

## Registration of Animal Feed Additives in the EU

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### Date and venue

5-6 June 2019 **Ref: 10558**  
HI London - Kensington Forum  
97 Cromwell Road,  
London SW7 4DN  
Phone: +44 (0) 207 341 3355  
Fax: +44 (0) 207 373 1448

### Programme schedule

Registration and refreshments: 09.00  
Day one: 09.30 - 17.00  
Day two: 09.00 - 17.00

### Accommodation

We have arranged a preferential rate for accommodation at the venue. To take advantage of this, please contact the hotel and state you are a **Management Forum delegate** quoting the special code 'QGM'. There are limited rooms available at this rate so please book early to avoid disappointment.

**Email:** [reservations@hikensington.co.uk](mailto:reservations@hikensington.co.uk)  
**Web:** [www.hikensingtonforumhotel.co.uk](http://www.hikensingtonforumhotel.co.uk)

For information on alternative accommodation, please visit our website: [management-forum.co.uk/accommodation](http://management-forum.co.uk/accommodation)



### Three ways to book

[management-forum.co.uk](http://management-forum.co.uk) [info@management-forum.co.uk](mailto:info@management-forum.co.uk) +44 (0)20 7749 4730

### Fees and payment

#### EARLY BOOKING DISCOUNT Book BEFORE 26 March 2019

£1199.00 + VAT = £1438.80 • €1679.00 + VAT = €2014.80

#### FULL PRICE Book AFTER 26 March 2019

£1399.00 + VAT = £1678.80 • €1959.00 + VAT = €2350.80

#### Multiple booking discount for 2nd or subsequent delegates - 15%

£1189.15 + VAT = £1426.98 • €1665.15 + VAT = €1998.18

#### Payment options

1. Invoice which can be paid by bank transfer or credit/debit card
2. Online through our secure website when registering



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To find out more, please visit: [management-forum.co.uk](http://management-forum.co.uk)



**FEE:** The fee includes all meals and refreshments for the duration of the course and a complete set of course materials. If you have any particular requirements, please advise customer services when booking.

**PLEASE NOTE:** Management Forum Ltd reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, Management Forum will refund the registration fee and disclaim any further liability.



For event cancellation policy and T&Cs see our website

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# Registration of Animal Feed Additives in the EU

A practical and interactive two-day course

5-6 June 2019, London



### Key areas covered and course objectives:

- Understand the EU regulatory framework and relevant legislation
- Roles of the EU Commission, the EURL, EFSA and Member States
- Types of feed additives and acceptable claims
- Data required – product characterisation safety, quality and efficacy
- EC, EURL and EFSA guidelines and guidance documents
- How to conduct a strategic data audit and gap analysis
- Managing EU registration projects
- Writing successful feed additive dossiers
- Post-submission hurdles – dossier validation and EFSA clock-stops
- Interacting with the EU Commission, Member States and EFSA

Expert faculty:

**Dr Elinor McCartney**, Director, Pen & Tec Consulting SLU

**Laura Payo Lewis**, Regulatory Affairs Director, Pen & Tec Consulting SLU

## Introduction and objectives

This course will provide a comprehensive introduction to the entire regulatory dossier submission for approval of a feed additive in the EU, taking participants through all the necessary steps to obtain marketing authorisation.

Presentations will cover the regulatory framework and data required to establish the characterisation, quality, safety and efficacy of the different types of feed additives. An important part of the programme will be devoted to working on case studies in the workshop sessions.

## Who should attend?

- Managers working in:
  - Regulatory affairs
  - Marketing
  - R&D
  - Product development
- Scientists in CROs where clients demand EFSA-compliant studies
- Those seeking to review special problems in the registration of feed additives in the EU

**A certificate of attendance for professional development will be available to each participant who completes the course**

## Group discounts are available

For more information contact customer services on **+44 (0)20 7749 4730** or email: **inhouse@management-forum.co.uk**

## Expert faculty



### Dr Elinor McCartney

established Pen & Tec Consulting in 2000, coinciding with publication of the EU

white paper on food safety, which is dedicated to providing specialist services in new product development and registration of feed additives in Europe. She has managed the growth of services to include all categories of feed additives. Elinor is a graduate of the Royal (Dick) Veterinary College, where she obtained her PhD in enteric diseases of piglets.

Elinor helps clients understand EU/EFSA legislation, guidelines and guidance and has assisted many applicants to achieve or maintain EU approval of a wide range of products, including technological, sensory, nutritional, zootechnical and coccidiostat feed additives.



### Laura Payo Lewis

is a regulatory consultant for the food and animal health industry. She has a Masters in Biotechnology from the

University of Salamanca and interned in the cell culture quality control department of Intervet/Schering-Plough Animal Health in 2010. Laura specialises in EU food and feed enzyme and probiotic registrations, and has developed expertise in US FDA regulatory requirements.

Since 2011, Laura has been working at Pen & Tec Consulting, a regulatory affairs consultancy focused on helping companies to understand and comply with European food and feed laws, in order to successfully sell their products and minimise their time to market.

## Programme

### Day one

- 09.00 ▶ Registration and refreshments
- 09.30 ▶ Introduction and objectives of the course
- 09.45 ▶ EU regulatory framework – the basic legislation and procedures
- 10.45 ▶ Refreshments
- 11.00 ▶ EURL and EFSA guidance documents
- 11.30 ▶ Workshop: Strategic planning – matching commercial and regulatory objectives
- 12.30 ▶ Section II – Identity
- 13.00 ▶ Lunch
- 14.00 ▶ Section II – Requirements for microorganisms intended for use as additives or production strains
- 14.30 ▶ Workshop: Building Section II
- 15.30 ▶ Refreshments
- 15.45 ▶ Section III – Safety for target animals, consumers, users and the environment
- 17.00 ▶ End of day one

### Day two

- 09.00 ▶ Review of day one – discussion, questions and answers
- 09.30 ▶ Workshop: Building Section III
- 10.30 ▶ Refreshments
- 10.45 ▶ Section IV – Efficacy
- 11.45 ▶ Good study design – ticking EFSA boxes
- 12.45 ▶ Lunch
- 13.45 ▶ Workshop: Building Section IV
- 14.45 ▶ Refreshments
- 15.00 ▶ Workshop presentations
  - Presentation by each team
  - Review and discussion
- 15.30 ▶ Writing and managing the dossier
  - Writing the dossier
  - Post-marketing monitoring plan
  - EFSA completeness check
  - Quality control, submission and follow-up
  - Handling EFSA clock-stops
- 16.30 ▶ Final discussion, questions and answers
- 17.00 ▶ End of course

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