

# DBA

An NSF International Company

**Q** **P**  
Qualified Person  
& Professional  
Development Training



## Module 6

Monday 14 to Thursday 17 September 2009

York Marriott Hotel, York, UK

# Mathematics & Statistics



University of  
**Strathclyde**

# Mathematics & Statistics

## About This Course

The introduction of the EU requirement for Product Quality Reviews together with ICH Q8, Q9 and Q10 mean that the Pharmaceutical Industry and the Regulatory Authorities are becoming increasingly aware of the benefits that statistical techniques can provide and the vital information that can be obtained by trend analysis. This module is designed for delegates who have little or no experience in the application of statistical techniques.

The provision of useful information is essential to the Qualified Person and other professionals in helping them to:

- understand the reliability and accuracy of data and information arising from samples taken from a population
- monitor and detect adverse trends before a process goes out of control
- assess the capability and reliability of a process
- understand the interaction of process parameters via experimental design

## Course Outline

### Basic Statistical Quantities

- Terminology and definitions
- Measures and visual plots to describe populations and samples
- Deciding how much data to collect to enable appropriate decision making to occur

### Statistical Techniques

- ISO 2859 – Specification for sampling procedures and tables, application of sampling by attributes
- Shewhart and Cusum control charts
- Process Capability ( $C_p$  and  $C_{pK}$ )
- Statistical Process Control (SPC)
- Outlier testing
- Regression analysis

- The Statistical Test
- Analysis of Variate (ANOVA)
- Experimental design e.g. Taguchi
- Multi-variate analysis

### Practical Application of Statistical Techniques

- Practical examples of the application of statistical techniques using teamwork sessions
- Experience of the application of statistical techniques in a QA system within a manufacturing environment
- The role of computers in the application of statistical techniques
- Six Sigma: what is it and what are its benefits



## Course Tutors



Professor George Gettinby  
Dept of Statistics and Modelling Science,  
University of Strathclyde, Glasgow, UK



Pete Gough  
David Begg Associates, UK

### Plus invited guest speakers

## Discussion and Working Groups

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

Additionally, discussion periods, including a course tutor panel session, provide delegates with an opportunity to obtain answers to their specific questions and concerns.

# Booking Form

## Qualified Person & Professional Development Training - Series 10 Module 6 - Mathematics & Statistics

York Marriott Hotel, York, UK

Monday 14 to Thursday 17 September 2009

(Course begins at 09.00 on Monday and closes at 16.00 on Thursday)

**First/only delegate attending:** £2524.00  plus 15% Value Added Tax (VAT)

**Additional delegate(s) from same site:** £2019.20  plus 15% Value Added Tax (VAT)

20% discount applies to second and subsequent delegates from the same site for this module

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

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

Surname	Mr/Mrs/Miss/Ms/Dr
First Name	Job Title
Company	
Full Street Address	
	Post Code
Delegate Tel No	Delegate Fax No
Delegate Email	

Accommodation: I require accommodation Yes  No

Please indicate any special/extra requirements (dietary/accommodation)

*To guarantee your accommodation reservation, credit card details must be supplied*

Card Number & Expiry Date (please write clearly)

**Please Note:** There are a limited number of rooms at the York Marriott Hotel which will be allocated on a first come first served basis. We will endeavour to hold rooms on your behalf up to 4 weeks before the start of the course but after that date we cannot guarantee bedroom or rate availability.

**Cancellations: Please note that any charges imposed by the hotel as a result of you not taking up your reservation will remain your responsibility.**

**Course Fees:** Sterling cheques, payable on a UK bank to David Begg Associates (York) Ltd, for the full invoiced amount of **£2902.60** (first/only delegate) or **£2322.08** (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 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.

Date Purchase Order number

Cheque enclosed Yes  No

Authorised Signature

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

### David Begg Associates (York) Ltd

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David Begg Associates (York) Ltd.

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# Why This Training Will Benefit YOU

## The Aspiring Qualified Person

- This series of 12 modules held over a 21 month period has been carefully designed to meet the requirements for theoretical training detailed in the latest UK Qualified Person Study Guide and EC Directives 2001/82/EC and 2001/83/EC.
- All our training courses provide practical, face-to-face tuition in sufficient depth to prepare you fully for the challenges that lie ahead.
- Our training is generally considered as the best available and our QPs are held in high regard within the industry.
- As well as being accepted in the UK, our training courses are well known and accepted by several other EU countries, including Ireland, The Netherlands, Austria, Hungary and Malta.
- You are more likely to become a QP with us than with any other training provider!

## The Pharmaceutical Technical Professional

- Not all the people attending these courses intend to become QPs. Many use the training to develop as technical managers within other areas of pharmaceutical manufacture and control.
- Increasingly, companies are using these modules as part of a modular technical and professional development plan for their staff.
- Additionally, many industry professionals attend the courses as part of their Continuing Professional Development.

## To Book on this Course

- Fax the completed and signed form from this brochure to our QP 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.

The logo for DBA is displayed in a large, bold, orange font at the bottom right of the page. The letters 'D', 'B', and 'A' are stylized and connected, with the 'B' being particularly prominent.



# The Venue



The historic city of York has many attractions for visitors; the famous Minster, many museums, the Jorvik Viking Centre and excellent shopping. London is two hours away by train and there is a direct rail link to Manchester Airport. Leeds/Bradford Airport is also nearby.

Situated by the racecourse, just a short distance from the city centre, the York Marriott Hotel knows how to ensure you enjoy your stay. All rooms have air conditioning, multiple data points and phones with voicemail. There is ample free parking, full indoor leisure facilities, heated swimming pool and sauna.

## Hotel Accommodation

- David Begg Associates has a block booking of bedrooms at the York Marriott Hotel at the specially negotiated bed and breakfast rate of £122.34 (including VAT) per delegate per night.
- The nights of Sunday 13 to Wednesday 16 September 2009 inclusive will usually be reserved. We are happy to make a hotel reservation on your behalf up to 4 weeks before the course start but after that date bookings must be made direct to the hotel as we are unable to guarantee that accommodation will be available.
- 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 no indication is made on the Booking Form, no accommodation will be reserved by us.

## Booking your place couldn't be easier!

**Phone** +44 (0) 1751 432999 **Email** [qp@DBA-global.com](mailto:qp@DBA-global.com)

**Fax** +44 (0) 1751 432450 **Online** [www.DBA-global.com](http://www.DBA-global.com)

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