

www.DBA-global.com

A-Z of Pharmaceutical Water Systems

**Monday 30 November
to Thursday 3 December 2009**

Manchester Marriott Victoria & Albert Hotel,
Manchester, UK

DBA

About This Course

Water is one of the most important raw materials used in the pharmaceutical industry.

It is also, unfortunately, one of the most difficult to control!

This course is designed to provide you with a practical understanding of the importance of...

- System design
- Validation
- Maintenance
- Monitoring

...in achieving quality assurance and compliance with worldwide regulatory expectations.

What You Will Learn

- Current EU and US regulatory requirements for pharmaceutical water systems
- Key design features for GMP compliant water systems
- How to qualify and validate water systems to meet current EU and US requirements
- How to design an effective monitoring programme and how to deal with results which exceed expectations
- How to deal with system changes

Who Should Attend

This course will be of immense value to...

- Engineers
- Production staff
- Validation specialists
- Quality Control staff (especially Microbiologists)
- Quality Assurance professionals
- Qualified Persons

Please contact us if you are unsure of the suitability of this course for your needs.

Course Outline

- **System Design and Validation**
 - How to specify, install and qualify key items of equipment
 - The design and validation of water systems to meet the needs of the process, product and patient, including retrospective validation of established systems
 - The role of contractors; their management and control
 - Effective change control
- **System Maintenance, Monitoring and Management**
 - Planned preventative maintenance – what needs to be done, why and when
 - How to establish programmes to monitor the physical, chemical and microbiological performance of the system
 - Methods of sanitisation – their theory, practice, strengths and limitations
 - Importance of change control and system management
- **Microbiological and QC Testing**
 - The basic microbiology of water systems
 - Sampling methods and techniques
 - Analytical and microbiological test methods
 - Regulatory and pharmacopoeial requirements
 - Methods of trending, interpretation and reporting of data to maximise benefit
- **Troubleshooting and Risk Assessment**
 - Auditing of water systems to identify risks and improve performance and efficiency
 - Practical guidance on troubleshooting when things go wrong!
 - How to manage out of specification results (chemical and microbiological data)
- **Regulatory Issues**
 - Current regulatory concerns and impending changes
 - Published standards

Discussions and Working Groups

A significant proportion of 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.

There will also be a practical demonstration of orbital welding.

Your Tutors



Mike Russell
David Begg Associates, UK

Mike is a microbiologist with considerable experience in the design and control of water systems.



Phil Precious
SOFINN (UK) Ltd

Phil is a chemical engineer and acknowledged expert in pharmaceutical water system design, installation, validation and troubleshooting.



John Hutcheson
Hutch₂O

John trained as a chemist and has spent most of his working life in the design, installation and validation of pharmaceutical water systems.

Booking Form

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Please reserve me a place on this course...

First/only delegate attending: £2210.00 Plus 15% Value Added Tax (VAT)

Additional delegate(s) from same site: £1768.00 Plus 15% Value Added Tax (VAT)

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)

Course begins at 09.00 on Monday 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 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 £2541.50 (first/only delegate) or £2033.20 (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

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.



Hotel Accommodation

- David Begg Associates has a block booking of bedrooms at the Manchester Marriott Victoria & Albert, at the specially negotiated bed and breakfast rate of £127.23 (including VAT) per delegate per night.
- The nights of Sunday 29 November to Wednesday 2 December 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.