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# DBA

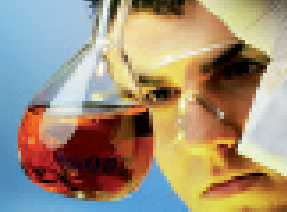
**The Pharmaceutical  
Training Experts**

**How to Simplify and  
Improve Your Deviation  
and CAPA System**

**Monday 12 and Tuesday 13 April 2010**

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

# About This Course



## How good is your Deviation and CAPA system... or are you at RISK?

- Can you guarantee that your deviation incidents *never happen again*, **or** are costly repeat incidents common place?
- Do you use every incident as a *learning opportunity* for 'Continuous Quality Improvement', **or** are deviations considered to be just a 'compliance tool'?
- Do you *really identify root cause*, **or** just inaccurately conclude 'Human Error' for most incidents?
- Does your *system efficiently 'Triage' incidents* based on risk, **or** do you treat every incident the same ... which is costly as well as dangerous!
- Can you *report, investigate and resolve deviation incidents in hours* **or** only within the ridiculously long and inefficient '30 days'?
- Years after the incident, can you *accurately reconstruct the history of the event* from the report **or** are you left guessing in front of a frustrated inspector?

Your Deviation and CAPA system is a crucial part of your Quality System. It *should* protect your patients against poor quality medicines *and* drive Continuous Quality Improvement by stopping inefficient, wasteful and often dangerous practices. This course is not just about how to conduct a root cause investigation. It is much, much more.

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## What You Will Learn

- How to use your deviations to drive down costs and reduce complexity by removing non value-adding activities and driving forward Continuous Quality Improvement
- How to make 'repeat' incidents a thing of the past!
- How to apply structured, risk-based decision making tools and techniques to ensure that every incident is investigated to root cause in a consistent and thorough manner
- How to report, investigate and resolve incidents within hours, not days or weeks
- How to 'Triage' or prioritise deviations so that you focus your time and resources on what really matters
- How to make sure that your deviation reports provide an accurate history of events!

## Who Should Attend

This course will be invaluable to anyone involved in the review and approval of batch manufacturing records, and the investigation of deviations, out of specifications, customer complaints, product recalls or any unplanned quality incident.

Reserve your place today

email: [courses@DBA-global.com](mailto:courses@DBA-global.com)

# Course Outline

## The What, How and When of Deviation Reporting

- How to 'map' a deviation incident
- How to use risk assessment to classify deviations
- How to collect and analyse information efficiently
- Use of practical problem solving skills, including process flow diagrams, force field and pareto analysis
- Techniques to identify root cause

## Corrective and Preventative Action (CAPA)

- How to identify which CAPAs are appropriate
- How to implement CAPAs successfully and on time!

## Deviation Management: Best Industry and Regulatory Practices

- How to prevent excessive reporting of deviations (over-load)
- How to write deviation reports to satisfy the needs of the QP, senior management and the regulator
- How to move from 'fire fighting' to genuine quality improvement

# 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 is a Qualified Person and has particular experience of change control systems and deviation reporting.



**Terry Snape**  
David Begg Associates, UK

Prior to joining David Begg Associates, Terry had 30 years' senior technical management experience (pilot plant production, factory management, QC, QA and RA). He has extensive experience of managing deviation systems and overseeing CAPA plans.

## 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.

***"Excellent course – provided really practical answers and solutions to complex problems"***

Michel David, F. Hoffman-La Roche, Switzerland

***"Excellent course with excellent course tutors"***

Clare Lovegrove, MSD, UK

***"Course was that good I didn't want it to finish"***

Ana Klaric, Pliva, Croatia

***"Great interactive learning"***

Claire Gardiner, Warner Chilcott, Northern Ireland

# Booking Form

## How to Simplify and Improve Your Deviation and CAPA System

Monday 12 and Tuesday 13 April 2010

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

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 Monday and finishes at 15.00 on Tuesday**

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 Sunday 11 and Monday 12 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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