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# DBA

The Pharmaceutical  
Training Experts

How to Simplify and  
Improve Your  
Documentation System

Tuesday 13 and Wednesday 14 October 2009

Manchester Airport Marriott Hotel, Manchester, UK

# What previous attendees said about this course

These are just some of the comments we have received about our How to Simplify and Improve Your Documentation System course. This is the kind of feedback we've come to expect after a DBA course.

“*The course was very beneficial and provided good ideas on simple document design*”

Chris Bate, Eisai

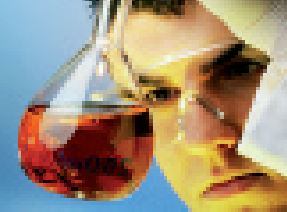
“*Course provided hands on practical information tips and tricks on how to keep things simple*”

Marcella Mijnlieff, DSM

“*Course provided good advice on how to simplify documents and work instructions*”

Gabriella Cassisa, Merck Serona SpA

# About This Course



The Pharmaceutical Industry generates vast amounts of documentation of all types, shapes and sizes. Documents are intended to assist manufacture and assure compliance. However, for many companies, documentation systems have become a major business and regulatory concern. For many of you:

- Your documentation systems have become so complex they are almost unworkable
- The number of procedures and policies has spiralled out of control. You now have a system you can no longer afford
- Your documents are actually the *root cause* of non-compliances, quality problems and massive inefficiencies

This course is designed to help you to make your documentation system simple, effective and compliant.



## What You Will Learn

- Current industry best practice for document design and control
- How to avoid unnecessary complexity
- How to write documents that people can use and reduce errors due to non-compliances and 'human error'
- How to get the best from YOUR documents

## Who Should Attend

This course is for anyone involved in...

- Designing documents and documentation systems
- Managing documentation systems
- Writing documents
- Reviewing and approving documents

Reserve your place today

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

# Course Outline

## **Good Industry Practices – Learning from the Best**

- How to reduce the number of unnecessary documents
- How to make your documents simple, understandable and usable
- How to dramatically improve procedural compliance
- How to generate good quality documents faster

## **Designing a Documentation System that Works!**

### **The What, Why and How of:**

- Corporate policies
- Site (local) policies
- Standard Operating Procedures
- Centralised vs decentralised systems

## **How to Write Policies and Procedures that Actually Work**

- Design tools and techniques
- Language, style and readability
- What to include and how to avoid information overload

## **Getting Down to Specifics – Practical Guidance on the Structure and Essential Content of:**

- Policies
- Standard Operating Procedures
- Log books, records and reports
- Work instructions
- Deviations and quality incidents

## **Computerised Systems – Getting the Basics Right**

- Electronic records and signatures: principles and practice
- The most up-to-date regulatory expectations relating to validation and operation
- Managing the transition from paper to paperless

## **The Document Life Cycle – The What, How and Who of:**

- Information and data gathering
- Documentation generation, review and approval
- Validation
- Implementation (including training)
- Archiving and destruction

# Your Tutors



## **Martin Lush**

**David Begg Associates, UK**

Martin is a Senior Partner with David Begg Associates. His career spans 24 years in the pharmaceutical industry, where he held senior management positions in manufacturing and Quality Assurance with AstraZeneca in the UK. He has extensive experience of designing, implementing and auditing a wide range of documents and documentation systems.



## **David Selby**

**David Begg Associates, UK**

David has held numerous senior management positions within Glaxo and has extensive 'hands on' knowledge of documentation systems in both large and small companies. He also has experience of electronic documentation systems.

## **Discussion and Working Groups**

A significant proportion of the course will be devoted to group work, where delegates have the opportunity to put theory into practice.

Additionally, a tutor-led panel session will provide delegates with an opportunity to obtain answers to their specific questions.

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# Booking Form

## How to Simplify and Improve Your Documentation System

Tuesday 13 and Wednesday 14 October 2009

Manchester Airport Marriott Hotel, Manchester, 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 at 15.00 on Wednesday**

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.

**David Begg Associates (York) Ltd** The Georgian House · 22/24 West End · Kirkbymoorside · York · UK · YO62 6AF

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Please write clearly in BLOCK CAPITALS



# The Venue

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The Manchester Airport Marriott Hotel is just five minutes by courtesy bus from the airport terminal buildings and railway station. Transport will also be available, free of charge, at the close of the course to take you from the hotel to your terminal building.

Situated adjacent to the M56 motorway, it is also easily accessible by road. With its comfortable bedrooms, swimming pool and fitness room, the hotel is an excellent place to relax as well as learn.

- David Begg Associates has a block booking of bedrooms at the Manchester Airport Marriott Hotel, at the specially negotiated bed and breakfast rate of £122.34 (including VAT) per delegate per night.
- The nights of Monday 12 and Tuesday 13 October 2009 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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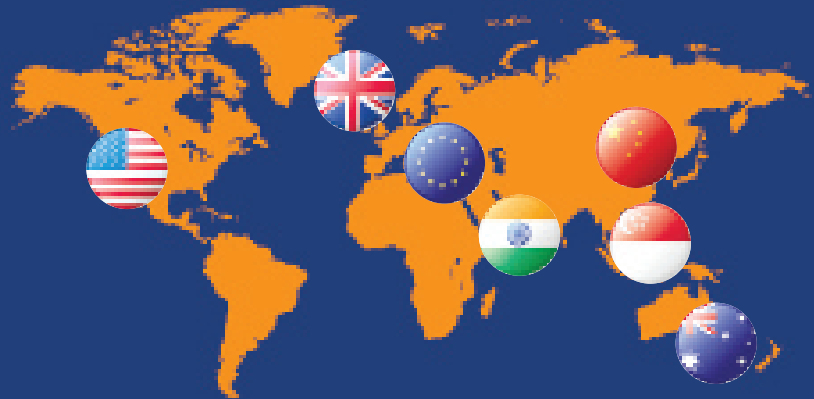
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