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# Supply Chain Assurance

**Tuesday 30 June to Wednesday 1 July 2009**  
London Marriott Hotel Kensington,  
London, UK

**DBA**

## About This Course

Over recent years the Pharmaceutical Industry has moved to more global strategies for R&D, Manufacturing and sourcing of its ingredients. The growth of outsourcing, often to countries with less mature Pharmaceutical Industry understanding and regulatory systems, has also been significant as companies seek to lower their costs of operating.

In parallel, significant public health issues have occurred related to the supply chain of; excipients (e.g. Glycerol), APIs (e.g. Heparin) and counterfeiting of finished medicinal products. The response from the European Commission and FDA has been to propose new legislation to mitigate the risks.

This course will cover the proposals from the regulators, the responses from the Pharmaceutical industry, its suppliers of excipients and APIs, and related associations, along with good industry practices for 'end to end' supply chain assurance.

## What You Will Learn

- FDA initiatives and views on Supply Chain Assurance
- EU initiatives and views on Supply Chain Assurance
- What has gone wrong – Case Study
- Views and proposals from Excipient and API suppliers
- Examples of industry practices for Supply Chain Assurance

## Who Should Attend

- Management involved in Supply Chain activities
- Personnel involved in procurement, logistics, packaging
- Personnel involved in outsourcing/supplier assurance of ingredients
- Quality Professionals
- Qualified Persons

# Course Outline

## Current and developing regulatory expectations including:

- EU
  - Proposed amendments to EU legislation
  - APIs
  - Excipients
  - Counterfeiting
  - API Inspection cooperation pilot
  - Distribution chain
- USA
  - FDA Globalisation Act
  - Good Importer Practices
  - Secure Supply Chain pilot

## Case studies of what has gone wrong

- Heparin
- Glycerol
- Gentamycin

## Views of ingredient suppliers/other groups

- IPEC - Excipients
- APIC - APIs
- Certification schemes

## Industry Practices for Supplier Assurance

- Supplier Assurance programmes
- Quality Risk Management
- Quality Agreements

## Opportunities for industry and regulators to work together

## Your Tutors



**Neil Wilkinson**  
**David Begg Associates, UK**

Neil joined DBA from AstraZeneca, where he was Senior Director of Global Quality.

Neil has held roles in QC,QA, Production, Supplier Assurance, Global Manufacturing/Compliance and Global Quality. Neil was EFPIA topic leader on the ICH Q10 Expert Work Group and has worked with PDA on their recent Supplier Ingredient Initiatives.



**Gary Rees**  
**David Begg Associates, UK**

Before joining DBA, Gary spent many years with Wyeth, where he rose to Vice President, Quality and Compliance for the European, Mid-East and African regions.

Gary has extensive experience with the challenges of 'global' QA/Compliance programmes and working with external suppliers.

### **Discussion and Working Groups**

This course will be highly interactive. There will be ample opportunity for delegates to put theory into practice via real life case studies.

The course also includes a panel discussion period, during which delegates can obtain answers to their specific questions and concerns.

# Booking Form

## Supply Chain Assurance

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London Marriott Hotel Kensington, London, UK

Please reserve me a place on this course...

**First/only delegate attending:** £1280.00  Plus 15% Value Added Tax (VAT)

**Additional delegate(s) from same site:** £1024.00  Plus 15% Value Added Tax (VAT)

**Includes:** tuition, comprehensive course notes, attendance certificate, lunches, refreshments and course dinner on Tuesday evening

**Excludes:** all hotel accommodation and other dinners (see Hotel Accommodation section)

**Course begins at 09.00 on Tuesday and finishes before 17.00 on Wednesday**

Please write clearly in BLOCK CAPITALS

Mr/Mrs/Miss/Ms/Dr  First Name  Surname

Job Title  Company

Full Street Address

Post Code

Delegate Tel No  Delegate Fax No  Delegate Email

Accommodation: I require accommodation (please tick box) YES  NO  See Hotel Accommodation section for details

