A PRACTICAL APPROACH TO VETERINARY VACCINE DEVELOPMENT AND REGISTRATION IN THE EU

4 & 5 March 2014, Conf. No. V3-8314

MANAGEMENT FORUM

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If you have NOT received confirmation seven days after registering, please contact Registration Department.

Registration Information

Dates
4 March 2014
Start: 09.30 – Finish: 17.00
5 March 2014
Start: 09.00 – Finish: 16.15

Registration & Coffee
4 March 2014 09.00

Venue and Accommodation
The Rembrandt Hotel, 11 Thurloe Place, London SW7 2RS
Hotel Tel: +44(0)20 7589 8100.
Hotel Fax:+44(0)20 7225 3476.
Email: *reservations_rembrandt@sarova.co.uk*
Subject to availability, a limited number of bedrooms have been reserved at the hotel at a special rate.

All bookings should be made directly with the hotel or online at *www.sarova.com/rembrandt*, quoting promo code 'manforum'.

Directions
Opposite V&A Museum. Nearest underground station: South Kensington.
www.sarova-rembrandthotel.com/location-local-attractions

Fee
£1,275 + VAT if applicable. The fee includes course documentation as well as mid-session refreshments and lunch. Invoice and confirmation will be forwarded to you.

Conference No. V3-8314

Discounted Rates
Available on application for personnel from non-profit making organisations and registered charities.
Group discount available on request

Cancellation Policy:
Over 14 days prior to the Seminar: Cancellation fee of £75. 7/14 days prior to the Seminar: 50% of the fee. Fewer than 7 days or if no notification received: Registrant liable to pay FULL seminar fee.
NB: Cancellations must be received in writing by *registrations@management-forum.co.uk*
Management Forum reserves the right to cancel/ alter the programme, the speakers, the date or venue. If an event is cancelled Management Forum is not responsible for airfare, hotel or other costs incurred by registered delegates.

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MANAGEMENT FORUM

New Programme

A PRACTICAL APPROACH TO VETERINARY VACCINE DEVELOPMENT AND REGISTRATION IN THE EU

Benefits in Attending:

- **Establish** what data you need to generate for your application and how to present the data in your dossier
- **Clarify** how to submit your dossier for Marketing Authorisation (MA)
- **Understand** how to get through the MA review process
- **Know how** to maintain your MA's once you've got them

With:

Dr Mel Munro, Project Manager, Biologicals Regulatory Affairs, Triveritas

Juliet Greenslade, Project Manager, Biologicals Regulatory Affairs, Triveritas

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CPD CERTIFIED
The CPD Certification Service

4 & 5 March 2014
The Rembrandt Hotel, London

INTRODUCTION

This seminar has been designed to give practical advice and an overview of how to successfully develop a veterinary vaccine and achieve market approval in the EU. The programme will take participants through a step-by-step approach to the process and will also provide key guidance on how to maintain your MA once achieved. The workshops will assist delegates to gain a better understanding of the requirements in practice. There will be ample time for discussion during the two days.

WHO SHOULD ATTEND

This seminar will be beneficial to all those working with Veterinary Vaccines from development to market approval and will provide a comprehensive insight to the requirements to achieve a successful application.

Personnel in the following areas will find this course useful:

New entrants to Registration Departments, Veterinary Medicinal Product Manufacturers, Registration Managers, personnel within Research and Development Departments, Academics with an interest in commercialising opportunities; and personnel from Micro/Small Enterprises.

ATTENDANCE LIMITED – EARLY REGISTRATION RECOMMENDED

This limitation, a unique feature of all **MANAGEMENT FORUM** seminars, will give participants the opportunity for a thorough discussion of the complex issues to be covered by the programme.

A Certificate of Attendance for Professional Development will be given to each participant who completes the course

COURSE LEADERS

Dr Mel Munro, Project Manager, Biologicals Regulatory Affairs, Triveritas. Mel has worked in regulatory affairs in the Animal Health Industry since 2002. She has been involved in all aspects of veterinary vaccine development and spends most of her time assisting clients with Start-to-Finish projects, taking ideas for veterinary medicines from proof of concept right through to Marketing Authorisations (MA). On a daily basis, Mel is responsible for preparing reports, documents and Dossiers for MA submissions, and for running National, Decentralised and Centralised Procedures. She also provides gap analysis of existing products and strategic advice on new product developments. Over her career she has been involved in various vaccine development projects ranging from inactivated and live viral and bacterial vaccines, to novel vaccines that include products of rDNA technology and GMO's.

Juliet Greenslade, Project Manager, Biologicals Regulatory Affairs, Triveritas. Juliet has over 16 years experience working in the Animal Health Industry. Her degrees are in Immunology and Medical Microbiology. Juliet started her career as a Medical Microbiologist in a large teaching hospital (5 years) before moving into the Animal Health arena. Initially she worked as a Scientist and GLP study Director in Biologicals R&D at Intervet. After some 6.5 years doing this she moved into Regulatory Affairs, first with Schering-Plough as a Senior Regulatory Manager and then with Pfizer (now Zoetis) as an Associate Director before joining Triveritas in 2010. During her time working in "big pharma", Juliet took responsibility for developing and registering new products, life-cycle maintenance of existing products and advising on regulatory strategy. In Juliet's current role as Project Manager, Biologicals Regulatory Affairs, at Triveritas, she assists clients (large and small) in a variety of areas, from advising on regulatory strategy and product development, through to preparing Expert Reports, writing Dossiers and running regulatory procedures on behalf of clients.

PROGRAMME

DAY ONE

09.30 ▶ **Welcome and Introductions**

09.45 ▶ **A Practical Guide to EU Veterinary Medicine Legislation**
- The Institutions, the Agency and other bodies
- The Regulations, Directives and Guidelines

10.15 ▶ **Vaccine Development – the MA Application Dossier**
- **Part 2**: Quality Aspects

11.15 ▶ **Coffee**

11.30 ▶
- **Part 3**: Safety Aspects

12.15 ▶
- **Part 4**: Efficacy Aspects

13.00 ▶ **Lunch**

14.00 ▶
- **Part 1**: Administration Dossier
- Benefit Risk Assessment & DACS

14.30 ▶ **Using SPCs for Vaccine Development**

15.00 ▶ **Coffee**

15.15 ▶ **Interactive Session in Groups on Project Planning**
- Inactivated Vaccine
- Live Vaccine

16.15 ▶ **Workshop - Presentations from the Groups**

17.00 ▶ **Q&A and End of Day One**

DAY TWO

09.00 ▶ **Vaccine Development – Specific Cases**
- MUMS/Limited Markets
- Multi-strain Dossiers
- GMO Vaccines

09.45 ▶ **Labelling**

10.00 ▶ **eSubmissions**

10.30 ▶ **Coffee**

10.45 ▶ **European Licensing Procedures**

11.45 ▶ **Marketing Authorisation Maintenance**
- Renewals
- Pharmacovigilance

12.30 ▶ **Lunch**

13.30 ▶ **Marketing Authorisation Maintenance (cont)**
- Variations

14.30 ▶ **Variations Workshop**

15.15 ▶ **Coffee**

15.30 ▶ **Workshop - Groups Report Back**

16.15 ▶ **Q&A and Close of Forum**