MANAGEMENT FORUM

ANIMAL FEED ADDITIVES and Post-Conference Workshop: MANAGING EU FEED ADDITIVE PROJECTS

APPLICATION TO REGISTER

25 & 26 November 2008,
Conf. No. V11-8408 / V11-8508

Please PRINT your details:

Title..... First name.....
(Dr, Mr, Mrs, etc)
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Department.....

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Expiry date...../.....

☐ Cheque enclosed payable to Management Forum Limited
☐ Bank transfer on receipt of invoice W

YOU MAY REGISTER BY:-

+44 (0) 1483 730008

Management Forum Ltd, 98-100 Maybury Road, Woking, Surrey GU21 5JL, UK

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 25 & 26 November, 2008

Times 25 November, 2008 Start 09.30 – Finish 17.00
26 November, 2008 Start 09.30 – Finish 17.00

Registration & Coffee
25 November, 2008 09.00

Venue
The Rembrandt Hotel, 11 Thurloe 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 Thurloe Place, London SW7, at a special rate of £127.66 (Superior) inc. English breakfast, £144.69 (executive) inc. English breakfast. All +17.5% VAT – subject to availability.
A special rate for Friday, Saturday and Sunday of £114.90 (Superior) inc. English breakfast +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_rembrandt@sarova.co.uk
All bookings should be made directly with the hotel or online at www.sarova.com/rembrandt, quoting promo code 'manforum'.

Conference Fee
£540 +17.5% VAT per event OR £1,050 +17.5% VAT for both events. The fee includes course documentation as well as mid-session refreshments and lunch. Invoice and confirmation will be forwarded to you.

I would like to attend (please tick)
Both Events ☐
November 25 ONLY, Conf. No. V11-8408 ☐
November 26 ONLY, Conf. No. V11-8508 ☐

Conference No. V11-8408 & V11-8508

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.

In the event of circumstances beyond its control, Management Forum reserves the right to alter the programme, the speakers, the date or the venue.

Exhibition spaces and promotional opportunities will be available at this meeting.
For further information please contact Judith Black
(email: judith.black@management-forum.co.uk)

MANAGEMENT FORUM LTD., 98-100 Maybury Road, Woking, Surrey GU21 5JL, UK
Tel: +44 (0)1483 730071 Fax: +44 (0)1483 730008 Website: www.management-forum.co.uk

Annual Conference

A REGULATORY UPDATE ON ANIMAL FEED ADDITIVES

Will you be ready by 2010?

How to comply with EU legislation - successfully

An excellent opportunity to network with professional colleagues and experts in the EU regulatory field and benefit from a concise overview of the complex process of obtaining approval of feed additives in the EU

You can register online at www.management-forum.co.uk or by telephone on +44 (0)1483 730071, or fax 730008

Programme to include:

- Implementation of EU Regulation on Feed Additives (1831/2003): 'State of Play', Including New Data Requirements for Feed Additive Dossiers (Regulation 429/2008)
- Requirements for Feed Additive Dossiers
- Regulatory Expectations (New EU Regulation 429/2008)
- Experience to Date (EFSA, CRL, EU Commission, Comitology)
- Future Trends

Chairman:
Ray Harding Managing Director, Cyton Biosciences Limited

Speakers:
Dr. Elinor McCartney Director, EU Pen & Tec Consulting SCP
Diederik Standaert FPS Health, Food Chain Safety and Environment - Directorate General for Animals, Plants and Food – Service Food, Feed and Other Consumption Products, Belgian Authorities

25 November 2008, The Rembrandt Hotel, London

Post-Conference Workshop

MANAGING EU FEED ADDITIVE PROJECTS – FROM CRADLE TO CRADLE

A practical workshop on EU feed additive registration

CPD CERTIFIED
The CPD Certification Service

MANAGEMENT FORUM
25 YEARS

Programme to include:

- Planning the dossier – strategic options
- Selecting feed additive categories
- Pre- and post-submission tactics
- Managing project resources and priorities
- Interpretation of guidelines, guidance and other essential documents
- Safety – the greatest obstacle
- Efficacy – dealing with complexity
- Quality – minimum standards
- Designing dossier studies – the protocol
- Preparing and reviewing study reports
- Dossier preparation – tricks of the trade
- Post-submission hurdles

With:
Dr. Elinor McCartney EU Director, Pen & Tec Consulting SCP

26 November 2008, The Rembrandt Hotel, London

INTRODUCTION

As a result of the EU White Paper on Food Safety, published in 2000, there have been sweeping changes to legislation concerning the food chain, especially feed and feed additives. The EU feed additive regulation (EC No 1831/2003) replaced the existing feed additive Directive 70/524/EEC and introduced a new system for assessing feed additive dossiers. The new evaluation procedure involves the EU Commission, EFSA (European Food Safety Authority) and the Standing Committee on the Food Chain and Animal Health, which includes delegations from 27 EU Member States (Comitology).

Regulation 1831/2003 re-categorised feed additives and created new functional groups. Functional groups may be expanded in the future to include new types of feed additives. Antibiotic growth promoters were prohibited in the EU from January 2006 and although coccidiostats remain as feed additives, maintaining approvals under the new legislation presents considerable challenges for all feed additives.

The EU plans to review all currently authorised feed additives within the next decade, most likely starting with products recently classified as additives. Many existing feed additives have never before been subjected to an EU assessment according to current standards of safety, quality and efficacy.

A new feed additive register was first published in November 2005 and is regularly updated. Amino acids, silage agents and many other products have been classed as feed additives for the first time in the EU, and will maintain authorisations only if a suitable dossier is submitted by November 2010, approved by EFSA and receives a qualified majority vote in Comitology.