Please indicate any special needs (dietary/accommodation):

To guarantee your accommodation reservation, credit card details must be supplied (please write clearly)

Card Number  Expiry Date

*Sterling cheques, payable on a UK bank to David Begg Associates (York) Ltd, for the full invoiced amount of £1472.00 (first/only delegate) or £1177.60 (additional delegate(s) from same site) (net of ALL bank charges) to be attached to this Booking Form and sent to David Begg Associates (York) Ltd at the address below. Settlement must be received at least 10 working days prior to the course start date. A VAT invoice will be provided. VAT Reg No GB 927 3679 85. Under UK law all applications are subject to VAT irrespective of the country of origin of participants. Most VAT registered companies/organisations can reclaim this tax. Cancellations within 25 working days of the course start date are subject to charges (see Cancellations section). If a Purchase Order number is necessary to effect settlement of our invoice please provide it in the box below.*

Purchase Order number

Authorised Signature  Date  Cheque enclosed

To aid prompt confirmation of your booking, please ensure you submit a completed application form which bears an authorised signature and Purchase Order number

The programme and other information contained in this brochure are correct at the time of printing and are published in good faith. David Begg Associates reserves the right to make any changes which may become necessary.

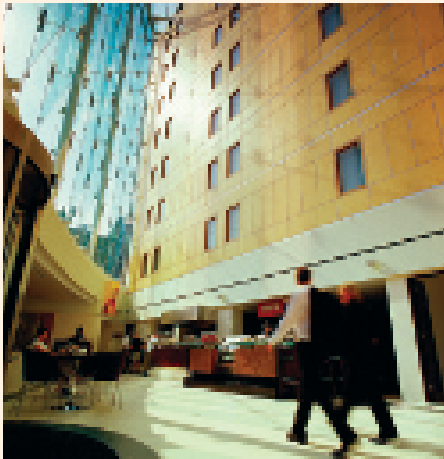
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# The Venue

Located close to central London in the heart of Kensington, the London Marriott Hotel Kensington is one of the most contemporary hotels in London, a combination of superb, vibrant facilities and modern design with a stunning 7-storey atrium lobby. Retreat and recharge in the comfort of one of the guest rooms. The hotel also has high-speed internet access. Enjoy a great dinner in the fabulous new Fratelli Grill, or a selection of excellent martini cocktails and wines in the Nabuco Bar.



## Hotel Accommodation

- David Begg Associates has a block booking of bedrooms at the London Marriott Hotel Kensington, at the specially negotiated room only rate of £171.35 (including VAT) per delegate per night.
- The nights of Monday 29 to Tuesday 30 June 2009 inclusive will usually be reserved.
- Accommodation should only be reserved through us using the Booking Form. Credit card details must be provided to ensure this reservation is kept for you. Please do not contact the hotel directly as this could cause duplicate reservations.
- Your account with the hotel should be settled at check out.
- Any charges made by the hotel as a result of you not taking up your reservation for any reason will remain your responsibility.
- Where at all possible, your booking for accommodation should be received six weeks before the course start date. Places on the course will be available after this time but we cannot guarantee bedroom or rate availability.
- Where no indication is made on the Booking Form, no accommodation will be reserved by us.

## To Book on this Course

- Fax the completed and signed form from this brochure to our Course Administrator. Your place will then be confirmed by post and a course fee invoice will be issued.
- Provisional bookings can be made via our website, in the Training Courses section. Online reservations must be confirmed by the completion of a Booking Form (pdf brochure and Booking Form files can be downloaded via the website).
- Make sure you write a Purchase Order number on the Booking Form if this is necessary for settlement of our invoice.
- Reserve a place by telephone or email (contact details are on the Booking Form), confirming as above.

## Cancellations

Written cancellations with a full refund will be accepted up to 25 working days before the start date of the course. A cancellation fee of 50% will be payable for cancellations received between 10 and 25 working days before the start of the course. If you cancel within 10 working days of the course start date, full course fees will be chargeable. Delegate substitutions may be made at any time up to the start of the course.