

TRIBUNE

Issue 02

The newsletter from Triveritas

Autumn 2006



Roland Ludwig

Pascale Sierra

Julian Braidwood

CONTINUED MAINLAND EU EXPANSION

Pascale Sierra heads up Triveritas France

Following last year's successful opening of the Berlin office, Triveritas is pleased to announce the opening of its new office in France.

Strengthening Triveritas's presence in mainland EU has been a key objective because it extends our opportunities to support our clients' businesses. Moreover, AFSSA-ANMV is a leading regulatory agency in the EU so it makes sense to build a strong alliance in France where the market for veterinary products is reportedly the second largest in the world.

Triveritas France can now provide experts with local knowledge, a feel for the local trends and strong connections in France to trial sites and vets. The company is in a position to build a stronger relationship with EMEA and AFSSA-ANMV.

Finding the right person with the necessary expertise and experience was important so we are delighted that **Pascale Sierra** has joined the team as Director of Triveritas France.

Pascale has eight years industry experience working in top-ten animal health companies including Pfizer and Merial in the clinical development for new veterinary products and also in regulatory affairs. She is fluent in English and familiar with UK approaches having lived and worked in England for three years.

"With all her past experience, Pascale is a real asset for our range of services," commented Julian Braidwood. "Start-to-finish service and clinical trial management will be boosted by her strong project management skills. She has valuable experience of the centralised authorisation procedure, MRL submissions and scientific writing. In addition, her strength in data management will be invaluable in an area where Triveritas has been looking to enhance its capabilities."




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START-TO-FINISH... FROM IDEA TO MARKET

Your entire project from concept to international registrations for both biological and pharmaceutical products



Need a new product developing, but you don't have the resources or expertise to do the development and formulation in-house? New to the veterinary market and need an expert hand to get your product on to the market? Triveritas offers a specialist CRO service to the animal health industry with the expertise, networks and resources to offer you a start-to-finish service tailored to your needs.

Working with Triveritas's start-to-finish means that strategic regulatory advice goes hand in hand with effective project planning so that your latest idea or product development is in safe and expert hands.

The service draws together Triveritas's extensive industry knowledge and experienced

team of project managers, regulatory specialists and veterinarians, in combination with a close network of formulation specialists, to offer a complete package to clients.

"We're currently taking a 3 year start-to-finish development project through to decentralised submission in 25 EU member states plus other international registrations," explains Dr Mel Ford. "Our clients find that outsourcing the complete development process in this way can also be cost effective, releasing in-house resources for other projects and enabling a new concept to develop outside of existing company structures and constraints."

WHAT'S HAPPENING IN GERMANY?

Germany's industry association recently reported a 5.6% growth for the animal health market and figures of €559m; US\$696m - good news for Triveritas Germany and for our clients looking to develop and expand in Europe.

With his years of experience as a vet involved in clinical trial monitoring and marketing, our German Director, **Roland Ludwig**, has an extensive network of contacts that enables Triveritas to source locally, keeping client costs as low as possible.

Clinical trial potential

Germany is one of the largest pig producing countries and Roland has focused on expanding his network for sourcing pigs for field trial work. He has also been working with veterinarians to build stronger links with small animal breeders and these links are bearing fruit, providing **Triveritas Germany** with access to valuable resources to support client projects in this important area.

STRENGTH AND EXPERIENCE IN BIOLOGICALS

A unique biologicals consultancy service to the animal health market

Triveritas provides a niche in the market with expertise that is second-to-none. Our team of biologicals experts is headed by Dr Angela Colston who has over 15 years experience in R&D and registration in this growing area and is a notable clinical and safety biologicals expert in her own right. The team has substantial experience across a wide variety of technologies from viral and bacterial vaccines to GMOs, protein sub-unit vaccines and plasma products.



Angela Colston
BVM&S PhD MRCVS

"Having an experienced biologicals team in-house is unusual among the CROs working in animal health," Angela says. "Triveritas has technical expertise and knowledge across a whole range of specialist areas necessary for biologicals development, including molecular biology, immunology and cell biology up to PhD level. Because of this, we

can help companies to meet the increasing technical demands for biologicals, including validation of new technologies and process optimisation."

Currently providing the complete start-to-finish service to clients, the biologicals team can advise clients on Proof of Concept and high-level strategic planning, manage the whole development project from formulation, pre-clinical and clinical project management to regulatory submission.

As Angela emphasises: "Our team of biologicals' regulatory specialists is experienced in EU dossier compilation and regulatory submissions as well as negotiation with regulatory authorities across the EU. With our detailed knowledge of the biologicals' regulatory environment, Triveritas also provides strategic advice that meets legislative requirements in an ever-changing regulatory environment, giving you the service that you need to develop biologicals for the future."

EXPANDING EXPERTISE IN QA

Triveritas's QA team ensures that quality stays at the heart of the business as it grows and offers expert consultancy services in the three major disciplines.

"We have built the business around quality," says Director and BARQA Fellow, **Sue Lester**, "and it is one of the central tenets in our triangular logo, meeting customer requirements on **time** and **cost** as well as maintaining appropriate **quality** standards."



Sue Lester
BSc (Hons) FRQA

As a QA professional with 17 years experience across GxPs and other quality disciplines, Sue has successfully combined her management role with implementation of the company's QA programme. In 2004 **Helen Davies**, a veteran GLP Study Director, was recruited to the team and **Suzanne Whiting** joined earlier this year. Though still a relative youngster, Suzanne trained with Pfizer Animal Health and was previously with Ridgeway Research, leading a successful inspection by the MHRA GLP monitoring authority and auditing many GLP and VICH GCP studies.

With a background in animal health from both Sponsor companies and CROs, the Triveritas QA team's approach is both pragmatic and sympathetic – not exactly typical QA auditors! This expertise is also available to you, the clients.

www.triveritas.com

COMING UP SOON

October 2006

London Julian Overview to the Animal Health Industry Introduction to Regulatory Affairs

Berlin Julian/Roland Alliances and Partnerships in Animal Health – Start-to-Finish

January 2007

London Julian Companion Animals

Spring 2007

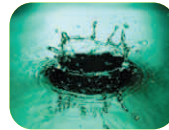
London Angela Immunological Submissions in the EU

For further details of attendance, please contact the Business Development Team on: **+44 (0) 845 123 2888**



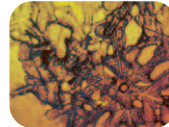
RANGE OF SERVICES

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 TRIALS



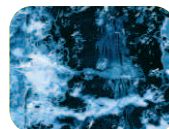
We have access to experienced EU investigators and provide fully compliant support and monitoring at all stages.

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

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Sue Lester
BSc (Hons) FRQA

Dr Angela Colston
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