

**APPLICATION TO REGISTER**





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**YOU MAY REGISTER BY:-**

 +44 (0) 1483 730008  
 Management Forum Ltd  
 www.management-forum.co.uk  
 E-mail: registrations@management-forum.co.uk

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

**REGISTRATION INFORMATION**

**Dates**  
 19 March 2009 Start: 09.30 - Finish: 16.45  
 20 March 2009 Start: 09.00 - Finish: 16.00  
**Registration & Coffee**  
 19 March 2009 09.00

**Venue**  
 The Rembrandt Hotel, 11 Thurlow Place, London SW7.  
**Directions**  
 Opposite V&A Museum.  
 Nearest Underground station: South Kensington.  
 Map available on Website under Hotels and Venues.

**Accommodation**  
 A limited number of bedrooms have been reserved at The Rembrandt Hotel, 11 Thurlow Place, London SW7, at a special rate of £131.07 (Superior). £148.93 (Executive) both including English breakfast. Excluding 17.5% VAT - subject to availability. A special rate for Friday, Saturday and Sunday of £118.30 (Superior) including English breakfast excluding 17.5% Vat - subject to availability when booked as additional nights.  
 Hotel Tel: +44(0)20 7589 8100.  
 Hotel Fax: +44(0)20 7225 3476.

Email: reservations\_rembbrandt@sarova.co.uk  
**All bookings should be made directly with the hotel or online at [www.sarova.com/rembrandt](http://www.sarova.com/rembrandt), quoting promo code 'manforum'.**

**Fee**  
 £1,100 +17.5% VAT. The fee includes course documentation as well as mid-session refreshments and lunch. Invoice and confirmation will be forwarded to you.

**Conference No. V3-8209**

**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 [lesley@management-forum.co.uk](mailto:lesley@management-forum.co.uk).**  
 In the event of circumstances beyond its control, Management Forum reserves the right to alter the programme, the speakers, the date or the venue.

If you do not want to receive future mailings from Management Forum please contact [nick@management-forum.co.uk](mailto:nick@management-forum.co.uk)  
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**Website: [www.management-forum.co.uk](http://www.management-forum.co.uk)**

**A Practical Workshop**

# VETERINARY IMMUNOLOGICAL SUBMISSIONS

Preparing your Dossier for EU Submission – SPC and Part II

**Benefits of Attending:**

**Day One: Summary of Product Characteristics (SPC)**

- Understand the Purpose of the SPC
- Clarify What to Include and Where
- Gain Practical Advice on How to Prepare an SPC
- Discover How to Use the SPC as a Tool for Development of a Vaccine
- Know How to Design the Necessary Studies for Vaccines

**Day Two: Preparation of Part II of the Dossier**

- Better Understand Development Pharmaceuticals
- Clarify What to Include in Part II
- Take Away Manufacturing Methods and Flowcharts
- Discover the Use of Effective English
- Consider Starting Materials
- Receive Guidance on the Quality Control Section
- Know How to Prepare Your Dossier Descriptions

With:

**Dr Rhona Banks**, Director of Regulatory Affairs, Triveritas, UK

Register on-line at [www.management-forum.co.uk](http://www.management-forum.co.uk)

or telephone +44 (0) 1483 730071



**19 & 20 March 2009**  
**The Rembrandt Hotel, London**



## INTRODUCTION

This course has been designed to offer a practical hands-on workshop to provide experience in the requirements of preparing your immunological dossier for EU submission. It will focus on the Summary of Product Characteristics (SPC) and Part II of the dossier. This is an excellent opportunity to experience a step-by-step guide through the Marketing Application procedure for registering veterinary vaccines.

## WHO SHOULD ATTEND

Basic to Intermediate level training for Regulatory, R & D and Production personnel involved with developing and registering vaccines for veterinary medicines.

## COURSE LEADER

*Dr Rhona Banks*, Director of Regulatory Affairs, Triveritas, providing specialist contract services to Animal Health and related companies. Rhona joined Triveritas in 2007 and was previously Assistant Regional Technical Director, Biologicals at Fort Dodge Animal Health (FDAH). Rhona has extensive experience in Marketing Authorisations and Licence Applications in the EU (including the new EU countries) using the National Centralised, Mutual Recognition and Decentralised procedures. She has provided effective training on all aspects of EU regulatory requirements relating to vaccines for a number of years.

## 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.

## DOCUMENTATION

Delegates will receive a course material folder containing comprehensive documentation provided by the speakers, which will be a valuable source of reference for the future.

Register on-line at [www.management-forum.co.uk](http://www.management-forum.co.uk)  
or telephone +44 (0) 1483 730071

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

## PROGRAMME

### DAY ONE

#### SUMMARY OF PRODUCT CHARACTERISTICS

- 09.30 ► **Welcome and Introductions**
- 09.45 ► **Background and Purpose of the SPC**
- 10.45 ► **Coffee**
- 11.00 ► **What to Include and Where**
- 11.30 ► **Interactive Workshop in Groups**
- Preparing an SPC
  - Actual practice using examples of data from reports
  - Group presentations
  - Discussion
- 12.45 ► **Lunch**
- 13.45 ► **SPC as a Tool for Development of a Vaccine**
- 15.15 ► **Tea**
- 15.30 ► **Interactive Workshop in Groups**
- Design the necessary studies for vaccine (example provided)
  - Group presentations
  - Discussion
- 16.45 ► **End of Day One**

### DAY TWO

#### PREPARATION OF PART II OF THE DOSSIER

- 09.00 ► **Brief Review of Day One**
- 09.15 ► **Development Pharmaceuticals**
- 09.45 ► **What to Include**
- 10.15 ► **Manufacturing Methods and Flowcharts**
- 10.45 ► **Coffee**
- 11.00 ► **Interactive Session**
- Using examples of flowcharts and detailed descriptions
  - Consideration of how much detail to include ensuring that the flow chart and detailed description are compatible with each other
  - Discussion
- 12.30 ► **Lunch**
- 13.30 ► **Use of Effective English**
- 13.45 ► **Starting Materials**
- 14.15 ► **Quality Control Section**
- 14.45 ► **How to Prepare Your Dossier Descriptions**
- 15.15 ► **Tea**
- 15.30 ► **Discussion of Key Learning Points**
- 16.00 ► **Close of Forum**