



[www.DBA-global.com](http://www.DBA-global.com)

# Sterile Products Manufacture

**Monday 28 September to Thursday 1 October 2009**  
Manchester Marriott Victoria & Albert Hotel,  
Manchester, UK

**DBA**

# About this Course

Sterile products manufacture represents the most hazardous activity (to the patient!) performed by pharmaceutical companies.

This is why it attracts so much regulatory scrutiny!

Recent regulations and guidelines from EU (Annex 1) and FDA "Sterile Drug Products Produced by Aseptic Processing" are confusing to many and very difficult – and expensive – to comply with in full.

This course is designed to help you comply with these and other documents in a way that is...

- Practical
- Scientifically sound
- Cost-effective

This is by far the most popular of our courses – hundreds of people attend it every year, either through this residential course or via courses run in their companies – and delegate feedback is excellent!

## What You Will Learn

- Current EU and FDA requirements for...
  - design and qualification of clean rooms
  - environmental standards for controlled environments
  - control of key utilities
  - sterilisation processes
  - process simulations (media fills)
  - inspection and integrity testing
- How to satisfy these expectations in a practical way
- How to identify the root cause of any problem... and make the right risk-based decision!

## Who Should Attend

The course will be particularly suitable for...

- Production managers, supervisors and operators
- Qualified Persons
- QA and QC personnel
- Engineers and microbiologists who provide crucial support to manufacturing operations

# Course Outline

## Current Standards and Regulatory Requirements

- ISO 14644
- EU GMP Guide Annex 1
- FDA Guideline "Sterile Drug Products Produced by Aseptic Processing"

## The Clean Room

- Design
- Qualification
- HVAC systems and HEPA filter selection

## Alternatives to Conventional Clean Rooms

- Isolator technology

## Critical Utilities

- Steam – generation and quality expectations
- Water – generation, storage and control

## Sterilisation Processes

- EU and US expectations for...
  - steam sterilisation
  - dry heat sterilisation
  - filtration
- Other sterilisation processes
  - ethylene oxide
  - irradiation
  - vaporised hydrogen peroxide

## Environmental Monitoring

- Monitoring techniques
- Designing an effective monitoring programme
- Setting alert and action levels
- Data management

## Process Simulations (Media Fills)

- Understanding the strengths and weaknesses of the media fill
- Current regulatory expectations
- How to demonstrate compliance

## Disinfection Practices

- The importance of TACT
- Selection of disinfectants
- Validation of disinfection procedures

## Container Integrity Testing and Particulate Inspection

- Methodologies
- Strengths and weaknesses
- Regulatory expectations

## People Issues

- Gowning and gowning practices
- Qualification of clean room operators
- Good aseptic practices

## Problem solving and trouble-shooting tools and techniques

## Discussion and Working Groups

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

Additionally, discussion periods including a tutor-led panel session will provide delegates with an opportunity to have their specific questions answered.

## Your Tutors



**Peter Monger**  
**David Begg Associates, UK**

Peter is a former UK medicines inspector with many years' experience of inspecting steriles operations and of advising companies on current compliance issues.



**Mike Russell**  
**David Begg Associates, UK**

A pharmaceutical microbiologist, Mike gained his PhD in the microbiology of sterile products manufacture and has published papers on environmental monitoring. Mike has extensive knowledge of EU requirements for sterile products.

## What previous attendees have said...

*"It was a great course"*

*Astrid Dekkers-Aben, Nobilon International*

*"Exercises, discussions and case studies were really good"*

*Lars Josefsson, AstraZeneca*

*"Very complete and very good training"*

*Veerle Brochez, Janssen Pharmaceutica*

*"Very knowledgeable and experienced presenters"*

*Kevin Lavin, Schering Plough*

*"Very good course!"*

*Silvija Cindric Katic, Pliva*

# Booking Form

## Sterile Products Manufacture

Monday 28 September to Thursday 1 October 2009

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

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.

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

Tel: +44 (0) 1751 432999 Fax: +44 (0) 1751 432450 Email: courses@DBA-global.com Website: www.DBA-global.com

David Begg Associates (York) Ltd. Registered in England & Wales No. 3432550 Registered Office 22/24 West End, Kirkbymoorside, York YO62 6AF An NSF International Company

# 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 Sunday 27 to Wednesday 30 September 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.