritas can provide strategic advice on how to do it, how long it should take and how much it is likely to cost. We provide advice on all aspects of VMP development; from sourcing ingredients through to the studies needed and regulatory submission. If you provide the idea, we can supply:

- full regulatory advice
- MS project timelines covering the full development
- approximate costings

“Advice on EU and US co-development is proving particularly attractive to a lot of our clients,” confirms Julian. “The big advantage is that we can advise from recent experience on where they can and can’t avoid duplication, saving them time and money.”

Finding and filling the gaps

If you have a product licensed in a non-EU country and want to expand your portfolio into the EU, we can also help. Our experts will examine your existing dossier and prepare a Gap Analysis that highlights exactly what you need for an EU submission.

“The Gap Analysis process involves a detailed evaluation of the data,” says Julian, “Followed by comparison with the EU licensing requirements. Then, to address any aspects that are not fully covered, we draft a strategic plan, including approximate costs for the additional work. This is a vital step when expanding your portfolio from one country to another. It helps you avoid unnecessary additional work whilst also ensuring that the dossier for the new market is complete.”

If you need help breaking into new markets, please contact the Business Development team on +44 (0) 845 123 2888.

www.triveritas.com

EVENTS DIARY

Recent presentations...

06 February – London

Companion animal product development

Speaker - Julian Braidwood

05 March – Prague

The new Variations procedure

Speaker - Rhona Banks

19 & 20 March – London

Veterinary immunologicals workshop

Speaker - Rhona Banks

Coming up...

05 May – London

Immunological regulatory issues

Speaker - Rhona Banks

18 June – London

Veterinary product development and registration

Speaker - Julian Braidwood

16 & 17 July – London

Veterinary Clinical Trials

Speaker - Julian Braidwood

**For further details contact
the Business Development Team on
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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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