Meeting current and future EU regulatory requirements for feed additives is a major challenge for businesses operating in this sector. This conference will review the legislation, examining both procedures and data requirements, and discuss the main issues that confront companies in this important industry sector.

WHO SHOULD ATTEND

Regulatory, Business Development and Strategic Marketing Managers responsible for marketing feed additives in Europe, plus anyone wishing to update themselves on the current status and evolution of the regulation of animal feed additives in Europe.

This conference is an ideal introduction to the following day's workshop, which will offer delegates the opportunity to work together in an informal and fun environment to solve specific regulatory problems.

CHAIRMAN

Ray Harding established Cyton Biosciences Limited in 1997 to provide specialist services in new product development and registration for the bioscience industries in Europe. He has worked in the veterinary pharmaceutical industry since 1979 in marketing development, product development, project management and product registration, and was previously employed by Glaxo, Pitman Moore and Rhône Mérieux. He is past President of the Federation of European Veterinarians in Industry and Research. Cyton Biosciences won the Queen's Award for Enterprise 2003.

SPEAKERS

Dr. Elinor McCartney directs EU Pen & Tec Consulting SCP and specialises in the EU registration of feed additives. Originally from Edinburgh, Scotland, Elinor has more than 25 years experience in product development and regulatory affairs in Europe. She is a veterinary surgeon with a PhD in Veterinary Pathology from Edinburgh University and a Masters in Business Administration (with distinction) from the Open University. Elinor has tutored for the Open University Business School in various EU countries.

Diederik Standaert works for the Directorate General for Animals, Plants and Food – Service Food, Feed and other Consumer Goods (Belgian Authorities). He is the representative of the Belgian delegation at the Standing Committee for the Food Chain and Animal Health – Animal Nutrition Section and its working groups. He is also involved in working groups at the Council that discuss new proposals concerning feed legislation including additives, undesirable substances and compound feed. In the past he acted as Rapporteur for different feed additive dossiers. He is responsible for the transposition and/or implementation of EU Directives, Decisions and Regulations concerning feedingstuff legislation into national law.

Reserve your place on-line at www.management-forum.co.uk or telephone +44 (0) 1483 730071. If you require further information contact andrea.james@management-forum.co.uk

PROGRAMME – 25th November 2008

Annual Conference

A REGULATORY UPDATE ON ANIMAL FEED ADDITIVES

9.30 ▶ Chairman's Welcome and Introduction

9.45 ▶ Implementation of Regulation (EC) No 1831/2003 on Additives for Use in Animal Nutrition
- 'State of Play', including new guidelines for feed additive dossiers

10.45 ▶ Discussion

11.00 ▶ Coffee and Networking

11.20 ▶ General Dossier Requirements
- Specific requirements for each additive category
- Special cases (e.g. feed additives derived from food additives, pets/companion animals)

12.30 ▶ Discussion

12.45 ▶ Lunch

13.45 ▶ Managing the Requirements of the New EU Guidelines: A Challenge for Industry
- Non-zootechnical additives – how to protect investment
- Zootechnical additives
- Coccidiostats and Histomonostats
- Misfits

15.00 ▶ Discussion

15.15 ▶ Tea

15.30 ▶ Panel Discussion: Issues and Strategies that Confront Companies
- Interpreting the data requirements
- Design of appropriate studies
- Fixing problems/case studies
- Applicable guidelines and guidance documents
- Acceptable arguments/justification

16.45 ▶ Chairman's Closing Remarks

17.00 ▶ Close of Conference

Post-Conference Workshop

MANAGING EU FEED ADDITIVE PROJECTS – FROM CRADLE TO CRADLE

With: **Dr Elinor McCartney,** Director, EU Pen & Tec Consulting SCP

INTRODUCTION

The feed additive Regulation (EC) No 1831/2003 lays down the procedure for approval of feed additives intended for the EU market. The approval process requires demonstration of the safety, quality and efficacy of the additive. Safety must be established for target animals, users, consumers and the environment. Evidence of efficacy is required in relation to feed characteristics, animal nutrition, produce, performance or the environment. Quality must be demonstrated and must meet all current EU specifications. In many cases, new feed additive applications must be submitted by November 2010.

Feed additives that fail to submit a valid application dossier by 2010 will be removed from the feed additive register and prohibited from sale in the EU.

Many companies are now planning and executing EU studies with a view to dossier submission by the November 2010 deadline.

New feed additives must achieve approval prior to accessing the EU market.

A speedy, successful application is critical for early market access.

BENEFITS IN ATTENDING

The main workshop objective is to help managers construct dossiers that achieve EU approval with minimum delays and using resources efficiently. This workshop will provide participants the opportunity to work together in an informal and fun environment to solve specific regulatory problems.

WHO SHOULD ATTEND

- **Registration managers responsible for planning and preparing EU feed application dossiers**
- **Product managers, marketing personnel and business development managers**
- **R&D scientists responsible for new product development**
- **Project managers within the feed additive area**
- **Staff from EU institutes offering services targeted at EU feed additive dossiers**

PROGRAMME – 26th November 2008

9.30 ▶ Welcome and workshop objectives

9.45 ▶ Regulation (EC) No 1831/2003 – A star is born? (including exercises on feed additive categories/dossier planning)

11.00 ▶ Coffee

11.15 ▶ Efficacy, Quality and Safety – the greatest of these is SAFETY (including safety exercises)

12.15 ▶ Quality – the essentials (including quality exercises)

13.00 ▶ Lunch

14.00 ▶ Efficacy – "Statistics is Fun" (including efficacy exercises)

15.15 ▶ Tea

15.30 ▶ Case studies, problems, solutions (including problem solving exercises)

16.45 ▶ Concluding remarks

17.00 ▶ Close of workshop