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A photograph of two glass vials and a syringe, likely containing sterile products, arranged on a light background. The vials are in the background, and the syringe is in the foreground, angled towards the left. The image is slightly blurred, giving it a soft, professional appearance.

Risk-Based Decision Making in Sterile Products Manufacture

dealing with the unexpected

Monday 26 to Thursday 29 January 2009

Amsterdam Marriott Hotel,
Amsterdam, The Netherlands

DBA

About this Course

Manufacturing sterile products is easy – *until things go wrong!*

When things go wrong catastrophically, decision making is relatively straightforward. However, things are rarely so “black and white”. The biggest challenge facing anyone in sterile products manufacture is to deal with the “grey area” problems which arise almost daily and which require decisions which are...

- scientifically justified
- based on an objective and realistic assessment of RISK
- in compliance with regulatory requirements and expectations
- and GOOD for your business!

This unique course is designed to help YOU to do all these things!

This is not a “typical” training course where someone lectures to you for days at a time. The majority of the course will be spent on tasks in small groups, 'real life' problems that many of you face each day.

- “Key Point” lectures will provide you with the most up-to-date information, sufficient to promote informed and lively discussion.
- You will then be given 'real life' problems to solve in small groups. Tutors will guide and facilitate discussions, encourage debate and provide you with model answers. *You will learn from each other as well as from us.*
- It is not what you know that matters. It is what you do with what you know that *really* matters. The objective of this course is to help you improve your problem solving and decision making skills when presented with any situation associated with the manufacture of Sterile Products.

For Whom Intended

This course is intended for staff with several years' experience of sterile products manufacture and who are required to take decisions when things don't go according to plan!

Thus, the course will be of immense value to managers and supervisors in the following disciplines:

- Quality Assurance (including Qualified Persons)
- Production
- Quality Control
- Quality Compliance
- Validation
- Engineering

Course Outline

The Theory

Lectures will cover essential information on current EU and US requirements for...

- clean rooms and controlled environments
- sterilisation processes
- environmental monitoring
- process simulations
- container integrity testing and visual inspection
- environmental monitoring
- personnel monitoring

As well as...

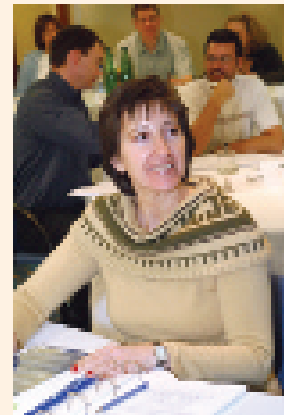
- Risk management principles and the major risk assessment techniques:
HACCP and FMEA

The Practice

You will be split into small 'working groups' and asked to take decisions on a range of scenario situations, such as...

- unexpectedly high pre-filtration bioburden counts
- momentary drop in temperature and pressure during autoclave cycle
- filling room occupancy higher than has been simulated during media fills
- HEPA filter integrity test failure during requalification
- sterile filtration of solution takes longer than is permitted in the manufacturing instruction

- higher than normal reject rate during visual inspection
 - high microbial counts on hands of operator detected at exit monitoring
 - unplanned deviation from approved steriliser loading pattern
- ... *and many more*



Your Tutors



Martin Lush
David Begg Associates, UK

A microbiologist by training, Martin has extensive experience of the manufacture and control of a wide variety of sterile dosage forms. Since joining David Begg Associates from AstraZeneca, Martin has helped many companies to achieve EU and FDA GMP compliance.



Mike Russell
David Begg Associates, UK

Also a microbiologist, Mike has worked with Glaxo, Roche, Centocor and Cambridge Antibody Technology. He has published papers on environmental monitoring.



Terry Snape
David Begg Associates, UK

Before joining David Begg Associates, Terry was Technical Director with Bio Products Laboratory, England's producer of Plasma products. He has in-depth experience of aseptic processing and lyophilisation.

What Previous Attendees Said About This Course

"Very impressive course"

Maria Vanenburg, Teva Pharma, The Netherlands

"Very good course. Very good balance between lectures and practical case studies"

Xandra Bouwstra, NVI Vaccines, The Netherlands

"Very, very good course tutors"

Annelies Sprenkels-Mink, HAL Allergy, The Netherlands

"Great combination of lectures and problem solving exercises"

Solveig Pedersen, Sykehusapoteket, Norway

Booking Form

**Monday 26 to Thursday 29
January 2009**
at the
**Amsterdam Marriott Hotel,
Amsterdam, The Netherlands**

**Course Fee £2310.00
(pounds sterling)**

Risk Based Decision Making in Sterile Products Manufacture

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

David Begg Associates (York) Ltd

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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.

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 **£2310.00 pounds sterling** (net of ALL bank charges) to be attached to this Booking Form and sent to David Begg Associates (York) Ltd at the address above. Settlement must be received at least 10 working days prior to the course start date. VAT – the course fee is exempt from VAT which will be reflected on the invoice provided. 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.*

Authorised Signature Purchase Order number

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 Venue

The Amsterdam Marriott Hotel is among the superior hotels in Amsterdam, it offers an ideal location across from the Leidseplein's fine shopping, dining and entertainment. As a guest, you'll find well appointed guest rooms with high speed internet to keep you in touch. A well equipped fitness room will help keep you in shape. Fine dining awaits in their two restaurants.

Marriott
AMSTERDAM



Hotel Accommodation

- David Begg Associates has a block booking of bedrooms at the Amsterdam Marriott Hotel, at the specially negotiated bed and breakfast rate of €206.00 (including VAT) per delegate per night.
- The nights of Sunday 25 to Wednesday 28 January 2009 inclusive 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 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.