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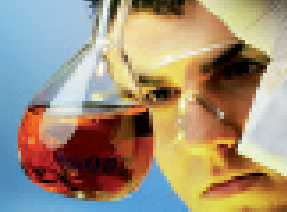
The Pharmaceutical
Training Experts

How to Simplify and
Improve Your Change
Management System

Wednesday 14 and Thursday 15 April 2010

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

About This Course



To stay in business your company must be lean, agile and 'compliant'. There will always be new regulatory requirements to comply with, new products to introduce, new suppliers to engage and new policies, procedures and equipment to implement. The key to your success is how you manage change. Good change management systems are SIMPLE change management systems. This course will provide you with the practical tools and techniques needed to improve the efficiency and effectiveness of your change management system.

We will show you how to:

- **Simplify your system** to improve effectiveness and reduce costs
- **Review and approve changes in minutes – not days or months.** Speed and effectiveness is possible!
- **Design and use SIMPLE change management documentation.** If your policy is longer than 3-4 pages it is over complicated and probably unworkable
- **IMPLEMENT CHANGES SUCCESSFULLY.** Did you realise that 75-80% of most approved changes fail to deliver any lasting benefit!
- Comply fully with **ICHQ10** requirements 3.2.3 'Change Management Systems'



What You Will Learn

- We will help you improve the **speed** and **effectiveness** of your change control system to allow you to review and approve change requests in hours, not weeks or even months!
- We will show you how to **simplify** your change control documentation
- We will demonstrate how your change control system can **stop unnecessary and costly change**, thereby preventing 'initiative overload'
- We will ensure that you will have a comprehensive understanding of the **current regulatory requirements** for change control in the EU and USA
- We will show you how to use **risk management** and other decision making skills, in order to **implement changes successfully**

Who Should Attend

This course is designed for anyone involved in the...

- Implementation of **any** change to products, processes, plant and procedures
- Design and execution of change control systems
- Submission of change requests
- Review and approval of change requests

Reserve your place today

email: courses@DBA-global.com

Course Outline

Change Control – the Regulatory Aspect

- How to satisfy EU and FDA requirements and expectations
 - What do regulators look for?
 - How do auditors 'assess' your change control system?
- Future developments

Change Control – the Business Aspect

- Managing change in a global business
- Benchmarking – how the best companies manage change control. How do you compare?
- Using change control to add value
- How to 'fast track' important changes
- How to stop unnecessary change and 'initiative overload'
- Managing change with suppliers and third parties

The PRACTICE of Effective Change Control

The 'Who, How, What and Why' of change control in the following areas...

- Manufacturing operations
- Equipment qualification and process validation
- QC laboratories

- Engineering department (what is really LIKE for LIKE?)
- Automated and computer systems
- Suppliers and other third parties

Change Control Administration – the Paperwork Aspect

- Designing change control forms that work
- Managing the change control system
- Alternatives to paper

Change Control – the Decision Making Aspect

- Using RISK ASSESSMENT to assess impact and set priorities
- The role of key people...
 - The change sponsor
 - Subject experts
 - Review panel
 - Regulatory Affairs
 - The Qualified Person
 - The Regulatory Auditor

Change Control – the People Aspect

- Anticipating and managing resistance to change
- Implementing change successfully

Your Tutors



Martin Lush
David Begg Associates, UK

Martin is Senior Partner with DBA and has worked in the Pharmaceutical Industry for over 30 years. He has extensive experience of helping companies to improve the efficiency of their change control systems.



Terry Snape
David Begg Associates, UK

Terry has a wealth of experience in dealing with change applications and he has worked with several international companies to simplify their change management systems.

What previous attendees said about this course

These are just some of the comments we have received and are typical of the kind of feedback we've come to expect after a DBA course.

"Overall a very helpful course, I was interested in how others get over the challenges faced within their own businesses"

Dorothy Lyall, Allergy Therapeutics Ltd

"Very informative, worthwhile and an excellent course to have done"

Marian Reynolds, Abbott Ireland Diagnostics Division

"Added significant value to our current procedure... great information on real situations"

Alan Brown, Merck Sharp & Dohme

"Good practical course, excellent"

Jan Van Zeelst, Sanquin Bloodbank
Northwest, The Netherlands

"Thoroughly enjoyed the course"

Jennifer Sullivan, Ipsen Biopharm Ltd, Ireland

Booking Form

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Please reserve me a place on this course...

First/only delegate attending: £1320.00 Plus VAT at the prevailing rate

Additional delegate(s) from same site: £1056.00 Plus VAT at the prevailing rate

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

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

Course begins at 09.00 on Wednesday and finishes at 15.00 on Thursday

Please write clearly in BLOCK CAPITALS

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

Job Title Company

Full Site 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 (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

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The Manchester Marriott Victoria & Albert Hotel stands on the banks of the River Irwell, near the city centre but convenient for Manchester Airport (19km), the city's Piccadilly rail station (3km) and the UK's motorway networks. Recently lovingly restored, this Grade II listed building bears many modern features. The hotel has its own car park and the Living Well Health Club with pool, gymnasium, sauna and steam room is just a few minutes from the hotel. Also nearby are the Imperial War Museum North West, Lowry Museum and Manchester's three theatres. A few minutes' walk takes you to the city's main shopping and eating district.

- David Begg Associates has a block booking of bedrooms at the Manchester Marriott Victoria & Albert, at the specially negotiated bed and breakfast rate of £107.22 (plus VAT at the prevailing rate) per delegate per night.
- The nights of Tuesday 13 and Wednesday 14 April 2010 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.

**Booking your place
couldn't be easier!**

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