

Practical Aspects of Controlled Temperature Storage and Distribution

Monday 28 to Wednesday 30 September 2009
London Marriott Hotel Kensington,
London, UK

DBA



About This Course

- For many years now Regulators and Inspectors have been working with the industry to improve 'Cold Chain' for storage and shipment in the 2-8°C range. This has been of particular importance for the new protein based biotech products and vaccines.
- However, in recent years the emphasis has moved to include controlled temperature storage and distribution of small molecule products including tablets, capsules, liquids, creams and ointment.
- Despite this regular audit observations continue to highlight areas of weakness and fault with company's systems.

"It's all about risk and data" – without data the risks cannot be determined – without this information how can the QP certify lots?

What You Will Learn

- Legislative and regulatory expectations
- Current best practices
- Where to find solutions

Who Should Attend

This course will be invaluable to:

- QPs
- QA group
- Logistics managers and others responsible for Warehouse and Distribution Operations
- Auditors

For both –

- Cold Chain products
- Controlled room temperature products

Course Outline

Introduction to Controlled Temperature Requirements Regulatory Expectations

Cold Chains

- Cold temperature storage and distribution
- Equipment and trailer validation
- Insulated packaging qualification
- Best practice in Cold Chain distribution

Information for service providers

- European road transport
- Insulated packaging
- Cold Chain warehousing and downstream distribution

Controlled room temperature

Designing a temperature monitoring programme

- Using the data
- To release or not?

Temperature mapping

Handling deviations

Your Tutors



Mike Halliday
David Begg Associates, UK

Mike has audited and consulted widely on international expectations for controlled temperature storage and distribution of medicines.



Stewart Green
David Begg Associates, UK

Stewart was formerly Director of Quality for Wyeth's biotech products in the UK. He therefore has extensive experience of requirements for controlled temperature storage and distribution.



Gary Rees
David Begg Associates, UK

Before joining DBA, Gary spent many years with Wyeth where he rose to Vice President, Quality Compliance for the European, Mid-East and African regions. Gary has extensive experience of the challenges of global supply chains and the importance of controlled temperature storage and distribution of medicines.

Plus guest speakers from the industry and service provider.

An ideal mix of lectures and discussions

Like all David Begg Associates courses, this course will provide ample opportunity for discussion and debate.

Delegates will learn from each other as well as from the tutors and will definitely feel 'involved' in the learning process.

Booking Form

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London Marriott Hotel Kensington, London, UK

Please reserve me a place on this course...

First/only delegate attending: £1690.00 Plus 15% Value Added Tax (VAT)

Additional delegate(s) from same site: £1352.00 Plus 15% Value Added Tax (VAT)

Includes: tuition, comprehensive course notes, attendance certificate, lunches and refreshments

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

Course begins at 09.00 on Monday and finishes at 15.00 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 £1943.50 (first/only delegate) or £1554.80 (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.

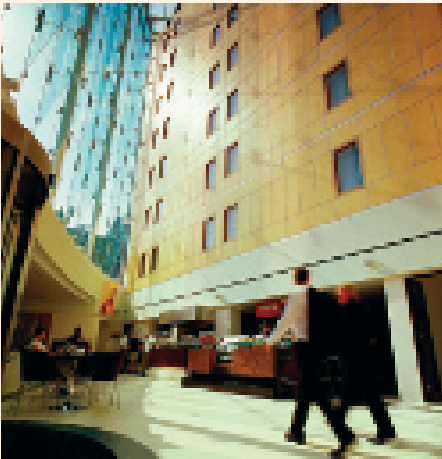
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The Venue

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 £189.75 (including VAT) per delegate per night.
- The nights of Sunday 27 to Tuesday 29 September 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.