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Good Autoclave Practice

**Tuesday 3 to Thursday 5
November 2009**

Manchester Marriott Victoria & Albert Hotel
Manchester, UK

DBA

About This Course

A comprehensive course on the practicalities of...

- Autoclave selection
- Cycle design
- Equipment qualification
- Cycle validation
- Ongoing performance monitoring and management

What You Will Learn

- Current regulatory expectations for steam sterilisation
- Current European and US regulatory expectations for steam sterilisation – how they differ and why
- How to qualify and validate effectively
- How to troubleshoot problems
- Best practices for monitoring and management of autoclaves

What previous attendees have said...

“All the tutors were excellent – interested, helpful and clearly experts in their field.”

Maurice Rodgers, Wyeth Biopharma, Ireland

“Very good course – practical approach.
Thank you.”

Ella Joffe, Sopharma JSC, Bulgaria

“Thanks. I really enjoyed the course and look forward to more.”

Emily Kelleher, Eli Lilly, Ireland

Course Outline

Current Regulatory Issues, Standards and Best Industry Practice for Steam Sterilisation

- EU and US expectations compared and contrasted
- The role of HTM 2010, EN 285 and other guidance documents

Microbiology of Sterilisation

- The conditions needed to kill microbes
- The kinetics of sterilisation (Fo, D and Z)

Steam

- Steam quality testing
- Causes and consequences of steam quality problems

Moist Heat Cycle Types

- Applications
- Advantages and disadvantages

Good Validation Practices

- The WHO, WHAT, WHY and HOW of...
 - Design Qualification
 - Factory Acceptance Testing

- Installation Qualification
- Operation Qualification
- Performance Qualification/Cycle Validation
 - ♦ max and min loads
 - ♦ worst case loads
 - ♦ use and abuse of biological indicators

Biological Indicators

- Selection and Quality Control
- Management of failures

Life after Validation

- Planned Preventative Maintenance and Calibration
- Routine performance checks
- Change Control
- Revalidation

Good Autoclaving Practices

- Training of operators
- Management of failed cycles
- Measuring and monitoring performance

Your Tutors



Alan Heavey

David Begg Associates, UK

Alan is an acknowledged expert in steriliser qualification, validation and performance monitoring. He now works regularly in the USA, helping companies to comply with European GMP expectations.



Peter Monger

David Begg Associates, UK

Peter is a former UK medicines inspector and is an acknowledged expert in the field of GMP compliance for sterilisers.

Discussion and Working Groups

This course is designed to be highly participative. We invite you to bring along your specific autoclaving problems; we will do our best to provide you with sound, cost-effective solutions!

Booking Form

Good Autoclave Practice

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Manchester Marriott Victoria & Albert Hotel, Manchester, UK

Please reserve me a place on this course...

First/only delegate attending: £1690.00 Plus 15% Value Added Tax (VAT)

Additional delegate(s) from same site: £1352.00 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 Tuesday 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 £1943.50 (first/only delegate) or £1554.80 (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 £123.31 (including VAT) per delegate per night.
- The nights of Monday 2 to Wednesday 4 November 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

Bookings cancelled up to 25 working days of the course shall receive a full refund. Cancellations received between 25 and 10 working days before the course shall receive a 50% refund. No refund will be given to cancellations received within 10 working days of the course start date. Delegate substitutions may be made at no cost at any time up to the start of the course.